International Journal of Scientific Study

General Information

About The Journal

International Journal of Scientific Study (IJSS) is a monthly journal publishing research articles after full peer review and aims to publish scientifically sound research articles in across all science like Medicine, Dentistry, Genetics, Pharmacy, etc.

Each article submitted to us would be undergoing review in three stages: Initial Review, Peer Review & Final Review.

Abstracting & Indexing Information

Index Medicus (IMSEAR), Global Index Medicus, Index Copernicus, Directory of Open Access Journals(DOAJ), Google Scholar, WorldCat, SafetyLit, WHO Hinari, Genamics Journal Seek Ulrichsweb Serials Solutions , International Committee of Medical Journal Editors(ICJME) Geneva Foundation for Medical Education & Research(GFMER), Socolar, Bielefeld Academic Search Engine(BASE) , Research Bible , Academic Journals Database, J-Gate, Jour Informatics, Directory of Research Journal Indexing(DRJI), Scientific Indexing Services(SIS) Rubriq-Beta, SHERPA RoMEO, New Jour, EIJASR), IndianScience.in, CiteFactor, Scientific Journal Impact Factor (SJIF), Journal Index.net, ROAD, Global Impact Factor(GIF) , International Society for Research Activity (ISRA), Advanced Science Index, OpenAccessArticles.com, etc

Information for Authors

The authors should follow "Instructions to Authors" which is available on website http://www.ijss-sn.com/instructions-to-authors.html. Authors should fill the Copyright Transfer form & Conflict of Interest form. Manuscripts should be submitted directly to: editor@ijss-sn.com.

Publication Charges

International Journal of Scientific Study aims to encourage research among all the students, professionals, etc. But due to costs towards article processing, maintenance of paper in secured data storage system, databases and other financial constraints, authors are required to pay. However discount will be provided for the non-funding quality research work upon request. Details about publication charges are mentioned on journal website at: http://www.ijss-sn.com/publication-charges.html.

Advertising Policy

The journal accepts display and classified advertising Frequency discounts and special positions are available. Inquiries about advertising should be sent to editor@ijss-sn.com.

Publishing Details

Publisher Name: International Research Organization for Life & Health Sciences (IROLHS)

Registered Office: L 214, Mega Center, Magarpatta, Pune - Solapur Road, Pune, Maharashtra, India – 411028. Contact Number: +919759370871.

Designed by: Tulyasys Technologies (www.tulyasys.com)

Disclaimer

International Journal of Scientific Study

Editorial Board

International Journal of Scientific Study
March 2020 • Vol 7 • Issue 12

Contents

International Journal of Scientific Study
March 2020 • Vol 7 • Issue 12

International Journal of Scientific Study
March 2020 • Vol 7 • Issue 12

REVIEW ARTICLE

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Case Report

Central Line Induced Pneumothorax: A Case Report

Hina Afreen[1], Mohammed Hidayath Hussain[2]

[1]First Year Postgraduate, Department of Pulmonology, Shadan Institute of Medical Sciences, Hyderabad, Telangana, India, [2]Professor and Head, Department of Pulmonology, Shadan Institute of Medical Sciences, Hyderabad, Telangana, India

Abstract

Central venous catheter insertion is a commonly performed procedure. We report a case of central venous catheterization induced pneumothorax in a 45 years old male patient who underwent a surgery for sub-arachnoid hemorrhage and post-surgery, developed tension pneumothorax during internal jugular vein catheterization.

Key words: Central venous catheterization, Intercoastal chest drain, Pneumothorax

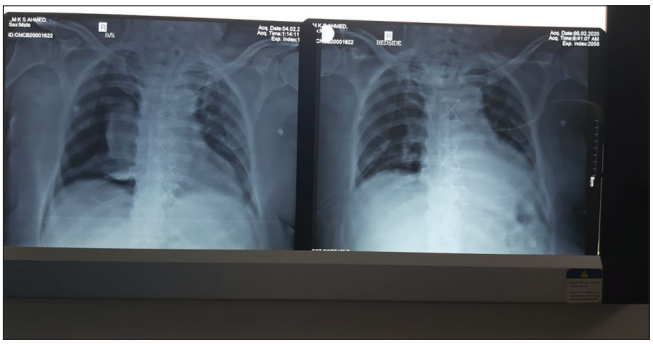
INTRODUCTION

Pneumothorax is a minor mechanical complication of central venous catheterization. It is usually unilateral and occurs commonly on the side of the central line placement.

Central venous catheterization carries the second highest risk of iatrogenic pneumothorax. Subclavian catheterization carries a higher risk than internal jugular catheterization. Below is a case of the right-sided pneumothorax that occurred as a complication of internal jugular vein catheterization.

CASE REPORT

This is a case of a 45-year-old male patient, smoker, with post-coronary artery bypass graft status and morbidly obese, who underwent a surgery for subarachnoid hemorrhage. The patient had no prior history of any pulmonary or pleural disease. On post-operative day 1, a decision to insert a central line was taken in view of the need of parental nutrition. A central venous line was placed in the right internal jugular vein (IJV). The patient was stable throughout the procedure, but immediately post-procedure, the patient developed breathlessness, sudden onset, and gradually progressive in nature. His saturations begin to fall and failed to maintain even with high flow oxygen, pulse rate was 140 bpm and blood pressure 140/70 mmHg, and respiratory rate of 33 cpm. A post-procedure chest X-ray showed right-sided pneumothorax. An emergency intercostal drainage tube was placed in the 5th intercostal space in the right side in the safe triangle. Post chest tube insertion, the patient's symptoms resolved and the patient was clinically better, oxygen saturation normalized. A post chest tube insertion, X-ray was taken and the X-ray picture showed tube in position with pneumothorax being resolved and lung expanded. The chest tube was placed for 2 days after which it was clamped for an observation period of 8 h and the patient had no complaints of dyspnea or chest pain during the observation period. A repeat X-ray was done after 8 h which was normal and hence the chest tube was removed.



Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

DISCUSSION

The central venous catheter (CVC) is a catheter placed into the IJV, subclavian vein, axillary vein, or the femoral

Corresponding Author: Mohammed Hidayath Hussain, Department of Pulmonology, Shadan Institute of Medical Sciences, Hyderabad, Telangana, India.

vein. Pneumothorax is one of the most common CVC insertion complications, reportedly representing up to 30% of all mechanical adverse events of CVC insertion.[1] There has been an increase in the use of CVCs over the past decade due to the increase in disease severity, age, and severe comorbidity of patients, especially in the intensive care unit setting. The increasing use of real-time ultrasound guidance for central venous catheterization has significantly decreased this risk for both internal jugular and subclavian approaches.[2,3] The incidence of pneumothorax varies between 1% and 6.6%, with higher incidences being reported in the following situations: Emergencies, large catheters size, catheters used for dialysis, and with the increased number of needle passes.[4] Subclavian vein insertion has been reported to have a higher incidence of pneumothorax than IJV insertion.[5,6] While it is standard practice to obtain a chest X-ray after catheterization to confirm placement and to exclude complication, initial films may fail to show a pneumothorax, a delayed pneumothorax may occur from 8 h to 4 days after insertion.

Furthermore, the experience of the physician inserting the catheter is very important. A beginner has more chances of causing pneumothorax than an experienced person. The number of needle insertions also determines the chances of pneumothorax being directly proportional in relation.

The chances of pneumothorax occurring during CVC also depend on the condition of the patient and his comorbidities, more chances being in emphysema patients, patients who are on mechanical ventilation, and in uncooperative patients. The vein chosen for CVC insertion also determines the chances of pneumothorax, a higher incidence of being when the subclavian vein is cannulated, as compared with the IJV (0.5–2% vs. 0.2–0.5%).[6-8]

During tension pneumothorax, progressive increase in the intrathoracic pressure in the pleural space pushes the mediastinum to the opposite hemithorax and obstructs venous return to the heart. This leads to circulatory instability and may result in cardiorespiratory arrest. To prevent life-threatening situations caused by tension pneumothorax, it is important to detect these occurrences early and decompress them quickly.

CONCLUSION

Can a pneumothorax during central venous catheterization insertion be avoided?

Inserting a central line has become a common practice nowadays for various reasons and hence the risks associated with the procedure also increased and have become common. Need to insert a central line cannot be avoided but taking precautionary measures can prevent the occurence of such complications. It is advisable to keep in mind the complication of pneumothorax during central line cannulation and ensures the availability of a pulmonologist for such emergencies. A routine practice of taking a post-procedure X-ray immediately after cannulation and monitoring the patient for any symptoms of dyspnea or chest pain should be made mandatory. Furthermore, there are evidence of delayed development of pneumothorax post central line insertion,[9] hence, repeat chest X-ray in symptomatic cases should be done even after an initial negative chest X-ray. The use of ultrasound while inserting a central line has reduced the risks of pneumothorax. There is increasing evidence for the same showing decrease pneumothoraces (from 2.4% to 0%) and hematothoraces (from 1.7% to 0%), at least for IJV insertion.[2] About 93% of infraclavicular axillary veins can be identified with ultrasonography and literature shows that 96% have been catheterized successfully.[10] This technique could avoid completely or reduce the complication of pneumothorax to a great extent.

REFERENCES

1. Mitchell SE, Clark RA. Complications of central venous catheterization. AJR Am J Roentgenol 1979;133:467-76.
2. Karakitsos D, Labropoulos N, De Groot E, Patrianakos AP, Kouraklis G, Poularas J, *et al*. Real-time ultrasound-guided catheterisation of the internal jugular vein: A prospective comparison with the landmark technique in critical care patients. Crit Care 2006;10:R162.
3. Fragou M, Gravvanis A, Dimitriou V, Papalois A, Kouraklis G, Karabinis A, *et al*. Real-time ultrasound-guided subclavian vein cannulation versus the landmark method in critical care patients: A prospective randomized study. Crit Care Med 2011;39:1607-12.
4. Kusminsky RE. Complications of central venous catheterization. J Am Coll Surg 2007;204:681-96.
5. McGee DC, Gould MK. Preventing complications of central venous catheterization. N Engl J Med 2003;348:1123-33.
6. Eisen LA, Narasimhan M, Berger JS, Mayo PH, Rosen MJ, Schneider RF. Mechanical complications of central venous catheters. J Intensive Care Med 2006;21:40-6.
7. Kaiser CW, Koornick AR, Smith N, Soroff HS. Choice of route for central venous cannulation: Subclavian or internal jugular vein? A prospective randomized study. J Surg Oncol 1981;17:345-54.
8. Molgaard O, Nielsen MS, Handberg BB, Jensen JM, Kjaergaard J, Juul N. Routine X-ray control of upper central venous lines: Is it necessary? Acta Anaesthesiol Scand 2004;48:685-9.
9. Cronen MC, Cronen PW, Arino P, Ellis K. Delayed pneumothorax after subclavian vein catheterization and positive pressure ventilation. Br J Anaesth 1991;67:480-2.
10. Sharma A, Bodenham AR, Mallick A. Ultrasound-guided infraclavicular axillary vein cannulation for central venous access. Br J Anaesth 2004;93:188-92.

How to cite this article: Afreen H, Hussain MH. Central Line Induced Pneumothorax: A Case Report. Int J Sci Stud 2020;7(12):1-2.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Muscle Work While Running at Different Speed

Antariksh P Waghmare

MBBS, MS, MCh, Department of Orthopaedic Surgery, TORT Centre, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom

Abstract

Background: Running is a fundamental skill and requirement of all athletic activities. Therefore, there is a need to understand lower limb muscles function during running. This is also important for refining the existing knowledge regarding increased performance during sports activities.

Aim: The aim of the study was to investigate the muscle work of different groups of lower limb muscles during running at different speeds.

Material and Methods: In total, 15 individuals were involved in the study. All of the subjects were made to run in a sports lab providing three good trials of each speed at their convenient slow, comfortable, and fast running speeds. Data were gathered using Vicon®, electromyography, and inverse dynamics tools and analyzed using SPSS® version 22 program. Muscle force was calculated with the inverse dynamic model using the kinetic and kinematic data of the trials collected from the participants.

Results: Hip flexors and knee extensors were found to have a major increase in muscle force when compared with slow to fast speeds while ankle flexors were found to show a steady increase in their muscle force with an increase in the speed. Similarly hip and knee angles showed a significant change in values while ankle angles did not change much during increasing speeds.

Significance: Our study implies the importance of the muscle groups of the lower limb while changing pace during running. It is important for professional athletes recovering from an injury. They can concentrate on the rehabilitation of individual muscle groups required according to the speed their sport involves. Furthermore, they can focus on the development of an individual muscle which is performing more significantly according to the speed their sport requires.

Key words: Electromyography, Lower limbs muscles, Running gait

INTRODUCTION

Running is a fundamental skill. It is a critical part of human body movement and fundamental requirements for almost all athletic activities. Therefore, there is a need to understand lower limb muscles function during running. This is also important for refining the existing knowledge regarding increased performance during sports activities.

There are different approaches that can be used to study the muscle function of the lower limb during running, which includes the measurement of muscle electromyography (EMG) activity, the use of inverse dynamics to determine lower-limb joint moments of force, motion capture system (Vicon®), force plate analysis, and joint force analysis. The present study analyzed functions of lower limb muscles based on all of the above-mentioned methods.

The previous study has concluded that primarily faster running is achieved by increasing stride length at a greater rate than stride frequency, but eventually, a threshold is reached and a shift in strategy occurs whereby the progression to maximum running speed is achieved by increasing stride frequency at a greater rate than stride length (Schache *et al.*, 2014). It has already been proven that during running, the hip flexor and knee extensor produce a large amount of torque which are primarily opposed by the hamstring muscles which in turn makes hamstring more prone to injuries (Schache *et al.*, 2014). The hamstring plays an essential role during running. During the terminal swing phase of the stride cycle, hamstring muscle will reach ultimate muscle-tendon unit stretch, produces peak force, and performs much negative work (energy absorption) (Higashihara *et al.*, 2010). Therefore, it has been suggested that, for running, the hamstrings which include two joints in

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Antariksh P Waghmare, Department of Orthopaedic Surgery TORT Centre, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom.

its course, are at maximum risk of injury during the terminal swing when they are contracting eccentrically (Higashihara *et al*., 2010). Accordingly, to achieve maximum running speed more work has to be done by the hip extensors and flexors (i.e., the hamstring muscles, iliopsoas, and gluteus maximus) to accelerate the knee and hip joints further vigorously during swing phase, thus maximizing stride frequency (Schache *et al*., 2014). The result from a study has shown that, while running, the quadriceps muscles (i.e., vastus medialis, vastus intermedius, vastus lateralis, and rectus femoris) are the major provider to braking the center of body mass during initial stance phase (Hamner *et al*., 2010). The soleus and gastrocnemius do not play any part in this activity.

To date, not enough material has been published regarding the lower limb muscle function at different speeds. Therefore, the purpose of this project was to explore the relationship between different muscle groups and forces acting on them during running at different speeds. The obvious assumption was muscle forces would increase with increasing speed. The research question was which muscle groups would contribute to the increase in speed. The results from this project will be used to find a positive relationship between the use of muscles during increasing speeds while running and their importance in rehabilitation while recovering from injuries. In addition, such information will help to identify potential factors that might be related to sports-related injuries.

MATERIAL AND METHODS

Ethical Considerations

Before participating in the study, all the participants who took part in the study gave written informed consent. Ethical committee approval was obtained from the university.

Subjects

Fifteen participants were recruited for the project, between the age group of 18–40 years and from both male and female gender ten males and five females (mean age of 27, mean body mass of 76.53 kg, and mean height of 1.71 m with standard deviation 0.09). Participants were selected randomly among the volunteers of students, with exclusion criteria being any physical deformities or medical conditions. None of them was professional athletes.

The participants were equipped with a pair of shorts and a short-sleeved shirt that was taped up as needed to allow the markers around the waist and upper thigh area to be visible by the cameras. They were also provided with appropriate size Nike® footwear before measuring and marker placement to standardize the runs. Anthropometric measurements were taken of each of the subjects with the footwear. A total of 16 reflective markers and four reflective wands were placed on specific regions of both lower limbs of the subject. The placement of these reflective markers was based on the Vicon® full-body plug-in gait model [Figure 1], and some extra markers, for example, medial knee and ankle ones were added to estimate joint centers more accurately. The marker placement and functions were validated in our previous studies, for example, Nair *et al*., 2004 and Ghaffar *et al*., 2015. The reflective wands were placed after the electrodes of the EMG were put onto the designated sites of a lower limb muscle group [Table 1] to maximize contact between the EMG and the skin (Gazendam and Hof, 2007). The muscle sites used in the study were: Rectus femoris, vastus medialis, vastus lateralis, biceps femoris, soleus, and tibialis anterior. These represent the major muscle groups of lower limbs which play an important role while running.

Data Collection

For the analysis of running gait, the Vicon® motion capture system along with the nexus version 2.4 software was used. There were 18 Vicon® cameras fixed in a predestined position in the lab along with the force plate. Delsys® EMG

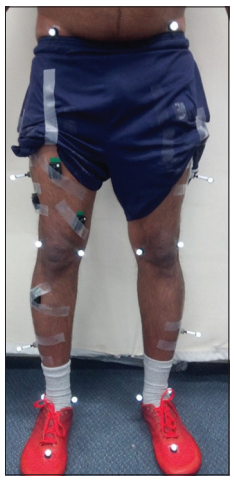


Figure 1: Placement of reflective marker on a participant

Table 1: Placement of electromyography electrode on the lower limb

S. No.	Name	Electrode position
1.	Rectus femoris	Anterior aspect of thigh between vastus medialis and vastus lateralis
2.	Vastus medialis	Anteromedial muscle bulge thigh
3.	Vastus lateralis	Anterolateral muscle bulge thigh
4.	Biceps femoris	Posterolateral aspect of thigh
5.	Soleus	Muscle bulge posterior of leg
6.	Tibialis anterior	Anterolateral leg

wireless system used for the study. At the beginning of data collection for each subject, the first few trials were done to establish an EMG baseline to make sure that the EMG was in proper working order. The static T-pose to indicate the presence of all 20 markers and a few trial of runs were performed before the actual trial of running. Once the troubleshooting for the EMG and static T-pose trials were sorted out, the format running trials began. Participants were asked to begin the forward running trials at the sports lab of the IMAR, with the first one being a warm-up trial at a comfortable speed. The subject then ran in the sports lab, at three different speeds (slow, comfortable, and fast) according to the participant's convenience for the length of sports lab, giving minimum of three trials for each speed, respectively. These trials for different speeds were randomized using computer randomizing method. Forty meters long sports lab equipped with motion recording cameras and force plate were used for the recordings.

The processing of the motion capture data was done by the Nexus 2.4 software, including labeling, pipelining, and detecting the events of the foot while running. The raw data from Vicon® of the trials were imported to provide values for the biomechanical variables defined in the model. The model itself uses inverse dynamics to calculate the muscle forces for multiple lower limb muscles through mathematical optimization methods (Wang *et al.*, 2004).

Inverse Dynamic Model

To estimate muscle force, an inverse-dynamic model was employed. Presumably from physiology, when producing joint moments, the muscles around the joint optimally use the forces to minimize the total muscle power. By mathematical optimization, the idea can be expressed as follows:

$$\sqrt[m]{\sum_{i=1}^{n}\left(\frac{f_i(t)}{PCSA_i}\right)^m} \quad (1)$$

$$\text{or } \sum_{i=1}^{n}\left(|v_i(t)|\, f_i(t)\right) \quad (2)$$

$$\text{Subject to } A\,F = M \quad (3)$$

Where $f_i(t)$ is the muscle force (n) in i^{th} muscle at time t; $v_i(t)$ is the muscle velocity in i^{th} muscle at time t; n is the number of muscles; F is a vector of muscle forces; A is the matrix of the moment-arm of muscles; M is a vector of joint moments; $PCSA_i$ is physiological cross-section area in i^{th} muscle; m is a power. The equations (1, 2) are the objective function, and the equation (3) is the constrained condition. These two equations construct a problem of mathematical optimization.

In our previous study (Wang *et al.*, 2004), it was shown that equation (1), the muscle force obtained was more similar to experimental EMG patterns than using equation (2); thus the equation (1) was adopted for general calculations. So far, there has not been a "golden" objective function, which can be widely accepted by the researchers in this field.

Here, we take the lower limb as an example to describe how the equations (1, 3) were used to calculate muscle forces. Assuming that the lower limb moves only in the sagittal plane and nine major muscles (groups) were involved in each movement, M in the equation (3) will include three moments of force at the hip, knee, and ankle; A will be a matrix of three by nine, including the moment arms of the muscles about the three joints. The matrices of A and M were given by the measurements of muscle attachments and the collection of kinematic and kinetic data. Thus, in the equation (1), nine muscle forces, F, would be calculated. Because the number of equations was three and the number of unknown variables (i.e. muscle forces) was nine, this is an undetermined mechanical problem, which cannot be solved by general algebraic methods. The equations (1, 3) were solved using Linear Programming (Matlab®, 2017).

When the model was applied to an individual, her/his body mass and height/leg length were input into the software, which will construct a specific musculoskeletal model for this individual and use her/his joint moments in the calculation of muscle forces. Thus, for each individual, the muscle attachments and muscle *PCSAs* were specified using a previous study (Wang *et al.*, 2004).

The current model includes nine major muscles, the rectus femoris, vasti, hamstrings, i.e., semimembranosus and semitendinosus; gluteus, i.e., gluteus maximus, medius and minimus, soleus, tibialis anterior, iliacus, gastrocnemius, and biceps femoris short head.

Statistical Analysis

All the data that were exported from the muscle and skeleton model were analyzed using SPSS® (version 2.4) and Mathlab® 2017. To analyze data in SPSS software, general linear model, repeated measurers, was used. When the variables were not normal distributed, a non-parametric test, for example, Wilcoxon signed-rank test or Friedman test, was used to find the P-values. The results obtained from this method will provide the mean value with standard deviation along with P-value in all the three speed trials.

RESULTS

Ten males and five females aged between 18 and 37 years with varying levels of physical activity participated.

Detailed anthropometric measurements were taken of the individual participants before the beginning of the trails. Gait parameters were calculated from the trials, and the following values were found, as shown in Table 2. Different muscle groups were found to have values with a significant difference during running at slow, comfortable, and fast speeds. Hip angle and knee angle showed a significant increase when compared between three speeds while running, but the ankle angle did not show any significant increase in Figure 2. Whereas, significant increase was found between hip, knee, and ankle moments while running at different speeds Figure 3. Significant increase was found in cadence, stride length, stride time, and running speed also when compared between slow, comfortable, and fast speed as shown in Table 2.

Muscle force was calculated, as shown in Table 3 and Figure 4. Gluteus maximus showed a significant

Table 2: Gait results derived from all of the running trials

Gait parameters	Slow	Comfortable	Fast	*P*-value
Hip range of movement (degree)	47.6±2.63	60.8±5.66	67.1±1.96	Slow versus comfortable: 0.048 Comfortable versus fast: 0.277 Slow versus fast: <0.001
Knee range of movement (degree)	66.4±1.75	76.9±2.63	90.1±3.26	Slow versus comfortable: <0.001 Comfortable versus fast: 0.001 Slow versus fast: <0.001
Ankle range of movement (degree)	46.1±1.72	48.2±1.95	50.1±1.63	Slow versus comfortable: 0.131 Comfortable versus fast: 0.153 Slow versus fast: 0.010
Cadence (steps/min)	151.6±2.43	162.7±2.66	189.1±5.02	Slow versus comfortable: <0.001 Comfortable versus fast: <0.001 Slow versus fast: <0.001
Stride length (m)	1.7±0.05	2.1±0.05	2.7±0.07	Slow versus comfortable: <0.001 Comfortable versus fast: <0.001 Slow versus fast: <0.001
Stride time (s)	0.7±0.01	0.7±0.01	0.6±0.01	Slow versus comfortable: <0.001 Comfortable versus fast: <0.001 Slow versus fast: <0.001
Running speed (m/s)	2.1±0.08	2.9±0.08	4.2±0.17	Slow versus comfortable: <0.001 Comfortable versus fast: <0.001 Slow versus fast: <0.001

Values are mean±standard error

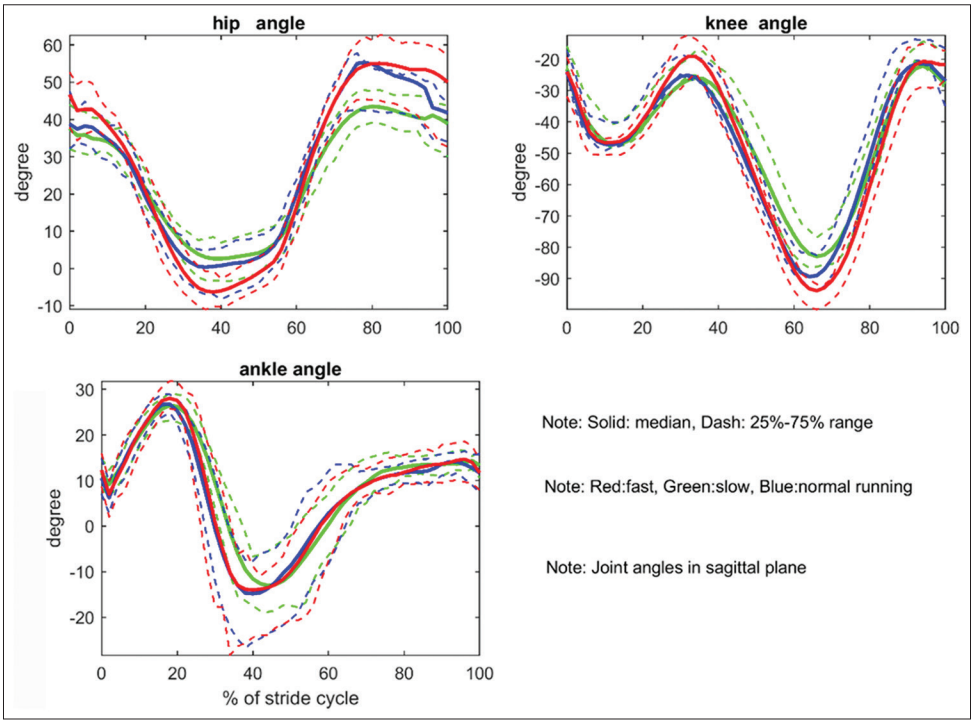


Figure 2: The joint angles in the sagittal plane for three types of running speeds

Table 3: Muscle force calculate of all subjects while running at three different speeds

Muscle force (N/kg)	Slow running	Comfortable running	Fast running	*P*-value
Gluteus maximus				
(Max.)	412.4±39.72	587.1±37.43	980±119.91	Slow versus comfortable: 0.002 Comfortable versus fast: 0.001 Slow versus fast: <0.001
(Mean)	57.8±4.73	78.3±5.67	115.5±9.52	Slow versus comfortable: <0.001 Comfortable versus fast: <0.001 Slow versus fast: <0.001
Rectus femoris				
(Max.)	853.2±160.3	1697.1±696.5	1579.8±438.2	Slow versus comfortable: 0.246 Comfortable versus fast: 0.871 Slow versus fast: 0.082
(Mean)	65.4±9.47	84.3±11.95	118.5±26.26	Slow versus comfortable: 0.001 Comfortable versus fast: 0.045 Slow versus fast: 0.011
Gastrocnemius				
(Max.)	705.9±77.68	882.8±72.60	1117.7±166.83	Slow versus comfortable: 0.031 Comfortable versus fast: 0.052 Slow versus fast: 0.007
(Mean)	106.1±7.10	118.1±8.15	129.2±11.82	Slow versus comfortable: 0.038 Comfortable versus fast: 0.229 Slow versus fast: 0.013
Vastus medialis				
(Max.)	1251.6±85.65	1438.2±136.95	2546.1±575.37	Slow versus comfortable: 0.398 Comfortable versus fast: 0.042 Slow versus fast: 0.027
(Mean)	97.1±7.05	135.6±16.99	164.1±24.13	Slow versus comfortable: 0.038 Comfortable versus fast: 0.282 Slow versus fast: 0.006
Tibialis anterior				
(Max.)	526.1±58.27	695.1±61.60	935.8±154.09	Slow versus comfortable: 0.024 Comfortable versus fast: 0.042 Slow versus fast: 0.011
(Mean)	45.5±2.97	60.2±4.08	79.7±6.99	Slow versus comfortable: <0.001 Comfortable versus fast: <0.001 Slow versus fast: <0.001
Soleus				
(Max.)	1209.2±121.5	1397.4±141.77	1681.3±134.23	Slow versus comfortable: 0.007 Comfortable versus fast: 0.017 Slow versus fast: <0.001
(Mean)	159.2±16.05	161.8±18.61	178.2±16.28	Slow versus comfortable: 0.819 Comfortable versus fast: 0.241 Slow versus fast: 0.147
Biceps femoris				
(Max.)	171.1±18.53	236.8±20.24	333.8±54.33	Slow versus comfortable: 0.011 Comfortable versus fast: 0.029 Slow versus fast: 0.006
(Mean)	21.1±1.58	26.7±1.67	34.3±2.88	Slow versus comfortable: <0.001 Comfortable versus fast: 0.001 Slow versus fast: <0.001
Semitendinosus and semimembranosus				
(Max.)	442.2±85.15	649.5±90.10	910.6±213.60	Slow versus comfortable: 0.035 Comfortable versus fast: 0.114 Slow versus fast: 0.016
(Mean)	55.8±7.84	79.7±10.93	107.2±20.74	Slow versus comfortable: 0.001 Comfortable versus fast: 0.038 Slow versus fast: 0.002

Values are mean±standard error

difference between the muscle force at different speeds, it showed an increase of 30% when speed changed from slow to comfortable running while muscle force increased by 40% when the speed shifted from

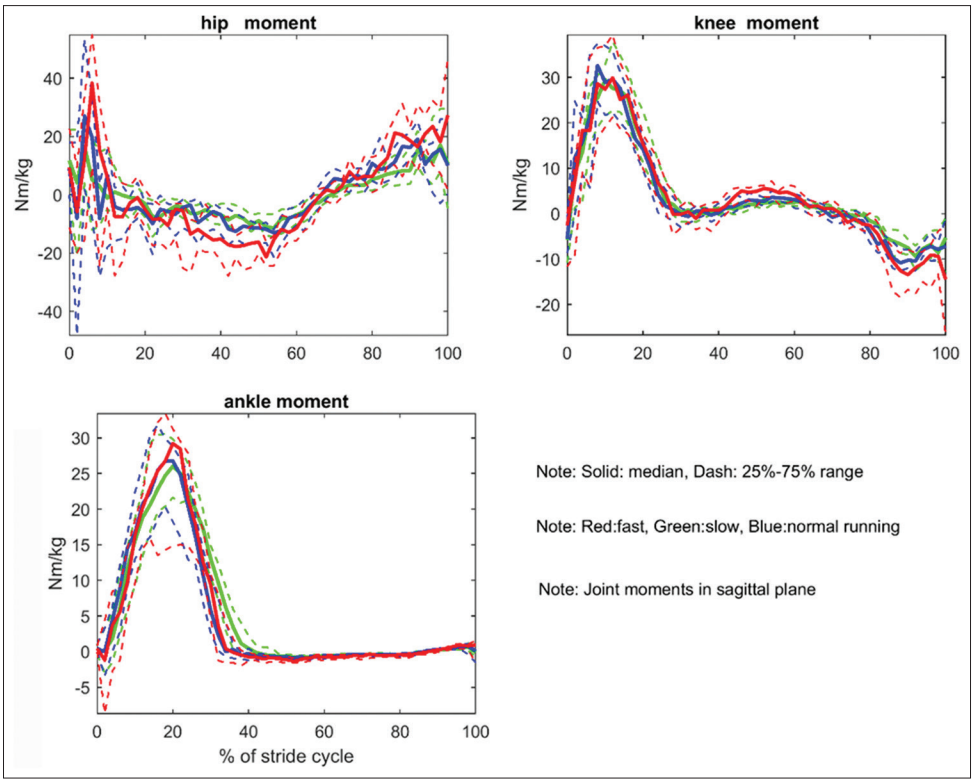


Figure 3: The joint moments in the sagittal plane for three types of running speeds

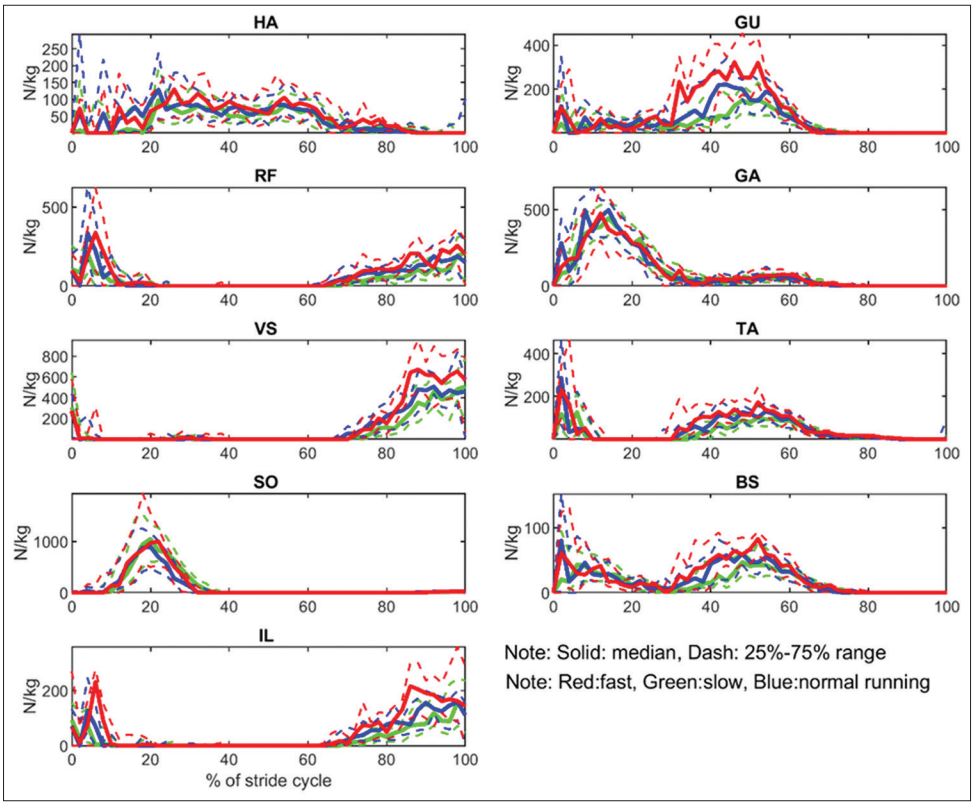


Figure 4: The muscle forces for three types of running speeds

comfortable to fast speed. Rectus femoris showed an increase in muscle force of 15% when compared between slow and comfortable running, but it changed to 33% when the pace shifted from comfortable to fast

running. Biceps femoris showed a significant difference between running at different speeds, it showed an increase of around 28% while the shift in speed from slow to comfortable and comfortable to fast pace. Semitendinosus and semimembranosus also showed a significant difference while running at different speeds with an increase in muscle force of 31% when shifting from slow to comfortable run and 28% increase of muscle force when changing the speed from comfortable to fast, as shown in Figure 4.

Gastrocnemius and soleus showed a significant difference when compared between different speeds, but the change in speed did not bring much change in their muscle force. Tibialis anterior, on the other hand, showed a significant difference in muscle force when running at a different speed with an increase of 25% when speed shifted from slow to comfortable or comfortable to fast pace of running.

EMG was calculated in stance and swing phase Figure 5. The maximum value and root mean square (RMS) of individual muscle in its stance and swing phase were calculated. RMS value was calculated because routine mean value can be nullified, as EMG values are presented on the positive and negative side of the axis. Table 4 shows the EMG data collected from the trials. EMG data of most of the muscle groups showed a gradual increase in amplitude with no significant difference in there RMS value. Rectus femoris, biceps, and femoris showed no change in their mean value when speed changed from comfortable to fast. Whereas, rise in their mean value was seen when speed was increased from slow to comfortable pace. Vastus medialis showed almost the same mean value with an increase in the speed from slow to comfortable to fast pace. Tibialis anterior also showed similar results without any rise in their mean values with an increase in the speed. Vastus lateralis and gastrosoleus showed a continuous rise in their mean value and maximum value when speed increased from slow to comfortable to fast pace.

DISCUSSION

The present study inspected differences in the amount of muscle activity during running at three different speeds, slow, comfortable, and fast. According to the study, rectus femoris and gluteus maximus showed two-fold increase of amplitude with a speed which proves that increase in speed is achieved by an increased swing phase by improving hip flexor and knee extensor action (Gazendam and Hof,

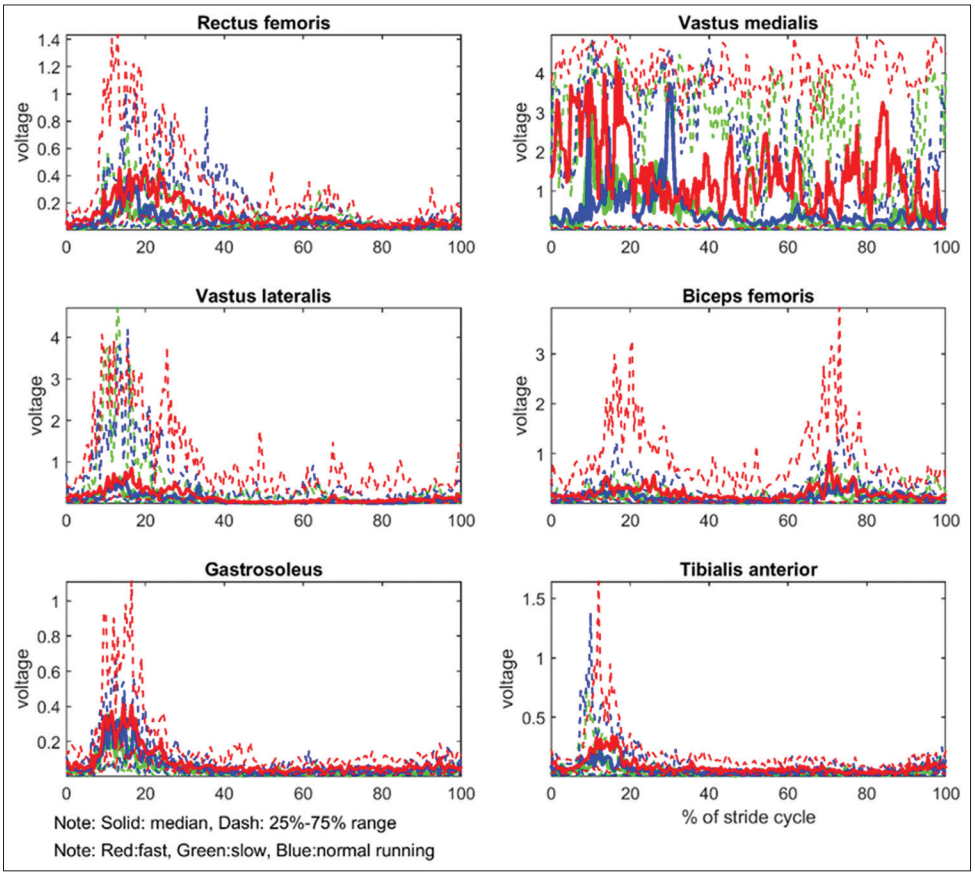


Figure 5: Electromyography patterns from some muscles

Table 4: EMG results calculated of six muscles of lower limbs

EMG (voltage)	Slow	Comfortable	Fast	*P*-value
Rectus femoris		1		Slow versus comfortable: <0.001
Stance Max.	0.5±0.08	.2±0.20	0.8±0.16	Comfortable versus fast: 0.108
				Slow versus fast: 0.060
Stance RMS	0.4±0.12	0.6±0.16	0.6±0.15	Slow versus comfortable: <0.001
				Comfortable versus fast: 0.719
				Slow versus fast: 0.003
Swing Max.	0.4±0.10	0.7±0.18	0.7±0.18	Slow versus comfortable: 0.010
				Comfortable versus fast: 0.782
				Slow versus fast: 0.099
Swing RMS	0.1±0.03	0.2±0.06	0.2±0.09	Slow versus comfortable: 0.005
				Comfortable versus fast: 0.404
				Slow versus fast: 0.039
Vastus medialis				Slow versus comfortable: 0.705
Stance Max.	2.3±0.48	2.4±0.47	1.8±0.38	Comfortable versus fast: 0.177
				Slow versus fast: 0.199
Stance RMS	2.3±0.32	2.4±0.31	2.3±0.3	Slow versus comfortable: 0.662
				Comfortable versus fast: 0.746
				Slow versus fast: 0.835
Swing Max.	2.1±0.46	1.9±0.45	1.8±0.40	Slow versus comfortable: 0.083
				Comfortable versus fast: 0.649
				Slow versus fast: 0.151
Swing RMS	2.1±0.32	2.1±0.32	2.1±0.29	Slow versus comfortable: 0.170
				Comfortable versus fast: 0.873
				Slow versus fast: 0.808
Vastus lateralis				Slow versus comfortable: 0.090
Stance Max.	0.5±0.13	0.7±0.11	0.8±0.12	Comfortable versus fast: 0.358
				Slow versus fast: 0.008
Stance RMS	1.0±0.23	1.1±0.22	1.3±0.27	Slow versus comfortable: 0.266
				Comfortable versus fast: 0.406
				Slow versus fast: 0.059
Swing Max.	0.3±0.07	0.7±0.22	0.7±0.22	Slow versus comfortable: 0.044
				Comfortable versus fast: 0.690
				Slow versus fast: 0.026
Swing RMS	0.5±0.17	0.6±0.17	0.8±0.25	Slow versus comfortable: 0.064
				Comfortable versus fast: 0.193
				Slow versus fast: 0.033
Soleus				Slow versus comfortable: 0.010
Stance Max.	0.6±0.07	0.9±0.14	1.5±0.29	Comfortable versus fast: 0.022
				Slow versus fast: 0.002
Stance RMS	0.3±0.1	0.4±0.13	0.8±0.21	Slow versus comfortable: 0.038
				Comfortable versus fast: 0.023
				Slow versus fast: 0.002
Swing Max.	0.1±0.02	0.2±0.06	0.3±0.09	Slow versus comfortable: 0.044
				Comfortable versus fast: 0.437
				Slow versus fast: 0.032
Swing RMS	0.1±0.06	0.2±0.10	0.6±0.2	Slow versus comfortable: 0.112
				Comfortable versus fast: 0.025
				Slow versus fast: 0.007
Tibialis anterior				Slow versus comfortable: 0.098
Stance Max.	0.8±0.16	1.1±0.2	1.1±0.1	Comfortable versus fast: 0.675
				Slow versus fast: 0.234
Stance RMS	0.1±0.03	0.3±0.07	0.4±0.11	Slow versus comfortable: 0.005
				Comfortable versus fast: 0.319
				Slow versus fast: 0.026
Swing Max.	0.4±0.08	0.5±0.06	0.6±0.08	Slow versus comfortable: 0.400
				Comfortable versus fast: 0.286
				Slow versus fast: 0.067
Swing RMS	0.0±0.01	0.1±0.01	0.1±0.04	Slow versus comfortable: 0.043
				Comfortable versus fast: 0.117
				Slow versus fast: 0.047
Biceps femoris				Slow versus comfortable: 0.047
Stance Max.	0.5±0.08	0.8±0.20	0.9±0.21	Comfortable versus fast: 0.471
				Slow versus fast: 0.019
Stance RMS	0.6±0.20	0.8±0.20	1.1±0.24	Slow versus comfortable: 0.011Comfortable versus fast: 0.080
				Slow versus fast: 0.006

(*Contd*...)

Table 4: (*Continued*)

EMG (voltage)	Slow	Comfortable	Fast	*P*-value
Swing Max.	0.5±0.01	0.7±0.12	0.7±0.15	Slow versus comfortable: 0.029 Comfortable versus fast: 0.873 Slow versus fast: 0.179
Swing RMS	0.5±0.15	0.6±0.17	0.8±0.20	Slow versus comfortable: 0.185 Comfortable versus fast: 0.193 Slow versus fast: 0.026

Values are mean±standard error. RMS is root mean square value and Max. is the maximum value, EMG: Electromyography

2007). Our study showed a similar result. This implies a major change in the muscle force of gluteus maximus and rectus femoris when sifting pace. This shows the importance of strengthening muscles around hip joint before any extreme increase in the running speed while recovering after an injury.

Furthermore, a study showed continuous activity of calf muscle as the speed progresses, especially soleus (Gazendam and Hof, 2007). Our study showed similar results, with an increase of 20% in muscle force of gastrocnemius when shifting speed from slow to comfortable and comfortable to fast, muscle force of soleus increased to 13% from slow to a comfortable speed, and 17% from comfortable to fast speed. This is also supported by the EMG data of soleus muscle, which steadily increases with the change in speed. This suggests that the ankle flexors did not show a major change in their muscle force when shifting speed, but they show a steady rise in their values as speed increases. This might imply the constant involvement of ankle flexors with increasing speed, suggesting no major change in their involvement with increasing frequency of the steps or changing the stride length.

Tibialis anterior has shown a very high significant difference during changing speed while running (Tsuji *et al*., 2015). The present study also showed about 25% change in muscle force when changing speed from slow to comfortable or comfortable to fast. EMG data of the tibialis anterior also supports this fact by showing a significant difference in both the running speeds. This finding represents the importance of ankle stabilizer with increasing speed. This proves the important role of balancing the body, with acceleration and deceleration done by ankle stabilizers with increasing speed while running. Furthermore, significant change in muscle force of tibialis anterior signifies its role while rehabilitation and building up of this muscle before the major rise in speed while running after recovery.

According to a study, running across different speeds produced almost same pattern across quadriceps femoris muscle with increase in EMG amplitude which was independent of muscle group (Jorge *et al*., 2013), but our study showed that mean EMG values of rectus femoris and biceps femoris did not increase significantly, whereas the muscle force of rectus femoris and biceps femoris increased significantly with increasing speed. Similar results were seen with vastus medialis and tibialis anterior. This indicates that mean EMG values are not correlated to muscle forces directly. So far, there are no accepted models to establish the relationship between EMG and muscle force, thus demanding more studies in the future related to this field.

There was a significant flexion of knee joint during jogging versus running similar to our study, which showed knee angle shift of 13% from running at slow speed to comfortable speed and 15% when the speed was changed to fast from comfortable running speed showing significant difference. There was 21% increase in hip angle when compared between slow to comfortable and 10% when compared between comfortable and fast run (Tsuji *et al*., 2015). Interestingly, there was no significant difference found in the ankle angle when shifting the speeds while running. This finding infers that the changes occurring at the hip and knee joint are more while the ankle continues to show a steady rise without any major difference with any change in the speed. These finding matches with the muscles force calculated while changing speed around hip and knee joints, which is more compared to muscles around the ankle joint. Suggesting it is important to strengthen muscles around hip and knee joints if there is a shift of speed, while ankle muscles are essentially performing at similar strength even for slow speed running with a steady increase in their values with increasing speed. This proves the need for the development of the strength of ankle flexors before shifting from walking to running.

Similar results were found with hip moment, which increased 27% when shifting pace from slow to comfortable and comfortable to fast. Knee moment changed only 10% when speed was changed from slow to comfortable, but there was 28% increase when pace shifted from comfortable to fast. Although, ankle moment shifted only 12% when pace changed from slow to comfortable and comfortable to fast.

All of the above findings suggest that muscles acting around the hip joint and knee joint play a major role while

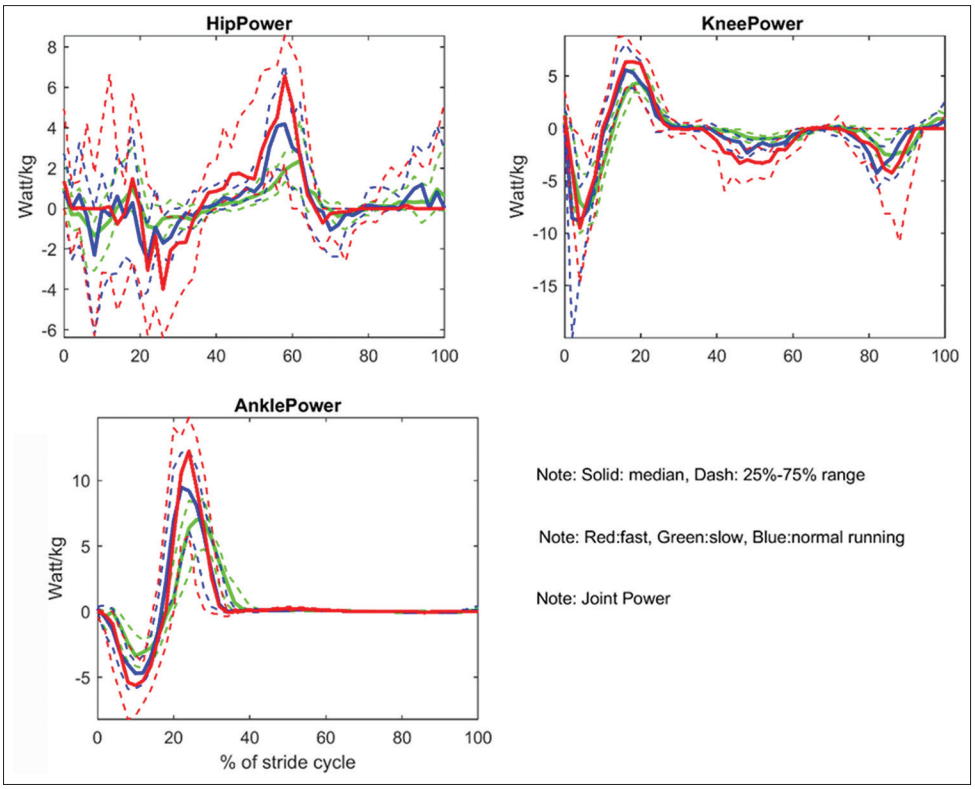


Figure 6: The joint powers for three types of running speeds

shifting pace during running. Even hip angle and hip moment change drastically with a significant change in their value when the change in speed occurred, as shown in Figures 2, 3 and 6. There was 21% increase in hip angle when compared between slow to comfortable and 10% when compared between comfortable and fast run. Interestingly, there was no significant difference found in the ankle angle when shifting the speeds while running. This finding infers that the changes occurring at the hip and knee joint are more while the ankle continues to show a steady rise without any major difference with any change in the speed. The above discussion suggests the importance of the development of muscles around hip and knee joint before a major shift in changing pace while running.

This shows that while shifting the pace, running at slow and comfortable speeds, there is major shift in hip and knee angles while little changes in ankle angle, this may suggest the more changes occurring around hip and knee joint causing those muscles to perform more while shifting pace from slow to fast speed compared to ankle flexors which shows steady increase in their mean value.

CONCLUSION

We can emphasize that to our best knowledge; this is the first study that compared muscle force of lower limbs while running at different speeds. More research is required to be done in this field as injuries related to running are major contributors of today's sports realm.

REFERENCES

1. Gazendam MG, Hof AL. Averaged EMG profiles in jogging and running at different speeds. Gait Posture 2007;25:604-14.
2. Ghaffar M, Raza S, Arnold G, Abboud R, Wang W. A lower limb biomechanical model without using wand-markers for motion analysis during walking and running. Nanotechnol Precis Eng 2015;5:383-90.
3. Glitsch U, Baumann W. The three-dimensional determination of internal loads in the lower extremity. J Biomech 1997;30:1123-31.
4. Hamner SR, Seth A, Delp SL. Muscle contributions to propulsion and support during running. J Biomech 2010;43:2709-16.
5. Hardt DE. Determining muscle forces in the leg during normal human walking an application and evolution of optimization methods. J Biomech Eng 1978;100:74-8.
6. Higashihara A, Ono T, Kubota J, Okuwaki T, Fukubayashi T. Functional differences in the activity of the hamstring muscles with increasing running speed. J Sports Sci 2010;28:1085-92.
7. Zuniga JM, Malek MH. Electromyographic responses of the superficial quadriceps femoris muscles during incremental treadmill running. Muscle Nerve 2013;48:938-44.
8. Nair SP, Gibbs S, Arnold G, Abboud R, Wang W. A method to calculate the centre of the ankle joint: A comparison with the Vicon Plug-in-Gait model. Clin Biomech (Bristol, Avon) 2010;25:582-7.
9. Novacheck TF. The biomechanics of running. Gait Posture 1998;7:77-95.
10. Pedotti A, Krishnan VV, Starke L. Optimization of muscle-force sequencing in human locomotion. Math Biosci 1978;38:57-76.
11. Schache AG, Dorn TW, Pandy MG. Lower-limb muscle function in human running. Adv Mech Rob Des Educ Res 2013;14:323-7.
12. Schache AG, Dorn TW, Williams GP, Brown NA, Pandy MG. Lower-limb

muscular strategies for increasing running speed. J Orthop Sports Phys Ther 2014;44:813-24.
13. Tsuji K, Ishida H, Oba K, Ueki T, Fujihashi Y. Activity of lower limb muscles during treadmill running at different velocities. J Phys Ther Sci 2015;27:353-6.
14. Wang W, Crompton RH, Carey TS, Günther MM, Li Y, Savage R, *et al*. Comparison of inverse-dynamics musculo-skeletal models of AL 288-1 Australopithecus afarensis and KNM-WT 15000 Homo ergaster to modern humans, with implications for the evolution of bipedalism. J Hum Evol 2004;47:453-78.

How to cite this article: Waghmare AP. Muscle Work While Running at Different Speed. Int J Sci Stud 2020;7(12):3-13.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Citrobacter spp. Isolated from Pus Samples in a Tertiary Care Hospital and its Antibiogram in Sonepat, Haryana, India

Sumit Kumar[1], Surinder Kumar[2], Seema Mittal[3], Pallavi Kumari[4]

[1]Associate Professor, Department of Microbiology, Bhagat Phool Singh Government Medical College (Women), Sonepat, Haryana, India, [2]Professor and Head, Department of Microbiology, Bhagat Phool Singh Government Medical College (Women), Sonepat, Haryana, India, [3]Assistant Professor, Department of Microbiology, Bhagat Phool Singh Government Medical College (Women), Sonepat, Haryana, India, [4]Assistant Professor, Department of Physiology, Post Graduate Institute of Medical Education and Research, Dr. Ram Manohar Lohia Hospital, New Delhi, India

Abstract

Introduction: *Citrobacter* infection occurs in a hospital setting in patients with multiple comorbidities and it occasionally causes disease in general population. Neonates and immunocompromised are highly susceptible to *Citrobacter* infections which are mainly caused by *Citrobacter freundii* and *Citrobacter koseri*, the incidence of nosocomial infections caused by antibiotic-resistant Gram-negative pathogens is increasing. This study was done to know the development of drug resistance in emerging pathogen *Citrobacter*.

Methods: The study was conducted in the department of microbiology in a tertiary care hospital for a period of 1 year. Bacterial identification was performed by routine conventional microbial culture and biochemical tests using standard recommended techniques. The antimicrobial susceptibility testing was performed by the Kirby–Bauer disk diffusion technique on Mueller-Hinton agar, as per the Clinical and Laboratory Standards Institute guidelines.

Results: In the present study, 1788 pus samples were processed for a period of 1 year, out of which in 808 pus samples, organisms were isolated. *Staphylococcus aureus* was isolated in 234 (28.96%) cases. *Escherichia coli* was isolated in 168 (20.79%) cases, *Pseudomonas* was isolated in 125 (15.47%) cases, and *Proteus* was isolated in 32 (3.96%) cases. *Enterobacter* spp. was isolated in 51 (6.31%) cases. *Acinetobacter* was isolated in 16 (1.98%) cases. *Candida* spp. was 17 (2.10%). *Citrobacter* spp. was isolated in 85 (10.52%) cases. In 85 cases of *Citrobacter* spp., 58 (68.23%) were *C. freundii* and 27 (31.76%) were *C. koseri.* In the present study, *Citrobacter* spp. was sensitive to amikacin in 36.47% of cases, gentamycin in 48.88% of cases, and levofloxacin in 29.41% of cases.

Conclusion: *Citrobacter* species is an emerging pathogen developing drug resistance. Drug options are limited in the current scenario; hence, injudicious and inadequate use of antibiotics should be avoided.

Key words: Antibiotic resistant, *Citrobacter,* Emerging pathogen, Enterobacteriaceae

INTRODUCTION

Citrobacter spp. is Gram-negative bacilli belongs to the family Enterobacteriaceae that are environmental organism commonly found in soil, water, and intestinal tracts. *Citrobacter* infection occurs in a hospital setting in patients with multiple comorbidities and it occasionally causes disease in general population. Neonates and immunocompromised are highly susceptible to *Citrobacter* infections which are mainly caused by *Citrobacter freundii* and *Citrobacter koseri*.[1]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Citrobacter have 11 different species.[2] *C. koseri* is associated with cases of neonatal meningitis and brain abscess and *C. freundii* with gastroenteritis, neonatal meningitis, and septicemia.[3]

Organisms of genus *Citrobacter* are straight facultatively anaerobic bacilli, found singly or in pairs, and are typically motile by peritrichous flagella. They catabolize glucose and

Corresponding Author: Dr. Sumit Kumar, B-24 Sangam Apartment, Rohini Sector -9, New Delhi - 110 085, India.

numerous other carbohydrates by the production of acid and gas. They are oxidase negative and catalase positive, methyl red positive, Voges–Proskauer negative, lysine decarboxylase negative, and usually citrate positive.[4]

They are a source of several types of infections such as urinary tract infection, respiratory, intra-abdominal, wound, bone, bloodstream, and central nervous system.[5]

Antimicrobial therapy of serious infections caused by *Citrobacter* species can pose a problem as these organisms may possess not only a variety of extended-spectrum β-lactamases but also inducible and derepressed AmpC beta-lactamases as well as metallo-β-lactamase producers.[6,7] *Citrobacter* is an important nosocomial pathogen and its multidrug-resistant isolates are increasingly being reported across the globe.[8]

The health-care system is greatly impacted by the emergence of antibiotic-resistant Gram-negative infections and according to the Centers for Disease Control and Prevention's National Nosocomial Infections Surveillance System, the incidence of nosocomial infections caused by antibiotic-resistant Gram-negative pathogens is increasing.[9]

This study was done to know the occurrence of *Citrobacter* spp. in pus samples and the development of drug resistance in emerging pathogen *Citrobacter*.

METHODS

The study was conducted in the department of microbiology in a tertiary care hospital for a period of 1 year. Pus samples were collected from patients, using strict aseptic precautions and accordance of standard protocols. Pus samples were collected from skin (furuncles, pustules, and abrasions), nasal wounds, ears, legs internal organs (lungs, kidney, and bladder), and catheters. Pus samples were kept in Cary-Blair transport medium until processed for Gram staining and culturing and immediately processed without delay. Bacterial identification was performed by routine conventional microbial culture and biochemical tests using standard recommended techniques. The samples were aseptically inoculated on blood agar (with 5% sheep blood) and MacConkey agar plates incubated aerobically at 35°C–37°C for 24–48 h. Identification and characterization of isolates were performed on the basis of Gram staining, microscopic characteristics, colony characteristic, and biochemical tests.

The antimicrobial susceptibility testing was performed by the Kirby–Bauer disk diffusion technique on Mueller-Hinton agar, as per the Clinical and Laboratory Standards Institute (CLSI) guidelines. Inocula were prepared for each bacterial isolate by adjusting the turbidity to 0.5 McFarland standard and spread on Mueller-Hinton agar plates and incubated overnight at 37°C for 24 h. The zone of inhibition was measured and isolates were classified as sensitive, intermediate, and resistant according to the CLSI tables and guidelines.

RESULTS

In the present study, 1788 pus samples were processed for a period of 1 year, out of which in 808 pus samples, organisms were isolated. *Staphylococcus aureus* was isolated in 234 (28.96%) cases. *Escherichia coli* was isolated in 168 (20.79%) cases, *Pseudomonas* was isolated in 125 (15.47%) cases, and *Proteus* was isolated in 32 (3.96%). *Enterobacter*

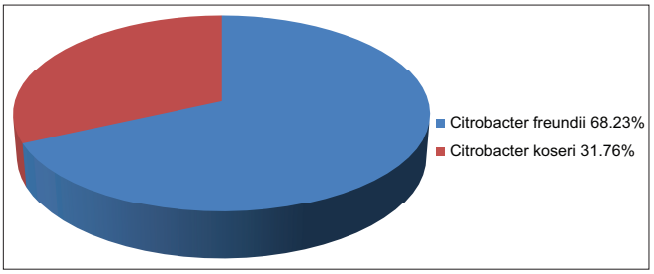


Chart 2: *Citrobacter* spp. isolated from pus samples

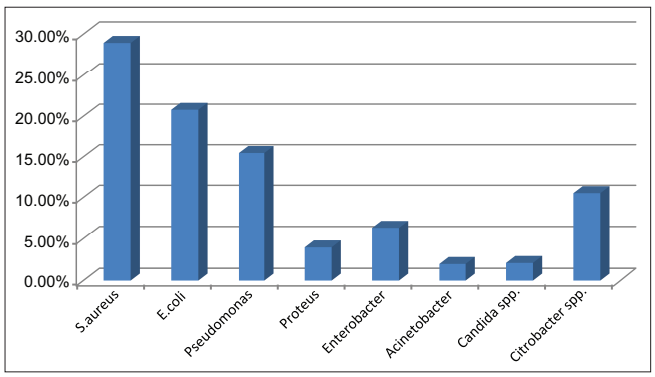


Chart 1: Organisms isolated from pus samples

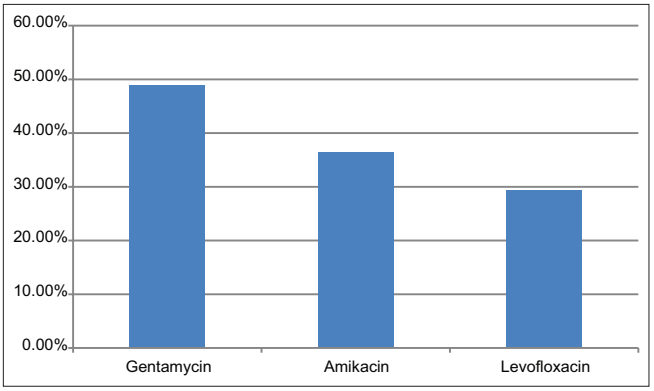


Chart 3: Antibiotic sensitivity pattern of *Citrobacter* spp.

spp. was isolated in 51 (6.31%) cases. *Acinetobacter* was isolated in 16 (1.98%) cases. *Candida* spp. was 17 (2.10%) [Chart 1]. *Citrobacter* spp. was isolated in 85 (10.52%) cases. In 85 cases of *Citrobacter* spp., 58 (68.23%) were *C. freundii* and 27 (31.76%) were *C. koseri* [Chart 2]. In the present study, *Citrobacter* spp. was sensitive to amikacin in 36.47% of cases, gentamycin in 48.88% of cases, and levofloxacin in 29.41% of cases [Chart 3].

DISCUSSION

In the present study, *Citrobacter* spp. was isolated in 85 (10.52%) of pus samples. In the study done by Praharaj *et al*., *Citrobacter* spp. was isolated in 19% of pus samples.[5] In a study done by Dhanya and Bhat, 40 *Citrobacter* were isolated, 28 (70%) are from pus sample.[6] In a study done by Rizvi *et al*., *Citrobacter* was isolated in 10.9% of samples.[7] In a study by Mohan *et al*., *Citrobacter* spp. was isolated in 41.1% of pus samples.[8] In a study done by Trojan *et al*., *Citrobacter* spp. was isolated in 3.5% of pus samples.[10] In a study done by Negi *et al., Citrobacter* was isolated in 7.9% of pus samples.[11] In a study done by Metri *et al*., *Citrobacter* was isolated in 48.1% of pus samples.[12] In a study done by Soni *et al*., 21.98% of pus samples were culture positive, in which 3.02% *Citrobacter* spp. was isolated in the inpatient department (IPD) pus samples and 3.12% samples of the outpatient department (OPD) pus samples, *Citrobacter* spp. was isolated.[13] In a study done by Mohanty *et al*., the total of 205 *Citrobacter* was isolated from all samples, out of which in 12.1% of pus samples *Citrobacter* spp. was isolated.[14]

In the present study, *Citrobacter* spp. was isolated in 85 (10.52%) cases. In 85 cases of *Citrobacter* spp., 58 (68.23%) were *C. freundii* and 27 (31.76%) were *C. koseri.*

In a study done by Praharaj *et al*., the total of 221 isolates of *Citrobacter* spp. was isolated, out of which 130 (58.82%) was *C. freundii* and 91 (41.17%) was *C. koseri.*[5]

In a study done by Dhanya and Bhat, out of 40 *Citrobacter* spp., 8 were *C. freundii* and 18 were *C. koseri.*[6]

In the study done by Rizvi *et al*., 110 *Citrobacter* spp. were isolated, out of which *C. freundii* was isolated in 12 (10.9%) samples and *C. koseri* was isolated in 16 (14.5%).[7]

In a study conducted by Mohan *et al*., 146 *Citrobacter* were isolated, out of which the most common species identified were *C. freundii* (49%) and *C. koseri* (28%).[8]

In the study done by Negi *et al., C. freundii* was isolated in 63.6% of cases and *C. koseri* was isolated in 36.4% of cases.[11]

In the study done by Metri *et al.,* 563 isolates of *Citrobacter* spp. were isolated and *Citrobacter koseri* was in 70% of samples.[12]

In a study done by Mohanty *et al*., *C. koseri* was isolated in 90.2% of cases and *Citrobacter freundii* in 9.8% of cases.[14]

In the present study, *Citrobacter* spp. is sensitive to AMIKACIN in 36.47% cases, sensitive to gentamycin in 48.88% of cases, and levofloxacin in 29.41% of cases.

In a study done by Dhanya and Bhat, *Citrobacter* spp. was resistant to amikacin in 42.5% of cases and was resistant to gentamycin in 52.5% of cases.[6]

In a study done by Mohan *et al*., *Citrobacter* spp. was sensitive to gentamycin in 26.7% and resistant in 73.3% of cases, sensitive to amikacin in 37.7%, and resistant to amikacin in 62.3% of cases and *Citrobacter* isolates were sensitive to levofloxacin in 48.6% of cases and resistant in 51.4% of cases.[8]

In a study done by Trojan *et al*., *Citrobacter* spp. was sensitive to levofloxacin in 67% of cases.[10]

In a study done by Negi *et al., Citrobacter* spp. was resistant to amikacin in 18.1% and gentamycin in 45.5% of cases.[11]

In the study done by Metri *et al., Citrobacter* isolates were sensitive to amikacin in 53.4% of cases.[12]

In the study done by Soni *et al*., *Citrobacter* spp. isolated from IPD samples were sensitive to gentamycin in 55% of cases and amikacin in 55% of cases, and in *Citrobacter* spp. isolated from OPD, all were resistant to gentamycin and in 100% of cases were sensitive to amikacin.[13]

CONCLUSION

Citrobacter species is an emerging pathogen developing drug resistance. Proper aseptic and barrier precautions along with appropriate antibiotic policy are needed to prevent the dissemination of such resistant strains, any type of unnecessary instrumentation should be avoided. Infection control practices should be observed and strictly followed to prevent spread of pathogen. Depending on the antibiotic sensitivity pattern of *Citrobacter* isolates, antibiotics should be used. Drug options are limited in the current scenario; hence, injudicious and inadequate use of antibiotics should be avoided.

REFERENCES

1. Lin SY, Ho MW, Yang YF, Liu JH, Wang IK, Lin SH, *et al.* Abscess caused by *Citrobacter koseri* infection: Three case reports and a literature review. Intern Med 2011;50:1333-7.

2. Ariza-Prota MA, Pando-Sandoval A, García-Clemente M, Fernández R, Casan P. Community-acquired pneumonia and empyema caused by *Citrobacter koseri* in an immunocompetent patient. Case Rep Pulmonol 2015;2015:670373.
3. Ranjan KP, Ranjan N. *Citrobacter*: An emerging health care associated urinary pathogen. Urol Ann 2013;5:313-4.
4. Doran TI. The role of *Citrobacter* in clinical disease of children: Review. Clin Infect Dis 1999;28:384-94.
5. Praharaj AK, Khajuria A, Kumar M, Grover N. Phenotypic detection and molecular characterization of beta-lactamase genes among *Citrobacter* species in a tertiary care hospital. Avicenna J Med 2016;6:17-27.
6. Dhanya A, Bhat S. Clinicomicrobiological study of infections due to *Citrobacter* species. J Evol Med Dent Sci 2015;4:7327-31.
7. Rizvi M, Fatima N, Rashid M, Shukla I, Malik A, Usman A, *et al*. Extended spectrum AmpC and metallo-beta-lactamases in *Serratia* and *Citrobacter* spp. in a disc approximation assay. J Infect Dev Ctries 2009;3:177-86.
8. Mohan S, Agarwal J, Srivastava R, Singh M. Observations on *Citrobacter* species from a tertiary care health center with special reference to multi-drug resistance and presence of CTX-M gene. Indian J Pathol Microbiol 2014;57:439-41.
9. Kim PW, Harris AD, Roghmann MC, Morris JG Jr., Strinivasan A, Perencevich EN. Epidemiological risk factors for isolation of ceftriaxone-resistant versus-susceptible *Citrobacter freundii* in hospitalized patients. Antimicrob Agents Chemother 2003;47:2882-7.
10. Trojan R, Razdan L, Singh N. Antibiotic susceptibility patterns of bacterial isolates from pus samples in a tertiary care hospital of Punjab, India. Int J Microbiol 2016;2016:9302692.
11. Negi V, Pal S, Juyal D, Sharma MK, Sharma N. Bacteriological profile of surgical site infections and their antibiogram: A study from resource constrained rural setting of Uttarakhand State, India. J Clin Diagn Res 2015;9:DC17-20.
12. Metri BC, Jyothi P, Peerapur BV. Anti-microbial resistance profile of *Citrobacter* species in a tertiary care hospital of Southern India. Indian J Med Sci 2011;65:429-35.
13. Soni S, Pandey A, Chauhan K, Saini D. Spectrum of aerobic bacterial pathogen isolated from pus samples and their antibiotic sensitivity pattern in a tertiary care hospital. Int J Sci Res 2019;8:10-2.
14. Mohanty S, Singhal R, Sood S, Dhawan B, Kapil A, Das BK. *Citrobacter* infections in a tertiary care hospital in Northern India. J Infect 2007;54:58-64.

How to cite this article: Kumar S, Kumar S, Mittal S, Kumari P. *Citrobacter* spp. Isolated from Pus Samples in a Tertiary Care Hospital and its Antibiogram in Sonepat, Haryana, India. Int J Sci Stud 2020;7(12):14-17.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Pattern of Congenital Heart Disease in Newborn at a Tertiary Care Hospital

Ilangovan Rakkappan[1], Mariyam Jahana Shirin[2]

[1]Assistant Professor, Department of Pediatrics, Government Theni Medical College, Theni, Tamil Nadu, India, [2]Junior Resident, Department of Pediatrics, Government Theni Medical College, Theni, Tamil Nadu, India

Abstract

Background: Congenital heart disease (CHD) has been defined as a gross structural abnormality of the heart or intrathoracic great vessels that are actually or potentially of functional significance. CHD accounts for about 10% of newborn deaths and nearly half of all deaths due to congenital malformations in developed countries. The vast majority of newborns escape early intervention. The most important role of a pediatrician today is to ensure that, as far as possible, serious CHD should not be missed, especially in the neonatal period and infancy where maximum attrition for CHD occurs.

Objective: The objective of the study was to identify the pattern of CHD using echocardiography in newborns born in a tertiary care hospital in Tamil Nadu.

Methodology: A cross-sectional observational study conducted for 1 year. One hundred and fifty newborns diagnosed to have CHD after they underwent routine clinical examination and pulse oximetry, followed by echocardiography, were included in this study. Study design: This is a cross-sectional study. Place of study: Government Theni Medical College. Study period: 1 year. Sample size: 150.

Inclusion Criteria: Newborns diagnosed to have CHD confirmed with echocardiography were included in this study.

Exclusion Criteria: Newborns whose parents refused to provide consent were excluded from the study.

Results: This study group includes 56% of girls and 44% of boys. It shows that 83% are term babies and the remaining 17% from preterm groups. Among these, 146 babies had acyanotic heart disease as 97% and rest four newborns as 3% had cyanotic disease. Among 146 acyanotic heart disease, 76 newborns (52%) had atrial septal defect (ASD), followed by patent ductus arteriosus (PDA) in 59 newborns (40%), ventricular septal defect (VSD) in 15 newborns (10%), pulmonary hypertension in eight newborns (5%), and magnetic resonance in only one newborn (0.6%). Among four newborns presented with cyanotic heart disease, two newborns presented with total anomalous pulmonary venous connection (50%), followed by transposition of great arteries (25%) and tetralogy of Fallot TOF (25%).

Conclusion: In our study, the pattern of CHD is ASD, followed by PDA and VSD.

Keywords: Congenital heart disease, Echocardiography, Newborn, Pulse oximetry

INTRODUCTION

Heart diseases constitute an important group of pediatric illness and major causes of childhood morbidity and mortality. They may be symptomatic or asymptomatic. Late diagnosis of heart disease in children carries a high risk of mortality and morbidity. To avoid this, mortality and morbidity early diagnosis is important. Heart diseases in children may be congenital or acquired. Congenital heart disease (CHD) is the one present since birth. Some cases of CHDs are asymptomatic and are diagnosed on routine health visits.[1-3] It is important to mind that children with CHDs are at increased risk of poor growth. The factors which play a role in poor growth may be feeding difficulties, excessive caloric requirement, and the cardiac lesions on growth and development.[4]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Classification of CHDs in Children

Congenital lesions are divided into two major categories: Acyanotic and cyanotic. Acyanotic lesions further divided

Corresponding Author: Dr. Ilangovan Rakkappan, B 56-Main Road, Rathinamnagar, Theni - 625 531, Tamil Nadu, India.

into three main categories.[5]

1. Left to right shunt
2. Acyanotic obstructive lesions
3. Acyanotic regurgitant lesions

Cyanotic lesions are further divided into two major categories.

1. Lesions with decreased pulmonary blood flow.
2. Lesions with increased pulmonary.

Definition of CHDs:

1. Normal: No echocardiographic abnormality or any of the following:
   - Patent ductus arteriosus (PDA) <2 mm in size without volume overload of the left ventricle,
   - Patent foramen ovale or atrial septal defect (ASD) <5 mm without volume overload of the right ventricle,
   - Mild turbulence at branch pulmonary arteries.
2. Insignificant CHDs:
   - Very small muscular ventricular septal defect (VSD), as these is likely to close spontaneously.
3. Significant CHDs:
   - These are divided into minor and major CHDs:
     a. Minor CHD:
     ASD >5 mm, PDA >2 mm with left ventricle volume overload, restrictive VSD, and valvular aortic/pulmonary stenosis with gradients <25 mmHg.
     b. Major CHD:
     CHD was likely to require intervention within the 1st year, including newborns with critical CHD that require intervention within the first 4 weeks of life.

Further divided into two categories; acyanotic and cyanotic CHDs;

i. Acyanotic CHD: Nonrestrictive VSD, valvular aortic/pulmonary stenosis with gradients >25 mmHg, and coarctation of aorta (nonduct dependent).
ii. Cyanotic CHD: Hypoplastic left heart syndrome, transposition complexes, aortic arch interruption, univentricular heart, tetralogy of Fallot (TOF), and TOF-such as conditions associated with pulmonary stenosis or atresia, total anomalous pulmonary venous connection (TAPVC), persistent truncus arteriosus, and Ebstein's anomaly.

4. Other cardiac findings on echocardiography
   Persistent pulmonary hypertension (PHT) of newborn, cardiac tumor, situs inversus dextrocardia, and arrhythmias (complete heart block, and supraventricular tachycardia).[6]

Clinical Evaluation of the Child with Heart Diseases

The clinical history, physical examination, chest radiography, pulse oximetry, and echocardiogram are the keystones in the diagnosis of CHDs in newborns.

Symptoms of CHDs are variable, sometimes asymptomatic, and subtle and may manifest anytime from fetal period to adulthood. Usually, critical CHDs present early in life. Some may go undiagnosed and identified in later life incidentally because of asymptomatic murmur.

Some cases of CHDs are asymptomatic and presents with an only heart murmur.[7] The main symptoms of CHDs are mostly non-specific such as poor feeding, failure to thrive or poor weight gain, and poor exercise tolerance. Developmental delay may be a presenting symptom. Easy fatigability and diaphoresis may be the other presenting symptoms. Easy fatigability presents as difficulty in feeding in newborns and in infants.

CHD affects neurodevelopment across the lifespan. In infants, the developmental delay can occur, ranging from mild hypotonia to persistent delay affecting many aspects of development including language, social skills, and feeding. The spectrum of neurodevelopmental impairment is wide. Some children have minimal or no impairment, whereas others are severely affected. In general, children with milder forms of diseases such as ASD and VSD have fewer neurodevelopmental sequelae than those with complex lesions such as single ventricle or hypoplastic heart syndromes. However, medical, environmental, and genetic factors all play a role.[8]

All newborns recruited into the study were screened using transthoracic echocardiography after the initial evaluation but within 48 h of life.

Some Common CHDs

ASD

Fossa ovalis ASD: Located in the central portion of atrial septum, in the position of foramen ovale. This type is amenable to closure by cardiac catheterization. Overall, the most common type (Ostium secundum type).

Sinus venosus ASD: At the junction of Superior vena cava and right atrium most commonly (Superior vena caval type).

Ostium primum type: Due to failure to over seal the septum primum most commonly seen in Down's syndrome.

Coronary sinus ASD: Defect in the roof of the coronary sinus.

Treatment: Surgical closure is better done before school entry to avoid late complications. Small defects <8 mm can be observed. Fossa ovalis with good margins may be closed percutaneously in the catheterization lab. Other defects need surgical closure.[9]

VSD

Most common type of CHD is VSD (15-20%) of which Perimembraneous VSD is most common type. Other types are inlet, outlet, and trabecular. Spontaneous closure is possible in small muscular types, about 30%.

Treatment: Medical treatment for congestive cardiac failure (CCF), RRTI, IEC, and anemia if occurs.

Surgical closure indicated in larger defects, evidence of ventricular volume overload, progressive aortic valve diseases, infundibular defects, chamber enlargement, and pulmonary arterial pressure more than 50% of systemic pressure.[10]

PDA

It is the persistence of normal fetal channel connection between aorta and pulmonary artery. Functional closure usually occurs between 12 and 24 h. Prematurity is associated with delayed closure of PDA.

Treatment of PDA: Indomethacin and ibuprofen can be tried in preterm infants in the neonatal period. Paracetamol therapy also has promising results and an alternative for PDA closure when indomethacin is contraindicated.[11]

After 10 days of post-natal age, the ductus rarely responds to medical therapy. Such patients need non-surgical closure such as coil closure and with occlusive devices.

Acyanotic Obstructive Lesions

Aortic stenosis

The most common cause is the bicuspid aortic valve. Severe forms of stenosis present early in the newborn. Less severe forms present later in life. Supra valvular aortic stenosis is seen in association with Williams's syndrome.

Treatment: Pressure gradient <50 needs regular follow-up.

1. Balloon valvuloplasty (Isolated stenosis without aortic regurgitation)[12] indicated in pressure gradient more than 50 with symptoms or ST-segment and T-wave changes in the electrocardiogram. Pressure gradient more than 75 without any symptoms.
2. Aortic valve surgery or valve replacement is indicated in failed valvuloplasty and cases associated with aortic regurgitation. Aortic valve replacement with a mechanical prosthesis or Ross surgery with pulmonary autograft is the surgical procedure.[13]

Coarctation of aorta

COA manifestation in CHD is 6-8%. Usually manifests as a discrete constriction of the aortic isthmus. Presence of aortic arch hypoplasia is relevant in developing hypertension.[14]

Clinical presentation depends on the presence of other lesions such as VSD and PDA. Severe disease presents as collapse or shock-like state in newborn after ductal closure. The infant may present with CCF. The hallmark of physical finding is discrepancy between upper limb and lower limb pulses and blood pressure.

Treatment: Treatment of CCF with inotropes and diuretics, followed by surgical repair in newborn. Percutaneous Balloon Angioplasty and stenting can be done as a bridging procedure in children with CCF also.[15]

Resection and end to end anastomosis and subclavian flap repair are the most common surgical approaches. Aneurysm and rupture are the most common complication, and this needs reintervention.[16-18]

Pulmonary stenosis

Valvular form is the common type. Other types are subvalvular and supra valvular. In the common form, the valve is thickened with fused or absent commissures. The pulmonary valve is dysplastic in Noonan syndrome. Supra valvular pulmonary stenosis often refers to the narrowing of the pulmonary artery branch. Most patients are asymptomatic and well developed. Critical pulmonary stenosis presents with cyanosis.

Treatment: Mild stenosis (Pressure gradient <50) needs yearly follow-up. Moderate (pressure gradient 50–79) and severe stenosis (pressure gradient more than 80) need balloon pulmonary valvotomy. Balloon pulmonary valvotomy has excellent short-term and long-term outcome.[19] Surgical valvotomy is indicated in patients with dysplastic valves and severe stenosis, which failed to respond to balloon valvotomy.

Common Cyanotic CHDs

Tetrology of Fallot's

The four components of TOF are VSD, aortic override of VSD, right ventricular outflow tract obstruction, and right ventricular hypertrophy. Other associated anomalies are valvular pulmonary artery stenosis, right-sided aortic arch, and ASD. About 5% of cases have an anomalous origin of the left anterior descending artery from the right coronary artery. Clinical severity of TOF varies with the degree of pulmonary stenosis. With mild obstruction, systolic murmur is the only presenting symptom known as pink tetralogy. With severe obstruction, the patient presents with cyanosis.[20]

Treatment: Surgical correction accomplished by patch closure of VSD and right ventricular muscle resection with or without pulmonary valvotomy. Cases with anomalous left coronary artery may need temporary BLALOCK

TAUSSING shunt followed by more complicated intracardiac repair and takedown of the shunt.

Transposition of great arteries (TGA)

Aorta and pulmonary artery arising from wrong ventricles leading to deoxygenated blood in systemic circulation and oxygenated blood back to lungs. VSD is the common associated anomaly in 25% cases. Newborn with intact VSD presents with severe cyanosis within 24 h of life. Reverse differential cyanosis is the hallmark of TGA with intact septum. Other presentations in TGV are a failure to thrive and CCF.

Treatment: Arterial switch operation is corrective surgery. In addition, the coronary artery must be moved to the new aortic root. Most successful when performed age <2 weeks. If the diagnosis is made late, then atrial switch operation (Mustard and Senning) may be performed. Rastelli operation is the procedure of choice when TGA is complicated with pulmonary artery stenosis or left ventricular outflow tract obstruction and a VSD.[21,22]

Total anomalous pulmonary venous return

All the pulmonary veins drain to systemic veins or the right atrium instead of draining to the left atrium. The obstructive type of TAPVR presents within few hours of life with cyanosis and respiratory distress, and the cyanosis never responds to any non-surgical intervention. The unobstructed type presents in the neonatal period or infantile period with CCF, RRTI, and FTT.

Treatment: Reanastomosis of pulmonary venous confluence to the posterior wall of the left atrium is choice.

Aim of the Study

The aim of the study was to identify the pattern of CHD using echocardiography in newborns born in a tertiary care hospital in Tamil Nadu.

MATERIALS AND METHODS

It is a cross-sectional observational study conducted over a period of 1 year at Government Theni Medical College, Tamil Nadu, we screened newborns for CHDs using echocardiography. Nearly 7000 deliveries occur in this hospital every year, but babies after confirmed to have CHD with echocardiography were recruited into the study. The ethical committee approval was obtained.

Informed Consent

An informed consent sheet with details of the study protocol was given to one of the parents and approval sought in writing before recruiting the newborn in the study. None of the parents refused to provide consent.

Initial Evaluation

The research officer performed routine clinical examination within 24 h of birth. This was recorded in a form that included the following parameters: Central cyanosis, murmur on chest auscultation, and respiratory distress. Furthermore, the field investigator for all newborns obtained non-invasive arterial oxygen saturation within 48 h of life. Oximetry values were obtained from one of the feet of the baby. A persistent saturation of <95% was considered abnormal.

Echocardiography

All newborns recruited into the study were screened using transthoracic echocardiography after the initial evaluation but after 72 h of life. A pediatric cardiologist performed echocardiography using the ultrasound system. The technique involved performing cross-sectional echocardiography, and Doppler and color flow imaging in various views. The cardiologist was not aware of the results of the initial clinical evaluation.

RESULTS

After an initial evaluation, 150 newborns with significant heart disease are recruited in the study. Among these, 84 (56% of total sample size) are girls and 66 (44% of total sample size) are boys [Figure 1]; 124 term and 26 preterm babies [Figure 2]. The pattern of CHD in our study is illustrated in the bar diagram below. Among these, 146 newborns had acyanotic heart disease (97%) and the rest four newborns (3%) had cyanotic heart disease. Among 146 acyanotic heart disease, 76 newborns (52%) had ASD followed by PDA in 59 newborns (40%), VSD in 15 newborns (10%), PHT in eight newborns (5%), and magnetic resonance in only one newborn (0.6%). Among four newborns with cyanotic heart disease, two newborns presented with TAPVC (50%), followed by TGA (25%) and TOF (25%) [Figure 3].

DISCUSSION

In our study, girl babies outnumbered boy babies with a ratio of 1.27:1. We found that CHD was more common in female births, which was very similar to the study conducted in Nigeria[23] by Antia *et al.* which showed a female preponderance. However, our finding is not similar to that reported by Nikyar *et al.* from Gorgan[24] where there is a male preponderance and found out the ratio of male:female is 1.35. Alabdulgader *et al.* from Saudi Arabia[25] and Stephensen *et al.* from Iceland[26] reported that the frequency was the same for males and females.

In this study of pattern of CHD in our hospital, term child (83%) is affected more with CHD than preterms (17%). In

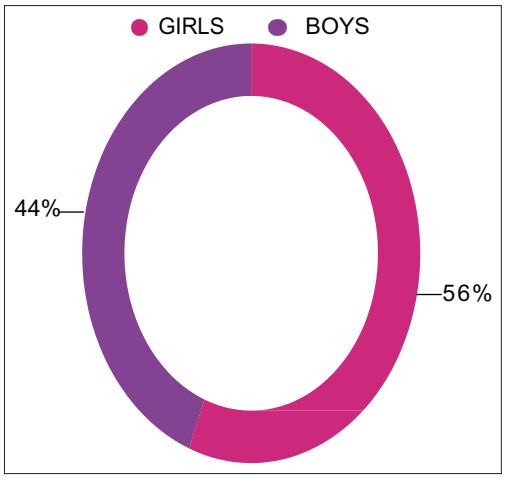


Figure 1: Distribution of congenital heart disease in boys versus girls

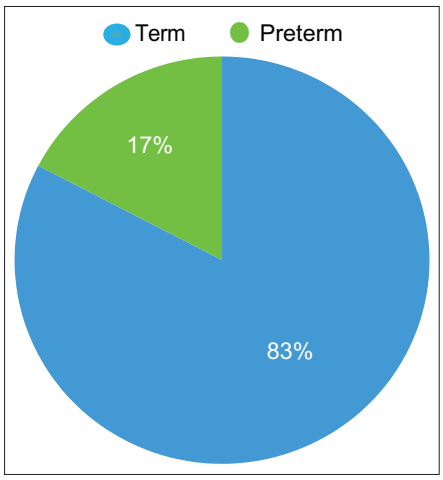


Figure 2: Distribution of congenital heart disease in term and preterm babies

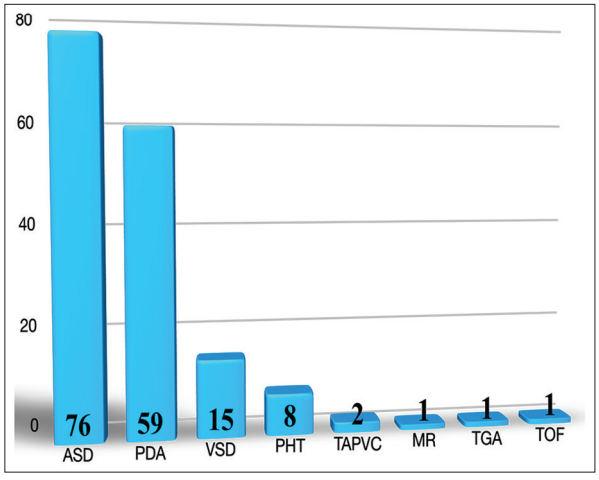


Figure 3: Pattern of congenital heart disease

contrast to our study, Steurer *et al.* in California[27] found out that preterm babies are at higher risk of CHD.

The most frequent type of CHD that we found in our study is to be ASD, which is in accordance with a recent study done in Saudi by Majeed-Saidan *et al.*[28] Furthermore, another study in Iran[29] cited the most common CHD in the newborn as ASD, while in other studies, the most frequent type of CHD was VSD.[30-34] In our study, the pattern of CHD is ASD, followed by PDA and VSD. Majeed-Saidan *et al.*[28] reported the pattern as ASD, followed by VSD. The study by Nikyar *et al.* in Gorgan, Northern Iran, reported the pattern as ASD followed by VSD and PDA.

CONCLUSION

CHD is one of the leading causes of morbidity and mortality in growing children in developing countries. Most of the babies born with CHD are expected to have a normal life when diagnosed and treated as early as possible. However, in developing countries, high incidence of preterm delivery and birth asphyxia CHD remains neglected and often overlooked.

The lack of awareness, nonavailablity of trained staffs, and absence of screening programs for CHD in peripheral level leads to delayed diagnosis and poor outcome of CHD. By various training programs, recruiting skilled staff and availability of instruments at the peripheral level, we can ensure early diagnosis and treatment of CHD, to prevent a serious risk of avoidable morbidity, mortality, and handicaps.

This study shows that the most common acyanotic CHD is ASD, and the most common cyanotic CHD is TAPVC and TOF. Our study has certain limitation since it was done at the periphery hospital level.

REFERENCES

1. Mitchell SC, Korones SB, Berendes HW. Congenital heart disease in 56,109 births. Incidence and natural history. Circulation 1971;43:323-32.
2. IAP Textbook.
3. Kuehl KS, Loffredo CA, Ferencz C. Failure to diagnose congenital heart disease in infancy. Pediatrics 1999;103:743-7.
4. Bode-Thomas F, Ige OO, Yilgwan C. Childhood acquired heart diseases in Jos, North central Nigeria. Niger Med J 2013;54:51-8.
5. Daymont C, Neal A, Prosnitz A, Cohen MS. Growth in children with congenital heart disease. Pediatrics 2013;131:e236-42.
6. Saxena A, Mehta A, Sharma M, Salhan S, Kalaivani M, Ramakrishnan S, *et al*. Birth prevalence of congenital heart disease: A cross-sectional observational study from North India. Ann Pediatr Cardiol 2016;9:205-9.
7. Mohammad N, Shaikh S, Memon S, Das H. Spectrum of heart disease in children under 5 years of age at Liaquat University hospital, Hyderabad, Pakistan. Indian Heart J 2014;66:145-9.
8. Rollins CK, Newburger JW. Cardiology patient page. Neurodevelopmental outcomes in congenital heart disease. Circulation 2014;130:e124-6.
9. Kumar RK. Congenital Heart Disease, IAP Textbook of Pediatrics. New Delhi, India: Jaypee Brothers; 2008.

10. Minette MS, Sahn DJ. Ventricular septal defects. Circulation 2006;114:2190-7.
11. Mohanty PK, Nagesh NK, Razak A. Oral paracetamol for closure of patent ductus arteriosus in selected preterm neonates. Indian Pediatr 2016;53:171-2.
12. Borghi A, Agnoletti G, Valsecchi O, Carminati M. Aortic balloon dilatation for congenital aortic stenosis: Report of 90 cases (1986-98). Heart 1999;82:e10.
13. Elkins RC, Knott-Craig CJ, Ward KE, Lane MM. The Ross operation in children: 10-year experience. Ann Thorac Surg 1998;65:496-502.
14. Kenny D, Hijazi ZM. Coarctation of the aorta: From fetal life to adulthood. Cardiol J 2011;18:487-95.
15. Bouzguenda I, Marini D, Ou P, Boudjemline Y, Bonnet D, Agnoletti G. Percutaneous treatment of neonatal aortic coarctation presenting with severe left ventricular dysfunction as a bridge to surgery. Cardiol Young 2009;19:244-51.
16. Rubay JE, Sluysmans T, Alexandrescu V, Khelif K, Moulin D, Vliers A, *et al*. Surgical repair of coarctation of the aorta in infants under one year of age. Long-term results in 146 patients comparing subclavian flap angioplasty and modified end-to-end anastomosis. J Cardiovasc Surg (Torino) 1992;33:216-22.
17. Sciolaro C, Copeland J, Cork R, Barkenbush M, Donnerstein R, Goldberg S. Long-term follow-up comparing subclavian flap angioplasty to resection with modified oblique end-to-end anastomosis. J Thorac Cardiovasc Surg 1991;101:1-3.
18. von Kodolitsch Y, Aydin MA, Koschyk DH, Loose R, Schalwat I, Karck M, *et al*. Predictors of aneurysmal formation after surgical correction of aortic coarctation. J Am Coll Cardiol 2002;39:617-24.
19. Jarrar M, Betbout F, Farhat MB, Maatouk F, Gamra H, Addad F, *et al*. Long-term invasive and noninvasive results of percutaneous balloon pulmonary valvuloplasty in children, adolescents, and adults. Am Heart J 1999;138:950-4.
20. Bertranou EG, Blackstone EH, Hazelrig JB, Turner ME, Kirklin JW. Life expectancy without surgery in tetralogy of Fallot. Am J Cardiol 1978;42:458-66.
21. Liebman J, Cullum L, Belloc NB. Natural history of transpositon of the great arteries. Anatomy and birth and death characteristics. Circulation 1969;40:237-62.
22. Fricke TA, d'Udekem Y, Richardson M, Thuys C, Dronavalli M, Ramsay JM, *et al*. Outcomes of the arterial switch operation for transposition of the great arteries: 25 years of experience. Ann Thorac Surg 2012;94:139-45.
23. Antia AU. Congenital heart disease in Nigeria. Clinical and necropsy study of 260 cases. Arch Dis Child 1974;49:36-9.
24. Nikyar B, Sedehi M, Mirfazeli A, Qorbani M, Golalipour MJ. Prevalence and pattern of congenital heart disease among neonates in Gorgan, Northern Iran (2007-2008). Iran J Pediatr 2011;21:307-12.
25. Alabdulgader AA. Congenital heart disease in Saudi Arabia: Current epidemiology and future projections. East Mediterr Health J 2006;12 Suppl 2:S157-67.
26. Stephensen SS, Sigfusson G, Eiriksson H, Sverrisson JT, Torfason B, Haraldsson A, *et al*. Congenital cardiac malformations in Iceland from 1990 through 1999. Cardiol Young 2004;14:396-401.
27. Steurer MA, Baer RJ, Keller RL, Oltman S, Chambers CD, Norton ME, *et al*. Gestational age and outcomes in critical congenital heart disease. Pediatrics 2017;140:e20170999.
28. Majeed-Saidan MA, Atiyah M, Ammari AN, AlHashem AM, Rakaf MS, Shoukri MM, *et al*. Patterns, prevalence, risk factors, and survival of newborns with congenital heart defects in a Saudi population: A three-year, cohort case-control study. J Congen Cardiol 2019;3:2.
29. Rahim F, Ebadi A, Saki G, Remazani A. Prevalence of congenital heart disease in Iran: A clinical study. J Med Sci 2008;8:547-52.
30. Alabdulgader AA. Congenital heart disease in 740 subjects: Epidemiological aspects. Ann Trop Paediatr 2001;21:111-8.
31. Begić H, Tahirović H, Mesihović-Dinarević S, Ferković V, Atić N, Latifagić A. Epidemiological and clinical aspects of congenital heart disease in children in Tuzla Canton, Bosnia-Herzegovina. Eur J Pediatr 2003;162:191-3.
32. Bassili A, Mokhtar SA, Dabous NI, Zaher SR, Mokhtar MM, Zaki A. Congenital heart disease among school children in Alexandria, Egypt: An overview on prevalence and relative frequencies. J Trop Pediatr 2000;46:357-62.
33. Squarcia U, Agnetti A, Carano N, Zavota L, Viola P, Haitink O. Epidemiological study of congenital heart diseases in the province of Parma during the years 1972-80 (author's transl). Pediatr Med Chir 1981;3:459-62.
34. Manetti A, Pollini I, Cecchi F, De Simone L, Cianciulli D, Carbone C, *et al*. The epidemiology of cardiovascular malformations. III. The prevalence and follow-up of 46,895 live births at the Careggi Maternity Hospital, Florence, in 1975-1984. G Ital Cardiol 1993;23:145-52.

How to cite this article: Rakkappan I, Shirin MJ. Pattern of Congenital Heart Disease in Newborn at a Tertiary Care Hospital. Int J Sci Stud 2020;7(12):18-23.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Surgical Site Infection and Antimicrobial Resistance Following Resection and Reconstructive Surgery for Oral Cancers: Are We Ready for the Superbugs?

Bharadhwaj Ravindhran[1], A M Hema[2], Sanjay Narayana Murthy[3], J T Swaroop[4], M Vijay Kumar[5]

[1]Assistant Consultant, Department of Surgical Oncology, Bharath Cancer Hospital and Institute of Oncology, Mysuru, Karnataka, India, [2]Senior resident, Department of Pharmacology, Mysore Medical College and Research Institute, Mysuru, Karnataka, India, [3]Intern, Department of Surgery, Mandya Institute of Medical Sciences, Mandya, Karnataka, India, [4]Assistant Professor, Department of Surgery, Mandya Institute of Medical Sciences, Mandya, Karnataka, India, [5]Chief, Department of Surgical Oncology, Bharath Cancer Hospital and Institute of Oncology, Mysuru, Karnataka, India

Abstract

Background: Surgical site infection (SSI) is the most common complication occurring in 19–47% of patients undergoing surgery for head-and-neck cancers. This study aims to assess the predictive factors of SSIs and antibiotic resistance patterns in patients undergoing resection and reconstructive surgery for oral cancers.

Materials and Methods: The clinicopathological data of all patients who underwent surgery for oral cancers at our oncological referral center in South India between October 2014 and May 2019 were reviewed. The differences between groups were compared using independent samples t-test or Mann–Whitney U-test and categorical data were analyzed by Pearson's Chi-square test, Fisher's exact, or continuity correction where appropriate. Receiver operating characteristic (ROC) curve analysis was performed to find the cutoff levels for the various predictors of SSI, using the Youden's index method. A linear regression analysis was done to define the cause-effect relationship of the categorical response variable with explanatory variables.

Results: Of the 135 patients who were studied in our cohort, 43 patients (31.2%) developed SSI. The most commonly isolated organism was *Staphylococcus aureus* (11%; *n* = 15) followed by *Enterococcus* species (4.4%; *n* = 6) followed by coagulase-negative *S. aureus* (3%; *n* = 4) and *Escherichia coli* (37%; *n* = 5). In this study, univariate and multivariate analyses have showed that diabetes mellitus, body mass index (BMI) >25 or <18, neutrophil-to-lymphocyte ratio (NLR) >3.75, platelet-to-lymphocyte ratio (PLR) >137.5, neoadjuvant chemotherapy or radiotherapy, prolonged operative duration, and prolonged anesthesia exposure may render patients more vulnerable to SSI. Moreover, among these parameters, a PLR >137.5, NLR >3.75, and BMI >25 or <18 were found to be highly predictive of SSI. The highly resistant organisms isolated were *S. aureus* and *Enterococcus* species in our study.

Conclusion: The identification of these risk factors in patients undergoing surgery for oral cancers can help in the identification of patients who may be at a higher risk of developing SSI and therefore help in improving the overall outcome, especially in an LMIC setting.

Key words: Oral cancer, Predictive factors, Reconstruction, Surgical site infection

INTRODUCTION

Surgical site infection (SSI) as defined by the Centers for Disease Control and Prevention (CDC) is the infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure, or within 90 days, if a prosthetic material is implanted at surgery. SSI is the most common complication, occurring in 19–47% of patients undergoing surgery for head-and-neck cancers.[1]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Several studies have suggested various risk factors for the development of SSIs, namely, smoking, alcohol intake, body mass index (BMI), pre-operative anesthesia risk (American Society of Anesthesiologists score), length of pre-operative hospital stay, pre-surgical tracheostomy,

Corresponding Author: Bharadhwaj Ravindhran, Department of Surgical Oncology, Bharath Cancer Hospital and Institute of Oncology, Mysuru, Karnataka, India.

previous surgery, blood loss, and prior chemotherapy or radiotherapy.[2] Few studies on free flap surgery have reported that flap SSIs were caused by bacteria that are not part of normal flora and many were resistant to the prophylactic antibiotic used.[3]

Existing studies have conflicting results and have imparted little emphasis on independent risk factors and antibiotic resistance pattern. This study aims to assess the predictive factors of SSIs and resistance patterns in patients undergoing resection and reconstructive surgery for oral cancers.

MATERIALS AND METHODS

This study involving a historical cohort was conducted in a high-volume oncology referral hospital in South India in an LMIC setting. After approval by the Institutional Ethics Committee, 135 patients who underwent resection and reconstruction for head-and-neck cancers were recruited between October 2014 and May 2019. Clinicopathological features were analyzed and correlated with SSI.

The compliance of the data to a normal distribution was determined using the Shapiro–Wilk test. Quantitative data are expressed as mean ± standard deviation, median ± interquartile range, or median and range (maximum-minimum). Categorical data are expressed as n (number) or percentage (%). Data were analyzed at a 95% confidence interval, and statistical significance was set at $P < 0.05$. Baseline demographic characteristics, laboratory findings, clinical presentation, bacteriology, and predisposing factors were compared between patients who developed SSI and patients who did not develop SSI. Receiver operating characteristic (ROC) curve analysis was performed to find the cutoff levels for the various predictors of SSI, using the Youden's index method. The differences between groups were compared using Mann–Whitney U-test, and categorical data were analyzed by Pearson's Chi-square test, Fisher's exact, or continuity correction where appropriate. A linear regression test was used to define the cause-effect relationship of the categorical response variable with explanatory variables. All statistical calculations were performed using the Statistical Package for the Social Sciences program (SPSS) version 16 (IBM).

RESULTS

The mean age of the cohort was 59.2 ± 14.9 years, with 76 (56.3%) patients being men. Among them, 43 patients (31.2%) developed SSIs. About 32.6% (n = 14) were diabetics and 20.9% (n = 9) had ischemic heart disease. All patients had a history of tobacco usage. Out of the patients who developed SSIs, 67.4% (n = 29) used chewable forms of tobacco and 27.9% (n = 12) smoked indigenous cigarettes/beedis. Only 4.7% (n = 2) were cigarette smokers. The most common site of lesion was buccal mucosa (38.5%; n = 52), followed by tongue 11.9% (n = 16), retromolar trigone, and the floor of mouth 10.4% (n = 14). About 71.9% (n = 97) of the patients had moderately differentiated squamous cell carcinoma (SCC), 14.1% (n = 19) had poorly differentiated SCC, and 11.1% (n = 15) had well-differentiated SCC. The most common flap used for reconstruction was the pectoralis major myocutaneous flap (51.1%; n = 69) followed by the nasolabial flap (20%; n = 27) and free radial forearm flap (19.3%; n = 26). The other types of flaps that were used were free fibular (5.9%; n = 8) and free anterolateral thigh flap (2.2%; n = 3).

Out of the patients who developed SSIs, the most commonly isolated organism was *Staphylococcus aureus* (11%; n = 15) followed by *Enterococcus* species (4.4%; n = 6) followed by coagulase-negative *S. aureus* (3%; n = 4) and *Escherichia coli* (37%; n = 5). The cultures of nine patients did not show any growth even on delayed incubation. About 46.5% (n = 20) of the patients who developed SSI were found to have highly resistant organisms while 48.8% (n = 21) had heavy growth of the organisms in culture. The highly resistant organisms were seen to be partially sensitive to tigecycline, colistin, or chloramphenicol. The comparison of attributes between patients who developed SSI and did not develop SSI is depicted in Table 1. The ROC curve to find the optimal cutoff ratios for NLR and PLR as predictors of SSI is depicted in Figure 1. Linear regression analysis shows that a PLR >137.5, NLR >3.75, and BMI >25 or <18 could satisfactorily predict the susceptibility of patients to SSI [Table 2]. The predictive power of the model was seen to be 72% (Nagelkerke R Square) and the Hosmer–Lemeshow goodness-of-fit test showed $P = 0.607$, indicating good fit.

DISCUSSION

SSIs are among the most serious but preventable post-operative complications that have shown to significantly increase morbidity and length of hospital stay in patients undergoing head-and-neck surgery.[4] Most SSIs may be attributed to the result of the contamination of surgical wounds from exposure to microorganisms that reside in oral and pharyngeal cavities.[5,6] The majority of published information regarding the predictive factors of SSI in patients with head-and-neck cancer has combined different surgical procedures with multiple surgical classifications; therefore, extrapolating risk factors and antimicrobial recommendations specifically for microvascular reconstructive surgery are controversial. In addition, optimal selection and duration of antibiotic prophylaxis for reconstructive surgery following head-and-neck cancer also remains controversial. In this

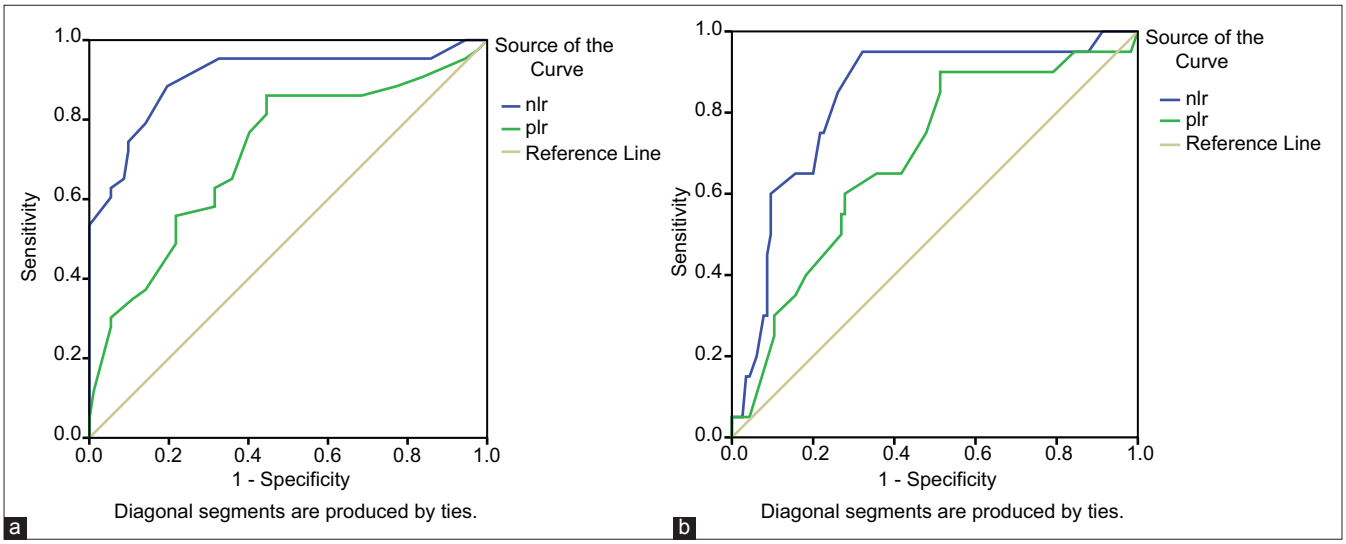


Figure 1: (a and b) Neutrophil-to-lymphocyte ratio and platelet-to-lymphocyte ratio as predictors of surgical site infections

Table 1: Comparison of attributes between patients who developed surgical site infections versus patients who did not develop surgical site infection

Attribute	Patients who did not develop SSI, *n*=92	Patients who developed SSI, *n*=43	*P* value
Age median (IQR)	55 (17)	62 (22)	0.71
Sex (*n*)	Male: 51 Female: 41	Male: 25 Female: 18	0.85
Diabetes	48.9% (*n*=45)	23.7% (*n*=14)	0.05
Ischemic heart disease	13% (*n*=12)	20.9% (*n*=9)	0.177
Body mass index <18 or >25	0	69.8% (*n*=30)	<0.001
Hemoglobin (g/dl) (Mean±SD)	12±2.01	11.6±2.3	0.17
Neoadjuvant chemotherapy and/or radiotherapy	84.8% (*n*=78)	55.8% (*n*=24)	<0.001
T-stage at presentation (Mean±SD)	2.68±1	2.95±1.01	0.341
Operating time (Mean±SD)	3.9±1.8	4.4±2.4	0.002
Anesthetic time (Mean±SD)	4.8±1.9	5.2±2.8	0.001
Neutrophil-to-lymphocyte ratio (Mean±SD)	3.1±0.7	4.8±1.1	<0.001
Platelet-to-lymphocyte ratio (Mean±SD)	130.5±19.1	149±19.5	0.005

SD: Standard deviation

Table 2: Linear regression analysis of the predictive factors of surgical site infections

Attribute	Unstandardized coefficients		Standardized coefficients	*t*	Sig.
	B	Std. error	Beta		
(Constant)	0.154	0.121		1.281	0.203
PLR >137.5	−0.208	0.057	−0.234	−5.529	0.01
NLR >3.75	0.404	0.057	0.427	7.080	0.000
Previous NACT-RT	−0.073	0.055	−0.068	−1.329	0.186
Body mass index >25 or <18	0.645	0.060	0.576	10.668	0.000
Diabetes	−0.037	0.047	−0.039	−0.774	0.440
Duration of surgery	0.023	0.082	0.100	0.280	0.780
Duration of anesthesia	−0.011	0.078	−0.052	−0.147	0.884

NLR: Neutrophil-to-lymphocyte ratio, PLR: Platelet-to-lymphocyte ratio

study, we analyzed all the possible factors which could predict SSI in patients undergoing resection and reconstructive surgeries for cancers of the oral cavity.

Durand *et al.* concluded that Gram-negative bacilli, Methicillin Resistant *S. aureus* (MRSA), and methicillin-susceptible *S. aureus* (MSSA) were significant SSI pathogens and late onset of infections was common after examining 504 flap surgical cases from 2009 to 2013.[3] Park *et al.* in their retrospective cohort listed that the risk factors are male sex, cardiovascular disease, blood loss >560 ml, and operation time >6 h. They concluded that

the most common pathogen was methicillin-resistant *S. aureus*.[2] A retrospective study of 267 patients done by Zirk *et al*.. (2018) concluded that Gram-positive facultative anaerobic bacteria mainly staphylococcal species were the predominant bacteria in donor site wounds. In addition, this study inferred that the incidence of multidrug-resistant pathogens (*Pseudomonas aeruginosa*) in an acute SSI can be maintained at a very low rate with regular wound dressing.[7]

In addition, Zirk *et al.* (2019), from their retrospective cohort study of 322 patients, demonstrated that smaller tissue transfers are less prone to infections of recipient site and present shorter length of hospital stay.[8] However, significant discrepancies exist between the findings of these studies, and independent risk factors and the pattern of antibiotic resistance still remain unclear.

Lofti *et al.* (2008) noted SSIs in 97 (38.8%) patients out of 258 patients in their prospective study.[9] In 2005, a prospective study done by Penel *et al.* showed that 117 (45%) out of 260 patients developed SSI.[10] Out of 277 patients, 92 patients developed SSI in the study conducted by Hirakawa *et al*., in 2012.[6] However, 21.3% (42) out of 197 demonstrated SSI in a study carried out by Kamizono *et al*.[11] Durand *et al.* in their retrospective cohort study inferred that the *S. aureus* (mainly MRSA or MSSA) were present in 36.6% of the flap SSIs.[3] Park *et al.* in their retrospective cohort study done in 2015 found that the major organism for the causation of SSI was *S. aureus* (32.6%) and 93.2% of *S. aureus* isolates were methicillin resistant.[2]

In this study, univariate and multivariate analyses have showed that diabetes mellitus, BMI >25 or <18, neutrophil-to-lymphocyte ratio (NLR) >3.75, platelet-to-lymphocyte ratio (PLR) >137.5, prior exposure to neoadjuvant chemotherapy or radiotherapy, prolonged operative duration, and prolonged anesthesia exposure may render patients more vulnerable to SSI. Moreover, among these parameters, a PLR >137.5, NLR >3.75, and BMI >25 or <18 were found to be highly predictive of SSI. The highly resistant organisms isolated were *Staphylococcus* and *Enterococcus* species in our study.

CONCLUSION

The identification of these risk factors in patients undergoing surgery for oral cancers along with robust technique and judicious use of antibiotics can help in early identification of patients who may be at a higher risk of developing SSI which may help us improve the overall outcome, especially in an LMIC setting.

The study was approved by the Institutional Ethics Committee of Bharath Hospital and Institute of Oncology (IEC letter no: 4/2019).

AUTHORS' CONTRIBUTIONS

Drs. Bharadhwaj Ravindhran and Hema AM contributed equally to the article and may be credited as joint first authors.

REFERENCES

1. Mazurek MJ, Rysz M, Jaworowski J, Nowakowski F, Krajewski R, Starościak S, *et al*. Contamination of the surgical field in head and neck oncologic surgery. Head Neck 2014;36:1408-12.
2. Park SY, Kim MS, Eom JS, Lee JS, Rho YS. Risk factors and etiology of surgical site infection after radical neck dissection in patients with head and neck cancer. Korean J Intern Med 2016;31:162-9.
3. Durand ML, Yarlagadda BB, Rich DL, Lin DT, Emerick KS, Rocco JW, *et al*. The time course and microbiology of surgical site infections after head and neck free flap surgery. Laryngoscope 2015;125:1084-9.
4. Watters K, O'dwyer TP, Rowley H. Cost and morbidity of MRSA in head and neck cancer patients: What are the consequences? J Laryngol Otol 2004;118:694-9.
5. Liu SA, Tung KC, Shiao JY, Chiu CC, YT YY. Preliminary report of associated factors in wound infection after major head and neck neoplasm operations-does the duration of prophylactic antibiotic matter? J Laryngol Otol 2007;122:403-8.
6. Hirakawa H, Hasegawa Y, Hanai N, Ozawa T, Hyodo I, Suzuki M. Surgical site infection in clean-contaminated head and neck cancer surgery: Risk factors and prognosis. Eur Arch Otorhinolaryngol 2013;270:1115-23.
7. Zirk M, Zalesski A, Peters F, Dreiseidler T, Buller J, Kreppel M, *et al*. Prevention and management of bacterial infections of the donor site of flaps raised for reconstruction in head and neck surgery. J Craniomaxillofac Surg 2018;46:1669-73.
8. Zirk M, Zalesski A, Peters F, Kreppel M, Zinser M, Joachim E, et al. Oral recipient site infections in reconstructive surgery-impact of the graft itself and the perioperative antibiosis. Clin Oral Investig 2019. DOI: org/10.1007/s00784-019-03078-6.
9. Lotfi CJ, Cavalcanti Rde C, Costa e Silva AM, Latorre Mdo R, Ribeiro Kde C, Carvalho AL, *et al*. Risk factors for surgical-site infections in head and neck cancer surgery. Otolaryngol Head Neck Surg 2008;138:74-80.
10. Penel N, Fournier C, Lefebvre D, Lefebvre JL. Multivariate analysis of risk factors for wound infection in head and neck squamous cell carcinoma surgery with opening of mucosa. Study of 260 surgical procedures. Oral Oncol 2005;41:294-303.
11. Kamizono K, Sakuraba M, Nagamatsu S, Miyamoto S, Hayashi R. Statistical analysis of surgical site infection after head and neck reconstructive surgery. Ann Surg Oncol 2014;21:1700-5.

How to cite this article: Ravindhran B, Hema AM, Murthy SN, Swaroop JT, Kumar MV. Surgical Site Infection and Antimicrobial Resistance Following Resection and Reconstructive Surgery for Oral Cancers: Are We Ready for the Superbugs? Int J Sci Stud 2020;7(12):24-27.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Utilization of Nerve Conduction Study for the Detection of Diabetic Polyneuropathy in a Tertiary Care Center in Madhya Pradesh

Aruna Singh[1], Vinit Kumar Tiwari[2], Brijesh Singh[3]

[1]Associate Professor, Department of Physiology, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, [2]Senior Resident, Department of Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India, [3]Associate Professor, Department of Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

Abstarct

Introduction: Diabetes mellitus is a group of metabolic disorders that share the phenotype of hyperglycemia. The clinical and economic burden of diabetic polyneuropathy (DPN) stems from its central role in the pathophysiology of foot ulceration and lower limb amputation, reduction in quality of life. Simple screening methods are of limited value in early neuropathy. Nerve conduction studies (NCSs) are the most sensitive and specific DPN detection method.

Material and Method: This study was conducted to detect the sensory-motor neuropathy in type 2 diabetes mellitus by clinical examination and nerve conduction study. In this study, 50 cases of type 2 diabetes were taken.

Results: Majority of patients presented with tingling sensation and followed by burning feet. In 50 patients of type 2 diabetes mellitus on clinical examination, most of the patients had involvement of both upper and lower limbs followed by only lower limb involvement, whereas on NCS, there were more patients with both upper and lower limbs involvement as compared to clinical studies. Maximum patients had symmetrical limb involvement clinically, but on NCS, the number of patients with symmetrical limb involvement was even more.

Conclusion: It was found that patients with diabetes mellitus, diabetic peripheral neuropathy is highly prevalent, but in the majority of patients, it is subclinical. Sensitivity and negative predictive values of the neurological examination are low. Therefore, routine nerve conduction velocity measurement for the assessment of diabetic peripheral neuropathy appears to be warranted in these patients. Thus, the author concluded in this study, detection of neuropathy is earlier and significant with NCS compared to clinical.

Key words: Diabetes mellitus, Diabetic polyneuropathy, Nerve conduction studies

INTRODUCTION

Diabetes mellitus is a group of metabolic disorders that share the phenotype of hyperglycemia. Depending on the etiology, factors contributing to hyperglycemia include reduced insulin secretion, insulin action, decreased glucose utilization, and increased glucose production.[1] The clinical and economic burden of diabetic polyneuropathy (DPN) stems from its central role in the pathophysiology of foot ulceration and lower limb amputation,[2] reduction in quality of life and decreased activities of daily living,[3] and susceptibility to falls and fractures.[4] The International Diabetes Federation estimated the total number of diabetic subjects to be around 40.9 million in India and this is further set to rise to 69.9 million by the year 2025.[5] Simple screening methods are of limited value in early neuropathy,[6] in the presence of neurological comorbidities,[7] and for the elderly.[8]

Nerve conduction studies (NCSs) are the most sensitive and specific DPN detection method.[6]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Aims and Objectives

This study was to detect sensory-motor neuropathy in type 2 diabetes mellitus by clinical examination and nerve

Corresponding Author: Vinit Kumar Tiwari, Department of Surgery, Shyam Shah Medical College, Rewa, Madhya Pradesh, India.

conduction study and to correlate the clinical features of peripheral neuropathy with nerve conduction study in type 2 diabetes mellitus.

METHODS

Fifty patients of type 2 diabetes mellitus with age more than 40 years and duration of diabetes 5 years or more visiting Shyam Shah Medical College and Sanjay Gandhi Memorial Hospital, Rewa, were taken for the present study excluding type 1 diabetics, chronic alcoholics, and due to other causes of peripheral neuropathy. Detailed history regarding symptoms such as paresthesia, tingling sensation, burning feet, and hyperesthesia was taken. Diagnosis of peripheral neuropathy was based on thorough clinical evaluation and nerve conduction study. All diagnosed Type 2 diabetic patients were subjected to nerve conduction study.

RESULTS

In this study, 50 cases of type 2 diabetes were taken, and we found that out of 50 patients, there were 60% of females and 40% of males. The age of patients varied from 40 to 70 years. The mean age was found to be 52.70 years. The duration of diabetes varied from 5 to 20 years. The maximum numbers of patients were in the duration of 5–15 years comprising 80% of the total. About 57% of patients presented with tingling sensation and 39% presented with burning feet. Hyperesthesia and foot ulcers were presenting complaints in only 6% of patients each. About 45% of patients had loss of ankle jerk, 43% had loss of vibration, 31% had loss of light touch, 29% had loss of joint position, and 16% had loss of superficial pain.

In 50 patients of type 2 diabetes mellitus on clinical examination, 40% had involvement of both upper and lower limbs followed by only lower limb involvement in 14% of patients. Isolated upper limb involvement was seen in 2% of cases but on NCS, 56% had involvement of both upper and lower limbs followed by only lower limb involvement in 16% of patients. Isolated upper limb involvement was seen in 6% of cases. About 22% were found normal on NCS [Table 1].

Table 2 shows that 47% of patients had symmetrical limb involvement clinically and 31% had asymmetrical limb involvement but on NCS, 61% of patients had symmetrical limb involvement and 22% had asymmetrical limb involvement.

Table 1: correlation of limb involvement clinically and on NCSs

Limb involvement	Clinically	On NCSs
Both upper limb and lower limb	20	28
Lower limb only	07	08
Upper limb only	01	03
Normal	22	11
Total	50	50
P	0.03	

NCSs: Nerve conduction studies

Table 2: correlation of the pattern of neuropathy clinically and on NCSs

Type of neuropathy	Clinically (%)	On NCSs (%)
Symmetrical	47	61
Asymmetrical	31	22
Normal	22	17
Total	100	100

NCSs: Nerve conduction studies

DISCUSSION

Diabetic neuropathy is one of the common microvascular complications in diabetics. Therefore, it is necessary to identify the "at-risk diabetic patients" for neuropathy. NCSs are one of the important methods for assessing nerve functions in diabetic neuropathy. Hyperglycemia causes nerve damage by various mechanisms. Hyperglycemia leads to elevated intracellular glucose and cellular toxicity in the endothelial cells of the capillaries associated with peripheral nerves.[9]

The present study has detected types of neuropathy in type 2 diabetes and correlated clinical features of peripheral neuropathy with nerve conduction study. In this study, the mean age of patients who are enrolled is 52.7 years. Prasad *et al.* conducted a similar study to test the hypothesis of alteration in electrophysiologic parameters of nerve before actual manifestations of neuropathy in type 2 diabetic patients, in which the mean age of patients was found to be 55.72 ± 7.12 years.[10]

In the present study, tingling sensation is the most common presentation of diabetic neuropathy followed by burning feet then hyperesthesia and foot ulcers. Kakrani *et al.* did a study on total of 50 diabetics. NCSs were performed. About 92% presented with complaints of tingling sensation and 64% had burning feet.[11]

The most common signs are loss of ankle jerk followed by loss of vibration then light touch and joint position. Shehab *et al.* conducted a study to assess the performance characteristics of ankle reflex in detecting diabetic peripheral neuropathy. Taking NCS as the gold standard,

ankle reflex yielded the highest sensitivity and specificity, closely followed by that of vibration sense.[12]

In the present study, it is found that the detection of neuropathy is earlier and significant with NCS compared to clinical examination ($P < 0.05$). Höliner *et al.* conducted a study to evaluate the prevalence of diabetic peripheral neuropathy in patients with diabetes mellitus and examined whether the neurological examination validly diagnoses diabetic peripheral neuropathy as compared with the gold standard of nerve conduction velocity in these patients and found similar results as compared to our study. It was found that patients with diabetes mellitus, diabetic peripheral neuropathy is highly prevalent, but in the majority of patients, it is subclinical. Therefore, routine nerve conduction velocity measurement for the assessment of diabetic peripheral neuropathy appears to be warranted in these patients.[13]

CONCLUSION

Thus, the author concludes that the detection of neuropathy is earlier and significant with NCS compared to clinical ($P < 0.05$).

Tingling sensation is the most common presentation of diabetic neuropathy followed by burning feet then hyperesthesia and foot ulcers. The most common signs are loss of ankle jerk followed by loss of vibration then light touch and joint position.

Simultaneous involvement of both upper and lower limbs is significantly more than single limb involvement by both NCS ($P < 0.05$) and clinical examination ($P < 0.05$) followed by only lower limb involvement.

Distal symmetrical polyneuropathy is the most common form of diabetic neuropathy as compared with other forms of sensory/motor neuropathy as detected by both NCS and clinically ($P < 0.05$).

Sensory-motor type of neuropathy is the most common type of neuropathy in type 2 diabetics detected on both NCS and clinically ($P < 0.05$).

REFERENCES

1. Ozougwu JC, Obimba KC, Belonwu CD, Unakalamba CB. The pathogenesis and pathophysiology of Type 1 and Type 2 diabetes mellitus. JAPI 2013;4:46-57.
2. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005;293:217-28.
3. Vinik EJ, Hayes RP, Oglesby A, Bastyr E, Barlow P, Ford-Molvik SL, *et al*. The development and validation of the Norfolk QOL-DN, a new measure of patients' perception of the effects of diabetes and diabetic neuropathy. Diabetes Technol Ther 2005;7:497-508.
4. Schwartz AV, Hillier TA, Sellmeyer DE, Resnick HE, Gregg E, Ensrud KE, *et al*. Older women with diabetes have a higher risk of falls: A prospective study. Diabetes Care 2002;25:1749-54.
5. Mohan V, Sandeep S, Deepa R, Shah B, Varghese C. Epidemiology of Type 2 diabetes: Indian scenario. Indian J Med Res 2007;125:217-30.
6. Perkins BA, Olaleye D, Zinman B, Bril V. Simple screening tests for peripheral neuropathy in the diabetes clinic. Diabetes Care 2001; 24:250-6.
7. Perkins BA, Bril V. Diabetic neuropathy: A review emphasizing diagnostic methods. Clin Neurophysiol 2003;114:1167-75.
8. Watanabe T, Ito H, Morita A, Uno Y, Nishimura T, Kawase H, *et al*. Sonographic evaluation of the median nerve in diabetic patients: Comparison with nerve conduction studies. J Ultrasound Med 2009;28:727-34.
9. Buse JB, Polonsky KS, Burant CF. Type 2 diabetes mellitus. In: Larsen PR, Henry M, Melmed S, Kenneth S, editors. Williams Textbook of Endocrinology. 10th ed. Philadelphia, PA: Saunders; 2003. p. 1427-83.
10. Prasad N, Pisharody IK, Karandikar MS, Diwanji SA, Raghav PR. Comparative analysis of electrophysiological parameters of median nerve in normal and diabetic subjects. Indian Med Gaz 2013;147:261-4.4.
11. Kakrani AL, Gokhale VS, Vohra KV, Chaudhary N. Clinical and nerve conduction study correlation in patients of diabetic neuropathy. J Assoc Physicians India 2014;62:24-7.
12. Shehab DK, Al-Jarallah KF, Abraham M, Mojiminiyi OA, Al-Mohamedy H, Abdella NA. Back to basics: Ankle reflex in the evaluation of peripheral neuropathy in Type 2 diabetes mellitus. QJM 2012;105:315-20.
13. Höliner I, Haslinger V, Lütschg J, Müller G, Barbarini DS, Fussenegger J, *et al*. Validity of the neurological examination in diagnosing diabetic peripheral neuropathy. Pediatr Neurol 2013;49:171-7.

How to cite this article: Singh A, Tiwari VK, Singh B. Utilization of Nerve Conduction Study for the Detection of Diabetic Polyneuropathy in a Tertiary Care Center in Madhya Pradesh. Int J Sci Stud 2020;7(12):28-30.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

A Clinical Audit – Magnetic Resonance Imaging Knee Image Acquisition Adequacy

Sagar G Maheshwari[1], Rahul Arkar[1], Amit Kharat[2], Rajesh Kuber[3]

[1]Assistant Professor, Department of Radio-diagnosis, Dr. D Y Patil Medical College, Hospital and Research Centre, Pune, Maharashtra, India, [2]Professor and Musculoskeletal Imaging Fellowship Director, Department of Radio-diagnosis, Dr. D Y Patil Medical College, Hospital and Research Centre, Pune, Maharashtra, India, [3]Professor and Head, Department of Radio-diagnosis, Dr. D Y Patil Medical College, Hospital and Research Centre, Pune, Maharashtra, India

Abstract

Objective: The objective of the study was to evaluate the adequacy of magnetic resonance imaging (MRI) scans of knee, performed at the Radiology Department of Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune, according to the American College of Radiologist guidelines.

Type of Study: This study was a clinical audit.

Place and Duration of Study: This study was conducted at Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune, from January 2018 to July 2018.

Materials and Methods: Retrospective study of approximate 40 patients who underwent MRI of knee in January 2018 for assessment of the quality of images obtained in the initial audit. Depending on the results of this first audit, a suggestion was made and reaudit was done 6 months later in July 2018 to look for improvement quality in local practice.

Results: In the initial audit, images were acquired in all the three necessary planes and the sagittal and coronal images had appropriate slice thickness as well as adequate anatomical coverage in all the patients. However, field of view (FOV) was inappropriately set in 34% of cases in axial plane, 90% in sagittal plane, and 95% in coronal plane. Furthermore, the anatomical coverage was not up to the mark in axial plane with 13 studies (66%) having adequate superior coverage, and 16 cases (80%) having recommended inferior anatomical coverage. The reaudit performed 6 months later showed improvement with 100% compliance to standards.

Conclusion: Initially, the first audit showed few lackings in acquiring of MRI knee images specifically with FOV to reduce the decrease in all planes and slight increase in anatomical coverage in the axial plane. These shortcomings and recommendations were made in departmental meetings and reaudit was done after 6 months. This reaudit showed 100% compliance.

Key words: Clinical audit, Image adequacy, Knee magnetic resonance

INTRODUCTION

Magnetic resonance imaging (MRI) is the imaging modality of choice to detect meniscal and ligament abnormalities. It is also good modality for the evaluation of bony and cartilage abnormalities, malignancy, and fluid accumulation.[1] As compared with diagnostic arthroscopy for evaluation of anterior cruciate ligament and menisci, MRI is superior.[2] However, this can be only possible if it is adequately performed and analyzed. Few pivotal image quality parameters include anatomical coverage, appropriate image plane, and slice thickness. Later two are highly important for good signal to noise ratio. It is crucial for optimal evaluation and for diagnosis of significant pathology. The aim of this audit was to evaluate the quality of imaging in MRI of knee joint, performed in the Radiology Department of Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune.

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. Sagar G Maheshwari, Department of Radio-diagnosis, Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India.

MATERIALS AND METHODS

The first audit was performed in the Radiology Department, Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune, in January 2018. The data were collected retrospectively from MRIs of knee, performed during the month of January. Forty-two knee MRIs were performed for various indications during this month, of which 40 were included in the audit. Two cases were excluded because the extensive motion artifacts and post-operative knee. The studies were assessed for various parameters, including both anatomical coverage and technical parameters (field of view [FOV] and slice thickness) and the data collected in a specially designed pro forma. Percentages were then calculated. The standard was set as 100% compliance to ACR guidelines.[1] These guidelines included technical parameters and anatomical coverage [Annexure]. Technical parameters considered imaging acquired in three orthogonal planes (sagittal, coronal, and axial), FOV of 16 cm or smaller and slice thickness of 4 mm in coronal and sagittal planes. Anatomical coverage extended proximally to include distal aspect of quadriceps tendon and suprapatellar recess and distally to include insertion of patellar tendon and pes anserine (insertion of Sartorius, Gracilis, and semitendinosus). Based on the findings of the first audit, recommendations were made and suggested to the whole radiology department through meetings. Display of printed ACR guideline poster was put in the console room for the MR technicians as well as for resident doctors. A reaudit was targeted after 6 months to check the compliance of these recommendations. Subsequently, a reaudit was done in the same department, 6 months later in the end of July 2018 without any information to technicians and resident doctors. Data of 32 patients, who had undergone MRI knee in the month, were assessed for different parameters as per previous pro forma. Excel sheet data were entered in Epi Info 7.0 version and percentages were then calculated.

RESULTS

As summarized in Table 1, images were acquired in all three, i.e., axial, coronal, and sagittal planes in 40 cases. However, the FOV was not set according to the recommendations in most of these cases; FOV was inadequate (more than 16 cm) in axial images in 14 of the 40 studies (34%) and in 36 cases in sagittal plane (90%). In the images acquired in coronal plane, an FOV of <16 cm was used in all the cases. The slice thickness had been appropriately set. Hundred percent of the cases studied had been performed using slice thickness of 4 mm or less in both coronal and sagittal planes. The anatomical coverage was adequate both superiorly as well as inferiorly in both sagittal and coronal planes as advised in the ACR guidelines in all the 40 studies. However, this was not the case with axial imaging where superior coverage was according to guidelines in only 26 (66%) cases and the inferior coverage was adequate in 32 cases (80%). However, the reaudit done 6 months later showed achievement of target compliance with standards of 100% as summarized in Table 1. The anatomical coverage in all three planes as well as all the technical parameters including FOV and slice thickness was according to the standards set showing 100% compliance.

DISCUSSION

MRI is the most commonly used imaging modality for the evaluation of knee joint.[3] Indeed, it is now the noninvasive imaging modality of choice complimentary to the clinical examination in the evaluation of injuries of the knee.[4] MRI is an excellent tool for the evaluation of bony, cartilaginous, ligamentous, and synovial pathologies of knee joint such as trauma to infection and neoplasm. However, image analysis can only be as good as the quality of the original images acquired.[5] Hence, proper image

Table 1: Comparison between initial audit and re-audit inadequacies

Parameter	Plane	Initial audit – total number of patients *n*=40	Inadequacy of initial audit in percentage *n*=40	Reaudit total number of patients *n*=32	Inadequacy of reaudit in percentage *n*=32
Images in 3-plane (sagittal, axial, and coronal)	(Sagittal, axial, and coronal)	40 (100)	0 (0)	32 (100)	0 (0)
Field of view (<16 cm)	Sagittal	4 (10)	36 (90)	32 (100)	0 (0)
	Coronal	2 (5)	38 (95)	32 (100)	0 (0)
	Axial	26 (66)	14 (34)	32 (100)	0 (0)
Slice thickness<4 mm	Coronal	40 (100)	0 (0)	32 (100)	0 (0)
	Sagittal	40 (100)	0 (0)	32 (100)	0 (0)
Superior coverage (suprapatellar joint recess)	Sagittal	40 (100)	0 (0)	32 (100)	0 (0)
	Coronal	40 (100)	0 (0)	32 (100)	0 (0)
	Axial	26 (66)	14 (34)	32 (100)	0 (0)
Inferior coverage (patellar tendon insertion)	Sagittal	40 (100)	0 (0)	32 (100)	0 (0)
	Coronal	40 (100)	0 (0)	32 (100)	0 (0)
	Axial	32 (80)	8 (20)	32 (100)	0 (0)

acquisition is crucial for proper diagnosis and evaluation. MRI quality relies on different parameters including magnetic field strength, sequences, slice thickness, inter-slice gap, image matrix and FOV, inherent contrast, and the use of surface coils.[6] When imaging knee joint, it is important to acquire images in all three planes sagittal, coronal, and axial for better evaluation and diagnosing abnormalities,[7] as the structures cannot be evaluated properly in a single plane. For cruciate ligaments, sagittal view is the better for evaluation; however, for menisci and collateral ligaments are best evaluated on coronal view and lastly, axial images are best for evaluation of periarticular fluid collection, plicae, patellofemoral joint, and femoral attachments of cruciate ligaments.[8]

In our department, image acquiring had been performed in all three planes in all the patients of MR knee. FOV is indirectly related to the spatial resolution which is the crucial parameter which determines the image quality.[6] For this reason, FOV in case of MRI of knee should be kept 16 cm or less and this was a parameter that had been inadequate in most of the cases specifically in sagittal and coronal planes. Another important factor is slice thickness which affects image quality and fortunately in all cases a slice thickness of 4 mm was present. Furthermore, it is important that all the structures related to knee joint are imaged. Superiorly, distal aspect of quadriceps tendon and suprapatellar joint recess should be included while scanning. Suprapatellar joint recess can have a number of conditions.[9] There are high chances to miss pathology in these areas if not images. These were included in all patients for coronal and sagittal planes, however, missed in axial plane for 14 MRI performed in our department. The second audit, done 6 months later, showed 100% compliance with the standards set. The main factor for compliance improvement was guidance to the technicians about correct protocol while performing MRI scans of the knee.

CONCLUSION

For assessment of knee abnormalities, MRI is the imaging modality. Proper image acquisition is important for evaluation of pathology which depends on the proper technical parameters and adequate anatomical coverage. To put in nutshell, audit and reaudit done for MR knee adequacy was helpful to improve the quality and diagnosis of various knee abnormalities.

ACKNOWLEDGMENT

I want to acknowledged MRI technician of the Radiology Department, Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra.

REFERENCES

1. ACR-SPR-SSR Practice Parameter for the Performance and Interpretation of Magnetic Resonance Imaging (MRI) of the Knee; 2015. Available from: https://www.acr.org/media/acr/files/practice-parameters/mr-knee.pdf. [Last accessed on 2018 Jan 02]
2. Ryzewicz M, Peterson B, Siparsky PN, Bartz RL. The diagnosis of meniscus tears: The role of MRI and clinical examination. Clin Orthop Relat Res 2007;455:123-33.
3. Avcu S, Altun E, Akpinar I, Bulut MD, Eresov K, Biren T. Knee joint examinations by magnetic resonance imaging: The correlation of pathology, age, and sex. N Am J Med Sci 2010;2:202-4.
4. Khanda GE, Akhtar W, Ahsan H, Ahmad N. Assessment of menisci and ligamentous injuries of the knee on magnetic resonance imaging: Correlation with arthroscopy. J Pak Med Assoc 2008;58:537-40.
5. Peterfy CG, Gold G, Eckstein F, Cicuttini F, Dardzinski B, Stevens R. MRI protocols for whole-organ assessment of the knee in osteoarthritis. Osteoarthritis Cartilage 2006;14 Suppl A: A95-111.
6. Allisy-Roberts P, Williams JR. Farr's Physics for Medical Imaging. Amsterdam: Elsevier Health Sciences; 2007.
7. Kaplan PA. Knee. In: Kaplan PA, Helms CA, Dussault R, Anderson MW, Major NM, editors. Muskuloskeletal MRI. 1st ed. Philadelphia, PA: WB Saunders; 2001.
8. Niitsu M. Magnetic Resonance Imaging of the Knee. Berlin: Springer Science and Business Media; 2012.
9. Dragoo JL, Abnousi F. Disorders of the suprapatellar pouch of the knee. Knee 2008;15:348-54.

How to cite this article: Maheshwari SG, Arkar R, Kharat A, Kuber R. A Clinical Audit – Magnetic Resonance Imaging Knee Image Acquisition Adequacy. Int J Sci Stud 2020;7(12):31-34.

Source of Support: Nil, **Conflicts of Interest:** None declared.

ANNEXURE

Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune
Knee MR Audit Pro forma

Date-
Investigator-

Parameters	Plane	Yes	No
Images in 3-plane	Sagittal		
	Coronal		
	Axial		
Field of view (<16 cm)	Sagittal		
	Coronal		
	Axial		
Superior coverage (suprapatellar joint recess)	Sagittal		
	Coronal		
	Axial		
Inferior coverage (patellar tendon insertion)	Sagittal		
	Coronal		
	Axial		
Slice thickness <4 mm	Sagittal		
	Coronal		

Source: ACR (American College of Radiology)

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Computed Tomography Characteristics of Intracranial Ring-enhancing Lesions

Bobby Varkey[1], M R Raman[2], S Vivek[3], Rabinath Prabhu[4]

[1]Senior Resident, Department of Radiodiagnosis, Pushpagiri Medical College, Thiruvalla, Kerala, India, [2]Assistant Professor, Department of Surgery, Al Azhar Medical College and Super Speciality Hospital, Thodupuzha, Kerala, India, [3]Associate Professor, Department of Community Medicine, Al Azhar Medical College and Super Speciality Hospital, Thodupuzha, Kerala, India, [4]Professor, Department of Radiodiagnosis, Justice K S Hegde Medical Academy, Mangalore, Karnataka, India

Abstract

Introduction: Ring-enhancing computed tomography (CT) lesions are those which consist of focal area of hypodensity on plain CT scan on which contrast administration shows ring-like enhancement. CT scan has largely replaced previous radiological procedures such as plain roentgenograms, pneumoencephalogram, cerebral angiography, and myelography.

Purpose: The purpose of the study was to determine the various CT morphological characteristics of ring-enhancing lesions in various intracranial pathological entities.

Materials and Methods: This is a cross-sectional study conducted in the department of radiology in a tertiary care center in Mangalore, Karnataka, from July 2015 to November 2016. A total of 30 patients were included in this study whose CT scan showed ring-enhancing lesion or lesions after contrast administration and with a final diagnosis following surgery or complete cure. The morphological features of the lesions observed were tabulated and analyzed using SPSS software version 16. Various morphological features are expressed as percentages.

Conclusions: CT morphology characteristics of ring lesion are strongly suggestive of the diagnosis such as tuberculoma, brain abscess, glioma, metastases, and nerocysticercosis; however, they have to be corroborated by clinical history, laboratory investigation, and histopathological examination to arrive at a definite diagnosis.

Key words: Computerized tomography, Contrast, Intracranial, Morphology, Ring-enhancing lesion

INTRODUCTION

Ring-enhancing computed tomography (CT) lesions are those which consist of focal area of hypodensity on plain CT scan on which contrast administration shows ring-like enhancement. Central necrosis and peripheral organization produces ring lesions. The ring may be single or multiple, small or large, usually uniform, and complete but can be irregular and in complete. Differential diagnosis of ring-enhancing lesions includes primary brain tumors, metastatic brain tumors, abscess, granuloma, resolving hematoma, brain infarct, multiple sclerosis, and primary central nervous system (CNS) lymphoma in patients with AIDS. The diagnosis of these brain lesions has been greatly improved by the introduction of CT; patients have the advantage of imaging the brain parenchyma for the presence of focal lesions without the use of any invasive procedures. In the present scenario, CT has become principal diagnostic test in establishing the diagnosis of brain pathology, especially abscess by virtue of its accuracy, reliability, safety, and wide availability in determining the location and size of each lesion.[1]

This study was conducted with the objective to determine the CT morphological characteristics of ring-enhancing lesions in various intracranial pathological entities in patients presenting with CNS symptoms.

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

MATERIALS AND METHODS

A cross-sectional study was conducted in a tertiary care center in Mangalore, Karnataka, during the time period

Corresponding Author: Dr. M R Raman, Department of Surgery, Al Azhar Medical College and Super Speciality Hospital, Ezhalloor, Thodupuzha - 685 605, Kerala, India.

of July 2015–November 2016. The study population was patients whose CT scan showed ring-enhancing lesion or lesions after contrast administration.

Study Subjects

Patients with intracranial ring-enhancing lesions in contrast CT scans after informed consent (from patients/bystanders), in whom a final diagnosis was reached either by surgery, biopsy, or from total healing response to antituberculous or cysticidal drugs or steroid therapy, were included in the study, while patients in whom contrast could not be administrated were excluded from the study.

Study Tool

- Whole-body CT scanner – Spiral CT (512 × 512 matrix)
- Contrast media – non-ionic contrast media
- IV cannula and syringes 5 ml, 10 ml, and 20 ml
- Emergency drugs such as inj. avil, hydrocortison, adrenaline, etc.

Technique of Examination (CT)

The usual CT examination was done by scanning the head in a series of axial slices at 10–15 degrees to the Reid's baseline in all patients with 5 mm thick slices in infratentorium and 8–10 mm thick slices in supratentorium. Occasionally, however, additional slices and intermediate slices were also scanned. Both plain and contrast-enhanced scans were done. Contrast enhancement was achieved by giving bolus injection of non-ionic contrast media intravenously.

Methodology

In this study, pre-operative neuroradiological examinations were performed on all patients. As a rule, all patients (with CNS symptoms) underwent a diagnostic CT scan (plain and after contrast medium administration). All these patients also underwent complete hemogram, ESR, chest X-ray, and routine urine analysis. Patients underwent further relevant tests such as Mantoux test, electroencephalography, abdominal ultrasound, and CT scan for reaching a definite final diagnosis.

Statistical Analysis

The observations made were tabulated and analyzed using SPSS software version 16. Various morphological features are expressed as percentages.

RESULTS

A total of 30 patients were included in this study whose CT scan showed ring-enhancing lesion or lesions after contrast administration. In this study, 43 lesions were detected in the CT films of the selected 30 study subjects.

Out of the 30 study subjects, 21 (70%) were male and 9 (30%) were female. In this study, maximum patients belonged to the age group of 11–20 years (26%). All age groups showed the male preponderance for all lesions [Table 1].

Most commonly diagnosed lesions in this study were metastases (8 cases) followed by tuberculoma and gliomas (7 cases each). Abscesses were diagnosed in 6 cases. Neurocysticercosis was least common (only 2 cases) in this study. All metastatic lesions (8 cases) showed multiple rings and all cysticercal (2 cases) lesions were as single ring. Majority of gliomas (6 cases) were single lesion. Single tubercular lesions (6 cases) were more than multiple (1 case). However, abscesses (single-3, multiple-3) were evenly distributed.

Based on the size of the lesion, most of the lesions (24) were <10 mm at the time of investigation. Five tubercular lesions were <10 mm and three were more than 10 mm. Six abscesses were <10 mm and three were more than 10 mm. Most of the gliomas were more than 10 mm at the time

Table 1: Distribution of intracranial lesion (diagnosis, *n*=30) according to age and sex of the study subjects

Age	Sex	Tuberculoma (7)	Abscess (6)	Glioma (7)	Metastases (8)	Cysticercosis (2)
<10 (1)	Male	1	-	-	-	-
	Female	-	-	-	-	-
11–20 (8)	Male	2	1	-	-	1
	Female	2	1	1	-	-
21–30 (3)	Male	1	2	-	-	-
	Female	-	-	-	-	-
31–40 (5)	Male	1	2	2	-	-
	Female	-	-	-	-	-
41–50 (6)	Male	-	-	1	2	-
	Female	-	-	1	1	1
51–60 (4)	Male	-	-	-	2	-
	Female	-	-	1	1	-
>60 (3)	Male	-	-	1	2	-
	Female	-	-	-	-	-

of diagnosis and only 2 lesions were 5–10 mm size. Nine metastatic lesions were <10 mm and 7 lesions were more than 10 mm. All cysticercal lesions were 5–10 mm of size.

On analyzing the lobes where the lesions were present, 38 lesions were located in the cerebral hemispheres and 5 lesions were in the cerebellum. Frontal and parietal lobes were most commonly involved (14 lesions each) followed by temporal (7 lesions); occipital lobe involvement was least common (3 lesions). Tubercular lesions were most common in parietal lobe (4 lesions). Abscesses frequently involved frontal (4 lesions) and parietal (3 lesions) lobes. Gliomas were distributed in frontal (2 lesions), temporal (3 lesions), and parietal (2 lesions) lobes, and in one case, it was in cerebellum. Majority of metastatic lesions (10) were in frontal and parietal lobes and 3 lesions were in the cerebellum. All cysticercal lesions were in frontal lobes.

In this study, lesions/rings occurred more frequently in subcortical (46.51%) location followed by corticomedullary junction (37.20%) and only 7 lesions were located in the cortex. Tubercular lesions mainly in subcortical in location (4) and 2 lesions each were in cortical and corticomedullary in location. Abscesses mostly (8) involved subcortical (4) and corticomedullary (4) area. Most of the gliomas (6) were in subcortical location. In metastases, subcortical area was involved in 6 lesions and corticomedullary junction was involved in 7 lesions. Only in 3 cases, cortex alone was involved. All cysticercal lesions involved corticomedullary junction. The CT characteristics of tuberculoma, abscess, glioma, metastases, and neurocysticercosis are given in Table 2.

DISCUSSION

Brain Abscess

In our study, males (5) were predominant. In the literature also, brain abscess is more common in males than females.[2] All the patients in our study were below 40 years of age. It is in accordance with the literature.[2,3] Half of the patients in this study had single lesion. However, in the literature, the incidence of single lesion is more than multiple lesions.[3] The CT appearance of abscess varies according to the stage of disease. Various reports correlate CT findings differently either after surgery or autopsy.[4,5]

Gliomas

However, Whelan and Hilal reported that ring enhancement is not synonymous with a well-formed capsule.[6] Glioblastoma is the most common primary malignant tumor of brain. Ring enhancement after contrast enhancement is a characteristic of malignant gliomas.[7,8] In our study also, all glioblastomas showed ring enhancement. All patients were above 40 years with slight male predominance (M: F=3:2). In our study, 80% of lesions were located in the supratentorial compartment. In our study, most of

Table 2: Computed tomography characteristics of the intracranial lesions (subjects=30 and total lesions=43) studied

Location (total)	Features	Tuberculoma, *n* (%)	Abscess, *n* (%)	Glioma, *n* (%)	Metastases, *n* (%)	Cysticercosis, *n* (%)
Wall enhancement	Regular (12)	3 (37.5)	3 (33.3)	1 (25)	4 (25)	1
	Irregular (31)	5 (62.5)	6 (66.6)	7 (87.5)	12 (75)	1
Surrounding edema	Mild (10)	2 (28.5)	2 (22.2)	2 (25)	2 (12.5)	2
	Moderate (14)	4 (57.1)	3 (33.3)	3 (37.5)	4 (25)	Nil
	Severe (6)	1 (14.2)	1 (11.1)	2 (25)	2 (12.5)	Nil
Outline	Well defined (13)	3 (37.5)	5 (55.5)	1 (12.5)	3 (18.7)	1 (50)
	Ill defined (30)	5 (62.5)	4 (44.4)	7 (87.5)	13 (81.25)	1 (50)
Wall thickness	Thin (15)	3 (37.5)	4 (44.4)	2 (25)	5 (31.25)	1 (50)
	Thick (28)	5 (62.5)	5 (55.5)	6 (75)	11 (68.75)	1 (50)
Mass effect	Present (23)	5 (71.5)	4 (44.4)	7 (87.5)	6 (87.5)	1 (50)
	Absent (7)	2 (28.5)	2 (22.2)	Nil	2 (12.5)	1 (50)
Side of lesion	Right (10)	3 (37.5)	2 (22.2)	3 (37.5)	2 (12.5)	Nil
	Left (13)	3 (37.5)	4 (44.4)	4 (50)	Nil	2 (100)
	Bilateral (7)	1 (12.5)	Nil	Nil	6 (87.5)	Nil
Midline shift	Present (15)	1 (14.3)	3 (50)	6 (75)	5 (81.25)	Nil
	Absent (15)	6 (85.7)	3 (50)	1 (12.5)	3 (18.75)	2 (100)
Density	Isodense (10)	4 (50)	1 (11.1)	1 (12.5)	4 (25)	Nil
	Hypodense (21)	2 (25)	7 (77.7)	4 (50)	6 (37.5)	2 (100)
	Hyperdense (12)	2 (25)	1 (11.1)	3 (37.5)	6 (37.5)	Nil
Associated findings	Nodular (3)	Nil	Nil	1 (12.5)	2 (12.5)	Nil
	Hydrocephalus (7)	1 (14.3)	Nil	3 (12.5)	3 (18.75)	Nil
	Hemorrhage (2)	Nil	Nil	1 (12.5)	1 (6.25)	Nil
	Calcification (1)	1 (14.3)	Nil	Nil	Nil	Nil
	Cyst (4)	Nil	Nil	2 (25)	1 (6.25)	1 (50)
Enhancement	Homogenous (17)	3 (37.5)	4 (44.4)	2 (25)	6 (37.5)	2 (100)
	Heterogenous (26)	5 (62.5)	5 (55.5)	6 (75)	10 (62.5)	Nil

the lesions (60%) were of mixed density. These findings agree with the result of Steinhoff who reported that mixed attenuation was the most frequent presentation with 38.5 to 65.3% incidence.[9] There was no associated calcification in gliomas in this study.

Tuberculoma

In our study, there was predominance of lesion in the male (M:F=5:2, 71%:29%). All the cases were under 40 years. According to the studies in India, approximately 20% of intracranial tumors are tuberculoma, more than half occurring in children and 75% below the age of 25 years.[10,11] Most of the lesions (4) were located in the parietal lobe in our study and it was solitary in 3 cases. It is reported that most common site of involvement is cerebral hemispheres and basal ganglion and these are usually solitary however multiple lesions can occur in 10 – 35% of cases.[12] Considering the number of lesions, Bhargava and Tendon report an incidence of multiple lesions in 55% of cases[13] while Weisberg *et al.* have reported solitary lesions in about 66% of cases.[14]

Our study showed that 50% of lesions were isodense, similar results were reported by Welcham (71.4%).[15] In our series, majority of cases showed irregular wall enhancement (5), ill-defined outline (5), thick wall (5), and heterogeneous enhancement (5). A study by Welchman reported 1.6% incidence of calcification in intracranial tuberculomas.[15]

Neurocysticercosis

There was 1 male (12 years) and 1 female patient (45 years) in this study. In the study by Morgado *et al.*, there was no sex predilection in adults, whereas in children, M:F ratio was 1:2.[16] In all our cases, lesions were situated in the supratentorial compartment involving the corticomedullary junction. Almeida-Pinto *et al.* have also reported a similar distribution of disease.[17]

One lesion showed regular enhancement, well-defined outline thin wall and other lesions showed irregular wall enhancement and thick wall. Both the lesions were parenchymal. According to Carbajal *et al.*, CT showed ring-like enhancement in some stages of the disease and all were parenchymal.[18]

Metastases

CT is a safe investigative tool for the diagnosis of brain metastases in patients with malignant tumors. In our study, all the patients were above 40 years, metastatic lesions were more common in males than females (3:1). Same results were reported by Simionescu.[19]

All eight patients showed multiple lesions. Seven lesions were more than 10 mm size. On non-enhanced CT scan, 6 lesions were hypodense and hyperdense respectively and 4 lesions were isodense. In the literature also, these lesions are iso or hyperdense.[20,21] In this study, 2 lesions showed nodule and 1 lesion showed hemorrhage and cyst, respectively, and patients had associated hydrocephalus. Deck *et al.* studied 1100 patients with CT scan, of which 57 showed evidence of intracranial metastases and 14 showed evidence of hydrocephalus.[22] In our study, we did not encounter any calcification similar to other studies.[20,21] All 8 patients (100%) showed cerebral edema in our study. Potts *et al.* reported approximately 90% of lesions showed marked necrosis. Surrounding edema was usually moderate or marked.[23]

CONCLUSIONS

In this study, the most common etiology for ring-enhancing CT lesions are metastases (26.6%) followed by tuberculoma (23.3%) and glioma (23.3%), abscess accounted for 20.2% and neurocysticercosis accounted for 6.6% of lesions.

Considering the CT characteristics of tuberculoma, 62.5% of lesions were <10 mm in size. Single lesions were more than multiple. About 50% of lesions were seen in parietal region. About 62.5% of lesions showed irregular wall enhancement, ill-defined outline, thick wall, and heterogeneous enhancement on contrast. All abscesses were present below 40 years. About 66.6% of lesions were <10 mm and single cases were more than multiple. Lesions mostly involved subcortical and corticomedullary (44.4%) regions, 66.6% of lesions showed irregular wall enhancement, 55.5% of lesions had well-defined outline, 44.4% had thin wall, and 55% of lesions showed heterogeneous contrast enhancement. Majority (75%) of gliomas were more than 10 mm and single lesions were more than multiple, 75% of lesions involved subcortical region, 87.5% of lesions showed irregular wall enhancement with ill-defined outline, and 75% of lesions showed heterogeneous enhancement. In this study, metastases were diagnosed after 40 years. All cases showed multiple lesions, 62.5% of lesions involved the frontal and parietal regions, 43.5% were in corticomedullary junction, 75% of lesions showed irregular wall enhancement, 68.75% of lesions showed thick wall, and 62.5% showed heterogeneous enhancement. In the two cases of neurocysticercosis, both the lesions were single, located in frontal lobe and involved corticomedullary junction. All lesions were <10 mm in size, showed homogenous enhancement. One case was cystic in nature.

Hence, it is clear from this study that CT scan is useful in detecting multiplicity of lesions, mass effect on surrounding brain structures, and hydrocephalus. We conclude that

CT morphology characteristic of ring lesion is strongly suggestive of the diagnosis; however, they have to be corroborated by clinical history, laboratory investigation, and histopathological examination to arrive at a definite diagnosis.

ACKNOWLEDGMENT

We are highly thankful to the staff of the Department of Radiodiagnosis, K S Hegde Medical College, Mangalore, Karnataka, for their support in this work. We immensely thank all the participants for their valuable time and cooperation.

ETHICAL APPROVAL

Approval taken from the Institutional Ethics Committee.

REFERENCES

1. Claveria LE, du Boulay GH, Moseley IF. Intracranial infections: Investigation by computerized axial tomography. Neuroradiology 1976;12:59-71.
2. Seydoux C, Francioli P. Bacterial brain abscesses: Factors influencing mortality and sequelae. Clin Infect Dis 1992;15:394-401.
3. Osenbach RK, Loftus CM. Diagnosis and management of brain abscess. Neurosurg Clin N Am 1992;3:403-20.
4. Enzmann DR, Britt RH, Yeager AS. Experimental brain abscess evolution: Computed tomographic and neuropathologic correlation. Radiology 1979;133:113-22.
5. Zimmerman RD, Weignarten K. Neuroimaging of cerebral abscess. Nueroimaging Clin North Am 1991;1:1-16.
6. Whelan MA, Hilal SK. Computed tomography as a guide in the diagnosis and follow-up of brain abscesses. Radiology 1980;135:663-71.
7. Yamada K, Goto S, Kochi M, Ushio Y. Stereotactic biopsy for multifocal, diffuse, and deep-seated brain tumors using Leksell's system. J Clin Neurosci 2004;11:263-7.
8. Butler AR, Horii SC, Kricheff II, Shannon MB, Budzilovich GN. Computed tomography in astrocytomas. A statistical analysis of the parameters of malignancy and the positive contrast-enhanced CT scan. Radiology 1978;129:433-9.
9. Steinhoff H, Lanksch W, Kazner E, Grumme T, Meese W, Lange S, *et al*. Computed tomography in the diagnosis and differential diagnosis of glioblastomas. A qualitative study of 295 cases. Neuroradiology 1977;14:193-200.
10. Okazaki H. Neoplams and related lesions. In: Fundamentals of Neuropathology. 2nd ed, New York: Igaky-Shoin; 1989. p. 203-74.
11. Wood M, Anderson M. Chronic Meningitis. Neurological Infections; Major Problems in Neurology. Vol. 16. Philadelphia, PA: WB Saunders; 1998. p. 169-248.
12. Decastro CC, Hesselink JR. Tuberculosis. Neuroimaging Clin North Am 1991;1:19-39.
13. Bhargava S, Tandon PN. Intracranial tuberculomas: A CT study. Br J Radiol 1980;53:935-45.
14. Weisberg LA. Cerebral CT in intra cranial inflammatory disease. Arch Neural 1980;37:137-42.
15. Welchman JM. Computerised tomography of intracranial tuberculomata. Clin Radiol 1979;30:567-73.
16. Morgado C, Gomes LB, de Campos JG. Neurocysticercosis. An imaging analysis of 35 cases. Acta Med Port 1994;7:269-75.
17. Almeida-Pinto J, Veiga-Pires JA, Stocker A, Coelho T, Monteiro L. Cysticercosis of the brain. The value of computed tomography. Acta Radiol 1988;29:625-8.
18. Carbajal JR, Palacios E, Azar-Kia B, Churchill R. Radiology of cysticercosis of the central nervous system including computed tomography. Radiology 1977;125:127-31.
19. Simionescu MD. Metastatic tumors of the brain: A follow-up study of 195 patients with neurosurgical considerations. J Neurosurg 1960;17:361-73.
20. Alexander E 3rd, Loeffler JS. The case for radiosurgery. Clin Neurosurg 1999;45:32-40.
21. Davis PC, Hudgins PA, Peterman SB, Hoffman JC Jr. Diagnosis of cerebral metastases: Double-dose delayed CT vs contrast-enhanced MR imaging. AJNR Am J Neuroradiol 1991;12:293-300.
22. Deck MD, Messina AV, Sackett JF. Computed tomography in metastatic disease of the brain. Radiology 1976;119:115-20.
23. Potts DG, Abbott GF, von Sneidern JV. National cancer institute study: Evaluation of computed tomography in the diagnosis of intracranial neoplasms. III. Metastatic tumors. Radiology 1980;136:657-64.

How to cite this article: Varkey B, Raman MR, Vivek S, Prabhu R. Computed Tomography Characteristics of Intracranial Ring-enhancing Lesions. Int J Sci Stud 2020;7(12):35-39.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Evaluation of Ornigreat Gel and Placebo (Hexigel 0.25%) as a Local Drug Delivery System in Association with Scaling and Root Planing in Patients with Chronic Periodontitis – An *In vivo* Study

Vineet Kotwal[1], Bhanu Kotwal[2], Amandeep Kaur[3], Manik Sharma[4], Rajiv Mengi[5], Vinod Tomar[5]

[1]Assistant Professor, Department of Periodontics, Indira Gandhi Govt. Dental College, Jammu, Jammu and Kashmir, India, [2]Lecturer, Department of Periodontics, Indira Gandhi Govt. Dental College, Jammu, Jammu and Kashmir, India, [3]Private Practitioner, Jammu, Jammu and Kashmir, India, [4]Associate Professor, Department of Periodontics, Indira Gandhi Govt. Dental College, Jammu, Jammu and Kashmir, India, [5]Consultant Dental Specialist, Department of Health, Government of Jammu and Kashmir, Jammu and Kashmir, India

Abstract

Aim: The aim of the study was to evaluate the comparative effect of Ornigreat gel and Hexigel as a local drug delivery system in association with scaling and root planing (SRP) in patients with chronic periodontitis.

Materials and Methods: A double-blind trial was conducted to test the comparative efficacy of the two commercially available Ornigreat gel and Hexigel at Indira Gandhi Govt. Dental College and Hospital, Jammu. These indices were recorded at baseline ("0 day"), 15th day, 30th day, 60th day, and 90th day in 40 sites, >4 mm pockets in 11 patients among which 20 sites received Ornigreat gel and other 20 sites receive Hexigel following SRP were compared.

Results: The results of the study showed that the combination of SRP and Ornigreat gel therapy was more effective in reducing the mean values of gingival index and sulcus bleeding index though not statistically significant, but the values of plaque index showed statistical significance on the 60th day and 90th day, and the probing pocket depths showed statistically significant difference from the 15th day to the 90th day at $P < 0.05$ in comparison with Hexigel.

Conclusion: The Ornigreat gel could be an efficient local drug delivery system when used in adjunct to SRP in comparison with Hexigel.

Key words: Gingival sulcus, Hexidine, Local drug delivery, Ornidazole

INTRODUCTION

Periodontitis is the most common type of periodontal disease, which results from extension of the inflammatory process started in the gingiva with progression to the supporting structures of the tooth in the presence of modifying/risk factors.[1]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

It has been very well documented that microorganisms play an important role in the etiology of periodontal diseases, and specific organisms are responsible for specific disease processes.[2] The use of chemotherapy as an adjunct in the treatment of periodontitis has received considerable attention during the past decade.[3]

Scaling and root planing (SRP) may fail to eliminate the bacteria because of their location within the gingival tissues or in tooth structures inaccessible to periodontal instruments.[4]

The various measures, which are employed for plaque control, include chemical and mechanical aids such as

Corresponding Author: Dr. Vineet Kotwal, Department of Periodontics, Indira Gandhi Govt. Dental College, Jammu, Jammu and Kashmir, India.

mouthwashes, toothbrushes, dentifrices, interdental cleaning aids, and oral irrigation devices.[5]

It has been noted that long-term regimens of various chemotherapeutic agents and systemic drugs are not advisable because of the possible development of resistant bacterial strains and it also causes common side effects such as gastrointestinal problems, hypersensitivity reactions, drug eruptions, and superinfections.[4,6]

Hence, local drug delivery systems have been explored as an alternative means of bypassing systemic complications and delivering the drug only at the specific diseased site.

Longer antimicrobial duration, therefore, requires systems to establish drug reservoirs in the periodontal pockets able to release active medication in sufficient quantities to counteract the expected continuous loss overtime affected by the flow of crevicular fluid. Goodson[7] pointed out that pharmacological agent to be effective *in vivo* must reach its site of action and be maintained there at a sufficient concentration long enough for the intended pharmacological effect to occur. These three criteria (site, concentration, and time) are strictly correlated.[7]

Local drug delivery devices or control release devices for periodontal applications are mostly based on diffusion of the drug across a membrane as the release controlling feature. They are of different types such as reservoir devices (membrane diffusion system), monolithic devices, gels, and hybrids. The mechanism of drug release may be either by pure diffusion, chemical reaction, counter-current diffusion, and externally imposed controls.[8]

It has also been observed that irrigation for longer periods of time with more concentrated solution resulted in higher levels of tetracycline substantivity.[7]

However, solid devices showed more sustained drug release with an accompanying prolonged alteration of subgingival microflora and improvement in clinical status, but unfortunately, solid drug delivery systems require clinician to both places and then remove the devices at the end of therapy.[3]

Various chemotherapeutic agents, including tetracycline, minocycline, doxycycline, metronidazole, ornidazole, and chlorhexidine, are available for local application. They come in the form of gels, paste, films, strips, and fibers.

Nitroimidazole compound is one such agent that acts by inhibiting DNA synthesis. It works on the principle that inactive form passively diffuses into cell where it is activated by chemical reduction. The nitro group gets reduced to anion radicals which causes oxidation of DNA, leading to strand breakage and cell death. Hence, it has both antimicrobial and mutagenic effect. This effect is primarily seen on obligate Gram-negative anaerobes such as *Porphyromonas gingivalis*, *Prevotella intermedia*, *Fusobacterium*, selenomonas sputigina, and *Bacteroides forsythus* and the Grampositive anaerobes such as *Peptostreptococcus* and *Campylobacter rectus* which are implicated in periodontal disease.[9]

The present study was conducted to evaluate the comparative effect of Ornigreat gel and Hexigel as a local drug delivery system in association with SRP in patients with chronic periodontitis.

MATERIALS AND METHODS

Case Selection

A total number of 40 sites in 11 cases both males and females in nearly equal numbers with chronic periodontitis visiting the Department of Periodontics, Indira Gandhi Govt. Dental College, Jammu, were selected for the study.

Inclusion criteria were as follows: A 30–60-year-old individual and in good health with no history of diabetes, rheumatic fever, blood dyscrasias, and immunologic anomalies; selected patients should show negative response to the allergic test against tetracycline antibiotic; no periodontal therapy within the previous 6 months; the selected site (sextant) should have at least three teeth with two sites having periodontal probing depth of 4 mm or more; both single and multirooted teeth. Exclusion criteria were as follows: Exposure to antibiotics within the previous 6 months; long-term exposure to anti-inflammatory medications or known hypersensitivity to antibiotics; female patients were excluded if they were pregnant or anticipated becoming pregnant during the course of the experiment; and active lactating mothers.

Material Used

Ornigreat was procured from humankind representative, Jammu, and placebo was made in Govt. Pharmacy.

Composition

Ornigreat – Chlorhexidine gluconate 0.25% W/W+Ornidazole 1 %W/W

Placebo (Chlorhexidine gel 0.25%) – the variant being without Ornidazole.

The stock solution of chlorhexidine gluconate (20% w/w) was subsequently added into the polymer solution to obtain chlorhexidine final concentration of 0.25% w/w. The physical properties of the gels (color, homogeneity,

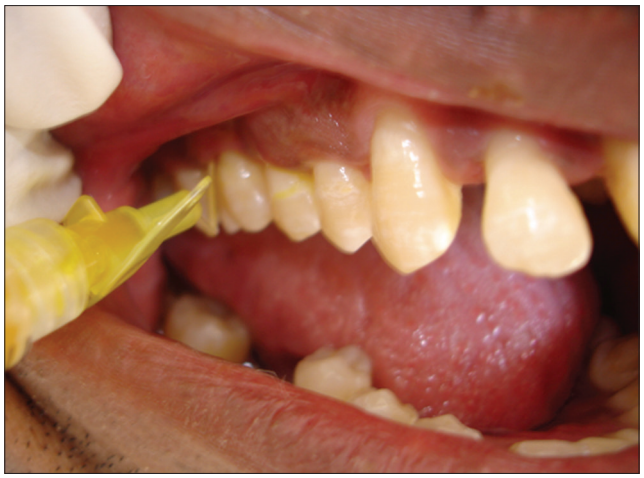


Figure 1: Tip of cannula at base of pocket

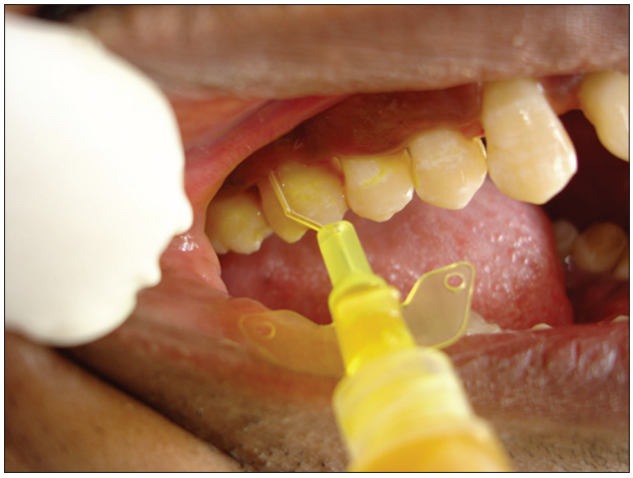


Figure 2: Tip of cannula extrudes as the gel is being placed

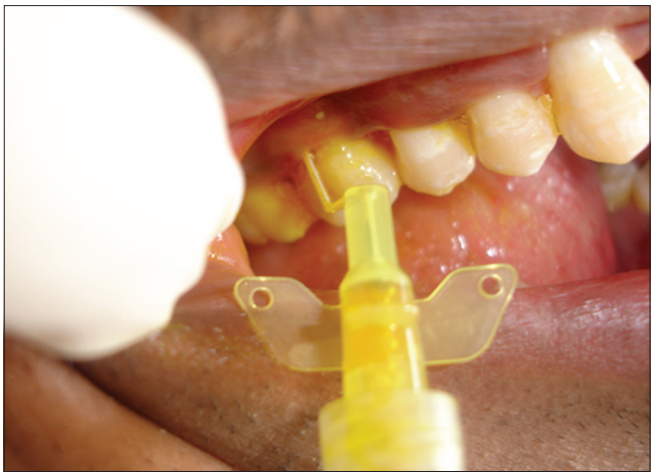


Figure 3: Gel filled up to the margin of the sulcus

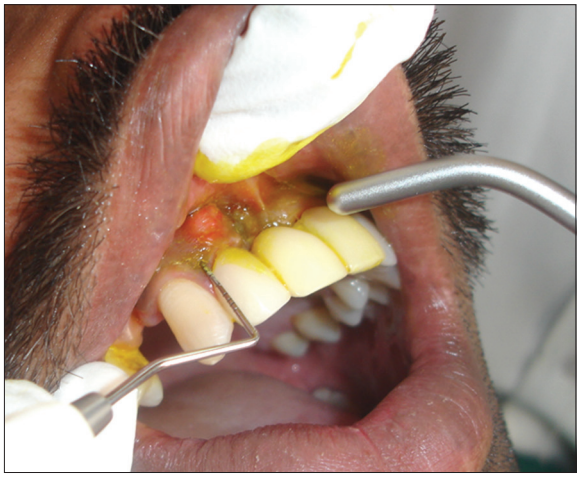


Figure 4: Thin layer of gel formed after the gel is dried

and taste) were observed. The pH values of the gels were measured. The sol-gel transition was observed at 4°C and 28°C. The viscosity response to temperature was investigated at various temperatures (20–50°C) using a viscometer (Remi Lab, Mumbai).

Placement of placebo gel using 24 gauge cannula:

Methods

After the subject selection, all patients were appraised of possible risk, discomfort, and inconvenience associated with the study. A written informed consent was taken from the patients who were to be a part of the study. Patients were advised to continue their present routine of oral hygiene maintenance and no special instructions were given. A total of 40 sites were included for the study. Therapy was divided into two groups, namely, Group A: 20 sites treated with SRP and polishing and then Ornigreat gel was placed in these sites. Group B: Other 20 sites are also treated with SRP and polishing and then placebo gel was placed in these sites. SRP was accomplished with ultrasonic and hand instruments. Teeth not selected for the experiment were treated with SRP only. A single investigator performed all treatment and clinical measurements. Clinical parameters such as plaque index (Turesky, Gilmore, and Glickman Modified Quigley-Hein index), gingival index (Ramfjord index), probing pocket depth (measurement is done by UNC 15 probe), and sulcus bleeding index (Muhlemann and Son, 1971) were recorded at baseline ("0 day" 0), 15th day, 30th day, 60th day, and 90th day in 40 sites, 20 received Ornigreat gel and other 20 received placebo gel following SRP and comparison was made between these two groups. The obtained data were tabulated and statistical analysis was applied using t-test and Chi-square test.

RESULTS

Plaque Index

The mean values were not statistically significant between the two groups ($P > 0.05$) at baseline (0), 15th day, and 30th day, but there was a statistically significant difference between the groups ($P < 0.05$) at 60th and 90th days

[Table 1]. Sulcus bleeding index and gingival index: Mean values were not statistically significant throughout the study period between these two groups [Tables 2 and 3]. Probing pocket depth: The mean value was not statistically significant between the groups ($P > 0.05$) at baseline (0 day), but it was statistically significant between the groups ($P < 0.05$) at the 15th day, 30th day, 60th day, and 90th day [Table 4 and Figures 1-4].

Table 1: Mean plaque index at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	2.77	1.05	1.10	5.00
	15	20	1.75	0.58	1.10	3.20
	30	20	1.95	0.54	1.30	3.70
	60	20	2.00	0.41	1.00	2.50
	90	20	2.21	0.75	1.00	3.20
Group B	0	20	3.10	0.88	1.50	5.00
	15	20	1.97	0.53	1.10	3.00
	30	20	2.10	0.35	1.30	2.70
	60	20	2.34	0.41	1.70	3.40
	90	20	2.8	0.43	1.80	3.40

Table 2: Mean sulcus bleeding index at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	0.58	0.44	0.08	1.60
	15	20	0.43	0.36	0.02	1.40
	30	20	0.41	0.40	0.00	1.40
	60	20	0.44	0.39	0.10	1.50
	90	20	0.47	0.39	0.07	1.50
Group B	0	20	0.89	0.68	0.00	2.30
	15	20	0.64	0.35	0.20	1.50
	30	20	0.70	0.56	0.00	2.10
	60	20	0.71	0.58	0.00	2.10
	90	20	0.74	0.63	0.00	2.20

Table 3: Mean gingival index at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	1.41	0.23	1.10	1.80
	15	20	1.17	0.14	1.00	1.50
	30	20	1.19	0.21	1.00	1.70
	60	20	1.25	0.22	1.00	1.70
	90	20	1.32	0.19	1.10	1.70
Group B	0	20	1.41	0.24	1.00	2.00
	15	20	1.21	0.22	1.00	1.70
	30	20	1.29	0.31	1.00	2.00
	60	20	1.32	0.25	1.00	1.80
	90	20	1.36	0.28	1.00	2.00

Table 4: Mean probing pocket depth at each visit among the study group

Study group	Visit (days)	Number of observation	Mean	Standard deviation	Minimum	Maximum
Group A	0	20	4.34	0.25	4.00	4.90
	15	20	3.42	0.38	2.80	4.30
	30	20	3.50	0.37	2.80	4.10
	60	20	3.80	0.30	2.90	4.20
	90	20	3.94	0.24	3.50	4.40
Group B	0	20	4.32	0.19	4.00	4.60
	15	20	3.92	0.51	2.60	4.70
	30	20	3.94	0.59	2.70	4.80
	60	20	4.25	0.53	2.70	4.80
	90	20	4.35	0.38	3.30	4.50

DISCUSSION

The pathogenic specificity in certain types of periodontitis has led to treatment strategies, which are primarily aimed at suppression or elimination of specific periodontal pathogens. These therapeutic rationales may rely heavily on systemic or local administration of antimicrobial agents following conventional SRP. Antimicrobials used in conjunction with periodontal debridement will provide more effective and predictable clinical results.[4] An important site for antibacterial drug delivery would seem to be from within the periodontal pocket, where local concentrations at the disease site can be established and maintained at any desired level for any duration.[8]

Traditional therapy for periodontal disease includes mechanical SRP, which removes the deposits from the tooth surface and shifts the pathogenic microbiota to one compatible with periodontal health.[10-13] However, the pocket anatomy is a significant limiting factor in mechanical access, and sufficient reduction of the bacterial load is difficult to achieve.[14] An increased interest in antibiotic therapy as an adjunct to standard periodontal treatment regime began in the late 1970s with the realization that certain bacteria are frequently associated with the disease process. Thus, emerging evidence of bacterial specificity in certain types of periodontitis has led to treatment strategies, which are primarily aimed at suppression or elimination of specific periodontal pathogens. These therapeutic rationales rely heavily on systemic or local administration of antimicrobial agents. Since the use of systemic antibiotics is associated with some disadvantages such as inability of systemic drugs to achieve high gingival crevicular fluid concentration,[15] an increased risk of adverse drug reactions,[16] increased selection of multiple antibioticresistant microorganisms,[17] and uncertain patient compliance,[18] the local administration of drugs is recommended.

Ornidazole specifically acts on Gram-negative anaerobic, facultative bacteria which are responsible for periodontal disease. Ornidazole requires a very low minimum inhibitory concentration to inhibit the growth of periodontal pathogens as compared to that of metronidazole. The antimicrobial activity of ornidazole has been proposed due to the reduction of nitro group to a more reactive amine that attacks microbial DNA, inhibiting further synthesis and causing degradation of existing DNA.[19-21]

This present study shows better improvement in clinical parameters at test sites where treatment with ornidazole along with scaling was performed in comparison with chlorhexidine gel.

As home care regime, the use of antimicrobial agent proves as a useful mode of initial periodontal therapy and could prevent the need of a surgical phase in such patients. Further studies are needed to investigate its use in persistent periodontitis.

CONCLUSION

Hence, it can be concluded that the topical application of ornidazole gel was better than chlorhexidine gel alone and can give desired beneficiary effect.

REFERENCES

1. Carranza FA, Adams DF, Newman MG. Slowly progressive periodontitis. In: Carranza FA, Newman MG, editors. Clinical Periodontology. 8th ed. Philadelphia, PA: W.B. Saunders; 1996. p. 326-9.
2. Unsal E, Akkaya M, Walsh TF. Influence of a single application of subgingival gel or tetracycline paste on clinical parameters of adult periodontitis patients. J Clin Periodontol 1994;21:351-5.
3. Eckles TA, Reinhardt RA, Dyer JK, Tussing GJ, Szydlowski WM, DuBous LM. Intracrevicular application of tetracycline in white petrolatum for the treatment of periodontal disease. J Clin Periodontol 1990;17:454-62.
4. Slots J, Rams TE. Antibiotics in periodontal therapy: Advantages and disadvantages. J Clin Periodontol 1990;17:479-93.
5. Perry DA, Schmid MO. Plaque control. In: Carranza FA, Newman MG, editors. Clinical Periodontology. 8th ed. Philadelphia, PA: W.B. Saunders; 1996. p. 493-509.
6. Jolkovsky DL, Ciancio SC. Antimicrobial and other chemotherapeutic agents in periodontal therapy. In: Carranza FA, Newman MG, editors. Clinical Periodontology. 8th ed. Philadelphia, PA: W.B. Saunders; 1996. p. 511-22.
7. Tonetti MS. The topical use of antibiotics in periodontal pockets. In: Lang NP, Karring T, Lindhe J, editors. Proceedings of the 2nd European Workshop on Periodontology. Vol. 78. Chicago, IL: Quintessence Books; 1997. p. 109.
8. Needleman IG. Controlled drug release in periodontics: A review of new therapies. Br Dent J 1991;170:405-8.
9. Edwards DI. Nitroimidazole drugs-action and resistance mechanisms. I. Mechanism of action. J Antimicrob Chemother 1993;31:9-20.
10. Lobene RR, Weatherford T, Ross NM, Lamm RA, Menaker L. A modified gingival index for use in clinical trials. Clin Prev Dent 1986;8:3-6.
11. Schneider HG, Göbbels E, Apel EM. Simplification of plaque index method of Quigley and Hein. Stomatol DDR 1989;39:91-4.
12. Ramfjord SP, Caffesse RG, Morrison EC, Hill RW, Kerry GJ, Appleberry EA, *et al*. Four modalities of periodontal treatment compared over five years. J Clin Periodontol 1987;14:445-52.
13. Claffey N, Nylund K, Kiger R, Garrett S, Egelberg J. Diagnostic predictability of scores of plaque, bleeding, suppuration and probing depth for probing attachment loss. 3.5 years observation following initial periodontal therapy. J Clin Periodontol 1990;17:108-14.
14. Cosyn J, Wyn I, De Rouck T, Sabzevar MM. A chlorhexidine varnish implemented treatment strategy for chronic periodontitis. J Clin Periodontol 2005;32:750-6.
15. Goodson JM. Antimicrobial strategies for treatment of periodontal diseases. Periodontol 2000 1994;5:142-68.
16. Walker CB. Selected antimicrobial agents: Mechanism of action, side effects and drug interactions. Periodontol 2000 1996;10:12-28.
17. Walker CB. The acquisition of antibiotic resistance in the periodontal microflora. Periodontol 2000 1996;10:79-88.
18. Loesche WJ, Grossman N, Giordano J. Metronidazole in periodontitis (IV) the effect of patient compliance on treatment parameters. J Clin Periodontol 1993;20:96-104.

19. Van Winkelhoff AJ, Van der Velden U, Clement M, De Graaff J. Intraoral distribution of black pigmented *Bacteroides* species in periodontitis patients. Oral Microbiol Immunol 1988;3:83-5.
20. Muller HP, Eickholz P, Heinecke A, Pohl S, Muller RF, Lange DE. Simultaneous isolation of *Actinobacillus actinomycetemcomitans* from subgingival and extracrevicular locations of mouth. J Clin Periodontol 1995;22:413-9.
21. Asikainen S, Chen C. Oral ecology and person to person transmission of *Actinobacillus actinomycetemcomitans* and *Porphyromonas gingivalis*. Periodontol 2000 1999;20:65.

How to cite this article: Kotwal V, Kotwal B, Kaur A, Sharma M, Mengi R, Tomar V. Comparative Evaluation of Ornigreat Gel and Placebo (Hexigel 0.25%) as a Local Drug Delivery System in Association with Scaling and Root Planing in Patients with Chronic Periodontitis – An *In vivo* Study. Int J Sci Stud 2020;7(12):40-45.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Role of Non-stress Test in Antenatal Fetal Assessment in High-risk Pregnancy in Comparison with Normal Pregnancy

Shireesha Mantena[1], P Yamini Shoba Vani[2]

[1]Assistant Professor, Department of Obstetrics and Gynecology, Kakatiya Medical College, CKM Hospital, Warangal, Telangana, India, [2]Associate Professor, Department of Obstetrics and Gynecology, Kakatiya Medical College, CKM Hospital, Warangal, Telangana, India

Abstract

Background and Objectives: Non-stress test (NST) is one of the most widely used primary tests for the assessment of fetal well-being. It is a graphical recording of fetal heart activity and uterine contractions simultaneously and continuously when uterus is quiescent with fetal movements. It has been incorporated into biophysical profile system. It is simple, inexpensive, non-invasive, easily performed, and interpreted. Hence, it can be used to screen a large population as an outpatient department procedure. This study was done to observe the efficacy and diagnostic value of NST for antenatal surveillance and comparison of test results with mode of delivery and adverse perinatal outcome.

Materials and Methods: A total of 100 high-risk (HR) pregnant women (study group – selected based on inclusion and exclusion criteria) and 100 low-risk (LR) pregnant women (control group) were randomly enrolled into study and followed up with NST from 32 weeks of gestation and repeated at appropriate intervals in cases of the HR group.

Results: In the LR group, there was an increased incidence of intrapartum fetal death (IPFD), meconium-stained amniotic fluid (MSAF), and decreased liquor quantity in non-reactive (NR) subgroup compared to reactive NST (R-NST) subgroup. However, in the HR group, NR-NST was associated with significantly increased incidence of decreased liquor quantity, low Apgar score at 5 min of birth, and perinatal mortality compared to the R-NST subgroup. Although the statistical incidence of IPFD was not significant in the NR-NST subgroup compared to R-NST, it appeared clinically significant. MSAF incidence was not significant in these two NST result subgroups. Sensitivity, specificity, and negative predictive value of NST in the LR group were 100%, 81.8%, and 100%, respectively; likewise, in the HR group, they are 75%, 78.1%, and 98.7%, respectively, for perinatal mortality.

Conclusion: NST is a valuable screening test for detecting fetal compromise in both HR and LR fetuses that may have a poor perinatal outcome. Predictive value of NST for perinatal mortality was higher in the LR group compared to the HR group though statistically was not significant.

Key words: Antenatal surveillance, Apgar score, Biophysical profile, Decreased liquor quantity, High-risk pregnancy, Intrapartum fetal death, Meconium-stained amniotic fluid, Non-stress test, Perinatal mortality

INTRODUCTION

Advances in the perinatal care in the past 30 years have resulted in a dramatic decrease in perinatal mortality. These advances include improvements in the fetal surveillance techniques and technologic aspects of neonatal intensive care.

Access this article online

IJSS

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

With the introduction of electronic fetal heart rate (FHR) monitoring, ultrasound and most recently, the computerized fetal assessment, more specific and direct examination of the fetus has become a reality.

Modern-day investigations for monitoring fetal health and well-being (biophysical assessment) such as electronic FHR monitoring (non-stress test [NST] and contraction stress test [CST]), biophysical profile (BPP), and color Doppler help to identify the high-risk fetus and to adopt preventive measures to forestall an adverse perinatal outcome.[1]

The primary purpose of biophysical monitoring is to detect fetal hypoxia and acidosis, which are the common causes

Corresponding Author: Dr. P Yamini Shoba Vani, Department of Obstetrics and Gynecology, Kakatiya Medical College, CKM Hospital, Warangal, Telangana, India.

of fetal death. Hence, monitoring and initiating timely interventions are essential.

Increasingly sophisticated, non-invasive diagnostic instruments have made the intrauterine environment more accessible to the physician.

The early identification of the fetus at risk of preventable morbidity or mortality from uteroplacental insufficiency due to maternal risk factors, placental disorders, or fetal diseases has become a major goal of perinatal medicine.

In the mid-1970s, numerous authors noted the correlation between fetal well-being and accelerations of heart rate in response to fetal movements. Since then, antepartum FHR testing (AFHRT) has been and remains the primary mode of evaluating fetal status such as NST and CST.[2]

NST is a graphical recording of fetal heart activity and uterine contractions simultaneously in labor. It can also be recorded when uterus is quiescent along with fetal movements recording.

Simplistically, the NST is primarily a test of fetal condition and it differs from the CST, which is a test of uteroplacental function.[3] It is one of the most widely used primary testing methods for the assessment of fetal well-being and has also been incorporated into BPP system. It is not only simple and inexpensive but it is also non-invasive and easily performed and interpreted. It consumes less time and has no contraindications for testing. More importantly, it can be used to screen a large population quickly and can be performed by trained paramedical staff.

In this study, the effectiveness and the role of NST have been evaluated for assessing the perinatal outcome of fetuses in high-risk (HR) pregnancies.[3-6]

Objectives

The objectives of the study were as follows:

1 To evaluate the efficacy and diagnostic value of NST for antenatal surveillance in HR and low-risk (LR) cases
2. To compare the perinatal outcome with the test results.

MATERIALS AND METHODS

This prospective study was undertaken in M.N.R Medical College and Hospital, Sangareddy, Medak district from October 2011 to September 2013. Women with HR pregnancies were randomly enrolled into the study and followed up with NST from 32 weeks of gestation and repeated at appropriate intervals. A total of 100 HR patients (study group) and 100 LR patients (control group) were studied.

Inclusion criteria for selecting the study group were as follows:

1. Patients of all age groups
2. Singleton, non-anomalous pregnancies of 32 weeks or more weeks of gestation
3. Only NST performed within 7 days before delivery will be considered for the fetal outcome
4. Patients with clinically suspected or diagnosed cases of intrauterine growth restriction (IUGR), pre-eclampsia, chronic hypertension, diabetes mellitus, previous fetal demise, decreased fetal movements, severe anemia, third trimester bleeding, post-dated pregnancy, rhesus isoimmunization, premature rupture of the membranes, and advanced maternal age (>35 years) are included in the study.

The exclusion criteria for the study group include:

1. Sedative usage in the mother 24 h before testing
2. Major congenital anomaly of the fetus detected by routine antenatal ultrasound scanning

The patients were divided into study group of HR pregnancies and control group of LR pregnancies which did not have the above conditions. NST was used for their surveillance from 32 weeks of gestation. NST was recorded weekly, biweekly, on alternate days, or even daily basis depending on HR factors and was followed up. NST was recorded weekly in the LR group. The patient was placed in the left lateral recumbent position with a pillow under the hips to displace the weight of the uterus away from inferior vena cava. The patient's blood pressure and pulse rate were recorded every 10 min during the procedure.

The cardiotocographic equipment of BPL fetal monitor model FM 9533 was applied to the maternal abdomen and patient was instructed to push the event marker button every time she felt fetal movement.

An ultrasound transducer placed on the maternal abdomen was used to direct an ultrasonic beam toward the fetal heart. The transducers detect Doppler shifted frequency changes in echoes created by moving cardiac structures. An autocorrelation process is used to determine the time interval between successive cardiac cycles.

When the sound waves strike an object, they bounce back creating an echo. The monitor also makes use of another characteristic of sound called the Doppler principle which states that echoes reflected by the moving objects, differ from those reflected by the non-moving objects. This allows the monitor to recognize echoes from the fetal heart because of the heart's beating motion.

The monitor also uses this beating motion to compute the FHR. This is why the transducers must be properly positioned and use of ultrasonic coupling gel to send the sound waves toward the fetal heart to receive its echoes. The raw Doppler signals are processed with on board autocorrelation algorithms to yield trains of FHR intervals that generate a baseline rate.

External tocodynamometer device registers uterine activity by detecting the changes in the surface abdominal wall tension. These signals have been correlated with actual intrauterine pressure readings. Maternal conditions that distort abdominal contours (e.g., Marked obesity) decrease the ability of tocodynamometer to record uterine contractions. The paper that is used for recording is heat sensitive and consists of two panels. The upper panel shows FHR and the lower panel shows uterine activity.

The simultaneous recording was traced for 10 min and if there was no acceleration meeting the required criteria, vibroacoustic stimulus was given with an artificial larynx of approximately 80 Hz and 82 db for 1–3 s. The NST was recorded for 20 min and extended up to 40 min for the non-reactive (NR) traces.

The NSTs were classified into three groups based on the presence or absence of at least two FHR accelerations of 15 bpm lasting for 15 s in a 20 min reading into

1. Reactive or normal test
2. NR or abnormal test
3. Suspicious or equivocal test – In these cases, NST was done with vibroacoustic stimulation and extended to 40 min and the results were further classified as reactive or normal and NR or abnormal test based on the reactivity criteria.

One notable update in the ACOG guidelines (2008) is the three-tier classification system for FHR tracings (printouts of the FHR). Category 1 – FHR tracings are considered normal and no specific action is required. Category 2 – tracings are considered indeterminate. This category requires evaluation and surveillance and possibly other tests to ensure fetal well-being. Category 3 – tracings are considered abnormal and require prompt evaluation, according to ACOG. An abnormal FHR reading may require providing oxygen to the pregnant woman, changing the woman's position, discontinuing labor stimulation, or treating maternal hypotension, among other things. If the tracings do not return to normal, the fetus should be delivered.

The patients were then followed up till delivery/termination of pregnancy and the different variables of the perinatal outcome were noted. At the time of delivery, the following data variables were collected such as perinatal mortality, fetal distress during labor, and 5 min Apgar score. The end points used to judge the perinatal outcome include the following:

1. Perinatal death – intrapartum, immediate postpartum, or within the first 28 days of life
2. Fetal distress during labor – defined as an abnormal FHR (FHR <100 or >160) occurring during labor
3. A 5 min Apgar score of <7 – judged by an independent observer – a pediatrician. A 5 min Apgar score of <7 was considered as abnormal. Such newborn was immediately transferred to neonatal care unit
4. Meconium-stained amniotic fluid: The color of liquor during the labor was looked for and meconium staining of the liquor was noted
5. Decreased liquor quantity: The reduction in the amount of liquor appropriate for gestational age as noted by routine antenatal ultrasound examination and/or observed clinically during delivery
6. Cord factor – Any nuchal cords or cord presentations or abnormalities were noted.

Statistical Methods

Data recorded in the study have been subjected to appropriate statistical analysis. Chi-square test has been applied for comparison between the distribution of occurrences. To test the homogeneity of the groups with respect to the distribution of patients over different classes of a characteristic of interest, Chi-square (χ^2) test is carried out at 5% ($\alpha = 0.05$) level of significance. If $P < 0.05$, we conclude that the groups are heterogeneous and if $P > 0.05$, the conclusion is that the groups do not differ significantly, i.e., they are homogeneous.

RESULTS

This study included 100 HR and 100 LR pregnancies on whom NST was performed and those tracings were studied. They have been classified into the reactive and NR test groups based on the reactivity criteria. All the patients were followed up and were delivered in our hospital allowing the perinatal outcome variables to be obtained and analyzed.

The age distribution of patients in the HR and LR groups is tabulated in Table 1.

There was no statistical difference in the mean age between the two groups as $P > 0.05$. Hence, it is insignificant.

Parity distribution of the patients in both the LR and HR groups is shown in Table 2. Primigravida was observed more frequently in both the groups.

The patients in the HR and LR groups were classified based on the NST results into normal/reactive and abnormal/NR

test result categories. The incidence of abnormal test result was 24% in the HR group and 19% in the LR group, as shown in Table 3.

The patients in the LR and HR groups were followed up for mode of delivery. In the LR group, 33% of the patients underwent lower segment cesarean sections (LSCS), but in the HR group, the LSCS rate was as high as 72%.

In the LR group, 23% of cases were induced for labor while in the HR group, 15% of cases were induced for labor.

In the LR group, 27.2% of cases with reactive NST (R-NST) underwent LSCS and 57.9% of cases with NR-NST underwent LSCS.

In the HR group, 71.1% of cases with R-NST underwent LSCS, whereas 75% of cases with NR-NST underwent LSCS.

In the LR group, out of 33% of cases who underwent LSCS, 33.3% of them had NR-NST and 66.6% of them had R-NST.

Table 1: Age distribution of HR (*n*=100) and LR (*n*=100) pregnancy cases

Age (years)	LR group no. (%)	HR group no. (%)
18–20	24 (24)	27 (27)
21–25	63 (63)	51(51)
26–30	11 (11)	14 (14)
31–34	2 (2)	4 (4)
≥35	-	4 (4)

HR: High risk, LR: Low risk

Table 2: Parity-specific distribution of low-risk (*n*=100) and high-risk (*n*=100) pregnancy cases

Gravida	Low-risk group no. (%)	High-risk group no. (%)
Primigravida	52 (52)	55 (55)
Multigravida	48 (48)	45 (45)

Table 3: Distribution of cases in low-risk and high-risk groups based on mode of delivery

Mode of delivery	Low-risk group no. (%)	High-risk group no. (%)
Vaginal	67 (67)	28 (28)
Lower segment cesarean sections	33 (33)	72 (72)

Table 4: Distribution of cases in the low-risk and high-risk groups based on induction of labor

Induction	Low-risk group *n*=100 (%)	High-risk group *n*=100 (%)
Induced	23	15
Not-induced	77	85

In the HR group, out of 72% of cases who underwent LSCS, 25% of them had NR-NST and 75% of them had R-NST [Tables 4-7].

Neonatal Outcome Variables

The perinatal mortality rate and Apgar scores are tabulated in Table 8 for both the LR and HR groups. There were five perinatal deaths in all among 200 pregnant women studied; four of them occurred in the HR group and one in the LR group.

Among the LR patients, there was no perinatal death in the reactive test group while there was one in the NR test group which was statistically insignificant ($P > 0.05$). The incidence of low Apgar score was significantly more in the NR test group compared to the reactive test group.

The perinatal mortality rate in the HR group was 1.31% (1/76) in the reactive test group and 12.5% (3/24) in the NR test group which was statistically insignificant ($P > 0.05$). The incidence of low Apgar score was more

Table 5: Distribution of cases in the low-risk and high-risk groups based on mode of delivery and non-stress test results

Mode of delivery	Low-risk group *n*=100 (%)		High-risk group *n*=100 (%)	
	R (*n*=81)	NR (*n*=19)	R (*n*=76)	NR (*n*-24)
Vaginal	59 (72.8)	8 (42.1)	22 (28.9)	6 (25)
Lower segment cesarean sections	22 (27.2)	11 (57.9)	54 (71.1)	18 (75)

NR: Non-reactive, R: Reactive

Table 6: Distribution of cases in the low-risk and high-risk groups who underwent LSCS based on NST results

NST result	Low-risk group *n*=33 (%)	High-risk group *n*=72 (%)
NR	11 (33.3)	18 (25)
R	22 (66.6)	54 (75)

NST: Non-stress test, LSCS: Lower segment cesarean sections, NR: Non-reactive, R: Reactive

Table 7: Neonatal outcome variables: Perinatal mortality and Apgar scores observed in the low-risk and high-risk groups

Parameter	LR group			HR group		
	R (*n*=81)	NR (*n*=19)	Total	R (*n*=76)	NR (*n*=24)	Total
Low Apgar score	9	4	13	10	9	19
Perinatal mortality	0	1	1	1	3	4

NR: Non-reactive, R: Reactive, HR: High risk, LR: Low risk

significant in the NR test group compared to the reactive test group.

The predictive accuracy of NST for perinatal mortality is tabulated in Table 8. The sensitivity of NST for predicting perinatal mortality was found to be 75% in the HR group, while it was 100% in the LR group as there were no perinatal deaths in the reactive test group among the LR group. The specificity and negative predictive value (NPV) for perinatal mortality were 78.1% and 98.7%, respectively, among high-risk pregnancies. On the other hand, NST was very specific among LR patients and picked up all the cases of perinatal deaths making specificity 81.8% and NPV 100% with a false-negative rate of 0%.

To test the equality of predictive accuracy in the HR and LR groups, Chi-square test was carried out and it did not show any statistical significance in the predictive values among the LR and HR groups.

There was no statistically significant difference in predictive value among the two groups.

DISCUSSION

Among the various antenatal surveillance modalities used for HR pregnancies such as NST, CST, BPP, modified BPP, Doppler velocimetry, etc., NST is one of the easiest tests to perform and cost effective. There are considerable numbers of clinical literatures that support the use of NST in the management of HR pregnancies.[7-15]

In our study, 24% (24/100) of cases of HR pregnancies were NR while in the LR group, 19% (19/100) tests were NR. The percentage of NR tests in our study is almost similar to other studies, for example, Nochimson *et al.*, in his study, had 23.8% (187/786) NR traces.

Table 8: Predictive accuracy of NST for perinatal mortality

Perinatal mortality	Low-risk group (%)	High-risk group (%)
Sensitivity	100	75
Specificity	81.8	78.1
PPV	5.26	12.5
NPV	100	98.7
FP	18.1	21.9
FN	0	25

PPV: Positive predictive value, NPV: Negative predictive value, NST: Non-stress test, FN: False negative, FP: False positive

Perinatal Mortality

In our study, out of 100 LR cases, there was only one perinatal death in the NR test group and none in the reactive test group. While in 100 HR cases, there were four perinatal deaths of which three were seen in the NR test group. Hence, the sensitivity of NST in the LR group was 100% in predicting the perinatal mortality while the sensitivity in the HR group was 75%. The specificity and NPV of NST in the HR group for perinatal mortality in our study are 78.1% and 98.7%, respectively, while in the LR group, it is as high as 81.8% and 100%, respectively. On the other hand, the sensitivity and positive predictive value (PPV) are found to be 75% and 12.5%, respectively, in the HR group and 100% and 5.26% in the LR group.

This shows that a reactive test is an excellent indicator of a healthy fetus, especially in the LR group.

In our study, perinatal mortality occurred almost 3 times more frequently with an NR-NST result than with R-NST result in the HR group. As outlined in Table 8, fetal distress during labor was 3 times more likely to occur when fetuses entered labor with an NR-NST. As shown in Table 9, Phelan reviewed 3000 tests in 1236 HR pregnancies. He found a sensitivity and specificity rate of 64% and 81% for intrapartum fetal death (IPFD), while in our study, the same was 75% and 78.1%, respectively [Table 9].

False-negative NST

The false positivity and false negativity rates are affected by the sensitivity and specificity of the test and by the prevalence of the condition in the tested population. In our study, the false-negative rate was 25% in the HR group and 0% in the LR group for perinatal mortality. This false-negative rate can be as low as 1% in a 228 case study of Flynn *et al.* to as high as 49% in Brettchneider *et al.* study of 246 cases, but generally, it is <5–10%.

While a reactive test very accurately predicts a favorable outcome in the fetus, it actually reflects the low prevalence of poor outcome rather than precision of the test.

Table 9: Comparison of predictive value of NST for perinatal mortality with other studies

Criteria	Our study	Brown *et al.* (1981)	Phelan (1981)	Keegan *et al.* (1980)	Sood (2002)
Number of patients	100	343	1236	634	222
Reactivity criteria accelerations/minutes	2/20	5/80	4/20	2/20	2/20
Sensitivity (%)	75	50	64	33	54
Specificity (%)	78.1	99	81	90	90
False positive (%)	21.9	57	97	97	-

Further Evaluation of NR-NST

According to Keegan *et al.*,[11] the very high false-positive rates of NST could be diminished if there was a method of fetal stimulation by means of assuring the NR fetus. For this purpose, vibroacoustic stimulation was used in our study to arouse the sleeping fetus as well as extended the testing time to 40 min.

Brown *et al.*[8] found that the percentage of NR tests decreases if the observation period is extended in their study of 1101 tests in 343 HR pregnancies in which 24% of patients had NR tests in the first 20 min.

At 40 min, 5% had NR tests and by 80 min, only 2% had NR tests.

Some studies suggest that a reactive test encouraged continuation of pregnancy. On the other hand, Lenstrup and Hasse concluded that a pathological NST was not an indication for immediate delivery, but it was rather an indication for closed observation and should be considered in conjunction with the other clinical data of the particular pregnancy.

Evaluation of NST predictability has classically been based on the single last test usually within 7 days before delivery. The concept of serial comparison of test results was applied by Devoe *et al.*[11] in a series of 148 patients who had at least four NSTs before delivery, percentage acceleration time (PAT) was calculated and the fetus was used as its own control in sequential NSTs. Test sensitivity improved from 30% to 75% using PAT compared to conventional NST interpretation while the specificity was 100%, PPV 100%, and NPV 96.2%.

Graca *et al.* and Gelman *et al.* have repeated NR NST within 24 h after glucose drink or meal and have found an inconsistent effect on NST reactivity, while Keegan *et al.*[11] have suggested eliminating the possibility of drug ingestion.

Richardson *et al.* found an inconsistent effect of external physical stimulation such as suprapubic and fundal pressure on FHR while Leveno *et al.* immediately extended the NST recording to 80 min to improve the reactivity of NST.

NST Associated with Other Surveillance Modalities

Nochimson *et al.*[15] concluded that additional discriminatory evaluation was required for NR-NST. For this purpose, the CST was used, but it appeared that a more discriminatory test which will better indicate the loss of fetal well-being may be required. The need for a better test is based on the reports indicating a false-positive rate of CST which was approximately 25%. Devoe *et al.*[13] have reported on the use of NST, amniotic fluid assessment, and umbilical artery Doppler velocimetry in 1000 HR patients.

Each had specificity of >90% and sensitivities ranged from 69% (NST) to 21% (Doppler velocimetry). NPV of each method exceeded 85%. Amniotic fluid measurements or Doppler velocimetry compared with NST, appeared to be less powerful screening test when used alone.

Trudinger *et al.* compared AFHRT with the study of umbilical artery flow velocimetry waveforms for the recognition of fetal compromise in 170 patients considered to be at high fetal risk. Fetal compromise was effectively recognized by the study of umbilical artery waveforms. The sensitivity of assessment by umbilical artery waveforms was 60% compared to 17% and 36%, respectively, for two methods of scoring FHR traces.

Miller *et al.* used the modified BPP, in which NST serves as an immediate indicator of fetal well-being and amniotic fluid index (AFI) reflects the long-term adequacy of placental function. The false-negative rate of the modified BPP is lower than that of NST and compares favorably with false-negative rates of CST and complete BPP.

Ingermarsson *et al.* found that the patients with reactive admission test had a low rate of intrauterine asphyxia in labor (0.9%), whereas half of the patients with ominous traces had intrauterine fetal asphyxia with a low scalp pH and neonatal depression.

Some investigators have also used the NST to detect IUGR which is an outcome potentially more specific for uteroplacental insufficiency. The specificity and false-positive rates in a study of 590 HR women by Baskett *et al.* were 89% and 94%, respectively.

Schifrin *et al.* and Kubli *et al.*[7] have demonstrated good results with the use of NST in screening LR pregnancy as shown similarly in our study. In our study, the predictive value of NST for mortality was higher in the LR group compared to the HR group (but not statistically significant). However, the use of NST for LR patients will lead to an even greater number of false-positive results because of lower incidence of abnormality in LR population, but may increase inappropriate intervention.

According to Jonathan (2008) in his study, when otherwise healthy women with history of the previous stillbirth are followed with antepartum fetal testing, the stillbirth rate was 3.3 per 1000, suggesting that fetal testing can avert recurrent stillbirths.

Briscoe (2005), in his study, found that in post-term pregnancies, antenatal surveillance with fetal kick counts, non-stress testing, AFI measurement, and BPP is used although no data show that monitoring improves outcomes.

Erica and Thorp (2012) reported that fetal umbilical artery Doppler evaluation should be used for fetal monitoring in HR pregnancies thought to be at risk of placental insufficiency.

According to Ott (1999), the combination of the non-stress test and middle cerebral and uterine artery Doppler ratio was an excellent predictor of perinatal outcome. The middle cerebral and uterine artery Doppler improves the sensitivity for the prediction of poor perinatal outcome when it is combined with the NST.

Grivell *et al*. (2010) concluded that fetal assessment in current practice often involves a combination of methods which may reduce the relevance of the effectiveness of this single method of testing.

Yelikar (2013) concluded that the fetal compromise was greater when both Doppler and NST were abnormal. Moreover, when NST was abnormal, the fetuses were more compromised than when only Doppler was abnormal. This suggests that Doppler detects changes earlier than the NST. This was further validated by the time interval (lead time of 5.86 days) between an abnormal Doppler and an abnormal NST, wherein the Doppler changes preceded that of the NST.

CONCLUSION

The antenatal surveillance of HR pregnancies with NST can effectively screen for the identification of HR fetuses and segregate the population that is at risk for perinatal mortality and morbidity.

The potential advantage of NST is that a decrease in decision to delivery time can be made for those patients with fetal distress so that a major improvement in the outcome among parturients can be achieved with abnormal (NR) NST results.

The use of NST in monitoring HR pregnancies may result in an increase in the incidence of operative delivery as seen in our study (72% LSCS rate in HR pregnancies when compared to 33% in LR pregnancies), and hence, associated high LSCS rates have to be considered in such pregnancies.

NR-NST was associated with significantly increased incidence of decreased liquor, low Apgar score at 5 min of birth (>0.05), and perinatal mortality (>0.05) compared to R-NST in the HR group. Although the incidence of IPFD was not statistically significant between the reactive and NR subgroups in the HR group ($P > 0.05$), it appeared to be clinically significant.

In LR pregnancy group, there was one incidence of IPFD ($P > 0.05$), decreased liquor quantity in the NR subgroup when compared to the reactive subgroup.

NST can be effectively used in both the HR and LR pregnancies. This is because an R-NST result has a high NPV for mortality and morbidity, hence can reliably identify a healthy fetus. NST effectively identified the perinatal mortality case in the LR group and hence had high sensitivity in the LR group when compared to the HR group. On the other hand, an NR test has a high false-positive rate, hence does not reliably identify a compromised fetus in both the HR and LR groups. Hence, it has to be further evaluated by other tests like Doppler.

In conclusion, NST is a valuable screening test for detecting fetal compromise in both HR and LR fetuses. It should be clear that the NST can only be intended as a preliminary test rather than sole part of the comprehensive evaluation of HR patients. An R-NST indicates an uncompromised fetus, while an abnormal (NR) NST should alert the clinician to consider the possibility of fetal compromise and has to be followed up by other biophysical tests.

A total of 100 HR and 100 LR pregnant women were enrolled in a study conducted between October 2011 to September 2013 at MNR Hospital to evaluate the role of NST as a means of antepartum surveillance and in predicting perinatal outcome. All the pregnancies were followed up by NSTs from 32 weeks onward till the delivery, either done weekly or biweekly for a period of 20 min and for NR results, the test was extended up to 40 min. The NST done within 7 days of delivery was used for correlation with the perinatal outcome. The mode of delivery, perinatal morbidity, and mortality were studied in all the women. The two groups were well matched in age distribution, but primiparity was more common in the LR and HR groups. The incidence of NR-NST result was 24% in the HR group and 19% in the LR group. The LSCS rate was higher in the HR group (72%) when compared to the LR group (33%). Although the statistical incidence of IPFD was not that much significant between the reactive and NR subgroups of the HR group, it appeared clinically significant. Low Apgar score at 5 min of birth and perinatal mortality was significantly more in NR-NST result compared to reactive test result in the HR group.

On analysis of data collected, the sensitivity of NST in detecting perinatal mortality was as high as 100% in the LR group, whereas it was 75.0% in the HR group. The NST was also found to have a high NPV of 98.7% while the specificity was 78.1% in detecting morbidity and mortality. The false-positive rate of NST predicting fetal compromise was 21.9% for perinatal mortality in the HR

group. Therefore, NST is a valuable screening test for detecting fetal compromise in both HR and LR fetuses that may have a poor perinatal outcome. NST along with other parameters such as BPP and Doppler velocimetry will give a better information regarding the impending fetal risk.

REFERENCES

1. Sarmiento RA. Antepartum care of the high-risk pregnancy. In: Arias F, Shirish ND, Amarnath GB, editors. Practical Guide to High-Risk Pregnancy and Delivery. 3rd ed. New Delhi: Elsevier; 2008. p. 3-29.
2. Krik AK. The nonstress test. Clin Obstet Gynaecol 1987;30:921-35.
3. Cunningham FG, Leveno KJ, Bloom LS, Hauth CJ, Rouse DJ, Spong CY. Antepartum assessment. In: Williams Obstetrics. 23nd ed. New York: McGraw-Hill; 2010. p. 334-46.
4. Aono J, Posel K. Foetal phonocardiography using the storage oscilloscope a preliminary report. S A J Obstet Gynaecol 1966;12:24-6.
5. Bloch B. Measurement of fetal scalp pH by continuous-recording scalp electrode and correlation with capillary blood pH. S Afr Med J 1978;54:448-50.
6. Hon HE. Fetal heart rate monitoring: For evaluation of fetal well-being. Postgrad Med 1977;61:139-45.
7. Kubli FW, Kaeser O, Hinselman M. Diagnostic management of chronic placental insufficiency. In: Pecile A, Finzi C, editors. The Fetoplacental Unit. Amsterdam: Expert a Medical Foundation; 1969. p. 332-9.
8. Brown VA, Sawers RS, Parsons RJ, Duncan SL, Cooke ID. The value of antenatal cardiotocography in the management of high-risk pregnancy: A randomized controlled trial. Br J Obstet Gynaecol 1982;89:716-22.
9. Hammacher K. The clinical significance of cardiotocography. In: Huntingford PJ, Huter EA, Saling E, editors. Perinatal Medicine. New York: Academic Press Inc.; 1969. p. 80-93.
10. Trierweiler MW, Freeman RK, James J. Baseline fetal heart rate characteristics as an indicator of fetal status during the antepartum period. Am J Obstet Gynecol 1976;125:618-23.
11. Keegan KA Jr., Paul RH, Broussard PM, McCart D, Smith MA. Antepartum fetal heart rate testing. V. The nonstress test--an outpatient approach. Am J Obstet Gynecol 1980;136:81-3.
12. Evertson LR, Gauthier RJ, Schifrin BS, Paul RH. Antepartum fetal heart rate testing. I. Evolution of the nonstress test. Am J Obstet Gynecol 1979;133:29-33.
13. Devoe LD, McKenzie J, Searle NS, Sherline DM. Clinical sequelae of the extended nonstress test. Am J Obstet Gynecol 1985;151:1074-8.
14. Keane MW, Horger EO 3rd, Vice L. Comparative study of stressed and nonstressed antepartum fetal heart rate testing. Obstet Gynecol 1981;57:320-4.
15. Nochimson DJ, Turbeville JS, Terry JE, Petrie RH, Lundy LE. The nonstress test. Obstet Gynecol 1978;51:419-21.

How to cite this article: Mantena S, Vani PYS. Role of Non-stress Test in Antenatal Fetal Assessment in High-risk Pregnancy in Comparison with Normal Pregnancy. Int J Sci Stud 2020;7(12):46-53.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Impact of Chewing Gum Protocol on Delayed Gastric Emptying Following Pancreaticoduodenectomy

M Uma Maheshwaran[1], R Ashwin[2], P Ravichandran[3], S Jeswanth[3], G Manoharan[3]

[1]Assistant Professor, Department of Surgical Gastroenterology, Tirunelveli Medical College and Hospital, Tirunelveli, Tamil Nadu, India, [2]Consultant, Dr. Rela Institute and Medical Centre, Chennai, Tamil Nadu, India, [3]Professor, Department of Surgical Gastroenterology, Institute of Surgical Gastroenterology and Liver Transplantation, Government Stanley Medical College, Chennai, Tamil Nadu, India

Abstract

Introduction: Delayed gastric emptying (DGE) is one of the most troublesome post-operative complications following pancreatic resection. Not only does it contribute considerably to prolonged hospitalization but it is also associated with an increased cost of treatment, necessitates the use of additional investigations and procedures, and can cause life-threatening complications.

Aim: This study aims to study the feasibility of implementing chewing gum protocol in pancreaticoduodenectomy (PD) with pancreaticogastrostomy, using historical control for comparison.

Materials and Methods: Patients having pancreatic, periampullary cancer and other diseases who were planned for elective PD procedures were included in the study. Patients were divided into two groups, control group: Traditional protocol and intervention group: Chewing gum intervention. The primary endpoint for this study was fixed as the occurrence of DGE following PD.

Results: Statistical analysis showed significant differences in the occurrence of DGE and its related parameters such as time for the removal of nasogastric tube (NGT) and time to start an oral solid diet. It also showed a significant difference in secondary parameters such as time to first flatus, time to stools, and post-operative hospital stay. Multivariate analysis also showed a significant beneficial effect of chewing gum.

Conclusion: In patients undergoing PD, implementing gum chewing in the early post-operative period is easy, inexpensive, and without any adverse events. Gum chewing has significantly reduced the incidence of DGE and its parameters such as time to the removal of NGT, resumption of solid diet, time to the passage of first flatus, time to the passage of first stool, and thereby reduced the post-operative hospital stay significantly.

Key words: Chewing gum, Delayed gastric emptying, Pancreaticoduodenectomy

INTRODUCTION

Pancreaticoduodenectomy (PD) is the standard approach for pancreatic cancers and certain benign pancreatic diseases. Pancreatic cancers are one of the major health concerns throughout the world. Pancreatic cancer is one of the leading causes of cancer death in the world. PD is technically a major demanding procedure. With careful patient selection and preparation, advanced operative techniques, ever-advancing principles of intensive care, post-operative comprehensive care, and advanced radiological interventions – perioperative mortality of pancreatic surgery has decreased markedly over the decades to <5% in high-volume centers.[1,2] Despite this, the post-operative morbidity due to complications remains still high (30%–50%).

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

In present, the major morbidity following PD is delayed gastric emptying (DGE) and rates of 19–57% are reported even from centers specializing in pancreatic surgery.[3,4] DGE is one of the most troublesome post-operative adverse outcomes following PD. It contributes considerably to prolonged hospitalization and also associated increased cost of medical treatment, necessitates additional investigations and procedures, and might lead to life-threatening major complications. In spite of immense advances in surgical care and techniques, DGE following PD is still a major

Corresponding Author: M Uma Maheshwaran, Department of Surgical Gastroenterology, Tirunelveli Medical College and Hospital, Tirunelveli, Tamil Nadu, India.

morbid complication in modern surgery. It seems difficult to ascertain the exact incidence of DGE due to variations in definitions. Many groups have proposed definitions of DGE based on time of nasogastric tube (NGT) removal, emesis after NGT removal, need for prokinetics, need of NGT reinsertion, and failure to progress with diet.

In an attempt of developing an objective, universally acceptable, consensus definition for DGE after major PD, the International Study Group of Pancreatic Surgery had developed a generally applicable, objective definition with three grades of DGE based on severity and its clinical impact primarily.[5]

The factors causing DGE are still unclear and are multifactorial.[1,6-10] The potential explanations for DGE after PD include altered neurohumoral pathways, decreased in plasma motilin concentrations due to resection of the duodenum, physiological responses to any collection and sepsis, extended nodal dissection along the common hepatic vessel with disruption of innervation to antrum pyloric region, systemic inflammatory mediators released during surgery and stress, intra-abdominal complications leading to gastroparesis and ileus, devascularized or denervated pylorus after PD, disruption of the pancreatic anastomosis, post-surgical transient acute pancreatitis, disrupted neuronal and hormonal homeostatic mechanisms, and obstruction mechanical or functional by addition of feeding jejunostomy. Various strategies were tried in the past to decrease DGE (DGE) incidence. Pharmacologic manipulations such as the addition of motilin stimulants – erythromycin and prokinetic drugs were tried.[10] Many refinements and modifications in surgical techniques such as pylorus-preserving resections, antecolic versus retrocolic gastrojejunostomy (GJ), the addition of a Braun enteroenterostomy, and uncut Roux-en-Y gastrojejunal reconstructions were also tried in the prevention of DGE.[3,4,11]

Aim

This study aims to study the impact of the implementation of chewing gum protocol in the early post-operative period following PD and evaluating its effects on DGE.

MATERIALS AND METHODS

This prospective comparative study was conducted in the Institute of Surgical Gastroenterology and Liver Transplantation, Stanley Medical College, Chennai, India, from April 2014 to October 2014. All patients suffering from pancreatic, periampullary, and other diseases, planned for PD, were prospectively included in this study.

Inclusion Criteria

- Patients having pancreatic, periampullary cancer and other diseases who were planned for elective PD procedure were included in the study
- All adults aged between 18 and 75 years having good performance status (performance score of more than 80).

Exclusion Criteria

The following criteria were excluded from the study:

- Deeply sedated patients
- Patients on mechanical ventilator support
- Edentulous patients who cannot chew gum
- Presence of intestinal obstruction
- Presence of post-operative bleed, vomiting, and major reoperation
- Who refused to participate in the study trial
- Emergency surgery procedures
- Patients having cerebral disorders – danger of aspiration
- Any contraindications for enteral feeding.

Consecutive patients of PD were included in this study, and the parameters analyzed and compared with an equal number of matched historical controls were operated and treated as per the traditional post-operative treatment protocol following classic PD.

Control group

This group comprised a consecutive equal number of comparable patients who were treated as per the traditional protocol in the historical period – just before the study period.

Intervention group

This group also received treatment identical to the control group, but with the only difference being, patients received chewing gum intervention as specified in the protocol mentioned earlier.

Along with traditional post-operative protocol, patients in the intervention group were allowed to chew sugarless chewing gum for 30 min, 3 times a day. From the 1st post-operative day, until they were tolerating a solid diet. During the administration of chewing gum, both patient and nursing staff were required to report any potential side effects/adverse events. The criterion to stop the study was either withdrawal of consent by the patient and/or any serious adverse events due to the administration of chewing gum.

The primary endpoint for this study was fixed as the occurrence of DGE following PD.

Descriptive statistics were done for all data and suitable statistical tests of comparison were done. Continuous

variables were analyzed with the unpaired *t*-test and categorical variables were analyzed with Fisher's exact test. Statistical significance was taken as $P < 0.05$. The data were analyzed using Epi Info software (7.1.0.6 version; Center for Disease Control, USA) and Microsoft Excel 2010.

RESULTS

All the 40 patients {control group (n=20) and test group (n=20)} completed the study. Both the groups were homogenous with regard to demographic data, with no differences in age and gender. The two groups were comparable in operative parameters, with no differences in etiology, presence of diabetes, total operating time, consistency of pancreas, and GJ type. The other post-operative data in both groups: Blood transfusion, pancreatic fistula, enteric/biliary fistula, collections, post-pancreatectomy hemorrhage, need for reoperations/interventions – were comparable in both groups and the difference was not statistically significant. On the statistical analysis of pre-operative parameters by conventional criteria, the association between site of tumor, the status of diabetes, pre-operative sepsis status, duration of surgery, blood loss/transfusions required, type of GJ, and chewing gum intervention groups is considered to be not statistically significant since $P > 0.05$ [Tables 1 and 2].

On analysis of post-operative variables statistically by conventional criteria, the association between the presence of collection, pancreatic fistula, post-pancreatectomy hemorrhage, presence of post-operative sepsis, need for reintervention/reoperation, mortality, and chewing gum intervention groups is considered to be not statistically significant since $P > 0.05$. On analysis of DGE-related parameters by conventional criteria, the association between emesis/distension, reinsertion of NGT, and chewing gum intervention groups is considered to be not statistically significant since $P > 0.05$ [Table 3].

After adjusting for age and gender, chewing gum intervention group demonstrated that the association between DGE, NGT removal, time to pass first flatus, time to first stools, time to resumption of oral solid diet, duration of post-operative stay, and chewing gum intervention groups is considered to be statistically significant since $P < 0.05$ [Tables 4 and 5].

Table 1: Demographic and operative parameters

Variables	Control group	Test group	*P*-value
Age	47.6	52.45	0.252
Gender			
Male	10	9	0.999
Female	10	11	
Etiology			
Pancreatic	7	10	0.659
Periampullary	11	7	
Solid pseudopapillary neoplasm	1	1	
Duodenal	1	1	
Duodenal neuroendocrine tumors	0	1	
Diabetes	9	9	0.999
Duration of surgery	361.5	365.5	0.815
Pancreas consistency			
Firm	14	13	0.504
Soft	5	7	
Hard	1	0	
Gastrojejunostomy type			
Retrocolic	12	8	0.749
Antecolic	8	12	

Table 2: Post-operative parameters

Parameter	Control	Test group	*P* value
Pancreatic fistula			
Grade A	9	6	0.576
Grade B	1	2	
Grade C	0	1	
Collections	1	2	0.548
PPH			
Grade A	1	2	0.513
Grade B	0	0	
Grade C	1	0	
Reoperation/intervention	3	2	0.34
Blood transfusion	9 (2 units)	13 (1.6 units)	0.204
Post-operative sepsis	5	6	0.74

Table 3: DGE parameters

Parameter	Control (n=20)	Test group (n=20)	*P* value
NGT removal (days)	5	3.6	0.0005
Resumption of oral solids (days)	12	8.65	0.006
Emesis/distension	4	4	0.999
NGT reinsertion	4	4	0.999
Need for prokinetics	4	4	0.999
DGE			
Grade A	14	9	0.031
Grade B	4	3	
Grade C	1	0	

DGE: Delayed gastric emptying, NGT: Nasogastric tube

DISCUSSION

Whipple PD is the standard procedure of choice for the treatment of benign diseases such as chronic pancreatitis as well as for the treatment of malignancies (carcinoma of the pancreatic head, neck, or uncinate process, distal common bile duct, ampulla of Vater, duodenum, solid pseudopapillary neoplasm, and neuroendocrine tumors).[6,12]

PD was selected as a target surgery for some important reasons. PD involves major resection of pancreaticoduodenal complex and complex reconstructions

Table 4: Secondary endpoints

Parameter	Control (*n*=20)	Test group (*n*=20)	*P* value
Passage of first flatus (days)	3.55	3.25	0.135
Passage of first stools (days)	5.6	4.7	0.007
Resumption of oral fluids (days)	8.65	5.84	0.005
ICU stay (days)	8.2	6.05	0.053
Post-operative stay (days)	20.35	15	0.005

Table 5: Multivariate logistic regression analysis

Variable	Odds ratio	95% CI	*P* value
NGT removal	10.18	1.09–94.73	0.042
Passage of first flatus	1.8	0.4130–8.0745	0.042
Passage of first stool	15	0.8232–273.3360	0.007
Resumption of oral fluids	4.72	0.243–0.918	0.027
Resumption of solid diet	10.1	1.09–94.73	0.042
Delayed gastric emptying	71.8	3.8448–1342.3922	0.004
Length of ICU stay	0.5	0.0250–10.9591	0.676
Length of post-operative stay	1.3	0.2880–6.1286	0.015

NGT: Nasogastric tube

involving gastrointestinal, biliary, and pancreatic continuity. PD is associated with considerable rates of mortality (up to 5%) and morbidity (reported up to 30%–50%)[1,2] even in high-volume centers specialized in pancreatic surgeries. Many reports suggest that other post-operative complications increase the incidence of DGE. Despite innumerable attempts to prevent or treat it, DGE continues to be a major troublesome clinical problem following PD, especially with pancreaticogastrostomy reconstruction.

DGE is an independent predictor of the prolonged hospital stay after PD. DGE is associated with considerable morbidity to the patient and causes major financial and psychological implications for the patient and health-care system and decreases the quality of life.

Any reduction in post-operative complications, especially DGE, and its associated morbidity in these patients undergoing PD will be beneficial to the patient, healthcare, and society in general. Impact of chewing gum in preventing/treating post-operative ileus following major abdominal surgeries such as gastric, colorectal, gynecological, obstetric, urological, and other procedures was proved by multiple trials including randomized control trials in the past, which was discussed in detail during the review of the literature.[13-20]

The pathophysiology behind the effect of chewing gum is mainly a sham feeding effect causing cephalovagal stimulation and possible neurohormonal stimulation of gastrointestinal motility and function without any additional risks involved. Implementation of the easily available gum chewing protocol in the early post-operative period following PD involves no dangerous side effects, inexpensive, and easy.

At present, even if fast-track recovery and reduced hospital stay are becoming increasingly common, the occurrence of DGE and prolonged hospital stay is causing a substantive economic impact. International differences in post-operative hospital stay must also be acknowledged while considering this study. The average post-operative hospital stay after PD is 14–21 days in Western Europe,[11,21] in recent reports, it averages 7–14 days in the United States,[6,9,22] and in most of the Asian countries, it remains longer, ranging from 19 to 28 days. In this study, we used sugar-free commercially available chewing gum with acceptable texture and flavor. All the patients were very positive and interested in participating in our study. This study clearly demonstrated that in the chewing gum group, the rate of all the grades of DGE was significantly lower and the average time to remove NGT, the start of a solid diet is shorter in the intervention group and the difference is significant. The same effect is also observed in the time to pass first flatus a first stools and the time to start an oral fluid diet, which indicates early recovery from post-operative paralytic ileus. While the post-operative hospital stay is significantly reduced in the chewing gum group, this study failed to demonstrate any significant effect on ICU stay. This study shows that gum chewing in the early post-operative recovery period following PD, significantly decreased the rate of DGE without any adverse effect. Gum chewing also resulted in a significant reduction in time to removal of an NGT, time to start oral fluids, and solid diet. It also resulted in an early passage of first flatus, first stools, and reduced post-operative stay in the hospital.

Limitations of this Study

- Non-randomized trial
- Historical control population
- Small sample size.

The main aim of this study is the effect of chewing gum on DGE and other secondary factors. We have done multivariate analysis using critical variables, instead of looking into each factor's effect on DGE. The quality in the selection of controls is also proven by comparability between groups statistically. A larger sample will surely improve the quality of the study by reducing the bias, but we have incorporated correction methodologies in statistical analysis to overcome the low sample size. Furthermore, we have performed a power analysis to decide the minimum sample size and/or study involved more than the required sample size.

CONCLUSION

In patients undergoing PD, implementing gum chewing in the early post-operative period is easy, inexpensive, and without any adverse events. Gum chewing has significantly reduced the incidence of DGE and its parameters such as time to the removal of NGT, resumption of solid diet, time to the passage of first flatus, time to the passage of first stool, and thereby reduced the post-operative hospital stay significantly. This has resulted in enhancing the confidence and well-being of the patient after this major surgery and reduced the cost of healthcare. Gum chewing did not influence vomiting/abdominal distension, reinsertion of NGT, and length of ICU stay.

REFERENCES

1. Bassi C, Falconi M, Salvia R, Mascetta G, Molinari E, Pederzoli P. Management of complications after pancreaticoduodenectomy in a high volume centre: Results on 150 consecutive patients. Dig Surg 2001;18:453-7.
2. Wagner M, Redaelli C, Lietz M, Seiler CA, Friess H, Büchler MW. Curative resection is the single most important factor determining outcome in patients with pancreatic adenocarcinoma. Br J Surg 2004;91:586-94.
3. Nikfarjam M, Houli N, Tufail F, Weinberg L, Muralidharan V, Christophi C. Reduction in delayed gastric emptying following non-pylorus preserving pancreaticoduodenectomy by addition of a Braun enteroenterostomy. JOP 2012;13:488-96.
4. Malleo G, Crippa S, Butturini G, Salvia R, Partelli S, Rossini R, *et al*. Delayed gastric emptying after pylorus-preserving pancreaticoduodenectomy: Validation of international study group of pancreatic surgery classification and analysis of risk factors. HPB (Oxford) 2010;12:610-8.
5. Wente MN, Bassi C, Dervenis C, Fingerhut A, Gouma DJ, Izbicki JR, *et al*. Delayed gastric emptying (DGE) after pancreatic surgery: A suggested definition by the international study group of pancreatic surgery (ISGPS). Surgery 2007;142:761-8.
6. Yeo CJ, Cameron JL, Lillemoe KD, Sohn TA, Campbell KA, Sauter PK, *et al*. Pancreaticoduodenectomy with or without distal gastrectomy and extended retroperitoneal lymphadenectomy for periampullary adenocarcinoma, Part 2: Randomized controlled trial evaluating survival, morbidity, and mortality. Ann Surg 2002;236:355-66.
7. Hocking MP, Harrison WD, Sninsky CA. Gastric dysrhythmias following pylorus-preserving pancreaticoduodenectomy. Possible mechanism for early delayed gastric emptying. Dig Dis Sci 1990;35:1226-30.
8. Liberski SM, Koch KL, Atnip RG, Stern RM. Ischemic gastroparesis: Resolution after revascularization. Gastroenterology 1990;99:252-7.
9. Balcom JH 4th, Rattner DW, Warshaw AL, Chang Y, Fernandez-del Castillo C. Ten-year experience with 733 pancreatic resections: Changing indications, older patients, and decreasing length of hospitalization. Arch Surg 2001;136:391-8.
10. Sturm A, Holtmann G, Goebell H, Gerken G. Prokinetics in patients with gastroparesis: A systematic analysis. Digestion 1999;60:422-7.
11. Bassi C, Falconi M, Molinari E, Salvia R, Butturini G, Sartori N, *et al*. Reconstruction by pancreaticojejunostomy versus pancreaticogastrostomy following pancreatectomy: Results of a comparative study. Ann Surg 2005;242:767-71.
12. Grace PA, Pitt HA, Longmire WP. Pylorus preserving pancreatoduodenectomy: An overview. Br J Surg 1990;77:968-74.
13. Vásquez W, Hernández AV, Garcia-Sabrido JL. Is gum chewing useful for ileus after elective colorectal surgery? A systematic review and meta-analysis of randomized clinical trials. J Gastrointest Surg 2009;13:649-56.
14. Short V, Herbert G, Perry R, Atkinson C, Ness AR, Penfold C, *et al*. Chewing gum for postoperative recovery of gastrointestinal function. Cochrane Database Syst Rev 2015;2:CD006506.
15. Noble EJ, Harris R, Hosie KB, Thomas S, Lewis SJ. Gum chewing reduces postoperative ileus? A systematic review and meta-analysis. Int J Surg 2009;7:100-5.
16. van den Heijkant TC, Costes LM, van der Lee DG, Aerts B, Osinga-de Jong M, Rutten HR, *et al*. Randomized clinical trial of the effect of gum chewing on postoperative ileus and inflammation in colorectal surgery. Br J Surg 2015;102:202-11.
17. Ertas IE, Gungorduk K, Ozdemir A, Solmaz U, Dogan A, Yildirim Y. Influence of gum chewing on postoperative bowel activity after complete staging surgery for gynecological malignancies: A randomized controlled trial. Gynecol Oncol 2013;131:118-22.
18. Craciunas L, Sajid MS, Ahmed AS. Chewing gum in preventing postoperative ileus in women undergoing caesarean section: A systematic review and meta-analysis of randomised controlled trials. BJOG 2014;121:793-9.
19. Ho YM, Smith SR, Pockney P, Lim P, Attia J. A meta-analysis on the effect of sham feeding following colectomy: Should gum chewing be included in enhanced recovery after surgery protocols? Dis Colon Rectum 2014;57:115-26.
20. Nimarta, Singh NV, Shruti, Gupta R. Effectiveness of chewing gum on bowel motility among the patients who have undergone abdominal surgery. Nurs Midwifery Res J 2013;9:108-17.
21. Falconi M, Valerio A, Caldiron E, Salvia R, Sartori N, Talamini G, *et al*. Changes in pancreatic resection for chronic pancreatitis over 28 years in a single institution. Br J Surg 2000;87:428-33.
22. Kim DK, Hindenburg AA, Sharma SK, Suk CH, Gress FG, Staszewski H, *et al*. Is pylorospasm a cause of delayed gastric emptying after pylorus-preserving pancreaticoduodenectomy? Ann Surg Oncol 2005;12:222-7.

How to cite this article: Maheshwaran MU, Ashwin R, Ravichandran P, Jeswanth S, Manoharan G. Impact of Chewing Gum Protocol on Delayed Gastric Emptying Following Pancreaticoduodenectomy. Int J Sci Stud 2020;7(12):54-58.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Estimation of Serum Vaspin Levels in Humans as a Novel and Therapeutic Biomarker of Visceral Obesity

D Thamizh Valli[1], A Parimala[2]

[1]Assistant Professor, Department of Physiology, Government Thiruvannamalai Medical College and Hospital, Thiruvannamalai, Tamil Nadu, India, [2]Professor, Department of Physiology, Government Medical College Omandurar Government Estate, Chennai, Tamil Nadu, India

Abstract

Background: Obesity is associated with metabolic complications and significantly increases the risk of developing insulin resistance. Visceral fat is potentially dangerous as it is the major player in the adverse metabolic consequences of obesity. In this context, one of the recently discovered and interesting adipokines that provide a new insight into the physiology, pathology, and treatment of obesity is vaspin. Vaspin is a visceral adipose tissue-derived serine protease inhibitor with insulin-sensitizing effects and its upregulation in obese individuals may be a defensive and a protective mechanism aimed to reduce insulin resistance in humans.

Aims and Objectives: This study aims to determine the circulating serum vaspin levels in humans with visceral obesity to assess its association and link to obesity-related metabolic alterations.

Materials and Methods: A cross-sectional study consisting of 120 obese subjects in the age group of 30–55 years having a body mass index (BMI) of ≥35 (Group I) and another 120 subjects of the same age group with a normal range BMI (Group II) was done with their measures of obesity and serum vaspin levels measured.

Results: The obese subjects (Group I) showed significant differences in the BMI, measures of obesity, and the serum vaspin levels (P □ 0.001). Pearson's correlation revealed that the serum vaspin levels were positively correlated with the measures of obesity.

Conclusion: From this study, it can be demonstrated that vaspin may be used as a circulating biomarker for early identification of obesity-related metabolic alterations and vaspin also plays an important role in the pathogenesis of obesity and its related metabolic disorders.

Key words: Insulin resistance, Obesity, Vaspin

INTRODUCTION

Obesity is a chronic, multifactorial disease involving environmental, genetic, physiological, metabolic, behavioral, and psychological components. It has been increasing at an alarming rate throughout the world to the extent that it is now a pandemic, affecting millions of people globally. It has become the second leading and a preventable cause of death worldwide, with increasing rates in adults, especially in women and children. Globally, the prevalence of obesity is estimated to be 36.9% for men and 38.0% for women.[1] There have been substantial increases in the prevalence of obesity in the developing countries as well, which is estimated to be 23.8% for men and 22.6% for women.[1]

India is now following a trend of other developing countries that are slowly and steadily becoming more obese. Obesity in India has reached epidemic proportions in the 21st century, with morbid obesity affecting 5% of the country's population.

Obesity implies an excess storage of fat to an extent that it may have a negative impact on health. The serious impact

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. D Thamizh Valli, Sri Dharani International School, Dharani Nagar, Sandhaimedu, Gingee - 604 202, Tami Nadu, India.

of obesity on individuals and societies throughout the world in terms of health, social, and economic costs is a major concern.

The mortality rates rise as obesity increases, particularly when obesity is associated with an increased intra-abdominal or visceral fat. Visceral fat is body fat that is stored within the abdominal cavity around a number of important internal organs such as liver, pancreas, and intestines. Visceral fat is also known as "active fat" as it plays a unique and potentially dangerous role in affecting how our hormones function. Carrying a high amount of visceral fat is known to be associated with insulin resistance, which can lead to an increased risk of many health conditions such as type 2 diabetes mellitus, heart diseases, breast cancer, colorectal cancer, and Alzheimer's disease.[2] Furthermore, the hyperinsulinemia that accompanies insulin resistance would magnify and mediate the detrimental effects of visceral obesity. Thus, insulin resistance plays a crucial role in the pathogenesis of all these disorders.[3]

The various measures of visceral obesity include the estimation of the body mass index (BMI), waist and hip circumference, waist–hip ratio, percentage of body fat, and the skinfold thickness.

However, the waist circumference is globally used as a parameter and is a simplest way to quantify central obesity.[4] This is because it correlates well with excessive visceral fat, which appears to be the most metabolically active fat, which is responsible in causing insulin resistance. Measures of central obesity help refine the clinical evaluation of obesity-related risk.

Apart from this important function, the visceral adipocytes are involved in the energy metabolism and are the source of hormones, cytokines, and metabolites that play an important role in whole-body metabolism and insulin resistance. These cytokines or the bioactive mediators also called the cell signaling proteins secreted by the visceral adipose tissue are known as adipokines or adipocytokines. These adipokines send signals to organs of metabolic importance including brain, liver, skeletal muscle, and the immune system – thereby regulating the blood pressure, homeostasis, lipid and glucose metabolism, inflammation, hemostasis, angiogenesis, and atherosclerosis.[5]

Obesity is strongly associated with alterations in the physiological functions of the visceral adipose tissue, leading to insulin resistance, chronic inflammation, and altered secretion of adipokines.[6] An excessive accumulation of visceral fat can cause a dysregulation of the function of the adipocytes, thus causing an over secretion of the deleterious adipokines and a hyposecretion of the advantageous ones. An adipose tissue dysfunction or adisopathy plays a crucial role in the different obesity-linked diseases, including inflammation, insulin resistance, and cancer.

The visceral adipose tissue that is diseased and does not function properly is called as sick fat or adisopathy, which results in endocrine and immune responses that would cause metabolic abnormalities and directly promote cardiovascular disease.[7,8]

The harmful effects of visceral fat are due to lipotoxicity. Unlike subcutaneous fat, visceral fat cells release their metabolic products directly into the portal circulation, which is, in turn, carried to the liver. These visceral fat cells that are enlarged with an excess of triglycerides pour the free fatty acids into the liver causing them to accumulate in the pancreas, heart, and other vital organs. These free fatty acids accumulate in cells, in various locations of the body resulting in an organ dysfunction, which produces impaired regulation of insulin, blood sugar, and cholesterol, as well as abnormal heart functions.

One of the newly discovered adipocytokines is vaspin (visceral adipose tissue-derived serine) which was found to have insulin-sensitizing effects. It is a member of serine protease inhibitor family which was first isolated from visceral adipose tissue of Otsuka Long-Evans Tokushima Fatty (OLETF) rats, a model of abdominal obesity and type 2 diabetes.[9]

In the diet-induced obese OLETF rats, serum vaspin levels were found to be very high at the age when obesity and the plasma insulin levels reached a peak, and the administration of vaspin to these obese rats was found to significantly improve their glucose tolerance and insulin sensitivity.[9]

Expression of vaspin gene in visceral adipose tissue of humans and an increased circulating levels in the serum was found to be positively associated with parameters of obesity, obesity-related diseases, insulin resistance, and glucose metabolism. It is also indicated that vaspin plays a role in the adipoinsular axis and is associated with insulin resistance in obese subjects.[10]

Thus, this study aims at estimating the serum vaspin levels as a novel, circulating, and therapeutic biomarker in obese subjects and to study its association and link to obesity-related metabolic alterations.

MATERIALS AND METHODS

After obtaining approval from the Institutional Ethics Committee, a cross-sectional study was conducted during the period of June 2016–May 2017 at the Institute of

Physiology and Experimental Medicine, Madras Medical College. The study subjects were recruited from the Institute of Internal Medicine and The Medical Endocrine Clinic, Rajiv Gandhi Government General Hospital, Chennai.

A total of 120 obese subjects in the age group of 30–55 years having a BMI of ≥35 (who were categorized as Group I) and another 120 subjects of the same age group with a normal range BMI (who were categorized as Group II) were selected for the study. Subjects with Type I and Type II diabetes, renal and hepatic diseases, hypertension, thyroid dysfunction, polycystic ovary syndrome, Cushing's disease, alcohol or drug abuse, smoking, cancer, hormonal therapies, chronic medication therapies (such as on antidepressants, anticonvulsants, hypoglycemic drugs, antihypertensives, lipid-lowering agents, oral contraceptives, and corticosteroids), pregnancy, and any other chronic medical or psychiatric illness were excluded from the study.

After obtaining an informed consent, a detailed history was obtained from all the study subjects and they underwent a careful and thorough physical examination and laboratory investigations to exclude any condition that might interfere with the study parameters.

The following were obtained and measured for all the study subjects using standard protocols:

1. The anthropometric measurements, i.e., the standing height and weight in light clothing without shoes were obtained using a stretch-resistant measuring tape and the BMI was calculated using the formula: wt (kg)/Ht (m^2)
2. The measures of obesity, i.e., the waist circumference and the hip circumference were obtained and the waist–hip ratio was calculated.
   According to the WHO Stepwise Approach to Surveillance protocol, the measurement for the waist circumference was made at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest at the end of a normal expiration, and the measurement for the hip circumference was taken around the widest portion of the buttocks. The measurement was made with a stretch-resistant measuring tape that provides a constant 100 g of tension, with the tape parallel to the floor. It was ensured that the subject was standing erect with relaxed abdominal muscles, the arms by the side, feet positioned close together, and the weight evenly distributed across the feet and the clothing removed from the waistline. The measurement was made with a stretch-resistant measuring tape that provides a constant 100 g of tension, with the tape parallel to the floor.
3. After an overnight fast, between 8 and 10 am, a blood sample was taken and serum collected and stored at −80°C
4. Serum vaspin levels were assayed using the commercially available human vaspin ELISA kit using a human vaspin sandwich ELISA technique
5. The serum vaspin levels were correlated with the measures of obesity in the obese subjects.

The sample handling, storage, and preparation were done according to the manufacturer's instructions.

Statistical Analysis

The mean and standard deviation of the variables were determined for the two study groups.

Unpaired Student's *t*-test was employed as the test of significance at 95% confidence interval and Pearson's correlation was done using the SPSS software version 21.

- $*P < 0.05$ was considered as statistically significant
- $**P < 0.01$ was considered as highly statistically significant
- $***P < 0.001$ was considered as very highly statistically significant.

RESULTS AND DISCUSSION

In the current study, the purpose was to estimate and investigate the role of vaspin as a novel and a potential biomarker of visceral obesity. This was with the view that serum vaspin levels could be used as an early identification of visceral obesity and its related metabolic alterations, which would, in turn, enable us to make early interventions to protect oneself from its ruinous complications.

In this study, the BMI, measures of obesity, and the serum vaspin levels were estimated and compared in both the obese and the non-obese subjects.

Moreover, the serum vaspin levels also correlated with the BMI and the measures of obesity in the obese subjects.

In this study, the obese subjects showed an elevated BMI when compared to the non-obese subjects. The vaspin levels also showed a significant positive correlation with their BMI values.

This means that the vaspin concentration increases with an increase in BMI.

The results presented here are in line with Youn *et al.* and Alberti *et al.* who observed a significant BMI adjusted correlation with vaspin.[11]

Table 1: The mean values of the study parameters

Parameters	(Group I) Mean±SD	(Group II) Mean±SD	*P* value
Body mass index	40.59±3.98	22.87±1.81	0.0001
Waist circumference (cm)	115±9.13	83.23±1.54	0.0001
Hip circumference (cm)	127±10.75	104.60±3.45	0.0001
Waist/hip ratio	0.95±0.073	0.79±0.02	0.0001
Serum vaspin levels (ng/ml)	1.26 ± 1.18	0.73±0.59	0.03

Table 2: Correlation of serum vaspin levels with the waist circumference, hip circumference, waist–hip ratio, and BMI

Variable	WC (cm)	HC (cm)	Waist/hip ratio	BMI
Vaspin				
r	0.6140	0.5775	-0.0815	0.722
P	0.0003	0.0008	0.67	0.00001

BMI: Body mass index, WC: Waist circumference, HC: Hip circumference

Regarding the measures of obesity, the waist circumference, the hip circumference, and the waist–hip ratio were found to be elevated in the obese subjects when compared to the non-obese subjects with a normal range BMI.

Moreover, the waist circumference of the obese subjects showed a significant positive correlation with their serum vaspin levels. This result is in accordance with Alberti *et al.* (2009) who proposed that the waist circumference is a globally used parameter to quantify central obesity and is the key culprit in insulin resistance and its related complications.[12] Thus, it can be proposed that greater the waist circumference of an individual, greater would be the serum vaspin levels. This finding in this study is to be highlighted as it suggests that a higher serum vaspin levels in the obese individuals are an indicator of visceral obesity and its related complications.

These results suggest that the obese subjects with a high serum vaspin levels may be prone to develop the obesity-related metabolic complications in future.

It was postulated that an increase in the serum vaspin levels in the obese individuals was due to an increased secretion of the adipokine vaspin from the visceral adipose tissues and represented a compensatory mechanism or a response associated with obesity to antagonize the action of the other unknown proteases that are upregulated in obesity and in states of insulin resistance. Hence, this upregulation is said to be a defensive mechanism against insulin resistance [Tables 1 and 2].[13-15]

CONCLUSION

The conclusions derived from the present study are as follows:

1. Vaspin, a visceral adipose tissue-derived factor with potential antiprotease properties and insulin-sensitizing effects is increased in obesity
2. Vaspin levels are positively correlated and associated with the BMI and the measures of obesity
3. Vaspin could be used as a biomarker of visceral obesity and as an indicator of cardiovascular risk
4. Vaspin also plays an important role in the pathogenesis of obesity and its related metabolic disorders.
5. Hence, vaspin can also be used as a circulating biomarker for early identification of obesity-related metabolic alterations and thus can enable us to make interventions at the earliest.

ACKNOWLEDGMENTS

I extend my sincere thanks to Dr. A Parimala, M.D, DCP, Professor of Physiology, Govt. Omandurar Medical College, for her support and guidance. I dedicate this work to my lovable family and thank God Almighty for helping me throughout this endeavor.

REFERENCES

1. Kopelman PG. Obesity as a medical problem. Nature 2000;404:635-43.
2. Colditz GA, Willett WC, Rotnitzky A, Manson JE. Weight gain as a risk factor for clinical diabetes mellitus in women. Ann Intern Med 1995;122:481-6.
3. Borst SE. Adipose tissue and insulin resistance. J Intern Med 2003;254:114-25.
4. Han TS, van Leer EM, Seidell JC, Lean ME. Waist circumference action levels in the identification of cardiovascular risk factors: Prevalence study in a random sample. BMJ 1995;311:1401-5.
5. Rabe K. Adipokines and insulin resistance. Mol Med 2008;14:741-51.
6. Björntorp P, Rosmond R. Hypothalamic origin of the metabolic syndrome X. Ann N Y Acad Sci 1999;892:297-307.
7. Juonala M, Magnussen CG, Berenson GS, Venn A, Burns TL, Sabin MA, *et al*. Childhood adiposity, adult adiposity, and cardiovascular risk factors. N Engl J Med 2011;365:1876-85.
8. Trujillo ME, Scherer PE. Adiponectin–journey from an adipocyte secretory protein to biomarker of the metabolic syndrome. J Intern Med 2005;257:167-75.
9. Bluher M. Vaspin in obesity and diabetes: Pathophysiology and clinical significance. Endocrine 2012;41:176-82.
10. Jian W, Peng W, Xiao S, Li H, Jin J, Qin L, *et al*. Role of serum vaspin in progression of Type 2 diabetes: A 2-year cohort study. PLoS One 2014;9:e94763.
11. Youn BS, Klöting N, Kratzsch J, Lee N, Park JW, Song ES, *et al*. Serum vaspin concentrations in human obesity and Type 2 diabetes. Diabetes 2008;57:372-7.
12. Alberti KG, Eckel RH, Grundy SM, Zimmet PZ, Cleeman JI, Donato KA, *et al*. Harmonizing the metabolic syndrome: A joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. Circulation 2009;120:1640-5.
13. Hida K, Wada J, Eguchi J, Zhang H, Baba M, Seida A, *et al*. Visceral adipose tissue-derived serine protease inhibitor: A unique insulin-sensitizing adipocytokine in obesity. Proc Natl Acad Sci U S A 2005;102:10610-5.
14. Klöting N, Berndt J, Kralisch S, Kovacs P, Fasshauer M, Schön MR, *et al*. Vaspin gene expression in human adipose tissue: Association with obesity

and Type 2 diabetes. Biochem Biophys Res Commun 2006;339:430-6.
15. Zvonic S, Lefevre M, Kilroy G, Floyd ZE, DeLany JP, Kheterpal I, *et al*. Secretome of primary cultures of human adipose-derived stem cells: Modulation of serpins by adipogenesis. Mol Cell Proteomics 2007;6:18-28.

How to cite this article: Valli DT, Parimala A. Estimation of Serum Vaspin Levels in Humans as a Novel, and Therapeutic Biomarker of Visceral Obesity. Int J Sci Stud 2020;7(12):59-63.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Right Direct Inguinal Hernia in Patients Underwent Open Surgery for Appendicitis – A Retrospective Study

V Thirulogachandran[1], S Karthikeyan[2], G Karthick[3]

[1]Senior Civil Surgeon, Department of General Surgery, Government Head Quarters Hospital, Dindigul, Tamil Nadu, India, [2]Associate Professor, Department of Surgical Gastroenterology, Government Thanjavur Medical College and Hospital, Thanjavur, Tamil Nadu, India, [3]Assistant Surgeon, Government Primary Health Centre, Dindigul, Tamil Nadu, India

Abstract

Introduction: Acute appendicitis is the most common surgical emergency faced in today's world. The inguinal hernia is the most common type of hernia seen in surgical practice. It can be of a direct and an indirect type. While the indirect type has a congenital cause, direct hernias are attributable to the weakness of abdominal wall musculature.

Aim: This study aims to study the prevalence of right (direct) inguinal hernia in patients who underwent open surgery for appendicitis.

Materials and Methods: In this retrospective study, 100 patients who underwent surgery for the right direct inguinal hernia were included in the study. Patients' demographic details, history of open appendectomy, and the clinical presentation were collected. The examination consisted of inspection, palpation, percussion, and auscultation and included various tests such as cough impulse and three-finger test. These findings were later confirmed with an ultrasound abdomen examination.

Results: Among these 100 patients, 13 of them had the previous history of open appendectomy, all the study patients were male and they had the right direct inguinal hernia after 5 years of surgery. Among these 13 patients, 10 had perforated appendicitis, 2 had abscess, and 1 had purulent appendicitis. Among these 13, 11 of them had cosmetic Rutherford Morrison or Lanz incision and 2 of them had classical McBurney's incision.

Conclusion: The choice of the incision during open appendectomy is important and the surgeon should avoid injury to the ilioinguinal nerve motor branches which supplies the internal oblique and transverse abdominis muscles, care must be taken during surgery, especially below the horizontal line extending from the anterosuperior iliac spine to the rectus muscle.

Key words: Appendectomy, Appendicitis, Inguinal hernia

INTRODUCTION

Acute appendicitis has been thought of as a sequence of events with an initial enticing event and natural progression, keeping in mind that patients presenting at different points in time present with different clinical pictures. Appendicitis is thought to begin with outflow obstruction of the lumen. Fecaliths (a hard mass of stool also known as appendicoliths when originating in the appendix) has often been cited as a cause for appendicitis and common teaching is to look for a fecalith in the abdominal radiograph; however, there is no clear-cut evidence that this is the case.[1] Fever is a consistent finding but may be absent at the early onset of symptoms. Tachycardia may present because of sympathetic response to abdominal pain; however, persistent tachycardia despite pain control in conjunction with hypotension may be caused by the systemic inflammatory response or sepsis. Abdominal examination reveals tenderness, most often in the right lower quadrant near the iliac fossa; this is known as McBurney's point after Charles McBurney, who

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. S Karthikeyan, Department of Surgical Gastroenterology, Government Thanjavur Medical College and Hospital, Thanjavur, Tamil Nadu, India.

initially described this clinical finding.[2,3] The exact point of maximal tenderness varies and is affected by the position of the appendix in relation to surrounding structures. Rebound tenderness, elicited either by gentle percussion or rapid release of pressure from the abdomen, indicates inflammatory irritation of the parietal peritoneum.[4] In 1894, Charles McBurney described the oblique right lower quadrant incision and muscle-splitting approach, which continued to be used until the late 20th century (before this, surgeons typically used a midline laparotomy approach). A Rutherford Morrison or Lanz incision is thought to provide a better cosmetic outcome, but the chances of injury to the motor branch of the ilioinguinal nerve are high which resulted in the development of right direct inguinal hernia as a complication.[5] Other common causes are placing a drain through the incision and tying sutures too tightly in the fleshy internal oblique and transverse abdominis muscles, leading to necrosis of the muscle.[6,7]

Aim

This study aims to study the prevalence of right direct inguinal hernia in patients who underwent surgery for open appendectomy.

MATERIALS AND METHODS

In this retrospective study, patients who underwent open appendectomy during the year 2014–2019 were included in the study. Patient's demographic details, history of open appendectomy, and clinical presentations were collected. Baseline investigations such as complete blood count, kidney function test, liver profile, chest and abdominal X-ray, and ultrasonography were done; some of these patients underwent contrast-enhanced CT abdomen and pelvis. The examination consisted of inspection, palpation, percussion, and auscultation and included various tests such as cough impulse and three-finger test. These findings were later confirmed with an ultrasound abdomen examination.

RESULTS

In this study, 100 patients who underwent surgery for the right direct inguinal hernia during the year 2014–2019 were included in the study. There were no female patients in the study group, 100 were male patients. The incidence of open appendectomy induced inguinal hernia in this study group was 13 patients (13%) [Figure 1]. The age of the patients with open appendectomy induced right direct inguinal hernia was more than 36 years. In open appendectomy induced inguinal hernia patients, 10 of them were doing heavy work and 3 of them were doing moderate work [Figure 2]. The open appendectomy induced inguinal hernia patients presented after 5 years of post-appendectomy with signs and symptoms of pain and swelling of the right inguinal region. About 44% of patients had pain, 43% of patients had swelling, and 13% of patients had pain and swelling. In these 13 patients, 10 of them had perforated appendicitis, 2 had abscess, and 1 had purulent appendicitis [Figures 3 and 4]. In these 13 patients, 11 of them had cosmetic Rutherford Morrison or Lanz incision and 2 of them had Classical McBurney's incision [Figure 5]. The patients were treated with the right direct inguinal hernioplasty with no complications during the post-operative period.

DISCUSSION

Appendectomy is one of the most common operative procedures; there have been few reports on the choice of incision in the right lower quadrant of the abdomen. The incision introduced by McBurney in 1894 is the time-honored approach.[5] The efficiency of this incision is well established. The importance of preserving the nerves of the abdominal wall during laparotomy has been realized, and the development of the right inguinal hernia after appendectomy and damage to the segmental nerve supply of the abdominal muscles has been reported.

It was previously reported that a right inguinal hernia may develop after appendectomy. Hoguet in 1911 first described the frequent development of the right inguinal hernia after appendectomy. He found eight right inguinal hernias in 190 patients who had had an appendectomy.[8] In 1951, Lichtenstein and Isoe reviewed 567 patients with inguinal hernia. In 67 of these patients, the appendix had been removed (40 hernias were right sided and 12 bilateral).[9] In a series of 1357 inguinal hernias, Walker found that 110 patients had the previous appendectomy.[10] Gue in 1972 found 41 post-appendectomy patients with

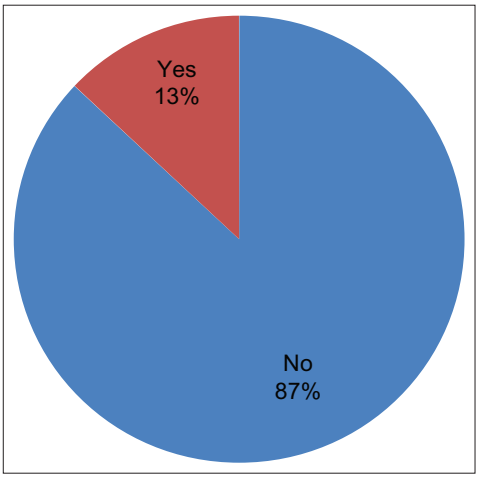


Figure 1: Distribution of incidence of the right direct inguinal hernia in open appendectomy

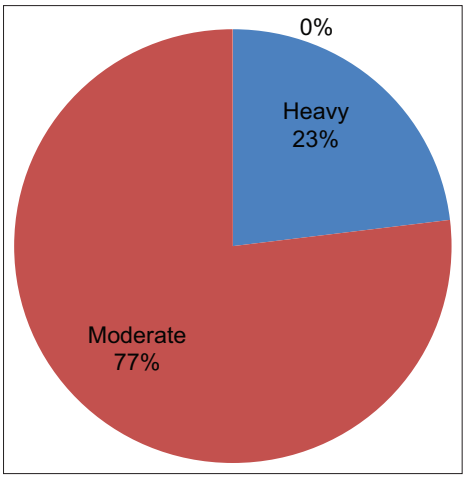


Figure 2: Distribution of the type of occupation

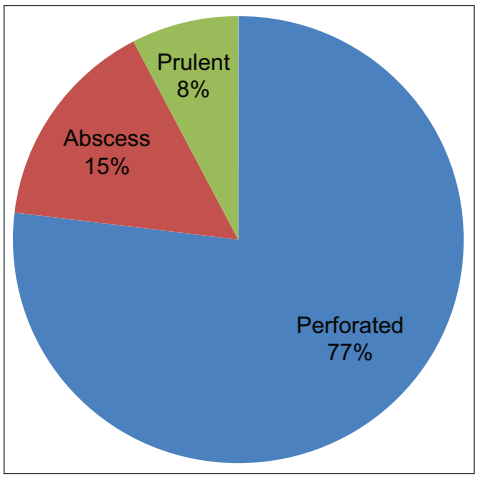


Figure 4: Distribution of the type of appendicitis

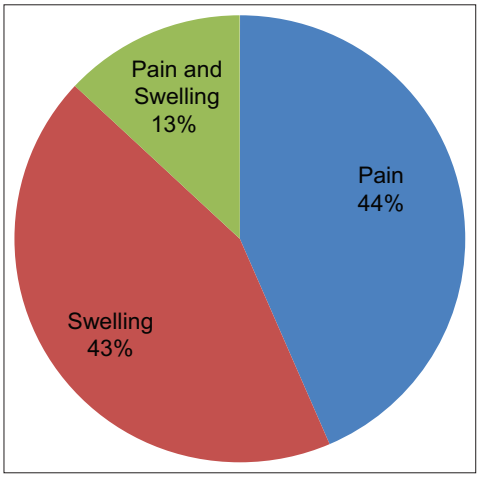


Figure 3: Distribution of signs and symptoms

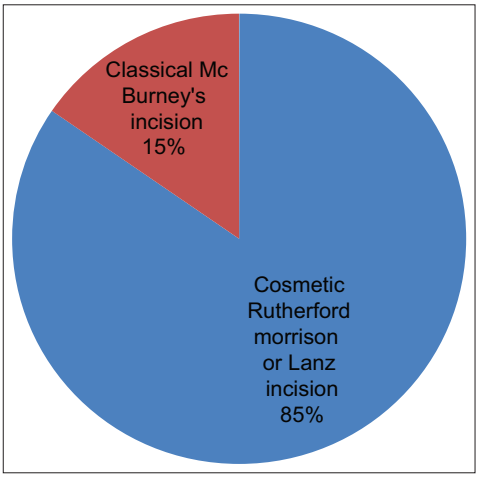


Figure 5: Distribution of surgical incision

the right inguinal hernia among 701 patients with inguinal hernia.[11]

Observations from the present study suggest that appendectomy predisposes to the development of a right-sided inguinal hernia. In spite of the tempting simplicity of etiologic reasoning, a cause-and-effect relationship cannot be confirmed based on these observations. This study emphasizes, however, that nerve injury should be avoided during surgery and also that the structures of the right lower abdominal wall should be preserved. Incisions below the anterior superior iliac spine should be avoided if possible because segmental nerves penetrate at this level. The possibility of herniation might thus be reduced.

CONCLUSION

The incidence of the right direct inguinal hernia is significantly greater in patients who underwent an open appendectomy. The choice of the incision during open appendectomy is important and the surgeon should avoid injury to the ilioinguinal nerve motor branch which supplies the internal oblique and transverse abdominis muscles, care must be taken during surgery, especially below the horizontal line extending from the anterosuperior iliac spine to the rectus muscle because segmental nerves penetrate at this level.

REFERENCES

1. Singh JP, Mariadason JG. Role of the faecolith in modern-day appendicitis. Ann R Coll Surg Engl 2013;95:48-51.
2. McBurney C. Experience with early operative interference in cases of disease of the vermiform appendix. N Y State J Med 1889;50:676-84.
3. McBurney C. IV. The incision made in the abdominal wall in cases of appendicitis, with a description of a new method of operating. Ann Surg 1894;20:38-43.
4. Shelton T, McKinlay R, Schwartz RW. Acute appendicitis: Current diagnosis and treatment. Curr Surg 2003;60:502-5.
5. Patnaik VV, Rajan SK, Bansal VK. Surgical incisions-their anatomical basis-part IV-abdomen. J Anat Soc India 2001;50:170-8.
6. Abou-Nukta F, Bakhos C, Arroyo K, Koo Y, Martin J, Reinhold R, *et al*. Effects of delaying appendectomy for acute appendicitis for 12 to 24 hours.

Arch Surg 2006;141:504-6.
7. Abrahamson J. Hernias. In: Zinner MJ, Schwartz SI, Ellis H, editors. Maingot's Abdominal Operations. 10th ed. Connecticut: Appleton & Lange; 1997. p. 479-580.
8. Hoguet JP. X. Right inguinal hernia following appendectomy. Ann Surg 1911;54:673-6.
9. Lichtenstein ME, Isoe IM. Right inguinal hernia following appendectomy. Am J Surg 1951;81:436-8.
10. Walker F. Leistenbruch als appendectomiefolge und folge anderer trauma der bauchwand. Wien Med Wochenschr 1954;104:538-9.
11. Gue S. Development of right inguinal hernia following appendicectomy. A 10-year review of cases. Br J Surg 1972;59:352-3.

How to cite this article: Thirulogachandran V, Karthikeyan S, Karthick G. Right Direct Inguinal Hernia in Patients Underwent Open Surgery for Appendicitis – A Retrospective Study. Int J Sci Stud 2020;7(12):64-67.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Study and Advantages of Laparoscopic Ventral Hernia Mesh Repair Versus Conventional Open Mesh Repair

S Umamaheswaran[1], S R Dhamodharan[2], V Lakshmi Thilagam[2], E Naveen[2]

[1]Assistant Professor, Department of General Surgery, Government KAPV Medical College and MGM, Government Hospital, Trichy, Tamil Nadu, India, [2]Junior Resident, Department of General Surgery, Madurai Medical College and Government Rajaji Hospital, Madurai, Tamil Nadu, India

Abstract

Background: An incisional hernia develops in 7%–11% of laparotomy incisions. Laparoscopic repair was applied to the ventral hernias (VH), with the expectation of earlier recovery, fewer postoperative complications, and decreased recurrence rates. This prospective study was performed to compare the outcomes after open and laparoscopic VH repair (LVHR).

Materials and Methods: It is a prospective study involved 55 patients with VH, who were subjected either to repair by laparoscopy or to open repair. The open surgical operations were performed by onlay mesh repair, whereas the laparoscopic repairs were performed using the intraperitoneal dual mesh intraperitoneal onlay mesh repair technique.

Results: The mean surgery duration was significantly lower in the laparoscopic repair when compared to open repair ($P < 0.001$). The mean duration of post-operative analgesics used in laparoscopic group is 4.3±0.50 days as compared to open VH repair 6.48±0.15 days ($P < 0.001$) which is significant. The mean post-operative stay in the hospital was shorter for the laparoscopic group than for the open hernia group (6.3 vs. 11.06 days; $P < 0.001$). Antibiotics used in the laparoscopy group are 5.85±0.50 days as compared to open repair 6.48±0.50 days ($P < 0.001$). Return to the activity or normal daily work is significantly low in the laparoscopic group as compared to open repair of hernia (2.2 vs. 4.34 days; $P < 0.001$). There were fewer post-operative complications in laparoscopy.

Conclusion: The findings demonstrate that LVHR in our experience was safe and resulted in shorter operative time, fewer complications, shorter hospital stays, and earlier returns to daily activity. Hence, it should be considered as the procedure of choice for VH repair.

Key words: Hernia, Hospital, Repair

INTRODUCTION

Ventral hernias (VH) are occurring as a result of weakness in the musculofascial layer of the anterior abdominal wall. Unlike all other hernias that surgeon evaluates and repair, incisional hernias (IH) are unique in that the surgeon contributes to the source and cause of the disease incidence of 6–13%.[1-10]

The VH repair is based on the principle of Rives-Stoppa open tension-free mesh repair. In the laparoscopic technique, the mesh is placed in an intraperitoneal location and where the rise in the intra-abdominal pressures is totally diffused along each square inch and keeps mesh in place.

The laparoscopic approach helps complete visualization of the fascia underlying the previous incision allows for the identification of smaller Swiss cheese defects that may be missed in an open approach.[10-19]

Nevertheless, open hernia repair can be a major operation with considerable morbidity due to mesh-related infections. "An increasing interest in laparoscopic surgery and the availability of new materials have encouraged the adoption of laparoscopic techniques in VH repair."[19-24]

"Laparoscopic VH repair (LVHR) was first described by LeBlanc and Booth in 1991."

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. S Umamaheswaran, 4/649-2, Mahalakshmi Nagar 2nd Street, K. Pudur, Madurai - 625 007, Tamil Nadu, India.

MATERIALS AND METHODS

This study which is prospective involved 55 patients with VH that presented during the period of June 2016 year–August 2017 year, for a period of 15 months admitted to a single surgical unit at Government Rajaji Hospital, Madurai, India.

Patients were subjected to either repair by open or laparoscopy and were followed for a period of up to 1 year from the date of surgery.

In our study, out of 55 patients, 35 patients underwent open onlay mesh repair, and 20 patients underwent laparoscopic intraperitoneal mesh repair for various types of VH.

Patients in both groups were comparable with respect to age.

The objective of the study is to compare laparoscopic versus open VH repair with regard to post-operative pain, operative results, perioperative and post-operative complications, hospital admission and duration of stay, and return to work.

All patients underwent routine laboratory investigations (complete blood count, blood serum chemistries, chest X-ray, electrocardiogram, and high-resolution ultrasound of the anterior abdominal wall to know the defect size).

Surgical Technique

Open onlay mesh repair

After taking patients to operation theater and under general anesthesia, endotracheal intubation and close monitoring, the operation was done. Foleys catheter was put for patients with lower abdominal VH repair and nasogastric tube for the upper abdominal hernia repair with perioperative single dose antibiotic inj.cefotaxime 1 g IV administered.

Then, after proper cleaning, painting, draping of the abdomen, and the skin incision were made according to the site and size of defect, subcutaneous flaps raised up to 5 cm around the defect and after that hernia sac dissected and opened, the contents reduced into the abdominal cavity. The defect in the linea alba was closed with nonabsorbable 1–0 Prolene suture, and an appropriate size of monofilament polypropylene mesh (dolphin mesh) of Futura surgicare was placed over the anterior rectus sheath and fixed with 2–0 Prolene. Hemostasis was achieved and 16 fg Romo Vac suction drain placed. Skin closed with 2-0 Ethilon.

Laparoscopic repair of VH

In laparoscopic repair of ventral hernia in all cases bowel was prepared, bladder was catheterized with Foleys, nasogastric tube placed.

After proper cleaning, painting, and draping under general anesthesia, the surgeon stands to the left of the patient. The monitor was placed opposite to the surgeon, and the instrument trolley was toward the leg of the patient. In general, three trocars are adequate for small to moderate size hernias. Pneumoperitoneum created through palmers point, 2–3 cm below the left costal margin in the midclavicular line, using open Hasson's method. 10 mm trocars at the palmers point and other two 5 mm trocars at left lumbar and iliac fossa along the anterior axillary line. Adhesions of the abdominal contents to the hernia sac and the surrounding abdominal wall are lysed, and the contents of the hernia sac are reduced. Hernia sac is excised, as much as possible to avoid seroma formation. Transfascial sutures applied with polypropylene 1–0 sutures with the help of a cobbler needle to obliterate the defect after reducing pneumoperitoneum partially. Size of the defect measured and appropriate size of the defect measured and appropriate size of dual mesh (Symbotex composite mesh, covidien) composed of monofilament polyester with absorbable collagen film and preplaced sutures and marking covering 4–5 cm beyond the defect was selected.

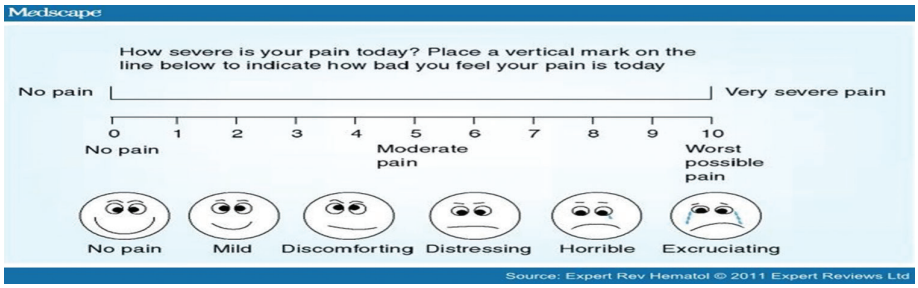
Mesh folded like banana leaf and introduced intraperitoneally through 10 mm trocar and mesh is unfolded so that white side polyester facing abdominal wall and marked site coated with absorbable collagen film facing viscera. Mesh is fixed transfascially in the middle with sutures provided along with mesh with the help of cobbler needle. Absorbable tackers (Absorba tack) 5 mm size used to fix the mesh all around and corners. Hemostasis was achieved before the removal of the trocars. All 10 mm trocar fascial defects were closed with 1–0 Vicryl and skin with 1–0 Vicryl. Catheter and ryles tube removed after extubating the patient.port sites sterile plaster dressing applied. Compressive dressing prepared from gauze is applied over the defect to prevent seroma formation for 5 days.

Patients were followed up 1 and 2 weeks after surgery and up to 1 year.

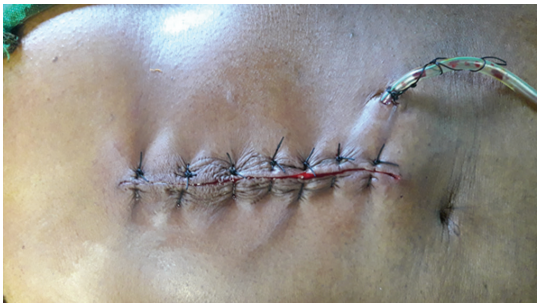
Statistical Analysis

Unpaired Student's *t*-test and paired *t*-test were used to find out the statistical significance. $P < 0.005$ was taken as significant. SPSS Version 20 was used for statistical analysis, and the following parameters were calculated.

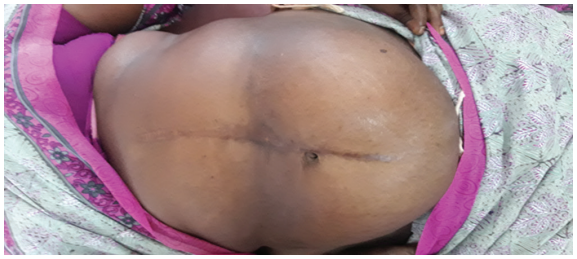
1. The operative time was calculated by measuring the time taken from skin incision to skin closure
2. Postoperative drainage fluid volume was calculated by Romo Vac suction drain for 1, 2, 3, 5, and 7 days
3. Post-operative pain was calculated using visual analog scale. We calculated pain during initial post-operative day 1 and day 3 and 5th day

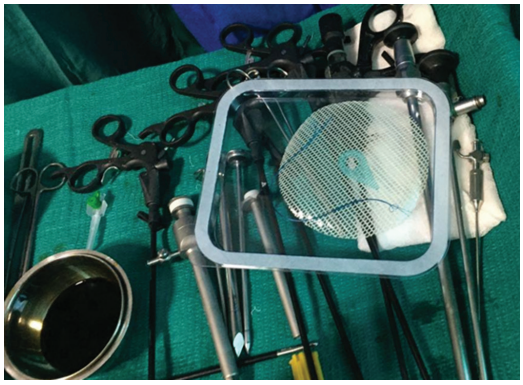


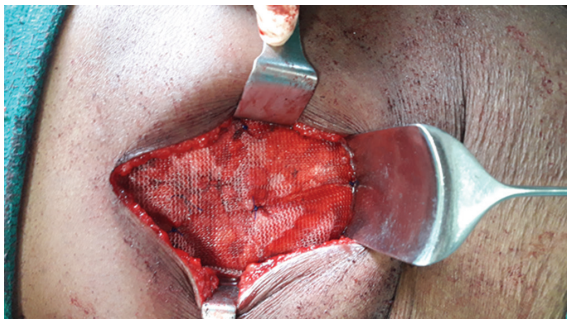
4. Eura HS quality of life scale calculated based on the following parameters and scoring calculated for the same, preoperatively and postoperatively on day 3 and 5 and day 7 and 4th week. Scoring of 0–10 given based on the condition of the patient evaluated
5. Intraoperative and post-operative outcomes were calculated for Seroma, wound infection, mesh infection, and bowel injury and recurrence rates.

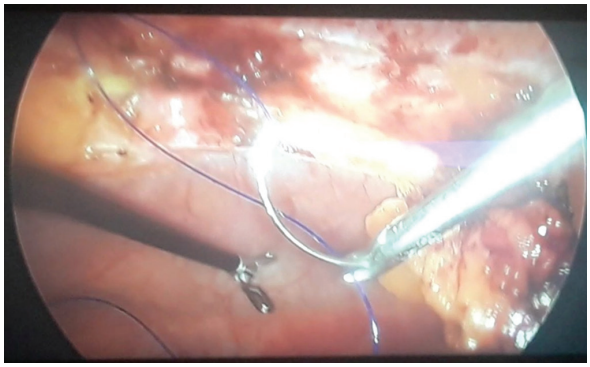


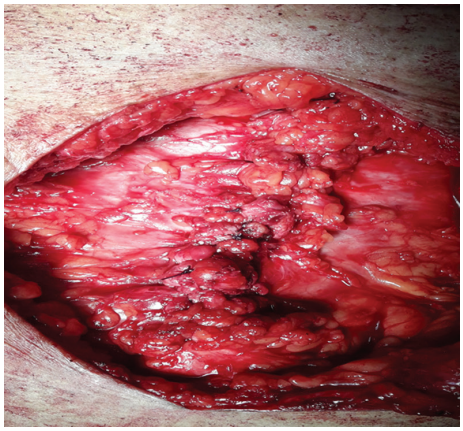
OPEN ONLAY MESH REPAIR

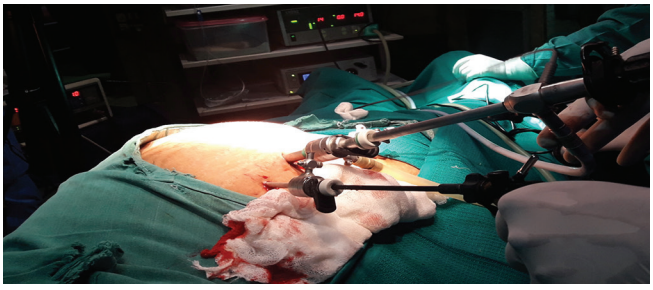


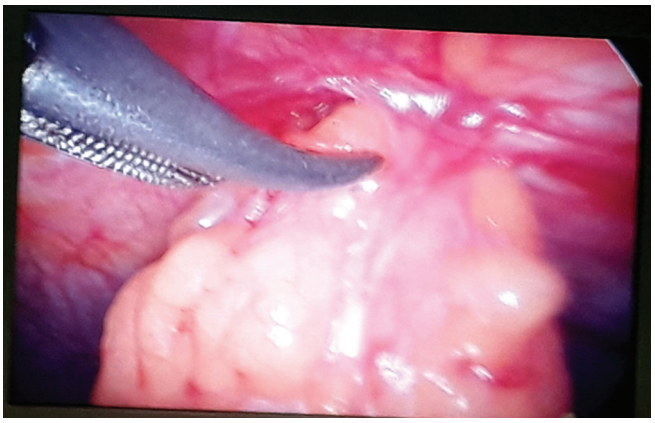


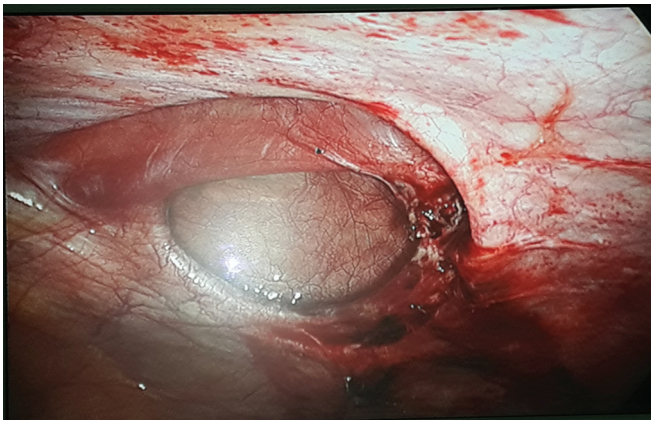


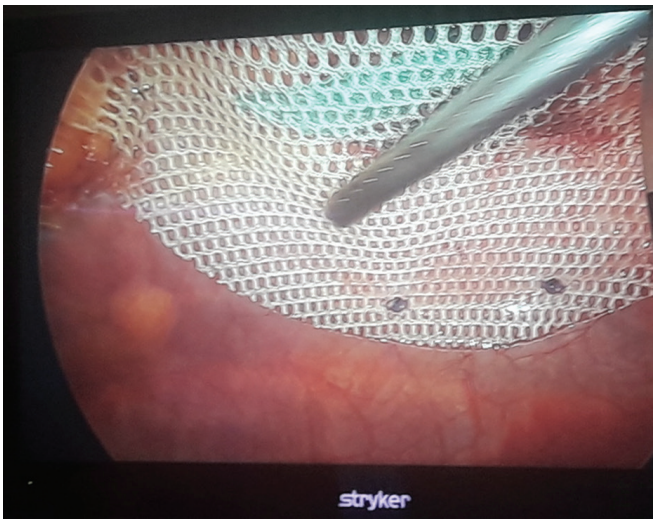












RESULTS

The patients in the groups were comparable at baseline in terms of age, presenting complaints, the type of hernia in both laparoscopic and open hernia repair.

The mean follow-up time was – 12 months.

The study group consisted of 20 patients in LVHR (14 women and six men) with a mean age of 41.1 years and 35 patients in open onlay mesh repair (26 women and nine men) with a mean age of 48.1 years.

The parameters used to compare the both groups show that patients in the laparoscopic group had defect size of 4.21 cm comparable with patients in open hernia repair with defect size of 5.71 cm ($P \leq 0.001$, significant).

The mean surgery duration was 76.95 min for the laparoscopic repair and 120.57 min for the open repair, as shown in figure ($P \leq 0.001$, significant difference).

The mean duration of post-operative analgesics used in the laparoscopic group is 4.3 days as compared to open VH repair 6.48 days, as shown in figure ($P \leq 0.001$), which is significant.

The mean post-operative stay in hospital was shorter for the laparoscopic group then for the open hernia group as depicted in figure (6.3 vs. 11.06 days; with $P - \leq 0.001$), which is significant.

Antibiotics used in the laparoscopy group are for 5.85 days as compared to open repair 8.51 days ($P \leq 0.001$), which is significant.

Return to the activity of normal daily work is significantly low in the laparoscopic group as compared to open repair of VH, as shown in figure (2.2 vs. 4.34 days; $P \leq 0.001$), which is significant.

There were fewer intraoperative and post-operative complications (seroma, wound infection, and enterotomy) among the patients who underwent laparoscopic repair then among the those who had open VH repair, as shown in Table 1.

Totally, 55 patients underwent laparoscopic and open VH repair and results analyzed, and the following conclusions were drawn.

In our study, totally 55 patients were studied, out of it, six patients are age <30 years, and 20 of them more than 50 years and others in between.

Out of 55 patients, 15 male and 40 female patients are selected for our study, as shown in Table 2.

Among <30 years, 4 patients underwent lap and 2 patients underwent open mesh repair. Among >50 years, 4 patients underwent lap and 16 patients underwent open mesh repair.

In between age group, 12 patients underwent lap and 17 patients underwent open repair, as shown in Table 3.

In our study, among 15 male patients, six patients underwent lap and nine patients underwent open repair. Among 40 female patients, 14 patients underwent lap and 26 underwent open repair, as shown in Table 4.

Among 55 patients, 28 patients are IH, and ten patients had paraumbilical hernia, nine patients had umbilical hernia, six patients had epigastric hernia, and two patients had VH, as shown in Table 5.

Among 55 patients, 20 patients underwent lap and 35 patients underwent open mesh repair of which six lap incisional and 22 open IH mesh repair done, as shown in Table 6.

Mean defect size for lap mesh repair 4.21 and for open mesh repair 5.71, with SD value for open 1.77 and for lap 0.92 with $P < 0.001$, as shown in Table 7.

Mean duration for lap 76.95 min and for open mesh repair 120.57 min, which is shorter for the laparoscopic group with $P < 0.001$, as shown in Table 8.

Mean pain score was less in lap group 3.45 versus 5.34 in open group with significant $P < 0.001$ in lap group, Table 9.

Mean analgesic needed for lap group was lesser 4.3 days and 6.48 days for open group, Table 10.

Mean antibiotic needed are less for lap group than with open mesh repair, Table 11.

Lap patients had early oral intake compared to open mesh repair, Table 12.

Lap patients had stayed less in hospital compared to open mesh repair, Table 13.

Return to daily routine was earlier in lap group compared with open mesh repair, Table 14.

Post-operative complications were less in lap group compared with open onlay mesh repair group, Table 15.

Table 1: Age-wise distribution

Age in years	No. of cases
<30	6
31–40	16
41–50	13
>50	20
Total	55

Table 2: Gender-wise distribution

Sex	No. of cases
Male	15
Female	40
Total	55

Table 3: Age versus procedure

Age versus procedure	Lap onlay mesh repair	open onlay mesh repair
<30 (6)	4	2
31–40 (16)	8	8
41–50 (13)	4	9
>50 (20)	4	16
Total (55)	20	35

Table 4: Gender versus procedure

Gender versus procedure	Lap onlay mesh repair	open onlay mesh repair
Male (15)	6	9
Female (40)	14	26
Total (55)	20	35

Table 5: Diagnosis and distribution

Diagnosis	No. of cases
Epigastric hernia	6
Incisional hernia	28
Umbilical hernia	9
Paraumbilical hernia	10
Ventral hernia	2
Total	55

DISCUSSION

LVHR was started by LEBLANC in 1993 year, after that evaluations were done to make laparoscopic surgery easier and safest for VH repair, with the use of laparoscopic approach large incisions and drain placement can be avoided.

The results of our prospective study revealed that as compared to open repair, laparoscopic repair is associated with shorter duration of surgery, reduced post-operative analgesic requirement, and antibiotic requirement.

Duration of hospital stay and return to the normal activity are significantly shorter for laparoscopic repair, then for open hernia repair. The reason for this is because of extensive subcutaneous dissection to have 5 cm mesh cover beyond the hernia defect, which causes more pain, longer duration of surgery, requirement of suction drain for longer period of time, and late return of normal daily activity. The complication rate for laparoscopic repair was very low.

Table 6: Diagnosis versus procedure

Diagnosis	Lap onlay mesh repair	Open onlay mesh repair
Epigastric hernia	3	3
Incisional hernia	6	22
Umbilical hernia	4	5
Paraumbilical hernia	7	3
Ventral hernia	0	2
Total	20	35

Table 7: Defect size comparison

Defect size	Mean	SD	*P* value
Lap onlay mesh repair	4.21	0.92	<0.001
Open onlay mesh repair	5.71	1.77	Significant

Table 8: Operative duration comparison

Operative duration in minutes	Mean	SD	*P* value
Lap onlay mesh repair	76.95	10.16	<0.001
Open onlay mesh repair	120.57	18.54	Significant

Table 9: Pain score comparison

Pain score	Mean	SD	*P* value
Lap onlay mesh repair	3.45	0.83	<0.001
	5.34	0.68	Significant

Table 10: Mean analgesic days

Analgesic days	Mean	SD	*P* value
Lap onlay mesh repair	4.3	0.86	<0.001
Open onlay mesh repair	6.48	1.07	Significant

Table 11: Mean antibiotic days

Antibiotic days	Mean	SD	*P* value
Lap onlay mesh repair	5.85	0.93	<0.001
Open onlay mesh repair	8.51	1.56	Significant

Table 12: Mean postop nil by mouth days

Post-operative nil by mouth days	Mean	SD	*P* value
Lap onlay mesh repair	2.05	0.61	<0.001
Open onlay mesh repair	3.63	0.49	Significant

Table 13: Hospital stay in days

Hospital stay in days	Mean	SD	*P* value
Lap onlay mesh repair	6.3	1.49	<0.001
Open onlay mesh repair	11.06	1.64	Significant

Table 14: Return to normal activity

Return to normal activity in days	Mean	SD	*P* value
Lap onlay mesh repair	2.2	0.62	<0.001
Open onlay mesh repair	4.34	0.8	Significant

Table 15: Post-operative complications

Post-operative complications	Seroma	Wound infections	Bowel injury	Mesh infection	Recurrence
Lap onlay mesh repair	8	1	0	0	0
Open onlay mesh repair	16	16	0	0	0
P value	0.898 NS	0.005 Sig.			

The laparoscopic procedure was associated with potentially less wound infection and seroma formation as compared with open repair. Recent analysis also suggested minimal post-operative morbidity, a shorter convalescence period, and an acceptable recurrence rates.[25-46]

The results of our study are quite comparable with studies done by Park *et al.*, Carbaja *et al.*, and Rameshaw *et al.*, and the following points were analyzed, Table 16.

1. Mean duration of surgery (minutes)
   - Park *et al.* lap-95, open – 78
   - Carbaja *et al.* lap – 87, open – 112
   - Rameshaw *et al.* lap – 56, open – 82
   - In our study lap – 76.95, open – 120.57

   with SD value for lap – 10.16 and for open – 18.54 with $P < 0.001$, which is significant.
2. Mean length of stay (days)
   - Park *et al.* lap – 3.4, open - 6.5
   - Carbaja *et al.* lap – 2.2, open – 9.1
   - Rameshaw *et al.* lap – 1.7, open – 2.8
   - In our study lap – 6.3, open – 11.06
3. Mean infection rate (%)
   - Park *et al.* lap – 00, open - 02
   - Carbaja *et al.* lap – 00, open – 18
   - Rameshaw *et al.* lap – 00, open – 03
   - In our study lap - 1, open – 16
4. Mean seroma rate (%)
   - Park *et al.* lap – 04, open - 02
   - Carbaja *et al.* lap – 13, open – 67
   - Rameshaw *et al.* lap – 00, open – 00
   - In our study lap - 8, open – 16

The results of our study strongly recommend that LVHR is the procedure of choice in an trained laparoscopic surgeons hands.

Table 16: Comparison similar studies

Observation	Park 11		Carbaja 12		Rameshaw 13		Our study	
	Lap	Open	Lap	Open	Lap	Open	Lap	Open
Operating time (min)	95	78	87	112	56	82	76.95	120.57
Length of stay (day)	3,4	6.5	2.2	9.1	1.7	2.8	6.3	11.06
Infection rate (%)	00	02	00	18	00	03	01	16
Seroma rate (%)	04	02	13	67	00	00	08	16
Patients	56	49	30	30	79	174	50	50

CONCLUSION

The present analytical study of comparative analysis and advantages of LVHR versus open VH repair was carried out at Government Rajaji Hospital, Madurai, during the period of June 2016–August 2017

Based on the data and results obtained in the present study, the following parameters were drawn

1. The average total duration of surgery is less using laparoscopic intraperitoneal mesh placement
2. The post-operative drainage is nil in the laparoscopic approach
3. The post-operative pain is less in the laparoscopic approach
4. The post-operative complications are less in the laparoscopic approach (seroma, wound infection, and recurrence)
5. The shorter hospital stay in the laparoscopic approach
6. Early return to normal work
7. Early mobilization
8. It is even possible to reduce post-operative time, because of standardized techniques, surgeons getting more skill, and use of mesh fixation devices, and newer mesh implantation.

Hence, LVHR is considered as the first line of choice in VH repair.

REFERENCES

1. Kingsnorth AN. Hernia's umbilicus and abdominal wall. In: Bailey and Love's Short Practice of Surgery. 24th ed. United Kingdom: Hodder Arnold; 2004. p. 1272-93.
2. Cassar K, Munro A. Surgical treatment of incisional hernia. Br J Surg 2002;89:534-45.
3. Mudge M, Hughes LE. Incisional hernia: A 10 year prospective study of incidence and attitudes. Br J Surg 1985;72:70-1.
4. Stoppa RE. The treatment of complicated groin and incisional hernias. World J Surg 1989;13:545-54.
5. Cobb WS, Kercher KW, Heniford BT. Laparoscopic repair of incisional hernias. Surg Clin North Am 2005;85:91-103.
6. Costanza MJ, Heniford BT, Arca MJ, Mayes JT, Gagner M. Laparoscopic repair of recurrent ventral hernias. Am Surg 1998;64:1121-5.
7. White TJ, Santos MC, Thompson JS. Factors affecting wound complications in repair of ventral hernias. Am Surg 1998;64:276-80.
8. Carbajo MA, del Olmo JC, Blanco JI, de la Cuesta C, Martín F, Toledano M, *et al***.** Laparoscopic treatment of ventral abdominal wall hernias: Preliminary results in 100 patients. JSLS 2000;4:141-5.
9. Heniford BT, Park A, Ramshaw BJ, Voeller G. Laparoscopic ventral and incisional hernia repair in 407 patients. J Am Coll Surg 2000;190:645-50.
10. LeBlanc KA, Booth WV, Whitaker JM, Bellanger DE. Laparoscopic incisional and ventral herniorraphy: Our initial 100 patients. Hernia 2001;5:41-5.
11. Park A, Birch DW, Lovrics P. Laparoscopic and open incisional hernia repair: A comparison study. Surgery 1998;124:816-21.
12. Carbajo MA, Martín del Olmo JC, Blanco JI, de la Cuesta C, Toledano M, Martin F, *et al***.** Laparoscopic treatment vs open surgery in the solution of major incisional and abdominal wall hernias with mesh. Surg Endosc 1999;13:250-2.
13. Ramshaw BJ, Esartia P, Schwab J, Mason EM, Wilson RA, Duncan TD, *et al***.** Comparison of laparoscopic and open ventral herniorrhaphy. Am Surg 1999;65:827-31.
14. Badiger S, Koppad SN, Kulkarni A, Kodliwadmath H. Comparative analysis of open versus laparoscopic ventral hernia repair. Int Surg J 2016;3:1167-72.
15. Mayo WJ. An operation for the radical cure of umbilical hernia. Ann Surg 1901;34:276-80.
16. Sanders DL, Kingsnorth AN. From ancient to contemporary times: A concise history of incisional hernia repair. Hernia 2012;16:1-7.
17. Bleichrodt RP, Vries TS DR, Malyar A, Goor VH, Hansson B, der B VK. Component separation technique to repair large midline hernias. Oper Tech Gen Surg 2004;6:179-88.
18. Sinnatamby CS. Last's Anatomy: Regional and Applied. 10th ed. Edinburgh: Churchill Livingstone; 2001.
19. Wolloscheck T, Konerding MA. Dimensions of the myopectineal orifice: A human cadaver study. Hernia 2009;13:639-42.
20. Alfieri S, Rotondi F, Di Giorgio A, Fumagalli U, Salzano A, Di Miceli D, *et al***.** Influence of preservation versus division of ilioinguinal, iliohypogastric, and genital nerves during open mesh herniorrhaphy: Prospective multicentric study of chronic pain. Ann Surg 2006;243:553-8.
21. Askar OM. Surgical anatomy of the aponeurotic expansions of the anterior abdominal wall. Ann R Coll Surg Engl 1977;59:313-21.
22. Askar OM. Aponeurotic hernias. Recent observations upon paraumbilical and epigastric hernias. Surg Clin North Am 1984;64:315-33.
23. Korenkov M, Beckers A, Koebke J, Lefering R, Tiling T, Troidl H. Biomechanical and morphological types of the linea alba and its possible role in the pathogenesis of midline incisional hernia. Eur J Surg 2001;167:909-14.
24. Deysine M. Epigastric hernias. In: Bendavid R, editor. Abdominal Wall Hernias: Principles and Management. New York: Springer; 2001. p. 685-7.
25. Pfeffermann R, Freund H. Symptomatic hernia. Strangulated hernia combined with acute abdominal disease. Am J Surg 1972;124:60-2.
26. Rutkow IM. Epidemiologic, economic, and sociologic aspects of hernia surgery in the United States in the 1990s. Surg Clin North Am 1998;78:941-51.
27. Dabbas N, Adams K, Pearson K, Royle G. Frequency of abdominal wall hernias: Is classical teaching out of date? JRSM Short Rep 2011;2:5.
28. Lau H, Patil NG. Umbilical hernia in adults. Surg Endosc 2003;17:2016-20.
29. Rodriguez JA, Hinder RA. Surgical management of umbilical hernia. Oper Tech Gen Surg 2004;6:156-64.
30. Muschaweck U. Umbilical and epigastric hernia repair. Surg Clin North Am 2003;83:1207-21.
31. Buch KE, Tabrizian P, Divino CM. Management of hernias in pregnancy. J Am Coll Surg 2008;207:539-42.
32. Eker HH, van Ramshorst GH, de Goede B, Tilanus HW, Metselaar HJ, de Man RA, *et al***.** A prospective study on elective umbilical hernia repair in patients with liver cirrhosis and ascites. Surgery 2011;150:542-6.
33. Arroyo A, García P, Pérez F, Andreu J, Candela F, Calpena R. Randomized clinical trial comparing suture and mesh repair of umbilical hernia in adults. Br J Surg 2001;88:1321-3.
34. Farrow B, Awad S, Berger DH, Albo D, Lee L, Subramanian A, *et al***.** More than 150 consecutive open umbilical hernia repairs in a major veterans administration medical center. Am J Surg 2008;196:647-51.
35. Bisgaard T, Kehlet H, Bay-Nielsen M, Iversen MG, Rosenberg J, Jørgensen LN. A nationwide study on readmission, morbidity, and mortality

after umbilical and epigastric hernia repair. Hernia 2011;15:541-6.
36. Courtney CA, Lee AC, Wilson C, O'Dwyer PJ. Ventral hernia repair: A study of current practice. Hernia 2003;7:44-6.
37. Yahchouchy-Chouillard E, Aura T, Picone O, Etienne JC, Fingerhut A. Incisional hernias. I. Related risk factors. Dig Surg 2003;20:3-9.
38. Lamont PM, Ellis H. Incisional hernia in re-opened abdominal incisions: An overlooked risk factor. Br J Surg 1988;75:374-6.
39. Llaguna OH, Avgerinos DV, Lugo JZ, Matatov T, Abbadessa B, Martz JE, *et al***.** Incidence and risk factors for the development of incisional hernia following elective laparoscopic versus open colon resections. Am J Surg 2010;200:265-9.
40. Millbourn D, Cengiz Y, Israelsson LA. Effect of stitch length on wound complications after closure of midline incisions: A randomized controlled trial. Arch Surg 2009;144:1056-9.
41. Krukowski ZH, Cusick EL, Engeset J, Matheson NA. Polydioxanone or polypropylene for closure of midline abdominal incisions: A prospective comparative clinical trial. Br J Surg 1987;74:828-30.
42. Mingoli A, Puggioni A, Sgarzini G, Luciani G, Corzani F, Ciccarone F, *et al***.** Incidence of incisional hernia following emergency abdominal surgery. Ital J Gastroenterol Hepatol 1999;31:449-53.
43. Sugerman HJ, Kellum JM Jr., Reines HD, DeMaria EJ, Newsome HH, Lowry JW. Greater risk of incisional hernia with morbidly obese than steroid-dependent patients and low recurrence with prefascial polypropylene mesh. Am J Surg 1996;171:80-4.
44. Available from: https://www.medscape.com/painscore.
45. Purushotham B, Madhu S. Comparative study between laparoscopic and open repair of umbilical and para umbilical hernia. Int Surg J 2015;2:204-13.3.
46. Misra MC, Bansal VK, Kulkarni MP, Pawar DK. Comparison of laparoscopic and open repair of incisional and primary ventral hernia: Results of a prospective randomized study. Surg Endosc 2006;20:1839-45.

How to cite this article: Umamaheswaran S, Dhamodharan SR, Thilagam VL, Naveen E. Comparative Study and Advantages of Laparoscopic Ventral Hernia Mesh Repair Versus Conventional Open Mesh Repair. Int J Sci Stud 2020;7(12):68-75.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Meckel's Diverticulum: Still Formidable during Acute Abdominal Surgeries – An Observational Study

V Thirulogachandran[1], D Maruthupandian[2], G Karthick[3]

[1]Senior Civil Surgeon, Department of General Surgery, Government Headquarters Hospital, Dindigul, Tamil Nadu, India, [2]Emeritus Professor, Department of General Surgery, The Tamil Nadu Dr. MGR Medical University, Chennai, Tamil Nadu, India, [3]Assistant Surgeon, Government Primary Health Centre, Sengurichi, Dindigul, Tamil Nadu, India

Abstract

Introduction: Meckel's diverticulum is a relatively common congenital diverticulum of ileum resulting from incomplete atrophy of the vitellointestinal duct in the embryo. Even though the majority of Meckel's diverticulum is asymptomatic, their potential to present with severe complications such as bleeding and perforation, intestinal obstruction has, nevertheless, caused much debate regarding whether a silent Meckel's should be pre-emptively resected when incidentally discovered during acute abdominal surgeries.

Aim: Our study aims to analyze the incidental finding of Meckel's diverticulum during acute abdominal surgeries and its surgical management.

Materials and Methods: This prospective observational study was conducted for the incidental findings of Meckel's diverticulum during acute abdominal surgeries. All the patients clinical, radiological, laboratory, and pathological findings were collected and the results were statistically analyzed and discussed.

Results: Out of 13 patients, 9 were males and 4 were females, based on age 10 years, patients had age below 40 years and 3 of them had above 40 years, based on clinical manifestations, 1 had perforative peritonitis, 1 had intestinal obstruction, 1 had acute diverticulitis, 1 had recurrent abdominal pain, and 9 were asymptomatic and incidentally found, among them 5 were found during appendectomy, 1 during gastrectomy, 1 during hernia surgery, 1 during traumatic Whipple's procedure, and 1 during gastrojejunostomy.

Conclusion: Symptomatic Meckel's diverticulum was associated with dreaded complications such as perforative peritonitis, intestinal obstruction, and diverticulitis with severe pain which made us conclude about even an asymptomatic Meckel's diverticulum found incidentally during acute abdominal surgeries need to be resected.

Key words: Intestinal obstruction, Meckel's diverticulum, Peritonitis

INTRODUCTION

Meckel's diverticulum was initially identified by Hildanus in 1598 and reported by Johann Friedrich Meckel, who established its embryological origin in 1809. It comprises the three layers of the intestinal wall and therefore is a true diverticulum that results from an incomplete obliteration of the omphalomesenteric duct.[1] The duct typically obliterates during the 7 months of gestation and failure of closure results in a diverticulum 98% of the time.[2] It is the most prevalent congenital anomaly of the gastrointestinal tract, occurring in 2% of the population with 2:1 male predominance. Meckel's diverticulum arises from the anti-mesenteric border of the distal ileum, typically 40–100 cm from the ileocecal valve, with a typical length of 2 inches and diameter of 2 cm. Blood supply to this diverticulum comes from the omphalomesenteric artery. The prevalence of Meckel's diverticulum is increased in children born with major malformation of the umbilicus, alimentary tract, nervous system, or cardiovascular system, in descending order.[3]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. D Maruthupandian, Department of General Surgery, The Tamil Nadu Dr. MGR Medical University, Chennai, Tamil Nadu, India.

Patients are usually asymptomatic.[4] Meckel's diverticulum involves a variety of complications such as intestinal obstruction, intussusceptions, ulceration, hemorrhage, vesico-diverticular fistulae, and rarely tumors.[5-9]

Ectopic tissue is a common finding in Meckel's diverticulum, originally demonstrated gastric mucosa in the diverticula in 1907, and subsequently heterotopic mucosa has been described in up to 50% of Meckel's diverticula, with gastric, pancreatic, small bowel, and colonic types being the most common, as arranged in descending order.[10,11]

Pre-operative diagnosis can be difficult. In adults, the diagnosis is usually made intraoperatively; therefore, pre-operative history, clinical findings, and supportive radiological imaging are essential to making a timely diagnosis. Less commonly, they are found on diagnostic imaging, including various modalities such as conventional radiography, contrast study using barium, and ultrasonogram. Therefore, contrast-enhanced computed tomography abdomen is the most sensitive diagnostic tool for making the diagnosis of Meckel's diverticulum and diverticulitis. A high index of suspicion is needed to diagnose a Meckel's diverticulum.

Surgical resection is the choice for symptomatic Meckel's diverticulum; this may include simple diverticulectomy or bowel resection. Diverticula with a broad base or those associated with complications such as hemorrhage are removed by bowel resection. Laparoscopic resection has also been reported in both the pediatric and adult population as a safe option.[12,13] Symptomatic Meckel's diverticulum found incidentally during acute abdominal surgeries needs surgical resection.

Aim

The aim of our study is to analyze the incidental finding of Meckel's diverticulum during acute abdominal surgeries and its surgical management.

MATERIALS AND METHODS

This prospective observational study was conducted to analyze the incidental findings of Meckel's diverticulum during other acute abdominal surgeries under different study parameters such as sex, age distribution, clinical manifestations, histopathological findings, length of Meckel's diverticulum, and surgical management. Medical records were reviewed retrospectively, including clinical presentation at admission, laboratory values, performed pre-operative diagnostics, intraoperative findings, and histological results. All patients clinical, radiological, laboratory, and pathological findings were collected.

RESULTS

Out of 13 patients, 9 patients (69%) were males and 4 patients (31%) were females [Figure 1].

Out of 13 patients, 10 patients (77%) had age below 40 years and 3 patients (23%) had age above 41 years [Figure 2].

Out of 13 patients, 9 patients had incidental findings, 1 had perforative peritonitis, 1 had intestinal obstruction, 1 had acute diverticulitis, and 1 had recurrent abdominal pain [Table 1].

Out of 13 patients, 3 symptomatic patients (23%) managed by open surgical resection, 1 symptomatic patient (8%) by laparoscopic procedure, and 9 asymptomatic patients (69%) had no resection [Figure 3].

Out of 4 patients, 3 patients (75%) had length of Meckel's diverticulum of about 6 cm, and 1 patient (25 %) had length of about 8 cm [Figures 3 and 4].

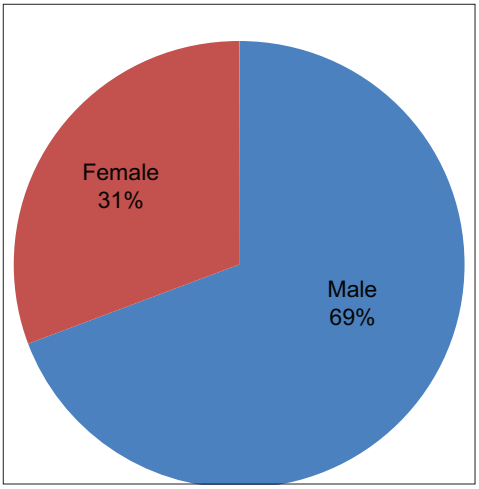


Figure 1: Sex distribution of Meckel's diverticulum

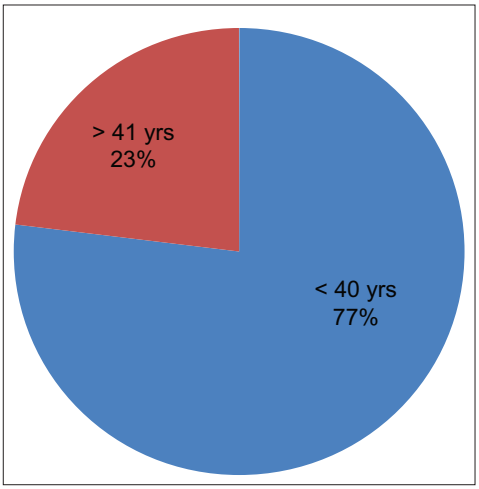


Figure 2: Age distribution of Meckel's diverticulum

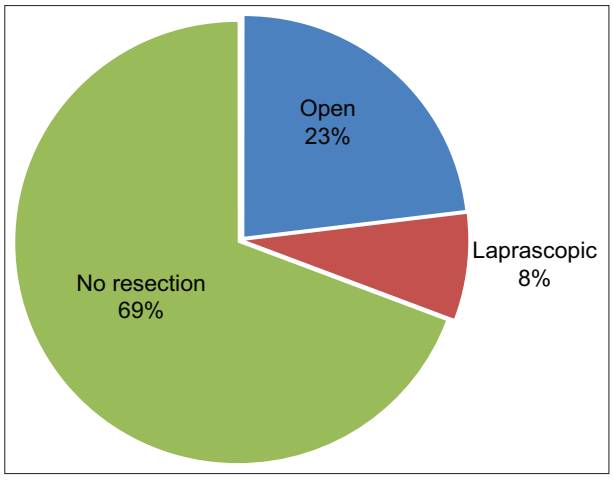


Figure 3: Surgical management of Meckel's diverticulum

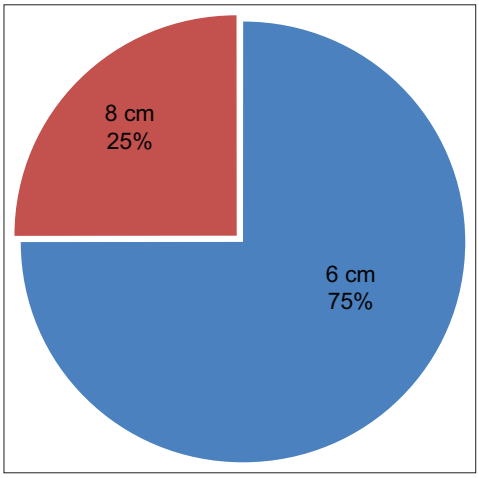


Figure 4: Size of Meckel's diverticulum

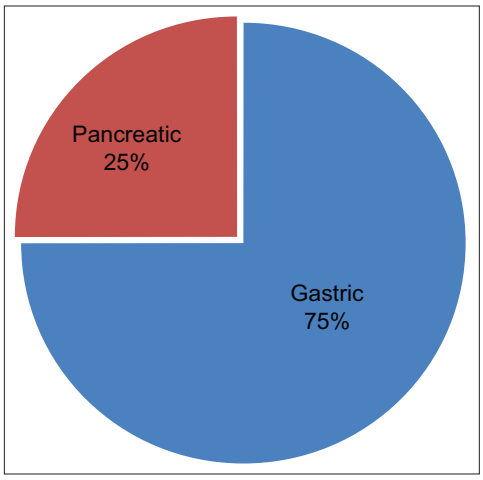


Figure 5: Histopathology of Meckel's diverticulum

Out of 4 patients with Meckel's diverticulum, 3 patients (75%) had the histopathological origin of gastric mucosa, and 1 patient (25%) had origin of pancreatic mucosa [Figure 5].

Table 1: Distribution of clinical manifestations

Clinical manifestations	No. of patients
Incidental findings	9
Perforative peritonitis	1
Intestinal obstruction	1
Acute diverticulitis	1
Recurrent abdominal pain	1

DISCUSSION

Meckel's diverticulum is more common in males than females, with male to female ratio ranging from 2:1 to 4:1. In our study, out of 13 patients, 9 patients (69%) were males and 4 patients (31%) were females. In our study, out of 13 patients, 3 patients (75%) had the histopathological origin of gastric mucosa, and 1 patients (25%) had origin of pancreatic mucosa.

Laparoscopy is not only a useful diagnostic method but also a therapeutic tool, especially in cases of bleeding Meckel diverticulum. It remains controversial whether all incidentally diagnosed Meckel diverticula should be resected. Some authors have promoted the removal of all asymptomatic Meckel diverticulum because of the high risk of subsequent complications and low risk associated with resection.[12,13] Some authors have advocated resection only in selected cases of Meckel diverticulum, such as who are suspected of having ectopic gastric mucosa or forming adhesive bands.[14,15] In our study, 4 patients who had symptomatic Meckel's diverticulum were removed and those 9 patients who had incidental finding of asymptomatic Meckel's diverticulum were not resected and kept under follow-up.

Many studies show that Meckel's diverticulum occurs mostly in children's or young adolescents. In our study, out of 13 patients, 10 patients (77%) had age below 40 years and 3 patients (23%) had age above 41 years.

CONCLUSION

Symptomatic Meckel's diverticulum was associated with dreaded complications such as perforative peritonitis, intestinal obstruction, and diverticulitis with severe pain which made us to conclude about even an asymptomatic Meckel's diverticulum found incidentally during acute abdominal surgeries need to be resected.

REFERENCES

1. St-Vil D, Brandt ML, Panic S, Bensoussan AL, Blanchard H. Meckel's diverticulum in children: A 20-year review. J Pediatr Surg 1991;26:1289-92.
2. Huang CC, Lai MW, Hwang FM, Yeh YC, Chen SY, Kong MS, *et al.* Diverse presentations in pediatric Meckel's diverticulum: A review of 100 cases. Pediatr Neonatol 2014;55:369-75.

3. Simms MH, Corkery JJ. Meckel's diverticulum: Its association with congenital malformation and the significance of atypical morphology. Br J Surg 1980;67:216-9.
4. Rattan KN, Singh J, Dalal P, Rattan A. Meckel's diverticulum in children: Our 12-year experience. Afr J Paediatr Surg 2016;13:170-4.
5. Dumper J, Mackenzie S, Mitchell P, Sutherland F, Quan ML, Mew D. Complications of Meckel's diverticula in adults. Can J Surg 2006;49:353-7.
6. Sagar J, Kumar V, Shah DK. Meckel's diverticulum: A systematic review. J R Soc Med 2006;99:501-5.
7. Sinha CK, Fishman J, Clarke SA. Neonatal Meckel's diverticulum: Spectrum of presentation. Pediatr Emerg Care 2009;25:348-9.
8. Leijonmarck CE, Bonman-Sandelin K, Frisell J, Räf L. Meckel's diverticulum in the adult. Br J Surg 1986;73:146-9.
9. Ymaguchi M, Takeuchi S, Awazu S. Meckel's diverticulum. Investigation of 600 patients in Japanese literature. Am J Surg 1978;136:247-9.
10. Weinstein EC, Cain JC, Remine WH. Meckel's diverticulum: 55 Years of clinical and surgical experience. JAMA 1962;182:251-3.
11. Deetz D. Perforations peritonitis von einem darmdivertikel mit magenschleimhautbau ausgehend. Dtsch Z Chir 1907;88:482-93.
12. Vane DW, West KW, Grosfeld JL. Vitelline duct anomalies. Experience with 217 childhood cases. Arch Surg 1987;122:542-7.
13. Pellerin D, Harouchi A, Delmas P. Meckel's diverticulum, revision of 250 children cases. Ann Chir Infant 1976;17:157-72.
14. Onen A, Ciğdem MK, Oztürk H, Otçu S, Dokucu AI. When to resect and when not to resect an asymptomatic Meckel's diverticulum: An ongoing challenge. Pediatr Surg Int 2003;19:57-61.
15. Felberbauer FX, Niederle B, Teleky B. The truth behind the 'rule of twos' the Meckel diverticulum revised. Eur Surg 2007;39:299-306.

How to cite this article: Thirulogachandran V, Maruthupandian S, Karthick G. Meckel's Diverticulum: Still Formidable during Acute Abdominal Surgeries – An Observational Study. Int J Sci Stud 2020;7(12):76-79.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

A Study of Clinical Profile and Management of Nodular Goiter

T Gnanakkumar

Senior Civil Surgeon, Department of General Surgery, Government Headquarters Hospital, Ramanathapuram, Tamil Nadu, India

Abstract

Introduction: Nodular goiters are enlargements of the thyroid gland. In the absence of thyroid dysfunction, autoimmune thyroid disease, thyroiditis, and thyroid malignancy, they constitute an entity described as non-toxic nodular goiter, which occur both endemically and sporadically.

Aim: The aim of the study was to study the clinical presentation and management of patients with nodular goiter.

Materials and Methods: In this prospective observational study, patients admitted with nodular goiter – solitary or multinodular were included in the study. The patients diagnosed as a case of solitary or multinodular will undergo detailed history taking, clinical examination, and investigations such as complete blood count, thyroid profile, fine-needle aspiration cytology, X-ray chest and neck, and ultrasonography of the neck. Histopathology of the excised specimens was studied to evaluate the incidence of malignancy.

Results: A total of 18 patients were included, 68% of cases were in 21–40 years age group, all patients had swelling, 33% had pain, 22% had difficulty in swallowing, 16 patients were euthyroid, and 2 patients had hypothyroidism. The incidence of malignancy was found to be 8%, 42% of the patients had benign follicular adenomas. The incidence of inflammatory goiter was 11% and 3% of patients showed evidence of toxicity. Preoperatively, regional lymph node metastasis evaluated and hemithyroidectomy in adenoma thyroid and colloid nodules, subtotal and total thyroidectomy in multinodular goiters and total thyroidectomy in carcinoma thyroid were done. About 89% had an uneventful post-operative period.

Conclusion: Nodular goiter of the thyroid was found to be more common in young and middle-aged patients. The majority of nodular goiter was found to be a benign lesion. The incidence of malignancy was found to be 8% overall, 12.5% nodules in female were malignant.

Key words: Fine-needle aspiration cytology, Histopathology, Malignancy, Papillary carcinoma, Thyroid tumors

INTRODUCTION

Thyroid disease affects many people worldwide. The spectrum of diseases is wide, ranging from minor structural changes not influencing the life of the patients to a variety of disorders that may reduce the quality of life and, in some circumstances, also affect life expectancy. Among the mild but frequent disorders are goiter and benign thyroid nodules. These two conditions often develop simultaneously, but many subjects harbor nodules within the thyroid gland without the development of goiter, and in populations with excessive iodine intake, goiters are often without nodules.[1,2]

Nodules are discrete lesions that may be detected by palpation, autopsy/surgery, ultrasound, or other types of imaging procedures. Nodular goiter is a recognizable thyroid enlargement "characterized by excessive growth and structural and/or functional transformation of one or several areas within the normal thyroid tissue."[3]

Nodular goiters are enlargements of the thyroid gland. In the absence of thyroid dysfunction, autoimmune thyroid disease, and thyroiditis and thyroid malignancy, they constitute an entity described as non-toxic nodular goiter, which occur both endemically and sporadically. In the early

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: T Gnanakkumar, Department of General Surgery, Government Headquarters Hospital, Ramanathapuram, Tamil Nadu, India.

phase of goitrogenesis, goiters are diffuse and, with time, such goiters tend to become nodular.[4]

Aim

The aim of the study was to study the clinical presentation and management of patients with nodular goiter.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of General Surgery at Government Headquarters Hospital, Ramanathapuram.

Inclusion Criteria

All patients admitted with nodular goiter solitary or multinodular were included in the study.

Exclusion Criteria

Patients with severe comorbid illness, patients with nodular goiter with regional lymphadenopathy, and patients with distant metastasis were excluded from the study. The patients diagnosed as a case of solitary or multinodular will undergo detailed history taking, clinical examination, and investigations such as complete blood count, thyroid profile, fine-needle aspiration cytology (FNAC), X-ray chest and neck, and ultrasonography (USG) of the neck. The patients underwent hemithyroidectomy, subtotal thyroidectomy, and total thyroidectomy and the histopathology of the excised specimens was studied to evaluate the incidence of malignancy. After surgery, the patients will be followed up for any immediate post-operative complications. The specimen will be sent for histopathological examination, and the results will be recorded.

RESULTS

In this study, 18 patients with nodular goiter of the thyroid were included in the study. A higher number of cases were noted in 21–40 years of age group [Figure 1]. In this study, 16 females and 2 males were included in the study. All the 18 patients complained about swelling in the front of their neck. Six patients had pain and 4 patients complained of some difficulty in swallowing [Figure 2].

About 77.7% of cases are solitary nodules of thyroid of varying sizes from 4 to 7 cm confined to the right or left lobe with or without, the involvement of the isthmus of thyroid was noted. About 33.3% of cases are multinodular goiter with varying sizes of nodules.

Sixteen patients were euthyroid, 2 patients had hypothyroidism, and no case of hyperthyroidism was noted [Figure 3]. None of the cases were found with lymph node metastasis. Nine cases were reported to have colloid nodules on FNAC and 8 cases reported as adenomatous goiter. One case of papillary carcinoma was reported in FNAC [Figure 4]. CT scan was done selectively for multinodular goiter to assess tracheal compression. All 18 patients were assessed for surgery under general anesthesia and preoperatively regional lymph node metastasis evaluated and hemithyroidectomy in adenoma thyroid and colloid nodules, subtotal and total thyroidectomy in multinodular goiters, and total thyroidectomy in carcinoma thyroid were done.

The incidence of malignancy was found to be 8%, 42% of the patients had benign follicular adenomas. Incidence of

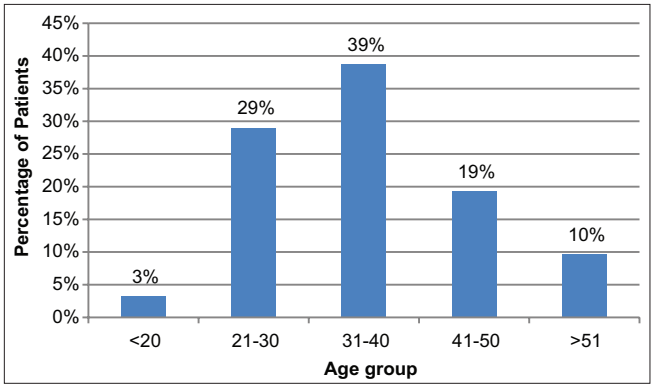


Figure 1: Distribution of age group

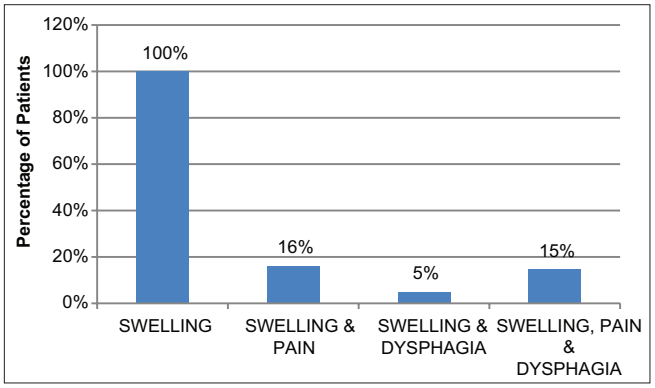


Figure 2: Distribution of symptoms

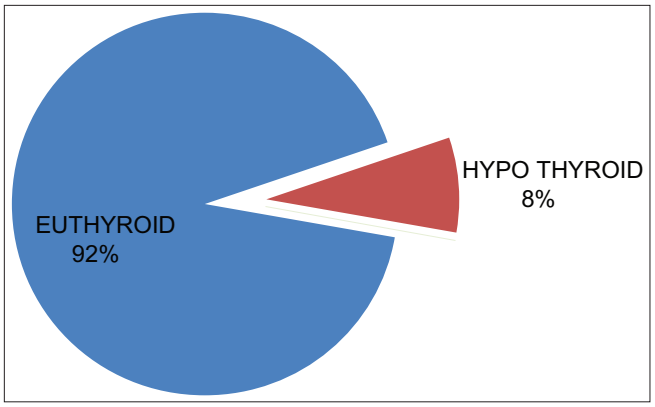


Figure 3: Distribution of thyroid function

inflammatory goiter was 11% and 3% of patients showed evidence of toxicity [Figure 5]. About 12.5% of nodules in females were malignant [Table 1]. The majority of patients, 89%, had an uneventful post-operative period. One patient developed hypothyroidism and was given L-thyroxine. One patient had transient dysphonia in the form of loss of pitch of voice which improved subsequently [Figure 6].

DISCUSSION

Surgical management of thyroid disease has changed significantly over the course of the 20th century. Advances in the investigations to diagnose thyroid disease have provided for adequate treatment and control of functional problems. The main indication for thyroid surgery is the presence of thyroid nodule, multinodular goiter, and malignancies. The risk of complications varies with the skill and experience of the surgeon, as well as the extent of resection. The basic principle of surgery to avoid damage to any vital structure dictates that the structure must be clearly identified.

Thyroid nodules are present in 4%–7% of the population by neck palpation (the incidence increases with increasing age) and 30% to 50% by USG.[5-7] It has been believed that fewer than 5% of these nodules are malignant and require surgical treatment and that extensive evaluation or surgical excision is not practical.[8] However, Stoffer *et al.*[9] reported that 13% of the glands resected in thyroid operations for any reason contained carcinoma.

Previous studies have shown that the diagnostic accuracy of fine-needle aspiration biopsy is improved with USG guidance compared with palpation alone.[10,11] In addition, USG guidance is required for aspiration of non-palpable thyroid nodules.[12,13]

Fine-needle aspirate cytology is a fast, accurate, and inexpensive test to obtain cellular samples. A series of reviews have reaffirmed its importance in the assessment of thyroid nodules.[14-16]

There are a variety of tests of thyroid function available. The number of investigations requested should be the minimum necessary to reach a diagnosis and formulate a management plan. Only a small number of parameters need to be measured as a routine, although this may require supplementation or repeat when inconclusive.[17] The serum thyroid-stimulating hormone (TSH) may be used as a single, initial test of thyroid function because of the high sensitivity of the TSH assay to diagnose both hyperthyroidism and hypothyroidism. TSH levels can be measured accurately down to very low serum concentrations, and if the serum TSH level is in the normal

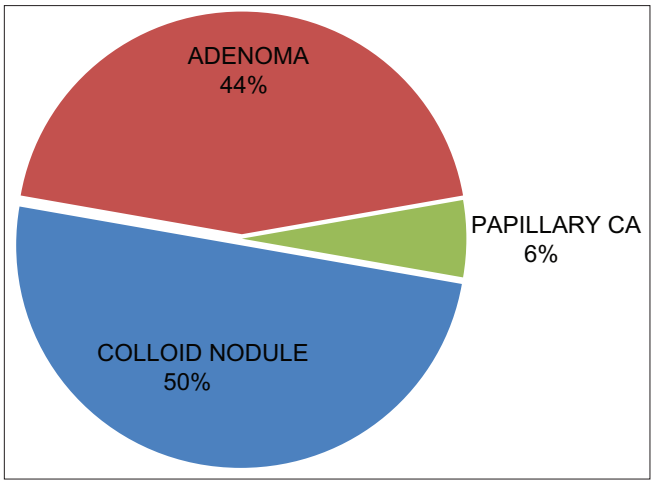


Figure 4: Distribution of cytological analysis – fine-needle aspiration cytology

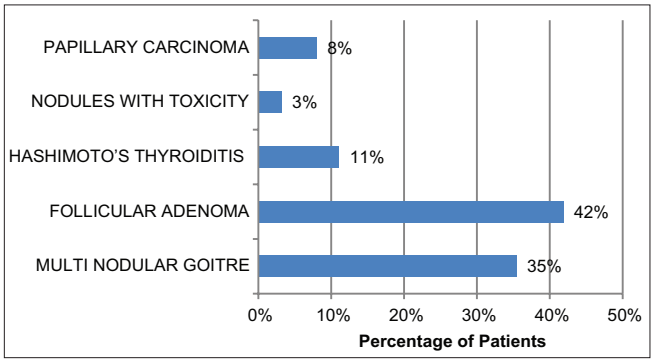


Figure 5: Distribution of pathological diagnosis

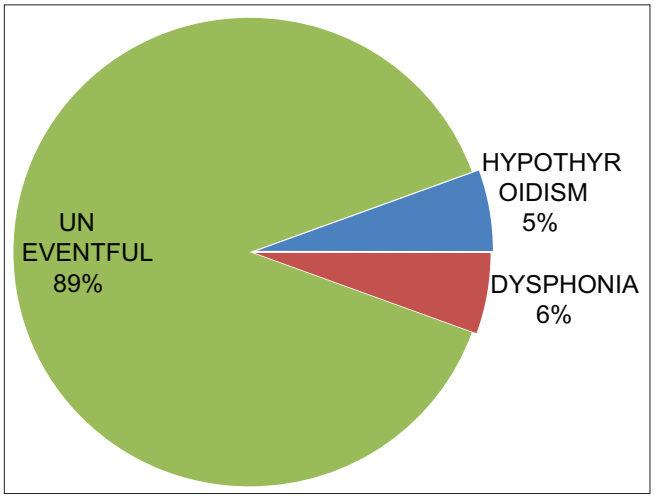


Figure 6: Distribution of complications

Table 1: Distribution of nodular goiter of the thyroid

Gender	Benign	Malignant	Total
Male	2	0	2
Female	14	2	16
Total	16	2	18

range, it is redundant to measure the T3 and T4 levels. Interpretation of deranged TSH levels, however, depends on knowledge of the T3 and T4 values.[18] In the euthyroid state, T3, T4, and TSH levels will all be within the normal range. Florid thyroid failure results in depressed T3 and T4 levels with the gross elevation of the TSH. Incipient or developing thyroid failure is characterized by low normal values of T3 and T4 and elevation of the TSH. In toxic states, the TSH level is suppressed and undetectable.[19]

CONCLUSION

Nodular goiter of the thyroid was found to be more common in young and middle-aged patients. The majority of nodular goiter was found to be benign lesions. The incidence of malignancy was found to be 8% overall, 12.5% nodules in female were malignant. About 89% of patients had an uneventful postoperative period. One patient developed hypothyroidism and 1 patient had transient dysphonia.

REFERENCES

1. Farquharson N, Moran B. Surgery of the neck. In: Farquharson's Text Book Operative General Surgery. 9th ed., Ch. 9. London: Edward Arnold; 2003. p. 155-78.
2. Koh KB, Chang KW. Carcinoma in multinodular goitre. Br J Surg 1992;79:266-7.
3. Chaudhary V, Bano S. Thyroid ultrasound. Indian J Endocrinol Metab 2013;17:219-27.
4. Tonacchera M, Pinchera A, Vitti P. Assessment of nodular goitre. Best Pract Res Clin Endocrinol Metab 2010;24:51-61.
5. Belfiore A, La Rosa GL, Padova G, Sava L, Ippolito O, Vigneri R. The frequency of cold thyroid nodules and thyroid malignancies in patients from an iodine-deficient area. Cancer 1987;60:3096-102.
6. Mazzaferri EL, de los Santos ET, Rofagha-Keyhani S. Solitary thyroid nodule: Diagnosis and management. Med Clin North Am 1988;72:1177-211.
7. Ezzat S, Sarti DA, Cain DR, Braunstein GD. Thyroid incidentalomas. Prevalence by palpation and ultrasonography. Arch Intern Med 1994;154:1838-40.
8. Giuffrida D, Gharib H. Controversies in the management of cold, hot, and occult thyroid nodules. Am J Med 1995;99:642-50.
9. Stoffer RP, Welch JW, Hellwig CA, Chesky VE, Mccusker EN. Nodular goiter. Incidence, morphology before and after iodine prophylaxis, and clinical diagnosis. AMA Arch Intern Med 1960;106:10-4.
10. Danese D, Sciacchitano S, Farsetti A, Andreoli M, Pontecorvi A. Diagnostic accuracy of conventional versus sonography-guided fine-needle aspiration biopsy of thyroid nodules. Thyroid 1998;8:15-21.
11. Rosen IB, Azadian A, Walfish PG, Salem S, Lansdown E, Bedard YC. Ultrasound-guided fine-needle aspiration biopsy in the management of thyroid disease. Am J Surg 1993;166:346-9.
12. Leenhardt L, Hejblum G, Franc B, Fediaevsky LD, Delbot T, Le Guillouzic D, *et al*. Indications and limits of ultrasound-guided cytology in the management of nonpalpable thyroid nodules. J Clin Endocrinol Metab 1999;84:24-8.
13. Hagag P, Strauss S, Weiss M. Role of ultrasound-guided fine-needle aspiration biopsy in evaluation of nonpalpable thyroid nodules. Thyroid 1998;8:989-95.
14. Ashcraft MW, Van Herle AJ. Management of thyroid nodules. II: Scanning techniques, thyroid suppressive therapy, and fine needle aspiration. Head Neck Surg 1981;3:297-322.
15. Hamburger JI. Fine needle biopsy diagnosis of thyroid nodules. Perspective. Thyroidology 1988;1:21-34.
16. La Rosa GL, Belfiore A, Giuffrida D, Sicurella C, Ippolito O, Russo G, *et al*. Evaluation of the fine needle aspiration biopsy in the preoperative selection of cold thyroid nodules. Cancer 1991;67:2137-41.
17. Are C, Zeiger MA. Thyroid Nodule in Current Surgical Therapy. 8th ed. Maryland Heights: Mosby, Cameron International; 2004. p. 58-82.
18. Das S. Examination of the thyroid gland. In: A Manual on Clinical Surgery. 6th ed., Ch. 27. Kolkata, India: Dr. S. Das; 2005. p. 284-97.
19. Kenneth AW. Cost-effective evaluation of the patient with a thyroid nodule. Surg Clin North Am 1995;75:357-63.

How to cite this article: Gnanakkumar T. A Study of Clinical Profile and Management of Nodular Goiter. Int J Sci Stud 2020;7(12):80-83.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Transpedicular Percutaneous Vertebroplasty in Management of Osteoporotic Vertebral Compression Fractures Assessment of Clinical Outcome: A Study of 21 Procedures

Virendra Agrawal[1], Udit Kothari[2]

[1]Assistant Professor, Department of Orthopaedics, K.J. Somaiya Hospital, Mumbai, Maharashtra, India, [2]Resident, Department of Orthopaedics, K.J. Somaiya Hospital, Mumbai, Maharashtra, India

Abstract

Introduction: Osteoporotic vertebral fractures that produce increased morbidity, persistent back pain, risk of collapse with time, and increased fracture risk. Subsequently, these vertebral fractures produce kyphotic deformity and effect on lung capacity. In our study purpose is to assess the clinical outcome, safety, and efficacy of transpedicular percutaneous vertebroplasty in osteoporotic vertebral compression fractures (VCFs).

Methodology: The study done between December 2017 and December 2019 at our institute. A total of 10 patients with 21 vertebral body collapse in that 13 dorsal vertebra and 8 lumbar vertebral body included in the study in neurologically intact individuals. Patients are considered for treatment, those with chronic pain refractory to medical therapy and bracing and those with severe disabling pain caused by fractures. Severe cardiopulmonary disease, coagulopathy, and cord compression are contraindications to vertebroplasty. Severe vertebral compression may also be a contraindication to treatment, because the vertebra may be compressed to such a degree that needle placement and cement injection become impossible. After treatment, they selected one of three possible responses for each: Significantly improved, worse, or approximately the same. As an overall assessment analgesic requirement, visual analog scale, grading of subjective satisfaction score, sleep, and ambulation improvement assessed. To ensure uniformity despite the variable follow-up period, patients were instructed to indicate their status at 2 weeks after the procedure, 6 months, and 1-year follow-up.

Results: Both pain and functional outcome improved significantly in immediate post-procedure at 2 weeks, 6 months, and 1 year. The majority (70%) of the patients were treated for 2 levels while 2 patients were treated for 3 levels and 1 patient was treated for 1 level. Visual analog scale (VAS) in the pre-procedure period is 8.3 which decrease in the post-procedure period at 2 weeks and 6 months is 2.6 and 3.6 subsequently and at 1-year average VAS score is 4. Mobility and sleep pattern is significantly improved in 8 patients (80%) at 1-year follow-up whereas remain same in 2 patients.

Conclusion: Significant relief in pain in the post-procedure period with minimum risk noticed for VCFs.

Key words: Bone cement, Osteoporosis, Pain, Polymethylmethacrylate, Spine, Transpedicular vertebroplasty, VAS score, Vertebral compression fracture, Vertebroplasty

INTRODUCTION

Vertebroplasty originally used for an open surgical procedure that introduces bone graft or acrylic cement to mechanically augment weakened vertebral bodies. Polymethylmethacrylate (PMMA) is the acrylic most commonly used as a bone filler, and its application in the treatment vertebral compression fractures (VCFs) has been reported extensively.[1] First, image-guided percutaneous vertebroplasty done in France in 1984, when Galibert *et al.*[2] injected PMMA into a C2 vertebra that partially destroyed by an aggressive hemangioma. The procedure relieved the patient's long-term pain. After that, percutaneous vertebroplasty was used to treat VCFs caused by osteoporosis.[3]

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. Udit Kothari, Department of Orthopaedics, K.J. Somaiya Hospital, Mumbai, Maharashtra, India.

METHODOLOGY

All patients undergoing percutaneous vertebroplasty at our institution between December 2017 and December 2019. All patients underwent various combinations of plain X-rays and magnetic resonance (MR) imaging to assess the fracture pattern and to exclude other causes of pain such as herniated intervertebral disc, facet arthropathy, spinal stenosis, aggressive hemangioma, myeloma, and osteolytic metastasis.

Before initiating percutaneous vertebroplasty, careful assessment and evaluation of the patient needed to ensure that the pain is related to VCF. Compression fracture pain usually worsens with weight bearing and improves with recumbency, pain is typically localized to the area of the fracture and lacks radicular qualities that suggest nerve root or cord compression. Local palpation over the posterior elements of the involved vertebral body will often elicit pain. Patients were excluded if the affected level was completely free of pain on palpation, if there was an overwhelming radicular component to the pain, or if the fracture seemed too compressed to permit percutaneous access and cement delivery. Patients with severe spinal canal compromise were also excluded from the study. Patients are considered for treatment, those with chronic pain refractory to medical therapy and bracing and those with severe disabling pain caused by fractures. Severe cardiopulmonary disease, coagulopathy, and cord compression are contraindications to vertebroplasty. Severe vertebral compression may also be a contraindication to treatment, because the vertebra may be compressed to such a degree that needle placement and cement injection become impossible. An absolute degree of vertebral compression that precludes treatment cannot be defined. An upper thoracic vertebra compressed by 50% may be impossible to treat safely, yet a lumbar vertebra compressed by 75% may still be treated because the remaining height is significant.

Clinical examination and plain X-ray are used to confirm the compression level with MR imaging done. MR images show both anatomic vertebral collapse and loss of normal signal from the marrow space of vertebrae with acute fractures. These findings are well appreciated on sagittal T1-weighted sequences because the edema associated with the compression produces a low (dark) signal intensity compared with the high (bright) signal normally seen in the marrowfat. Heavily T2-weighted sequences, such as sagittal short-tau inversion recovery sequences, are the most sensitive, with fluid representing marrow edema.[4]

High-quality fluoroscopic equipment is essential for the safe performance of vertebroplasty. The cannula must be placed accurately to avoid collateral damage, and the cement must be observed during injection to prevent extravasation. Fluoroscopic images taken in both plane with c arm equipment allows the procedure to be performed more rapidly.

Patients typically receive intravenous antibiotics 30 min before the start of the procedure. Prophylactic pre-operative antibiotics (typically 1 g of cefazolin 30 min before the procedure) are routinely administered to the patient. Antibiotics may also be administered in the cement. Such delivery is usually used for patients who are known to be immunocompromised. The level at procedure planned is prepared in a strictly sterile manner, with sterile drapes used over other regions. All personnel in the procedure room must observe a full sterile protocol. Proper fluoroscopic projection that places the pedicle of the vertebra over the vertebral body is chosen and local anesthetic is injected into the overlying skin, needle tract, and periosteum of the involved bone. A small incision is made with a scalpel. Using fluoroscopic guidance, an 11-gauge bone biopsy needle consisting of an access cannula with a beveled trocar is inserted through the skin and seated against the periosteum. Under biplane fluoroscopic guidance, the needle is advanced through the midportion of the pedicle and into the cancellous interior of the collapsed vertebral body. The entry site near the mammillary process and the angulation of the needle trajectory are slightly different from those used for pedicle screw placement. Initially, the needle, the contour of the pedicle, and the central X-ray beam are all positioned along the same axis, thus allowing the needle to be directed concentrically. Within the pedicle, the bevel of the needle is oriented so that the tip points laterally, avoiding the spinal canal.[5] Once within the vertebral body, however, the bevel is rotated to direct the needle tip toward the midline, which usually obviates the need for bipedicular access [Figures 1-3]. Similar rotations of the bevel can direct the needle away from the superior and inferior endplates. The needle should ultimately reach the anterior third of the vertebral body. The position is checked in both anteroposterior and lateral projections. The trocar is removed and transosseous venography is performed by injecting nonionic contrast material through the cannula. If rapid, brisk filling of either the perimedullary veins or the inferior vena cava is observed, anastomotic channels of the basivertebral venous plexus may be embolized with a slurry of microfibrillar collagen, saline, and contrast medium. This strategy minimizes the risk of pulmonary embolism or epidural compression when cement is subsequently injected into the vertebral body venography may also help evaluate the filling pattern and identify potential sites of PMMA leakage outside the vertebral body.[3] Such information may prompt repositioning of the needle by advancement, withdrawal,

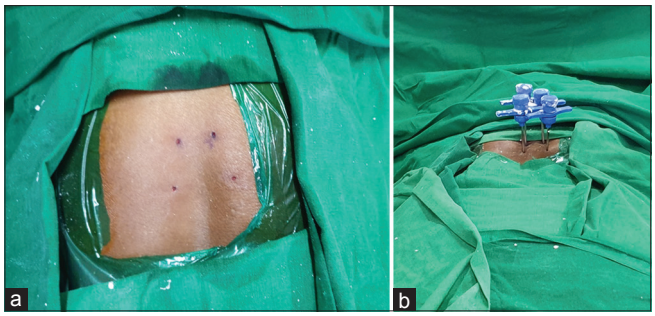


Figure 1: (a and b) Application of trocar needle after confirmation of collapse levels

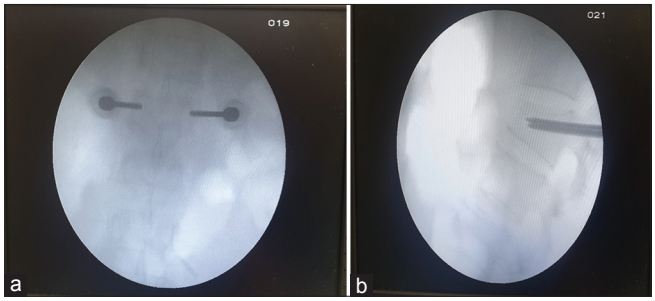


Figure 2: Anteroposterior (a) and lateral (b) fluoroscopic images after needle placement. The needles have been staggered by alternating between the right and left pedicles at contiguous levels (a). The needle tips have been placed near the midline (A) and in the anterior third of the vertebral body (b)

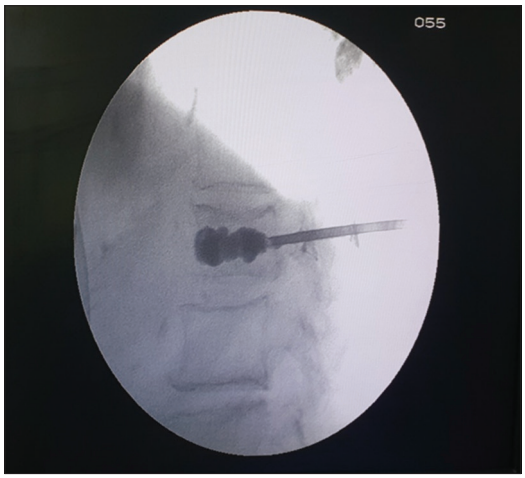


Figure 3: Fluoroscopic images of the thoracolumbar junction after injection of polymethylmethacrylate ideally, the cement permeates the anterior three-fourths of the vertebral body and at least two-thirds of its transverse dimension

or rotation. The optimum period for injection is generally between 5 and 15 min after combination when a semifluid texture similar to toothpaste is achieved. Insufficient polymerization of the acrylic cement at the time of injection may be one factor that contributes to migration into the vena cava and subsequent pulmonary embolism.[6,7] Conversely, by the time the mixture begins to heat up from the exothermic polymerization reaction, it is usually too viscous to deliver. Under continuous fluoroscopic monitoring, PMMA is injected into the interstices of the vertebral body.

Once the procedure is completed, the patient should be maintained recumbent for the next 2 h to prevent weight bearing and axial loading while the cement hardens. PMMA cements typically set within 20 min and achieve approximately 90% of their ultimate strength within 1 h of injection.[8] Antibiotic ointment should be applied to the needle introduction sites and then covered with a sterile bandage. The patient is made ambulatory overnight and is discharged 24 h later from the hospital following clinical and radiological assessment.

Our outcomes assessment had to be kept as simple as possible. Assessment of visual analog scale between 1 and 10 (1 is totally relived and 10 is same or worse pain), subjective satisfaction scale between 1 and 5 (1=worse, 2=same, 3=good, 4=very good, 5=excellent). Functional impact of pain on patients' lives to compare their ambulatory status, the ability to sleep comfortably, and analgesic/narcotic requirements before and after treatment.

After treatment, they selected one of three possible responses for each: Significantly improved, worse, or approximately the same. To ensure uniformity despite the variable follow-up period, patients were instructed to indicate their status at 2 weeks, 6 months, and 1 year after the procedure.

RESULTS

The procedure was performed in 10 patients involving 21 vertebrae (lower thoracic – 13 and lumbar – 8). Most patients were of the elderly age group with mean age of 64 years (range 50–70 years). All the patients presented with severe intractable pain with varying degree of impaired mobility of relatively longer duration. The procedure was successful in 10 patients. In 1 patient, it was extravasation of dye and bone cement in epidural space in the post-operative period for that open decompression with removal of bone cement from epidural space and surgical stabilization done. The bilateral transpedicular approach was done in all patients.

The majority (70%) of the patients were treated for 2 levels while 2 patients were treated for 3 levels and 1 patient was treated for 1 level. The amount of bone cement injected per vertebral body varied from 2 ml to 8 ml with an average of 5 ml.

The clinical response to the procedure was assessed immediately after the procedure, 2 weeks, 6 months, and

1 year period. The visual analog scale (1–10), grading of subjective satisfaction (1–5), analgesic requirement, ambulation after procedure, improvement in sleep were monitored. Average visual analog scale (VAS) in the pre-procedure period is 8.3 which decrease in the post-procedure period at 2 weeks and 6 months is 2.6 and 3.6 subsequently and at 1-year average VAS score is 4. Mobility and sleep pattern is significantly improved in 8 patients (80%) at 1-year follow-up whereas remain same in 2 patients. Average subjective satisfaction score at 6 month period is 3.8 and at 1 year of follow up period average score is 3.1. No recurrence of pain and further vertebral collapse was seen during a mean follow-up of 1 year.

DISCUSSION

Acute complications of a vertebral fracture include transient ileus, urinary retention, and the hazards of protracted immobilization, while long-term effects include kyphosis, deconditioning, insomnia, and depression.[9,10] Patients with osteoporotic compression fractures have significantly higher mortality rates than age-matched controls and are more than twice as likely to die from pulmonary causes.[11] Vital capacity, forced expiratory volume, and other measures of pulmonary function are significantly diminished in patients with spinal compression fractures as compared with those with back pain from other causes. In one model, each thoracic compression fracture reduced forced vital capacity by more than 9%.[12]

While bed rest, bracing, and analgesic medication remain the mainstay of therapy, refractory pain and debility complicate a significant percentage of compression fractures.[13] Surgical intervention is uncommon due to the technical impediments imposed by osteopenic bone and the high prevalence of comorbid conditions in this patient population. Percutaneous vertebroplasty, the injection of PMMA bone cement into the collapsed vertebral body, has emerged as an accepted form of therapy for osteoporotic compression fracture.[14] An injection of PMMA mechanically reinforces the vertebral body and may reduce pain by halting further compression, deformity, or micromotion.[15] Alternatively, it has been proposed that the heat generated by the exothermic polymerization of PMMA damages pain-sensitive nerve endings within the vertebra and surrounding tissues.[14]

One of the principal determinants of outcome is proper patient selection. The ideal candidate for percutaneous transhepatic portal venography (PTPV) presents within 4 months of the fracture and has midline, nonradiating axial pain that increases with weight bearing and is exacerbated by manual palpation of the spinous process at that level up to two-thirds of osteoporotic compression fractures never comes to the attention of the clinician.[16] Since some patients have associated fractures that are incidental, it is crucial to identify the symptomatic level requiring treatment. Exclusion criteria include collapse to <20% of the original height (vertebra plana) and other fracture patterns that preclude safe access to the vertebral body. With technical modifications, however, some have documented the feasibility of treating fractures collapsed more than 80%.[17] Patients with active infections of the spine or coagulopathy should not undergo vertebroplasty. One limitation of this procedure is that the outcome is not easy to evaluate. Outcomes are subjective, and in placebo effects cannot be excluded from the study. The study population included many elderly patients with memory deficits and others who are inherently difficult to question. Several patients developed new compression fractures during the course of follow-up, which made it a difficult assessment.

Extrusion of PMMA was common, especially when the fracture plane extended to the endplates or cortical surfaces. Extrusion may occur into the epidural space of the spinal canal, the neural foramen, the intervertebral disc space, or the paraspinal veins and lungs. Each pattern of extrusion carries distinct risks. Extrusion of bone cement is complication most commonly seen, in our study one patient after Percuteneous transpedicular vertebroplasty (PTPV) show bone cement exctrusion in inferior disc space, who ultimately improved after undergoing surgical removal and stabilisation of extruded intradiscal bone cement.

CONCLUSION

Tranpedicular percuteneous vertebroplasty provide significant pain relief related to osteoporotic vertebral compression fractures and decrease period of morbidity with a very low complication rate.

REFERENCES

1. Mavian GZ, Okulski CJ. Double fixation of metastatic lesions of the lumbar and cervical vertebral bodies utilizing methylmethacrylate compound: Report of a case and review of a series of cases. J Am Osteopath Assoc 1986;86:153-7.
2. Galibert P, Deramond H, Rosat P, Le Gars D. Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty. Neurochirurgie 1987;33:166-8.
3. Bascoulergue Y, Duquesnel J, Leclercq R, Mottolese C, Lapras C. Percutaneous injection of methyl methacrylate in the vertebral body for the treatment of various diseases: Percutaneous vertebroplasty. Radiology 1988;169P:372.
4. Wehrli FW, Ford JC, Haddad JG. Osteoporosis: Clinical assessment with quantitative MR imaging in diagnosis. Radiology 1995;196:631-41.
5. Martin JB, Jean B, Sugiu K, San Millán Ruíz D, Piotin M, Murphy K, *et al*. Vertebroplasty: Clinical experience and follow-up results. Bone

1999;25:11S-5S.
6. Cotten A, Boutry N, Cortet B, Assaker R, Demondion X, Leblond D, *et al*. Percutaneous vertebroplasty: State of the art. Radiographics 1998;18:311-20.
7. Padovani B, Kasriel O, Brunner P, Peretti-Viton P. Pulmonary embolism caused by acrylic cement: A rare complication of percutaneous vertebroplasty. AJNR Am J Neuroradiol 1999;20:375-7.
8. Mathis JM, Maroney M, Fenton DC, Belkoff SM. Evaluation of bone cements for use in percutaneous vertebroplasty. In: Proceedings of the 13th Annual Meeting of the North American Spine Society. San Francisco, CA, Rosemont, IL: North American Spine Society; 1998. p. 210-1.
9. Bostrom MP, Lane JM. Future directions. Augmentation of osteoporotic vertebral bodies. Spine (Phila Pa 1976) 1997;22:38S-42S.
10. Mathis JM, Petri M, Naff N. Percutaneous vertebroplasty treatment of steroid-induced osteoporotic compression fractures. Arthritis Rheum 1998;41:171-5.
11. Melton LJ 3rd. Excess mortality following vertebral fracture. J Am Geriatr Soc 2000;48:338-9.
12. Leech JA, Dulberg C, Kellie S, Pattee L, Gay J. Relationship of lung function to severity of osteoporosis in women. Am Rev Respir Dis 1990;141:68-71.
13. Rapado A. General management of vertebral fractures. Bone 1996;18:191S-6S.
14. Levine SA, Perin LA, Hayes D, Hayes WS. An evidence-based evaluation of percutaneous vertebroplasty. Manag Care 2000;9:56-60, 63.
15. Dean JR, Ison KT, Gishen P. The strengthening effect of percutaneous vertebroplasty. Clin Radiol 2000;55:471-6.
16. Tamayo-Orozco J, Arzac-Palumbo P, Peón-Vidales H, Mota-Bolfeta R, Fuentes F. Vertebral fractures associated with osteoporosis: Patient management. Am J Med 1997;103:44S-8S.
17. O'Brien JP, Sims JT, Evans AJ. Vertebroplasty in patients with severe vertebral compression fractures: A technical report. AJNR Am J Neuroradiol 2000;21:1555-8.

How to cite this article: Agrawal V, Kothari U. Transpedicular Percutaneous Vertebroplasty in Management of Osteoporotic Vertebral Compression Fractures Assessment of Clinical Outcome: A Study of 21 Procedures. Int J Sci Stud 2020;7(12):84-88.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Safety and Outcome of Laparoscopic Heller's Cardiomyotomy with Intraoperative Endoscopic Assessment and Dor's Fundoplication in Primary Achalasia Cardia: A Single-center Prospective Study

M Umamaheshwaran[1], A Shafique[2], R Selvasekaran[3]

[1]Assistant Professor, Department of Surgical Gastroenterology, Tirunelveli Medical College, Tirunelveli, Tamil Nadu, India, [2]Assistant Professor, Department of Medical Gastroenterology, Tirunelveli Medical College, Tirunelveli, Tamil Nadu, India, [3]Associate Professor, Department of Medical Gastroenterology, Thoothukudi Medical College, Thoothukudi, Tamil Nadu, India

Abstract

Introduction: Achalasia cardia is a primary esophageal motility disorder of an unknown etiology, characterized by abnormal peristalsis of the esophageal body and the absence of relaxation of the lower esophageal sphincter. Laparoscopic Heller cardiomyotomy is the surgical procedure of choice for achalasia cardia.

Aim: The aim of the study was to the immediate safety and long-term efficacy of laparoscopic Heller's cardiomyotomy with intraoperative endoscopy and Dor's anterior partial fundoplication in patients with achalasia cardia.

Materials and Methods: In this prospective study, laparoscopic Heller's myotomy with intraoperative endoscopy and anterior Dor's fundoplication were performed in all achalasia cardia patients. Patients' demographic, clinical features such as dysphagia grade and Eckardt score, intraoperative, post-operative parameters, and response to treatment on follow-up were analyzed.

Results: In 14 patients, 10 were females (71%), the mean age was 37±14.96 years. Mean pre-operative modified Takita's dysphagia grade was 2.93±0.73. Endoscopic classic findings and barium swallow bird beak sign were diagnostic in all cases. Pre-operative Eckardt score was 8.93±1.44. Eckardt score at discharge was 0.43±0.51 and at 12th month was 0.21±0.43. On analysis, there was a significant improvement in pre-operative values of modified Takita's dysphagia grade and Eckardt score to normal values postoperatively ($P < 0.0001$) and the durable effect was persistently observed in 3rd and 6th, 9th, and 12th-month follow-up.

Conclusion: Laparoscopic Heller's myotomy with intraoperative endoscopy and Dor's fundoplication are safe and effective with significant improvement in post-operative Takita's dysphagia score and Eckardt score.

Key words: Achalasia cardia, Dor's fundoplication, Eckardt score, Laparoscopy Heller's myotomy

INTRODUCTION

Achalasia cardia, even though a rare disease, is the most common esophageal motility disorder with annual incidence of around 1.6/100,000 persons and prevalence of around 10.8/100,000 persons.[1] It is associated with abnormalities of esophageal peristalsis and lower esophageal sphincter (LES), causing failure of relaxation of hypertensive LES with swallowing. Classic symptoms of Achalasia cardia are dysphagia, regurgitation especially nasal regurgitation during sleep or supine posture, with recurrent aspiration episodes in chronic cases.[2] It also causes retrosternal pain, vomiting, and weight loss in long-term cases. End-stage achalasia is defined by the esophageal diameter of more than 6 cm, deviation of long axis of the esophagus with associated sigmoid like

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. M Umamaheshwaran, Department of Surgical Gastroenterology, Tirunelveli Medical College, Tirunelveli, Tamil Nadu, India.

deformation.[3] Dysphagia is graded by severity according to Takita's classification.[4]

Table 1, retrosternal pain is mainly caused due to spastic, non-peristaltic, and nonfunctional contractions of the esophagus to propel the esophageal content into the stomach beyond the hypertensive LES. Weight loss is a long time effect due to either nutritional or development of malignancy in this background.

These classic four symptoms – dysphagia, regurgitation, retrosternal pain, and weight loss are included in a clinical Eckardt score.[5] Each component is assigned a score from 0 to 3 based on the patient's self-reported response, resulting in a total score that can range from 0 to 12.[5] Eckardt score is an exceptional tool for diagnosis and assessment of the efficacy of treatment during follow-up. Clinical and symptomatic success is defined by a score of 3 or less following a therapeutic intervention [Table 2]. Limitations are, this is a subjective assessment of the patient's symptoms. Objective confirmation of the efficacy of the intervention requires post-operative manometry and timed barium study with additional cost to the patient.

It is diagnosed with classic clinical symptoms, endoscopic findings, and barium swallow. Esophageal manometry with Chicago subtype Classification[6] helps in pre-operative prognostication of treatment response and selection of intervention.[7] Treatment of this condition is mainly palliative, relieving the obstruction at LES by dividing the hypertensive LES fibers. At present, available interventions are pharmacotherapy, endoscopic dilatation/botulinum toxin injection, laparoscopic Heller's cardiomyotomy (laparoscopic Heller's myotomy [LHM]), and per oral endoscopic myotomy (POEM).

Table 1: Modified Takita's dysphagia grading

Grade	Findings
I	Able to eat normally
II	Requires liquids with meals
III	Able to take only semisolid food
IV	Able to take only liquids
V	Able to swallow saliva but not liquids
VI	Complete dysphagia

Table 2: Eckardt score for symptomatic evaluation in achalasia

Score	Weight loss (kg)	Dysphagia	Retrosternal pain	Regurgitation
0	None	None	None	None
1	<5	Occasional	Occasional	Occasional
2	5–10	Daily	Daily	Daily
3	>10	Each meal	Each meal	Each meal

The purpose of this study is to evaluate the immediate safety and long-term efficacy of laparoscopic Heller's cardiomyotomy with intraoperative endoscopy and Dor's anterior partial fundoplication in patients with achalasia cardia.

The primary outcome of the study is the effective therapeutic response with a reduction in the dysphagia grade and Eckardt score at the follow-up assessment. Secondary outcomes included feasibility, rate of complications, and symptomatic relief.

MATERIALS AND METHODS

This is a prospective study of achalasia cardia patients diagnosed and treated between December 2017 and December 2018 in our institute by a single surgeon. Patients were regularly followed up, data were prospectively collected and analyzed for the safety and efficacy of the LHM intervention.

Inclusion Criteria

Diagnostic history, Eckardt score, upper endoscopy, high-resolution manometry, barium swallow study was included in the study.

After proper pre-operative evaluation and diagnosis, patients were given a detailed explanation of therapeutic options available such as pharmacologic, pneumatic dilation, surgery, and endoscopic (POEM) treatments. Those patients willing for surgical option and fit to undergo a major laparoscopic surgical procedure were included in this study. Unfit patients and those patients not willing for surgery were excluded from this study. Contrast computed tomography (CT) scan was performed in selected patients with severe weight loss, atypical findings, and advanced age at presentation.

Methodology

After general anesthesia, the patient was placed in a supine position strapped well, with legs apart using stirrups. Laparoscopic equipment placed at the head end of the patient. The surgeon stands between the patient's legs, with assistants standing at both sides of the patient. We use five ports, 10 mm left supraumbilical for the camera, 5 mm bilateral subcostal operating ports, 5 mm epigastric port for liver retraction, and 5 mm left lumbar port for assistance. Under reverse Trendelenburg position, dissection was limited to the anterolateral aspect of the abdominal esophagus and the diaphragmatic crura to prevent future reflux. The anterior vagal trunk was dissected and preserved. Heller's myotomy was started from the lower esophagus and extended for about 6 cm on the esophagus and gastric side for 1–2 cm by blunt technique with cautious and very minimal use of energy devices.

After completion of myotomy, intraoperative endoscopy was performed under laparoscopic vision, to ensure the adequacy and length of myotomy on both esophageal and gastric sides with the free unrestricted easy passage of endoscope across the LES. The myotomy site was immersed in saline and air leakage test was performed by insufflation of endoscopic air with direct visualizations by laparoscopy. After confirmation of the adequacy of myotomy and ruling out perforations, anterior partial Dor's fundoplication was performed by suturing the fundus of the stomach to both edges of myotomy and crura of the diaphragm.

Postoperatively gastrografin dye swallow study was routinely performed after 24 h for ruling out any leak and to confirm the free passage of dye across LES. Oral diet was started and the patient was discharged subsequently once they recover. Patients were followed weekly for the 1st month, 3rd, 6th, 9th months, and 1 year after surgery and dysphagia grade and Eckardt score obtained.

All data values are expressed as mean ± SD. Comparisons between pre-operative and post-operative values of Eckardt score and variable parameters were analyzed by using paired sample *t*-test, $P < 0.05$ was considered statistically significant.

RESULTS

A total of 14 patients with achalasia cardia were included in this study with 10 females (71%) and 4 males (29%), respectively [Figure 1]. Patients were aged between 13 and 66 years with a mean of 37±14.96 [Figure 2]. Three patients had diabetes and one patient had idiopathic thrombocytopenic purpura (ITP) as comorbidity.

The total duration of symptoms ranged from 6 to 72 months with a mean of 26.43±16.57. The most common symptom was dysphagia 73 months, Takita's grade 2 in 4 cases (28.6%), 3 in 7 cases (50.0%), and 4 in 3 cases (21.4%), respectively, followed by regurgitation [Figure 3]. The mean modified Takita's dysphagia score was 2.93±0.73. Retrosternal pain was present in most of the patients. Weight loss was observed in all patients which ranged between 4 and 12 kg with a mean of 7.64±2.53 kg. Endoscopic classic findings and barium swallow bird beak sign were diagnostic in all cases [Figure 4]. Manometry was performed in all cases and Type 2 was present in 12 patients (85.72%) and Types 1 and 3 were present in one patients (7.14%) each. A contrast CT scan chest was done in 4 patients. The maximum diameter of esophagus ranged between 3.70 cm and 10.30 cm with mean value of 5.96±2 cm. The sigmoid esophagus was present in 4 cases

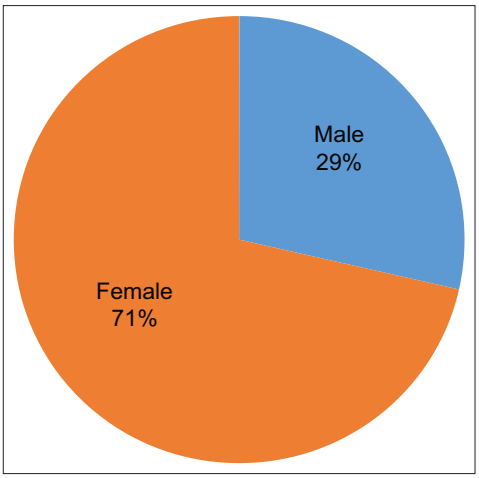


Figure 1: Distribution of gender

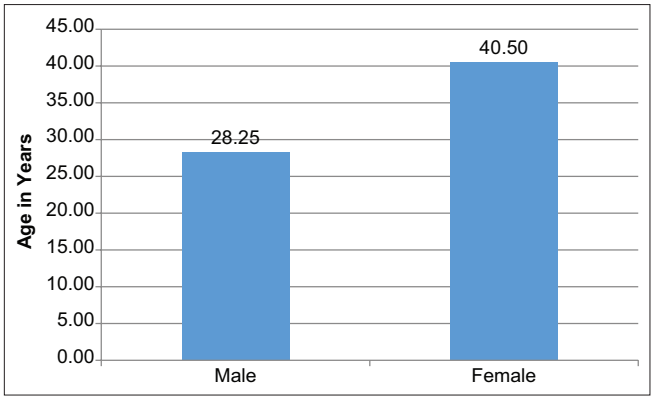


Figure 2: Distribution of age group

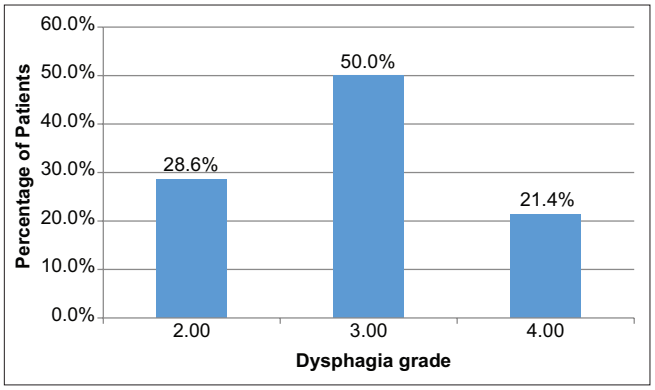


Figure 3: Distribution of dysphagia grade (Takita's)

(28.6%). Pre-operative Eckardt score ranged between 7 and 12 with mean value of 8.93±1.44.

All cases were performed by laparoscopic technique with no conversion. Intraoperative endoscopy was also performed in all cases to confirm the adequacy of myotomy and leak test was also done in all cases which were negative for any perforation. Extension of myotomy was needed in 5 cases (35.7%). Myotomy was extended on the gastric

Table 3: Distribution of study variables

Variables	Minimum	Maximum	Mean	Standard deviation
Age (years)	13.00	66.00	37.00	14.96
Duration of symptoms (months)	6.00	72.00	26.43	16.57
Weight loss (kg)	4.00	12.00	7.64	2.53
Maximum esophagus diameter (cm)	3.70	10.30	5.96	2.00
Duration of surgery (min)	90.00	150.00	111.07	19.53

side in 3 cases and esophageal side in 2 cases. All patients underwent anterior Dor's fundoplication without division of short gastric vessels and mobilization of fundus of the stomach. Drains were placed in all cases.

Duration of surgery ranged between 90 and 150 min with a mean of 111.07±19.53. The only intraoperative complication was bleeding that occurred in one patient with ITP which was controlled without any adverse effect [Table 3].

Post-operative hospital stay ranged between 3 and 7 days with a mean of 3.78±1.18. Gastrografin dye swallow study was done in all patients after 24 h, which confirmed free passage of contrast across the LES and did not reveal any leak [Figure 5]. Oral intake was resumed in all cases between post-operative days 2–5 with a mean of 2.42±0.85. Only one patient with ITP developed a small hematoma in the post-operative period which was managed conservatively without any adverse effect, but necessitated delayed oral intake with resultant delayed discharge on the 7th day. All patients were discharged after removal of drain, between 3 and 7 days with a mean value of 3.78±1.18.

Postoperatively, dysphagia improved to modified Takita's dysphagia grade 1 (able to eat normally) in all patients and the effect was observed until 12 months on follow-up. None of the patients had vomiting or weight loss in post-operative follow-up. Only one patient had occasional episodes of retrosternal pain during 3rd- and 6th-month review. Occasional episodes of regurgitation were observed in 5 patients in 3rd- and 6th-month follow-up (in those patients with extended myotomy). At 1 year follow-up, only 2 patients had occasional regurgitation and none of the patients had dysphagia, vomiting, retrosternal pain, or weight loss. The mean Eckardt scores were 0.43±0.51 at discharge and 0.21±0.43 at the 12th month. On statistical analysis, there was no significant statistical difference noted between 3rd and 6th, 9th, and 12th-month Eckardt scores [Figure 6].

On analysis, there was a significant improvement in pre-operative values of modified Takita's dysphagia grade and Eckardt score to normal values postoperatively ($P < 0.0001$)

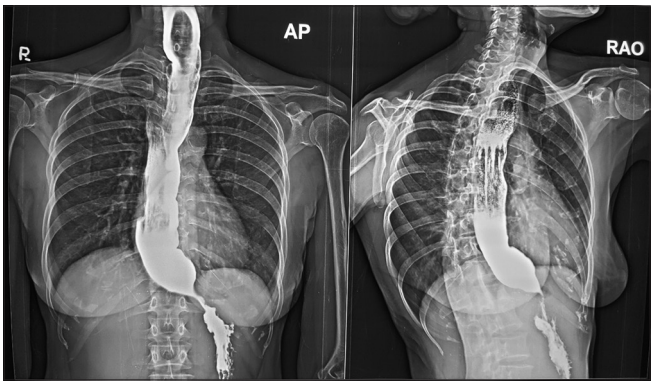


Figure 4: Pre-operative barium swallow

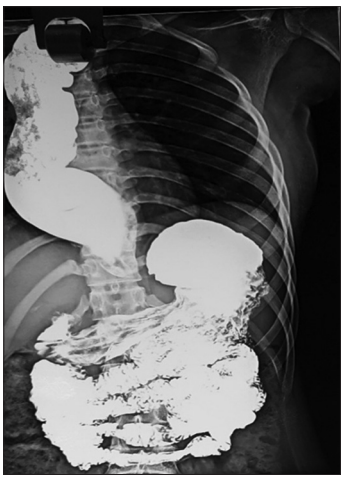


Figure 5: Post-operative swallow study

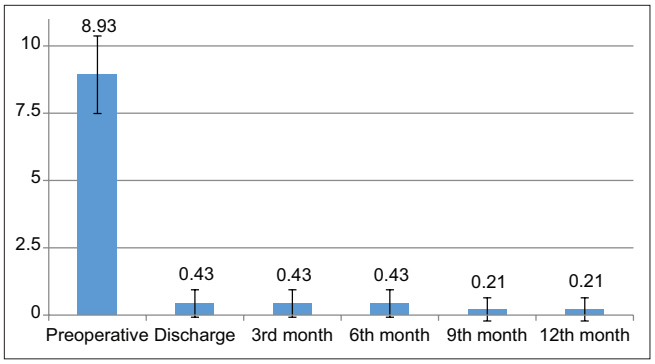


Figure 6: Distribution of Eckardt score

and the durable effect was persistently observed in 3rd and 6th, 9th, and 12th-month values.

DISCUSSION

Achalasia cardia is a rare motility disorder of the esophagus with specific clinical features and is diagnosed by classic endoscopic, barium swallow, and manometric findings. Symptoms were graded and classified as per Eckardt score. Treatment is mainly aimed at relieving the obstruction at hypertensive LES. Eckardt score is the best prognostic symptomatic assessment of functional recovery following intervention for Achalasia cardia.[8] A post-operative score of <3 is the goal for good functional outcomes which should be durable in the long term. A post-operative score of >9 indicated failure of the intervention.[8]

Of the available pharmacologic, endoscopic, and surgical treatment options – LHM is the gold standard intervention to treat this rare condition.[9] Heller's cardiomyotomy is done by dividing hypertensive lower esophageal and gastric muscle fibers. LHM has the advantages of minimally invasive surgery such as enhanced magnified vision, minimal pain, and early post-operative recovery.

For better symptomatic improvement, myotomy is done for at least 5 cm on esophageal aspect and extended myotomy is done in selective cases. The gastric aspect of myotomy is performed for at least 1–2 cm. Since myotomy is done under direct magnified laparoscopic vision, mucosal injuries can be detected intraoperatively and repaired immediately. Post-myotomy intraoperative endoscopy is done in all cases to confirm the adequacy of myotomy and an air leak test is also performed to detect microperforations and repaired immediately. Since limited esophageal mobilization was done only on the anterolateral aspect, anterior Dor's fundoplication is done in all cases to cover the myotomy site and to prevent reflux in the future.

Previous studies on achalasia cardia showed that LHM provides excellent symptomatic relief, with efficacy rates from 88% to 95% which lasts for 6–10 years.[10,11] It is recommended that the myotomy should extend for 4–5 cm in the distal esophagus and 2–3 cm into the gastric side.[12] Main intraoperative complication is esophageal perforation; in approximately 6.9% of patients, maybe repaired immediately during the surgery.[13,14] The most common post-operative side effect LHM is the development of reflux. Fundoplication can reduce the chance of developing GERD from 41.5% to 14.5%.[13] Both Dor and Toupet fundoplication is equally effective in reducing the GERD risk after LHM.[15]

Our present study included patients from all socioeconomic status and chronic symptoms of more than 6 months. All the patients were operated by a single surgeon at a single institute and uniform operative and post-operative protocol was followed in every patient. Sigmoid esophagus (end-stage achalasia) was present in 4 patients. Type 1 and Type 3 manometric types were present in one patient each. One patient had ITP which caused some intraoperative bleeding and was managed easily without any major complication.

Relief of dysphagia is the most important goal in the management of patients with achalasia, which is confirmed in our study [Figure 3]. All patients with a pre-operative Eckardt score of 7–12 had symptomatically improvement with a post-operative Eckardt score of 0–1, and the effect was persistent during follow-up up to 1 year which is statistically significant. The mean Eckardt scores significantly improved after LCM in all our patients. This successful effect was observed even in Type 1 and Type 3 manometric types. Our study also showed, even in four patients with end-stage sigmoid esophagus, LHM was safe and similarly effective in the long term.

Limitations of the Study

- Prospective observational study with no comparison
- Smaller sample size (rare disease)
- Non-randomized trial
- Shorter follow-up.

CONCLUSION

Achalasia cardia is a chronic esophageal motility disorder that impairs the patient's quality of life, work productivity, functional, and nutritional status. Laparoscopic Heller's cardiomyotomy is the gold standard surgical intervention of all the available interventions for primary achalasia cardia. Our present study confirmed the immediate safety and durable long-term benefits of LHM with intraoperative endoscopy and Dor's fundoplication. The same effect is observed even in Type 3 and severe cases with the sigmoid esophagus. A newer procedure like POEM is emerging as a safer alternative and its long-term effects should be compared with LHM in future studies.

REFERENCES

1. Sadowski DC, Ackah F, Jiang B, Svenson LW. Achalasia: Incidence, prevalence and survival. A population-based study. Neurogastroenterol Motil 2010;22:e256-61.
2. Fisichella PM, Raz D, Palazzo F, Niponmick I, Patti MG. Clinical, radiological, and manometric profile in 145 patients with untreated achalasia. World J Surg 2008;32:1974-9.
3. Panchanatheeswaran K, Parshad R, Rohila J, Saraya A, Makharia GK, Sharma R. Laparoscopic Heller's cardiomyotomy: A viable treatment option for sigmoid oesophagus. Interact Cardiovasc Thorac Surg 2013;16:49-54.

4. Peters JH, Meester TR, stein HJ. Surgical therapy for cancer of the esophagus and cardia. In: Castell DO, editor. The Esophagus. 2nd ed. New York: Little, Brown; 1995. p. 293-335.
5. Gockel I, Junginger T. The value of scoring achalasia: A comparison of current systems and the impact on treatment-the surgeon's viewpoint. Am Surg 2007;73:327-31.
6. Kahrilas PJ, Bredenoord AJ, Fox M, Gyawali CP, Roman S, Smout AJ, *et al*. The Chicago classification of esophageal motility disorders, v3.0. Neurogastroenterol Motil 2015;27:160-74.
7. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: Diagnosis and management of achalasia. Am J Gastroenterol 2013;108:1238-49.
8. Ren Y, Tang X, Chen Y, Chen F, Zou Y, Deng Z, *et al*. Pre-treatment Eckardt score is a simple factor for predicting one-year peroral endoscopic myotomy failure in patients with achalasia. Surg Endosc 2017;31:3234-41.
9. Youssef Y, Richards WO, Sharp K, Holzman M, Sekhar N, Kaiser J, *et al*. Relief of dysphagia after laparoscopic Heller myotomy improves long-term quality of life. J Gastrointest Surg 2007;11:309-13.
10. Boeckxstaens GE, Annese V, des Varannes SB, Chaussade S, Costantini M, Cuttitta A, *et al*. Pneumatic dilation versus laparoscopic Heller's myotomy for idiopathic achalasia. N Engl J Med 2011;364:1807-16.
11. Persson J, Johnsson E, Kostic S, Lundell L, Smedh U. Treatment of achalasia with laparoscopic myotomy or pneumatic dilatation: Long-term results of a prospective, randomized study. World J Surg 2015;39:713-20.
12. Triadafilopoulos G, Boeckxstaens GE, Gullo R, Patti MG, Pandolfino JE, Kahrilas PJ, *et al*. The Kagoshima consensus on esophageal achalasia. Dis Esophagus 2012;25:337-48.
13. Campos GM, Vittinghoff E, Rabl C, Takata M, Gadenstätter M, Lin F, *et al*. Endoscopic and surgical treatments for achalasia: A systematic review and meta-analysis. Ann Surg 2009;249:45-57.
14. Zaninotto G, Costantini M, Rizzetto C, Zanatta L, Guirroli E, Portale G, *et al*. Four hundred laparoscopic myotomies for esophageal achalasia: A single centre experience. Ann Surg 2008;248:986-93.
15. Rawlings A, Soper NJ, Oelschlager B, Swanstrom L, Matthews BD, Pellegrini C, *et al*. Laparoscopic dor versus toupet fundoplication following Heller myotomy for achalasia: Results of a multicenter, prospective, randomized-controlled trial. Surg Endosc 2012;26:18-26.

How to cite this article: Umamaheshwaran M, Shafique A, Selvasekaran R. Safety and Outcome of Laparoscopic Heller's Cardiomyotomy with Intraoperative Endoscopic Assessment and Dor's Fundoplication in Primary Achalasia Cardia: A Single Centre Prospective Study. Int J Sci Stud 2020;7(12):89-94.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Protection against Ultraviolet B Radiation-Induced Oxidative Damage by Antioxidants on Liver of Female Wistar rat

Payal Mahobiya

Assistant Professor, Department of Zoology, Dr. Harisingh Gour University, Sagar, Madhya Pradesh, India

Abstract

Introduction: Ultraviolet B (UVB) radiation exposures induced toxicity and generate oxidative stress on liver tissue and their alternative effect on biochemical process. Curcumin (Cur) and ascorbic acid (AA) act as a good antioxidant and shown the protective effect on animal tissue.

Materials and Methods: Twenty-four adult healthy female Wistar rats weighing 130–150 g were used. It is divided into four groups, the 1st group considers as control, the 2nd group considers as UVB treated, the 3rd group considers as UVB + Cur group, and the last 4th group considers as UVB + AA, exposure of radiation for 15 days.

Results: We found that UVB radiation shown on the female Wistar rat alteration on the animal body weight, liver weight, lipid peroxide, superoxide dismutase, and glutathione as compared to the control group.

Conclusion: It is concluded that UVB radiation shows the harmful effect on female Wistar rat and little preventive effect of Cur and AA.

Key words: Curcumin and ascorbic acid, Liver, Ultraviolet, Wistar rat

INTRODUCTION

Ultraviolet (UV) rays contain a band of electromagnetic radiations with wavelength from 200 nm to 400 nm. Being present in the sunlight, UV radiations are an important source of energy and have sufficient power to penetrate the body cells; consequently, the chemical and biological effects generated by these radiations have much greater than simple heating effects. Radiation emitted and transmitted through different sources are absorbed by the animal body tend to be a very high up environmental toxin. UV radiations have the potential to bear both positive and negative effects, thereby affecting the well-being of animals and humans. UV radiations are non-ionizing and are classified into three types, ultraviolet C (UVC), ultraviolet B (UVB), and ultraviolet A. UVC (200–280 nm, shortwave length) is lethal than UVB (280–320 nm, medium wavelength).[1-3] The liver's highly specialized tissues regulate a wide variety of high-volume biochemical reactions, including the synthesis and breakdown of small and complex molecules, many of which are necessary for normal vital functions.[4] When cells or tissues are exposed to radiation, the water molecules undergo dissociation (radiolysis) and produce free radicals and related species in the form of reactive oxygen species (ROS). These, in turn, can act on biomolecules such as DNA, lipids, and proteins and cause oxidative damage.[5,6] Acute effects mainly include hematopoietic cell loss, immune suppression, mucosal damage, and potential injury to the liver and other tissues. Because radiation-induced oxidative stress and tissue injury are attributed mainly to ROS[7] and structures, including DNA, lipids, proteins, and membranes,[8] these species also induced the cellular antioxidant defense enzymes such as superoxide dismutase (SOD), glutathione (GSH), and catalase.[9]

This study investigated the antioxidant role of curcumin (Cur) and ascorbic acid (AA) against UVB radiation-induced oxidative damage in liver tissue.

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. Payal Mahobiya, Department of Zoology, Dr. Harisingh Gour University, Sagar, Madhya Pradesh, India.

MATERIALS AND METHODS

Chemicals

AA was purchased from Sigma-Aldrich Co., USA, and Cur purchased from HiMedia and rests of the chemicals used were purchased from Central Drug House (P) Ltd., New Delhi.

UV Irradiation

UVB light (TL 20W/01 UVB Narrowband made in Germany), which emits UVB in the range of 280–320 nm (UVB), was used as the source to irradiate the Wistar rat. The irradiance was 2 h for 15 days.

Experimental Animals and Design

Female adult Wistar rat weighing 130–150 g was purchased from the College of Veterinary Sciences and Animal Husbandry, Mhow (22.55° N, 75.75° E, M.P), India. The ethical approval was given from the Department of Pharmaceutical Sciences, Dr. Harisingh Gour Vishwavidyalaya (A Central University) (Registration 379/CPCSEA/IAEC-2018/2017), Sagar (M.P.) (23.88° N, 78.73° E); international guidelines were followed for care and use of laboratory animals. All animals (n = 24) were housed in plastic cages and were fed on standard laboratory diet daily food and water *ad libitum*. Rats were kept on laboratory condition.

The experimental rats randomly divided into four groups. The experimental groups were administrated different doses as follows:

- Group I: (Control group) Normal food and water *ad libitum*
- Group II: (UVB-treated group) Received a dose of 280 nm of UVB radiation for 2 h for 15 days
- Group III: (UVB-treated group + Cur) UVB-treated group received a dose of Cur (25 mg/kg body weight [BW]) orally for 15 days
- Group IV: (UVB treated + AA) UVB-treated group received a dose of AA (250 mg/kg BW) orally for 15 days.

Sample Collection

After the last day of experiment, animals were sacrificed by cervical dislocation; liver was dissected out, washed in ice-cold phosphate buffer saline, and stored at −20°C for further analysis. All the procedures involving animals were conducted according to the requirements.

Measurement of BW and Liver Weight

BW measurement was performed before and after the experiment. Liver weight measurement was performed after the experiment. Both liver weight measurements were done with an electronic balance (Sartorius, BP210 S).

Tissue Homogenization

For the estimation of malondialdehyde (MDA) levels, lipid peroxide, SOD, and GSH, the liver tissues were first homogenized in 0.02 M tris(hydroxylmethyl)aminomethane hydrochloride (Tris-Cl) pH 7.4. After the preparation of 10% homogenate of each tissue, the samples were centrifuged at 1000 g for 30 min at 4°C. The supernatant was collected and stored at −20°C for further analysis. Protein estimation was performed according to the Lowry method.[10]

Estimation of MDA Levels

MDA assay was done for the detection of lipid peroxidation.[11] MDA is the end product of lipids after its peroxidation. One hundred microliters of tissue homogenate were incubated in 1 ml of 0.5 M Tris-maleate buffer (pH 5.9) in a water bath at 30°C for 30 min. After adding 1.5 ml of thiobarbituric acid, the mixture was incubated in a boiling water bath for 10 min using tight condensers. Then, it was allowed to cool and 3 ml pyridine:n-butanol mix (3:1 v/v) was added in it. Further, 1 ml of 1 N NaOH was added and rest for 10 min. The absorbance was noted at 548 nm. The level of lipid peroxidation was expressed in nmol MDA/mg protein.

Estimation of SOD

The activity of SOD was determined as photochemical inhibition of nitro blue tetrazolium (NBT) chloride. A reaction cocktail composing 2.25 mM methionine, 100 mM of phosphate buffer (pH 7.8), 2.25 mM NBT, 200 mM L-methionine, 1 M sodium carbonate, and 3 mM EDTA was prepared. A reaction cocktail was taken and 50 µl of tissue sample was added to the test tube. The reaction starts after adding 60 µM riboflavin. The reaction cocktail was illuminated in the presence of both light and dark, then absorbance was measured at 560 nm. Enzyme activity was expressed in unit/mg protein. One unit of enzyme is defined as the amount of 50% enzyme inhibiting the rate reaction.[12]

Estimation of GSH

GSH determination was performed immediately on the fresh homogenates using the spectrophotometric method described by Sedlak and Lindsay.[13] Briefly, 1 M Tris-cl, 2 mM 5, 5'-dithiobis-2-nitrobenzoic acid, and 50 mM sodium acetate mixture were added to the supernatant and incubated for 15–30 min at room temperature. The absorbance of the resulting yellow color was read against the blank at 412 nm.

Biochemical measurements were carried out at room temperature using a spectrophotometer.

Statistical Analysis

All statistical analyses were performed using one-way ANOVA. The data are expressed as mean ± standard deviation. Student's t-test was applied for comparison

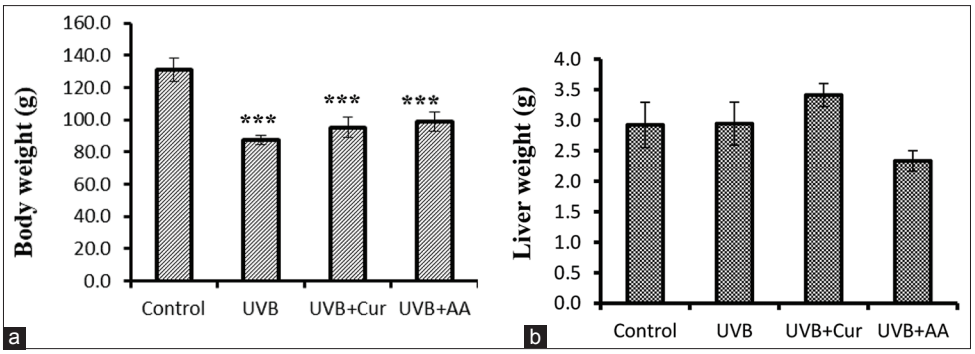


Figure 1: Effect of ultraviolet B radiation and both antioxidants administration on (a) body weight, (b) liver weight. Values are presented as mean ± standard error. ***$P < 0.001$ significance of difference from control

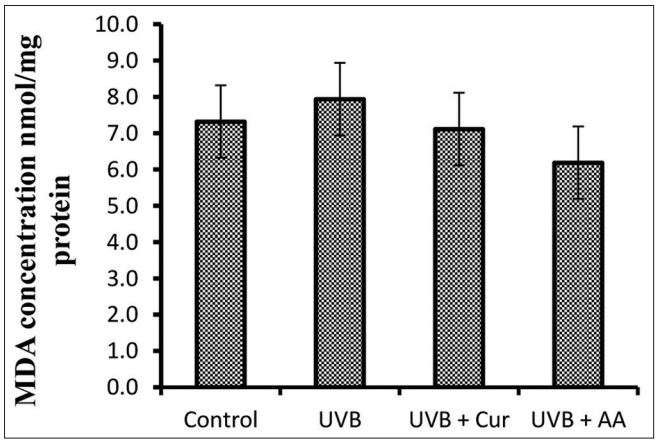


Figure 2: Effect of ultraviolet B (UVB) radiation and both antioxidants administration on the malondialdehyde (MDA) content. UVB-treated group shown significantly increases the MDA content in liver, while UVB + Curcumin and UVB + ascorbic acid group significantly decreased as compare to UVB-treated group. Values are presented as mean ± standard error

between control and each treated group individually. The level of significance at *$P < 0.05$, **$P < 0.01$, and P*** < 0.001 was considered statistically significant.

RESULTS

BW and Liver Weight

The BW of UVB-treated female Wistar rats shows a significant reduction in BW as compared to the control group. It was observed that Cur and AA treatment increase the BW significantly as compared to UVB, and there are significant differences as compare to the control group [Figure 1]. A significant decrease in the weight of liver was observed on UVB treatment in female Wistar rats, while a poorly significant increase was noted on antioxidants administration in both groups [Figure 1].

Lipid Peroxidation

The MDA values varied in the liver of the female Wistar rat under the stress of UVB treatment. The MDA concentration was significantly higher in the liver of the UVB-treated group as compared to control. UVB + Cur group exhibited a significant decrease of MDA concentration when compared to the control group [Figure 2].

SOD

The status of enzymatic antioxidants in liver of Wistar rat revealed that the specific activity of SOD in liver shows a significant decrease of $P < 0.05$ in UVB-treated groups as compared to control. The SOD activity shows a significant increase in UVB + Cur group and a decrease of $P < 0.05$ in UVB + AA group as compare to UVB-treated group [Figure 3].

GSH

GSH activity in liver shows a decrease in UVB-treated groups as compared to control. The GSH activity shows a significant increase in UVB + Cur group and UVB + AA group as compare to the control and UVB-treated group [Figure 4].

DISCUSSION

The results of the present study investigated that UVB irradiation caused tissue damage in the Wistar rat liver as manifest by increased MDA levels, decreased SOD, and GSH levels. The increase in MDA level in the irradiated group as compare to control group while the effect Cur and AA shown the significantly decrease as compare to irradiated group. In this discussion of the adverse effects, the major focus is on the effects on liver tissue. In addition, the possible protective effect Other reported that increased levels of lipid peroxidation in hepatic tissues as demonstrated by MDA levels, MDA is a good indicator of the degree of lipid peroxidation.[14] It has been reported that whole-body exposure of rats to high-energy radiation from Co-60 causes tissue damage in several organs as assessed by increased lipid peroxidation at 2, 12, and 72 h after irradiation.[15,16] Thus, radiation-induced damage might result in adverse health effects within hours to weeks, and delayed effects may be observable many months after

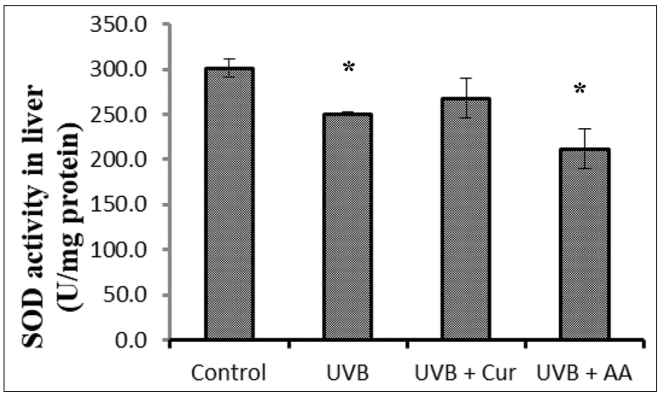


Figure 3: Effect of ultraviolet B (UVB) radiation and both antioxidants administration on the specific activity of superoxide dismutase (SOD). UVB radiation showed the significantly decreasing the SOD activity in liver. SOD activity is significantly lower in UVB + ascorbic acid than the UVB-treated group. Values are presented as mean ± standard error *$P < 0.05$, **$P < 0.01$, and ***$P < 0.001$

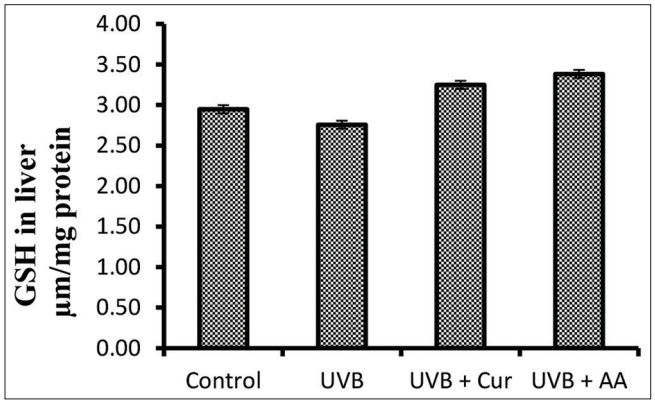


Figure 4: Effect of ultraviolet B (UVB) radiation and both antioxidants administration on the glutathione (GSH) activity. UVB radiation showed the significantly decreasing the GSH activity in liver. GSH activity is significantly higher in UVB + Curcumin and UVB + ascorbic acid as compare to the control and UVB-treated group

exposure.[17] In addition, there is evidence of an increase in the activity of antioxidant enzymes such as SOD and phospholipid hydroperoxide glutathione peroxidase and a decrease of MDA after precautions.[18,19]

CONCLUSION

The results obtained indicate that oxidative stress generated due to UVB radiation affects the biochemical parameters in Wistar rat. Cur and AA act as an antioxidant in reducing the oxidative stress and cure the liver tissues.

ACKNOWLEDGMENT

This study was supported by Dr. Harisingh Gour Central university, I am gratefully acknowledge the Department of Zoology, and the HOD for the great help for this study. There are no conflicts of interest in this study.

REFERENCES

1. De Laat A, Van Der Leun JC, De Gruijl FR. Carcinogenesis induced by UVA (365-nm) radiation: The dose-time dependence of tumor formation in hairless mice. Carcinogenesis 1997;18:1013-20.
2. Rai G, Kumar A, Mahobiya P. Effect of radiation on thyroid gland of Wistar rat. Int J Biol Res 2018;18:217-22.
3. Ferguson GW, Gehrmann WH, Chen TC, Dierenfeld ES, Holick MF. Effects of artificial ultraviolet light exposure on reproductive success of the female panther chameleon (*Furcifer pardalis*) in captivity. Zoo Biol 2002;21:525-37.
4. Anthea M, Hopkins J, McLaughlin CW, Johnson S, Warner MQ, Wright JD, *et al*. Human Biology and Health. Englewood Cliffs, New Jersey, USA: Prentice Hall; 1993.
5. Maurya DK, Devasagayam TP, Nair CK. Some novel approaches for radioprotection and the beneficial effect of natural products. Indian J Exp Biol 2006;44:93-114.
6. Olive PL. The role of DNA single-and double-strand breaks in cell killing by ionizing radiation. Radiat Res 1998;150:S42-51.
7. Gultekin FA, Bakkal BH, Guven B, Tasdoven I, Bektas S, Can M, *et al*. Effects of ozone oxidative preconditioning on radiation-induced organ damage in rats. J Radiat Res 2013;54:36-44.
8. Cadet J, Bellon S, Douki T, Frelon S, Gasparutto D, Muller E, *et al*. Radiation-induced DNA damage: Formation, measurement, and biochemical features. J Environ Pathol Toxicol Oncol 2004;23:33-43.
9. Zhang B, Su Y, Ai G, Wang Y, Wang T, Wang F. Involvement of peroxiredoxin I in protecting cells from radiation-induced death. J Radiat Res 2005;46:305-12.
10. Lowry OH, Rosebrough NJ, Farr AL, Randall RJ. Protein measurement with the folin phenol reagent. J Biol Chem 1951;193:265-75.
11. Placer ZA, Cushman LL, Johnson BC. Estimation of product of lipid peroxidation (malonyl dialdehyde) in biochemical system. Anal Biochem 1996;16:359-64.
12. Beauchamp C, Fridovich I. Superoxide dismutase: Improved assays and an assay applicable to acrylamide gels. Anal Biochem 1971;44:276-87.
13. Sedlak J, Lindsay RH. Estimation of total, protein-bound and non-protein sulfhydryl groups in tissue with ellman's reagent. Anal Biochem 1968;25:192-205.
14. Swantek JL, Tsen MF, Cobb MH, Thomas JA. IL-1 receptor associated kinase modulates host responsiveness to endotoxin. J Immunol 2000;164:4301-6.
15. Koc M, Taysi S, Buyukokuroglu ME, Bakan N. The effect of melatonin against oxidative damage during total-body irradiation in rats. Radiat Res 2003;160:251-5.
16. Koc M, Taysi S, Buyukokuroglu ME, Bakan N. Melatonin protects rat liver against irradiation-induced oxidative injury. J Radiat Res 2003;44:211-5.
17. Reiter RJ, Tan DX, Herman TS, Thomas CR Jr. Melatonin as a radioprotective agent: A review. Int J Radiat Oncol Biol Phys 2004;59:639-53.
18. Hernández F, Menéndez S, Wong R. Decrease of blood cholesterol and stimulation of antioxidative response in cardiopathy patients treated with endovenous ozone therapy. Free Radic Biol Med 1995;19:115-9.
19. Barber E, Menéndez S, León OS, Barber MO, Merino N, Calunga JL, *et al.* Prevention of renal injury after induction of ozone tolerance in rats submitted to warm ischemia. Mediators Inflamm 1999;8:37-41.

How to cite this article: Mahobiya P. Protection against Ultraviolet B Radiation-Induced Oxidative Damage by Antioxidants on Liver of Female Wistar rat. Int J Sci Stud 2020;7(12):95-98.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

A Prospective Study on Concurrent Chemoradiation in Inoperable Carcinomas Esophagus

S Vijayakumar

Associate Professor, Department of Radiotherapy, Thanjavur Medical College Hospital, Thanjavur, Tamil Nadu, India

Abstract

introduction: Despite many advances in both surgery and radiotherapy, the treatment of esophageal cancer remains a challenge for both surgeons and oncologists. The treatment of choice for patients with carcinoma esophagus is controversial. Recent studies have suggested that combined chemotherapy and radiation therapy may result in improved survival.

Aim: The aim of our study was to analyze the role of concurrent chemoradiation in inoperable carcinomas esophagus.

Materials and Methods: This single-arm prospective study was conducted in the Department of Radiotherapy, Thanjavur Medical College Hospital from August 2018 to August 2019 to analyze the role of concurrent chemoradiation in inoperable carcinomas esophagus. A total of 26 cases of inoperable cases of carcinoma esophagus were treated with once-weekly cisplatin 30 mg/ m^2 along with radiotherapy 60 Gy in 30 fractions in 6 weeks on telecobalt machine.

Results: Of 26 patients 16 patients were males, 10 patients were females, 17 patients had age <60 years, 9 patients had age above 61 years, 22 patients had squamous cell carcinoma, 4 patients had adenocarcinoma, 4 patients had lesion in upper part of esophagus, 14 patients had lesion in middle part, 8 patients had lesion in lower part, 4 patients had tumor dimension <5 cm, 22 patients had dimension >5.1 cm, 2 patients had tumor stage T1, 22 patients had T2, 2 patients had T3, 1 patient had Nx, 21 patients had No, 4 patients had N1, 15 patients had mild dysphagia, 8 patients had moderate dysphagia, 3 patients had severe dysphagia1 patients had diarrhea, 1 patient had fatigue, 4 patients had leukopenia, and 1 patient had neutropenia.

Conclusion: Combined modality therapy plays a significant role in the treatment of patients with carcinoma esophagus. Concurrent chemoradiation is a superior treatment in inoperable carcinoma esophagus in terms of local control and survival. Hence, concurrent chemoradiation can also be tried in early cases and surgical morbidity survival and quality of life can be improved.

Key words: Carcinoma esophagus, Cisplatin, Concurrent chemoradiation, Tele cobalt machine

INTRODUCTION

Cancer of the esophagus is a highly lethal malignancy, ranked as the 6th most common cause of cancer deaths worldwide. It is more common in men than women.[1] High-prevalence areas include Asia, southern and eastern Africa, and northern France.[2] The median survival is <10 months and <10% of patients survive for 5 years.

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Despite many advances in both surgery and radiotherapy, the treatment of esophageal cancer remains a challenge for both surgeons and oncologists. The treatment of choice for patients with carcinoma esophagus is controversial. Management of loco-regional esophageal cancer has undergone a major evolution over the past 25 years. Surgery has long been the standard of care; however, its role has been challenged due to the poor outcome in locally advanced disease. Recent studies have suggested that combined chemotherapy and radiation therapy (RT) may result in improved survival.

Currently, the standard non-surgical treatment of esophageal cancer is concurrent chemotherapy and radiotherapy with results comparable to the best surgical series. The seminal RT Oncology Group (RTOG 85-01)

Corresponding Author: S Vijayakumar, Department of Radiotherapy, Thanjavur Medical College Hospital, Thanjavur, Tamil Nadu, India.

trial demonstrated a survival benefit for the addition of cisplatin-based chemotherapy to RT in non-surgically treated patients.[3,4]

In the RTOG trial 5 years, overall survival in concurrent chemoradiation (cisplatin and 5-fluorouracil [FU] with radiation) group was 26% as compared to 0% in radiation alone group although a higher radiation dose of 64 Gy in 32 fractions was used in radiation alone group as compared to chemoradiation group (50 Gy in 25 fractions).

In the 5 study, in which 5-FU and mitomycin C were used along with radiotherapy 2- and 5-year survivals were 12% and 7% in radiation alone arm and 27% and 9% in chemoradiation arm. Patients treated in the chemoradiation arm had a longer median survival of 14.8 months versus 9.2 months in the radiation alone group.

MATERIALS AND METHODS

A single-arm prospective study of patients undergoes definitive chemoradiation treatment for locally advanced esophageal carcinoma at the Department of Radiotherapy, Thanjavur Medical College Hospital from August 2018 to August 2019 to analyze the role of concurrent chemoradiation in inoperable carcinomas esophagus under different study parameters such as type of carcinoma, site of involvement, stages of tumor involvement, stages of nodal involvement, degree of dysplasia, and tumor dimension. Inclusion criteria include histologically confirmed, potentially unresectable squamous cell carcinoma of the esophagus, Inoperable or locoregionally advanced disease, white blood cells (WBC) count >4000 cells/mL, and platelet count of >100,000 platelets/mL. Exclusion criteria include operable carcinoma esophagus, presence of tracheoesophageal fistula, WBC count <4000 cells/mL, and platelet count of <100,000 platelets/mL.

Staging, including contrast-enhanced computed tomography scan of thorax, abdomen, and upper gastrointestinal endoscopy and biopsy for histological confirmation will be done along with routine blood examinations. All patients will have to sign informed consent forms. Chemotherapy with cisplatin 30 mg/m^2 alone was given once in a week for a minimum 5–6 times concurrently with radiation. All the patients completed the chemotherapy schedule along with radiotherapy within time and none of the patients required dose reductions due to toxicity. Proper nutrition was maintained during treatment either through Ryle's tube feeding or orally or by intravenous route by parenteral nutrition given during chemotherapy. Patients were admitted only for 1 day every week for chemotherapy. During the treatment, a close observation was kept on the hematological, renal, and nutritional status of the patients and other toxicities were also noted. Radiotherapy was given on telecobalt machine to the total dose of 40 Gy/20 fractions in 4 weeks to the whole length of the esophagus with anteroposterior portals and then the fields were localized to tumor with 5 cm margins and spinal cord was spared using three fields and a boost dose of 20 Gy/10 fractions in 2 weeks was given totaling to 60 Gy in 30 fractions in 6 weeks. The patients will require to follow-up at 6 weeks from completion of therapy to assess response, toxicity, and disease status. Subsequent follow-up visits will be scheduled at 3 monthly. At follow-up, patients will undergo a thorough clinical examination for the detection of locoregional disease. Patients who drop out or do not complete the planned course of treatment will be excluded and the results were statistically analyzed and discussed.

RESULTS

Of 26 patients, 16 patients were males, 10 patients were females [Table 1].

Of 26 patients, 17 patients had age <60 years, 9 patients had age above 61 years [Table 2].

Of 26 patients, 22 patients had squamous cell carcinoma, 4 patients had adenocarcinoma [Table 3].

Of 26 patients, 4 patients had lesion in upper part of esophagus, 14 patients had lesion in middle part, and 8 patients had lesion in lower part [Table 4].

Of 26 patients, 4 patients had tumor dimension <5 cm, 22 patients had dimension >5.1 cm [Table 5].

Of 26 patients, 2 patients had tumor stage T_1, 22 patients had T_2, and 2 patients had T_3 [Table 6].

Of 26 patients, 1 patients had N_x, 21 patients had N_o, and 4 patients had N_1 [Table 7].

Of 26 patients, 15 patients had mild dysphagia, 8 patients had moderate dysphagia, and 3 patients had severe dysphagia [Table 8].

Of 26 patients, 1 patient had diarrhea, 1 patient had fatigue, 4 patients had leukopenia, and 1 patient had neutropenia [Table 9].

DISCUSSION

Esophageal cancer is usually associated with a poor prognosis due to a high local recurrence rate or distant metastasis.[6] Although surgery alone or chemoradiotherapy has been widely accepted as the standard treatment

Table 1: Cross-tabulation sex distribution

Sex	No. of patients
Male	16
Female	10

Table 2: Cross-tabulation between age distribution

Age (years)	No. of patients
<60	17
>61	9

Table 3: Cross-tabulation between types of tumor

Type of tumor	No. of patients
Squamous cell carcinoma	22
Adenocarcinoma	4

Table 4: Cross-tabulation between tumor location in esophagus

Tumor location in esophagus	No. of patients
Upper part	4
Middle part	14
Lower part	8

Table 5: Cross-tabulation between tumor dimensions

Tumor dimensions (cm)	No. of patients
<5	4
>5.1	22

for esophageal cancer, the 5-year survival rate is only 20–30%.[7,8]

It is well known that radiotherapy can cause numerous complications, including radiation esophagitis, radiation pneumonitis, and anorexia.[9,10] During radiotherapy, dysphagia of patients may become aggravated due to radiation edema of the esophagus, which induces a feeding disturbance. Patients who have undergone esophagostomy also suffer from continual problems associated with the functional domains and specific symptoms.

Anderson *et al.*[11] used 5-FU and mitomycin C in concurrent chemoradiation group and found a median overall survival of 35 months and a 2 years' survival of 64%. Sischy *et al.*[12] treated 135 patients with 5-FU and mitomycin C and 40 Gy radiotherapy or radiotherapy alone. The median survival for the multimodality group was significantly longer at 14 months than 9 months for radiotherapy alone.

Table 6: Cross-tabulation between tumor stages

Tumor stages	No. of patients
T1	2
T2	22
T3	2

Table 7: Cross-tabulation between nodal involvement

Nodal involvement	No. of patients
N_X	1
N_0	21
N_1	4

Table 8: Cross-tabulation between degree of dysphagia

Degree of dysphagia	No. of patients
Mild	15
Moderate	8
Severe	3

Table 9: Cross-tabulation between toxicity

Toxicity	No. of patients
Diarrhea	1
Fatigue	1
Leucopenia	4
Neutropenia	1

Herskovic *et al.*[3] randomized 121 potentially curable patients to 64 Gy radiation alone or 50 Gy concurrent with two courses of cisplatin and 5-FU. Long-term follow-up confirms a 3-year survival of 30% versus 0% favoring multimodal therapy.[4] These trials support concurrent chemotherapy and radiotherapy over radiotherapy alone.

Comparing our study with all others in the literature, we found lower toxicity and almost similar control and mean survival rates. Further, studies with a large number of patients are required to establish that low-dose cisplatin alone used once weekly along with radiotherapy can give similar results with less toxicities and can be well-tolerated by the patients.

CONCLUSION

Combined modality therapy plays a significant role in the treatment of patients with carcinoma esophagus. Concurrent chemotherapy with weekly cisplatin alone gives similar results to cisplatin and 5-FU or 5-FU and mitomycin C as used in other studies with lesser toxicities. Concurrent chemoradiation is a superior treatment in inoperable carcinoma esophagus in terms of local control

and survival. This implies that surgical and non-surgical therapy may be equivalent, especially considering that patients treated with combined modality therapy generally have more advanced disease and are less medically fit than patients who are treated with surgery alone.

REFERENCES

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2015. CA Cancer J Clin 2015;65:5-29.
2. Pickens A, Orringer MB. Geographical distribution and racial disparity in esophageal cancer. Ann Thorac Surg 2003;76:S1367-9.
3. Herskovic A, Martz K, Al-Sarraf M, Leichman L, Brindle J, Vaitkevicius V, *et al*. Combined chemotherapy and radiotherapy compared with radiotherapy alone in patients with cancer of the esophagus. N Engl J Med 1992;326:1593-8.
4. Cooper JS, Guo MD, Herskovic A, Macdonald JS, Martenson JA Jr., Al-Sarraf M, *et al*. Chemoradiotherapy of locally advanced esophageal cancer: Long-term follow-up of a prospective randomized trial (RTOG 85-01). Radiation therapy oncology group. JAMA 1999;281:1623-7.
5. Smith TJ, Ryan LM, Douglass HO Jr., Haller DG, Dayal Y, Kirkwood J, *et al*. Combined chemoradiotherapy vs. radiotherapy alone for early stage squamous cell carcinoma of the esophagus: A study of the Eastern cooperative oncology group. Int J Radiat Oncol Biol Phys 1998;42:269-76.
6. Chiu PW, Chan AC, Leung SF, Leong HT, Kwong KH, Li MK, *et al*. Multicenter prospective randomized trial comparing standard esophagectomy with chemoradiotherapy for treatment of squamous esophageal cancer: Early results from the Chinese university research group for esophageal cancer (CURE). J Gastrointestinal Surg 2005;9:794-802.
7. Ando N, Ozawa S, Kitagawa Y, Shinozawa Y, Kitajima M. Improvement in the results of surgical treatment of advanced squamous esophageal carcinoma during 15 consecutive years. Ann Surg 2000;232:225-32.
8. Wilson KS, Lim JT. Primary chemo-radiotherapy and selective oesophagectomy for oesophageal cancer: Goal of cure with organ preservation. Radiother Oncol 2000;54:129-34.
9. Yap JC, Malhotra HK, Yang GY. Intensity modulated radiation therapy in the treatment of esophageal cancer. Thorac Cancer 2010;1:62-9.
10. Lagergren P, Avery KN, Hughes R, Barham CP, Alderson D, Falk SJ, *et al*. Health-related quality of life among patients cured by surgery for esophageal cancer. Cancer 2007;110:686-93.
11. Anderson SE, Minsky BD, Bains M, Hummer A, Kelsen D, Ilson DH. Combined modality chemoradiation in elderly oesophageal cancer patients. Br J Cancer 2007;96:1823-7.
12. Sischy B, Ryan L, Haller DG. Interim report of EST 1282 phase III protocol for the evaluation of combined modalities in the treatment of patients with carcinoma of the esophagus stage I & II. Proc Am Soc Clin Oncol 1990;9:105.

How to cite this article: Vijayakumar S. A Prospective Study on Concurrent Chemoradiation in Inoperable Carcinomas Esophagus. Int J Sci Stud 2020;7(12):99-102.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparison of Bipolar Vessel Sealing System versus Suture Ligation in Selective Neck Dissection in Patients with Oral Cancer

R Balasubramaniam[1], P Senthil Kumar[2]

[1]Associate Professor, Department of Surgical Oncology, KAPV Government Medical College and Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, Tamil Nadu, India, [2]Assistant Professor, Department of Surgical Oncology, KAPV Government Medical College and Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, Tamil Nadu, India

Abstract

Introduction: Major head and neck surgery involve dissections close to crucial structures such as nerves and vessels. For this reason, it is very important to use safe instruments for dissection and hemostasis. In a wide variety of surgical procedures, advanced vessel sealing devices are replacing traditional techniques for vessel ligation.

Aim: Our study aimed to compare the bipolar vessel sealing system versus suture ligation in selective neck dissection in patients with oral cancer.

Methods: This prospective comparative study was conducted to compare the outcome of the bipolar vessel sealing system versus suture ligation in selective neck dissection in patients with oral cancer. Out of 40 patients enrolled in the study, 20 patients were in Group A (bipolar vessel sealing system) and 20 patients in Group B (Suture ligation). The outcome measures recorded were blood loss, operating time, duration of hospital stay, pre-operative blood transfusion, Fromme's surgical field scale, post-operative pain, and drainage volume. Treatment protocol and follow-up protocol were followed and the results were statistically analyzed and discussed.

Results: Out of 40 patients, 20 patients had bipolar vessel sealing system and 20 patients had suture ligation. In bipolar vessel sealing system of 20 patients, 12 patients were male and 8 patients were female, mean value of blood loss is 26.84 ± 22.34 ml, operating time is 48.56 ± 5.48 min, duration of hospital stay is 12.92 ± 1.28 days, mean value of post-operative pain in day 0 is 3.5 ± 1, day 1 is 3.1 ± 1, day 2 is 1.8 ± 0.5, and day 3 is 1.1 ± 0.5, and drainage volume (ml) in 24 h is 72.48 ± 28.46, 48 h is 24.57 ± 18.29, and 72 h is 7.24 ± 6.7. In suture ligation of 20 patients, 15 patients were male and 5 patients were female, mean value of blood loss is 39.28 ± 16.44 ml, operating time is 54.22 ± 4.14 min, duration of hospital stay is 13.87 ± 1.42 days, mean value of post-operative pain in day 0 is 4.01 ± 0.9, day 1 is 3.8 ± 1.1, day 2 is 2.4 ± 0.6, and day 3 is 1.6 ± 0.8, and drainage volume (ml) in 24 h is 98.28 ± 36.87, 48 h is 41.28 ± 21.24, and 72 h is 18.29 ± 9.45.

Conclusion: Bipolar vessel sealing system is more efficacious in terms of reducing blood loss, operating time, and better surgical field than conventional suture ligation. Thus, bipolar vessel sealing system is more advantageous compared to the traditional techniques, from both a clinical and economic point of view.

Key words: Bipolar vessel sealing system, Selective neck dissection, Suture ligation

INTRODUCTION

Prevention of blood loss during surgery is very significant and thus minimizing the intraoperative bleeding which not only provides a clear surgical field, reducing the risk of damage to vital structures but also helps in decreasing pre-operative complications such as hemorrhage or hematoma.

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

The use of suture ligation to achieve hemostasis continues to remain the gold standard in surgery despite having many disadvantages such as being time-consuming, risk of knot slippage, inflammation, poor wound healing, and foreign body reactions.[1] However, it is very difficult to use in the smaller fragile vessels. Electrocautery and conventional diathermy require cautious use as they may cause inadvertent thermal damage to the adjacent tissues.[2] Conventional

Corresponding Author: P Senthil Kumar, Department of Surgical Oncology, KAPV Government Medical College and Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, Tamil Nadu, India.

bipolar diathermies, although safer than monopolar, are effective only for vessels of smaller size.[2] These drawbacks have led to the development of new techniques such as ultrasonic scalpels and electrothermal bipolar vessel sealer (EBVS). These technologies have reported advantages such as time-saving and reduction in blood loss.

An EBVS has been developed as an alternative to suture ligatures, hemoclips, staplers, and ultrasonic coagulator for ligating vessels and tissue bundles. The instrument seals vessels up to 7 mm in diameter by denaturing collagen and elastin within the vessel wall and surrounding connective tissue. This novel hemostatic device is a safe, effective, and time-saving alternative to other methods for surgical hemostasis in different surgical operations. The EBVS utilizes a combination of mechanical pressure and high-frequency electrical energy to bring about hemostasis.[3,4] The thermal injury from EBVS is limited to <1.5–3 mm from the coagulated tissues.[2,4-6]

MATERIALS AND METHODS

This prospective comparative study was conducted to compare the outcome of the bipolar vessel sealing system versus suture ligation in selective neck dissection in patients with oral cancer under different study parameters such as age, blood loss, operating time, duration of hospital stay, pre-operative blood transfusion, drainage volume, post-operative pain, and Fromme's surgical field scale.

The study population consisted of patients with oral cancer CT1No, CT2No who reported to our department. Informed consent was obtained from all the patients before inclusion in the study. Adults above the age of 18 years with the American Society of Anesthesiologists physical status of classes I and II were included in the study. Patients below 18 years of age and those with comorbidities such as diabetes and bleeding disorders, pregnancy, previous surgery, or neck irradiation were excluded from the study.

A total of 40 patients were divided into Group A and Group B of 20 patients, each using computer-generated randomization. In Group I, bipolar vessel sealing system and in Group II suture ligation were used for achieving hemostasis. Conventional monopolar and bipolar diathermy was used for smaller blood vessels (<2 mm in diameter) in both groups.

All the procedures were performed under general anesthesia by the same surgical team to avoid any inter-operator bias. The standard protocol for selective neck dissection was followed. Level I, II, and III cervical lymph nodes along with the submandibular salivary gland were dissected Level IV cervical lymph was also removed in tongue subsite only. The various structures sealed or ligated included the facial artery and veins, submandibular duct, superior thyroid vein, external jugular vein, and common facial vein.

In Group A (n = 20), the bipolar vessel sealing system was used to ligate the vessels or structures (up to 7 mm in diameter), thinner tissues or vessels, one seal was performed, and for larger vessels, the double seal technique was used. Bipolar vessel sealing system was first applied distally, closer to the structures to be removed and then 3–4 mm proximally. Surgical clips or any other hemostatic aids were not used in either group. In Group B (n = 20), 2–0 silk/vicryl was used to ligated the vessels using the conventional knot-tying technique.

RESULTS

Of 40 patients, 20 patients had bipolar vessel sealing system and 20 patients had suture ligation. In bipolar vessel sealing system of 20 patients, 12 patients were male and 8 patients were female, and in suture ligation, 15 patients were male and 5 patients were female [Table 1].

Of 40 patients, the mean age group in the bipolar vessel sealing system is 54.23 ± 14.28, and in conventional suture, ligation is 49.44 ± 12.56 [Table 2].

Of 40 patients, in bipolar vessel sealing system mean value of blood loss is 26.84 ± 22.34 ml, operating time is 48.56 ± 5.48 min, and duration of hospital stay is 12.92 ± 1.28 days, and in conventional suture ligation mean value of blood loss is 39.28 ± 16.44 ml, operating time is 54.22 ± 4.14 min, ad duration of hospital stay is 13.87 ± 1.42 days [Table 3].

Table 1: Sex distribution between the two groups

Gender	BVS	Conventional
Male	12	15
Female	8	5

Table 2: Age distribution between the two groups

Age	BVS	Conventional
Mean±SD	54.23±14.28	49.44±12.56

Table 3: Blood loss, time for neck dissection, and duration of hospital stay between two groups

Variables	BVS	Conventional
Blood loss (ml)	26.84±22.34	39.28±16.44
Time for neck dissection (min)	48.56±5.48	54.22±4.14
Duration of hospital stay (days)	12.92±1.28	13.87±1.42

Of 40 patients, 8 patients in the bipolar vessel sealing system had a pre-operative blood transfusion, and in conventional suture ligation, 9 patients had pre-operative blood transfusion [Table 4].

Of 40 patients, in bipolar vessel sealing system Fromme's surgical field scale 0 is 3.5, 1 is 49.44, 2 is 30.48, 3 is 16.29, 4 is 3.5, and 5 is 0, and in conventional suture ligation system Fromme's surgical field scale 0 is 3.5, 1 is 11.24, 2 is 18.44, 3 is 48.57, 4 is 18.44, and 5 is 0 [Table 5].

Of 40 patients, in bipolar vessel sealing system mean value of post-operative pain in day 0 is 3.5 ± 1, day 1 is 3.1 ± 1, day 2 is 1.8 ± 0.5, and day 3 is 1.1 ± 0.5 and in conventional suture ligation mean value of post-operative pain in day 0 is 4.01 ± 0.9, day 1 is 3.8 ± 1.1, day 2 is 2.4 ± 0.6, and day 3 is 1.6 ± 0.8 [Table 6].

Of 40 patients, in bipolar vessel sealing system drainage volume in 24 h is72.48 ± 28.46, 48 h is 24.57 ± 18.29, and 72 h is 7.24 ± 6.7, and in conventional suture ligation drainage volume in 24 h is 98.28 ± 36.87, 48 h is 41.28 ± 21.24, and 72 h is 18.29 ± 9.45 [Table 7]. There was no rebleeding and mortality in both groups.

DISCUSSION

The bipolar vessel sealing system has been hypothesized as an alternative to suture ligation with advantages of reduced blood loss, operating time, and better perioperative outcomes. We evaluated the system in terms of blood loss, operating time, quality of the surgical field, post-operative pain, and duration of hospital stay.

Our results showed that the bipolar vessel sealing system was advantageous in reducing blood loss and operating time, providing a better surgical field, without increasing the perioperative morbidities when compared to suture ligation in selective neck dissection.

In our study, the blood loss during neck dissection in Group A was significantly less than in Group B. Several other authors have reported significantly less blood loss for the bipolar vessel sealing system compared to suture ligation.[7-9] Thus, it is statistically significant.

In our study, the operating time for neck dissection is reduced in Group A compared to Group B which is similar to several other studies.[7-12] Thus, it is statistically significant.

In our study, the quality of the surgical field was significantly better in Group A than in Group B which was obviously due to less intraoperative bleeding with the bipolar vessel sealing system. Thus, it is statistically significant.

In our study, post-operative pain score was low in Group A compared to Group B which is similar to other studies. Thus, it is statistically significant.

In our study, drainage volume in Group A is low compared to Group B which is similar to other studies.[10] Thus, it is statistically significant.

Most studies that have compared the hospitalization time reported no significant difference between the two groups, similar to our findings.[12-15]

In our experience, the vessel sealing system was easy to use without any technical difficulties and had a short learning curve. It is less time-consuming and tedious than suture ligation and does not have the risk of knot slippage and foreign body reaction. The reduction in blood loss is especially useful for patients presenting with advanced stages of the disease, often associated with anemia. Although the device is expensive, it can

Table 4: Pre-operative blood transfusion between the two groups

Pre-operative blood transfusion	BVS	Conventional
Yes	8	9

Table 5: Fromme's surgical field scale between the two groups

Fromme's surgical field scale	BVS	Conventional
0	3.5	3.5
1	49.44	11.24
2	30.48	18.44
3	16.29	48.57
4	3.5	18.44
5	0	0

Table 6: Post-operative pain between the two groups

Pain	BVS	Conventional
Post-operative day 0	3.5±1	4.01±0.9
Post-operative day 1	3.1±1	3.8±1.1
Post-operative day 2	1.8±0.5	2.4±0.6
Post-operative day 3	1.1±0.5	1.6±0.8

Table 7: Drainage volume between the two groups

Drainage volume (h)	BVS	Conventional
24	72.48±28.46	98.28±36.87
48	24.57±18.29	41.28±21.24
72	7.24±6.7	18.29±9.45

be reused, in contrast to standard diathermy which is disposable, thus being more cost-effective. Another drawback is the size of the tip of the instrument which has poor grasping qualities compared to standard bipolar forceps. It may sometimes feel cumbersome while dissection and is not suitable for coagulating smaller vessels for which the standard monopolar or bipolar cautery is needed.

CONCLUSION

The bipolar vessel sealing system is a safe device for achieving hemostasis in neck dissection procedures. It significantly reduced operating time and blood loss, providing a better surgical field without increasing the perioperative complications or morbidity. Patient compliance was better in terms of reducing post-operative pain compared to the suture ligation. Thus, we recommend the use of the EBVS for neck dissection procedures.

REFERENCES

1. Manouras A, Markogiannakis HE, Kekis PB, Lagoudianakis EE, Fleming B. Novel hemostatic devices in thyroid surgery: Electrothermal bipolar vessel sealing system and harmonic scalpel. Expert Rev Med Devices 2008;5:447- 66.
2. Landman J, Kerbl K, Rehman J, Andreoni C, Humphrey PA, Collyer W, *et al*. Evaluation of a vessel sealing system, bipolar electrosurgery, harmonic scalpel, titanium clips, endoscopic gastrointestinal anastomosis vascular staples and sutures for arterial and venous ligation in a porcine model. J Urol 2003;169:697-700.
3. Heniford BT, Matthews BD, Sing RF, Backus C, Pratt B, Greene FL. Initial results with an electrothermal bipolar vessel sealer. Surg Endosc 2001;15:799-801.
4. Harold KL, Pollinger H, Matthews BD, Kercher KW, Sing RF, Heniford BT. Comparison of ultrasonic energy, bipolar thermal energy, and vascular clips for the hemostasis of small-, medium-, and large-sized arteries. Surg Endosc 2003;17:1228-30.
5. Kennedy JS, Stranahan PL, Taylor KD, Chandler JG. High-burst-strength, feedback-controlled bipolar vessel sealing. Surg Endosc 1998;12:876-8.
6. Campbell PA, Cresswell AB, Frank TG, Cuschieri A. Real-time thermography during energized vessel sealing and dissection. Surg Endosc 2003;17:1640-5.
7. Janssen PF, Brölmann HA, Huirne JA. Effectiveness of electrothermal bipolar vessel-sealing devices versus other electrothermal and ultrasonic devices for abdominal surgical hemostasis: A systematic review. Surg Endosc 2012;26:2892-901.
8. Yao HS, Wang Q, Wang WJ, Ruan CP. Prospective clinical trials of thyroidectomy with LigaSure vs conventional vessel ligation: A systematic review and meta-analysis. Arch Surg 2009;144:1167-74.
9. Tan EK, Cornish J, Darzi AW, Papagrigoriadis S, Tekkis PP. Meta-analysis of short-term outcomes of randomized controlled trials of LigaSure vs conventional hemorrhoidectomy. Arch Surg 2007;142:1209-18.
10. Petrakis IE, Kogerakis NE, Lasithiotakis KG, Vrachassotakis N, Chalkiadakis GE. LigaSure versus clamp-and-tie thyroidectomy for benign nodular disease. Head Neck 2004;26:903-9.
11. Ozturk K, Kaya I, Turhal G, Ozturk A, Gursan G, Akyildiz S. A comparison of electrothermal bipolar vessel sealing system and electrocautery in selective neck dissection. Euro Arch Otorhinolaryngol 2016;273:3835-8.
12. Saint Marc O, Cogliandolo A, Piquard A, Famà F, Pidoto RR. LigaSure vs clamp-and-tie technique to achieve hemostasis in total thyroidectomy for benign multinodular goiter: A prospective randomized study. Arch Surg 2007;142:150-6.
13. Youssef T, Mahdy T, Farid M, Latif AA. Thyroid surgery: Use of the LigaSure vessel sealing system versus conventional knot tying. Int J Surg 2008;6:323-7.
14. Manouras A, Markogiannakis H, Koutras AS, Antonakis PT, Drimousis P, Lagoudianakis EE, *et al*. Thyroid surgery: Comparison between the electrothermal bipolar vessel sealing system, harmonic scalpel, and classic suture ligation. Am J Surg 2008;195:48-52.
15. Franko J, Kish KJ, Pezzi CM, Pak H, Kukora JS. Safely increasing the efficiency of thyroidectomy using a new bipolar electrosealing device (LigaSure) versus conventional clamp-and-tie technique. Am Surg 2006;72:132-6.

How to cite this article: Balasubramaniam R, Kumar PS. Comparison of Bipolar Vessel Sealing System versus Suture Ligation in Selective Neck Dissection in Patients with Oral Cancer. Int J Sci Stud 2020;7(12):103-106.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Versatility of Forehead Flap in Maxillofacial/Nasal and Intraoral Defects: A Retrospective Analysis

R Balasubramaniam[1], P Senthil Kumar[2]

[1]Associate Professor, Department of Surgical Oncology, KAPV Government Medical College and Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, Tamil Nadu, India, [2]Assistant Professor, Department of Surgical Oncology, KAPV Government Medical College and Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, Tamil Nadu, India

Abstract

Introduction: Difficulties to find the ideal donor site with perfect matching tissues have always made the reconstruction of facial complex defect a tough problem for surgeons. The main aim of reconstruction is to restore facial contour (esthetics) and function (mastication, deglutition, and speech).

Aim: The aim of the study was to analyze the versatility of forehead flap in maxillofacial/nasal and intraoral defects.

Materials and Methods: This retrospective study was conducted to analyze the versatility of forehead flap in maxillofacial/nasal and intraoral defects. A total of 25 consecutive patients, of either sex, who required soft tissue reconstruction of the maxillofacial region, including oral cavity and nasal defects due to tumor ablative surgery. Follow-up was done for up to 4 months – 1 year and on every follow-up visit, patients were questioned about the degree of satisfaction, with mouth opening, swallowing, and donor site esthetics. Cosmetic deformity judged subjectively.

Results: Of 25 patients, 17 patients were males, 12 patients were above 60 years. Maximum number of site of tumor involvement was noted in cheek 9 patients (36%) and in lower lip 5 patients (20%). About 44% patient had stage 2 tumors and 28% had stage 3 tumors. About 18 patient had adjuvant radiation, 1 patients had chemo RT, and 6 patients had no adjuvant treatment. About 16% of patients had a complication of altered forehead sensation.

Conclusion: Forehead flap is a reliable technique for the reconstruction of maxillofacial region defects. It is easy to rise and can provide coverage for wide defects as far as the para mandibular and submandibular regions. Moreover, it does not require patient repositioning.

Key words: Forehead flap, Orofacial, Reconstruction, Soft tissue defect

INTRODUCTION

Difficulties to find the ideal donor site with perfect matching tissues have always made the reconstruction of facial complex defect a tough problem for surgeons. The main aim of reconstruction is to restore facial contour (esthetics) and function (mastication, deglutition, and speech). Reconstruction of jaw and mouth defects represents a challenge to the surgeon.[1-5] These options include healing by secondary intention, primary closure, skin grafting, use of locoregional flaps (with or without tissue expansion), and free flap transfer. Recently, however, the reconstructive escalator or elevator approach has been advocated, because reconstruction should be individualized to each patient and not based on a rigid, stepwise approach.[6]

The use of orofacial prostheses has also contributed significantly to the restoration of an acceptable functional and esthetic status for patients following soft tissue defects.[7] Although each of these reconstructive options achieves different degrees of functional, esthetic, and psychological rehabilitation for patients, they have various advantages and disadvantages. The site, size, and shape of the defect and the medical history determine the choice of these flaps.

Access this article online

www.ijss-sn.com

Month of Submission : 01-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

Corresponding Author: Dr. P Senthil Kumar, Department of Surgical Oncology, KAPV Government Medical College and Mahatma Gandhi Memorial Government Hospital, Tiruchirappalli, Tamil Nadu, India.

When local flaps and grafts are inadequate, the forehead is a dependable option due to its reliability and anatomic likeness. The forehead flap is acknowledged as the best donor site for the nose and other facial part reconstruction due to its ideal color and texture. Reliability of success of this flap is a major advantage which comes from the adequate blood supply and local availability of feeder vessels, i.e., superficial temporal vessels and arcade formed from other vessels even though ligated and is a reason of its popularity.[8]

However, free flaps are technique-sensitive, usually require good blood vessels at the recipient site, increase operation time, require extensive post-operative monitoring, and may be contraindicated in some patients with comorbid conditions.[9,10] Locoregional flaps reduce vulnerability to infection and thrombosis, are easier to raise and transfer compared to free flaps, and can provide an excellent color match. The limited reach of locoregional flaps, difficulty in achieving three-dimensional reconstruction or coverage of extensive tissue defects, and the occasional need for a multistage procedure are some of their limitations.[11]

Aim

The aim of the study was to analyze the versatility of forehead flap in maxillofacial/nasal and intraoral defects.

MATERIALS AND METHODS

This retrospective study was conducted to analyze the versatility of forehead flap in maxillofacial/nasal and intraoral defects under different study parameters such as age, sex, site, stages of tumor involvement, previous management, primary management, type of reconstruction, and complications. Inclusion criteria include all the cases diagnosed with oral and nose malignancy and subjected to relevant investigations and underwent surgery were included in the adjuvant therapy was given based on final pathological report. Exclusion criteria include cases that had extensive nature of the disease and need neoadjuvant therapy or unresectable [Figures 1-3].

Information was sourced from the patient's case notes and operating theatre register. Information retrieved included age, gender, indication for surgical reconstruction, type of forehead flap, duration of hospital stays, and complications. All patients agree with this publication and use of photographs. Written informed consent obtained from all patients/parents/attendants, for inclusion in surgical procedure and use of the data for research purpose. Data recorded on a specialized pro forma. Medical records were reviewed retrospectively, including a clinical presentation at admission, laboratory values, performed pre-operative diagnostics, intraoperative findings, and histological results. All the patient's clinical, radiological, laboratory, and pathological findings were collected.

Preoperatively, the precise location of the superficial temporal artery was identified by palpation or with a pencil Doppler; to narrow the base of the flap precisely.

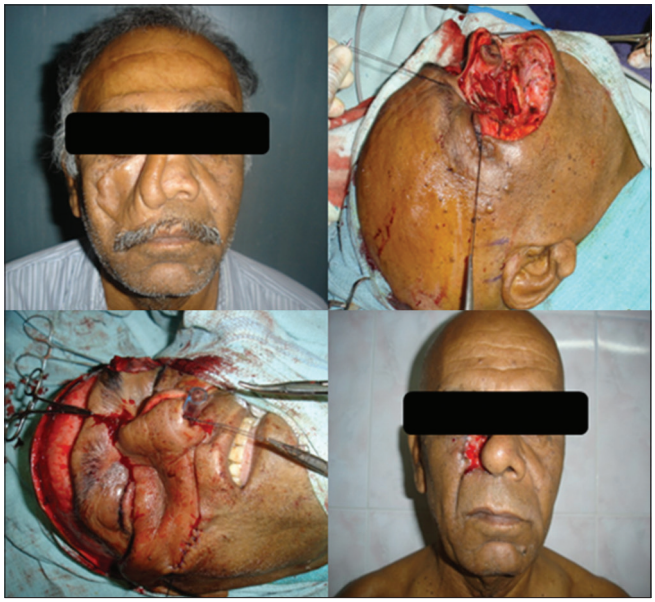


Figure 1: Flap for nasal defect

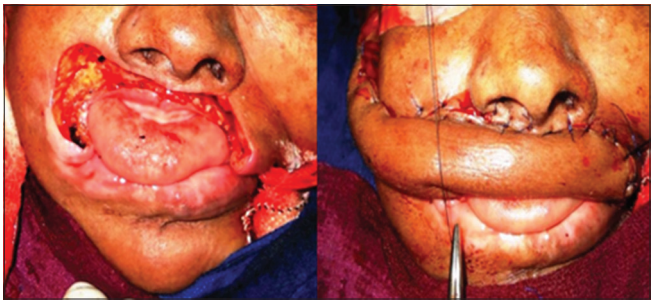


Figure 2: Flap for large upper lip defect

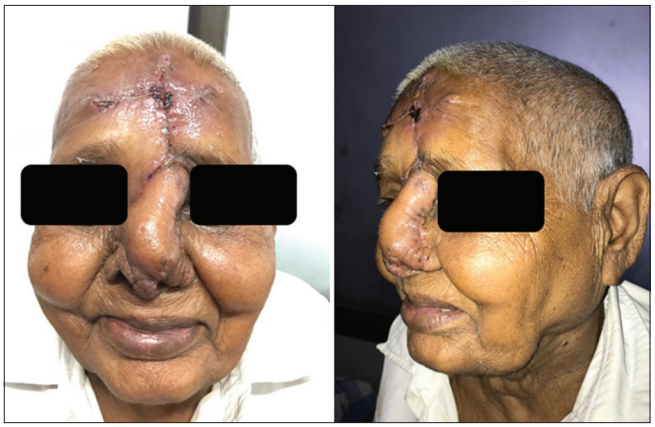


Figure 3: Flap for nasal defect

The flap elevated in a sub-facial plane just superficial to the periosteum of the frontal bone. The flap rotated over the lateral zygomatic arch onto the face. However, in some cases where needed when flap primarily designed for intraoral coverage, a tunnel between the donor site and the oral cavity created. Flap folded laterally and passed under the zygomatic arch, oral cavity entered through a tunnel made by a separate transverse cheek incision. After flap elevation for the face coverage, the flap was tailored to fit the defect and sutured the defect. The donor site was skin grafted. Postoperatively, the patient assessed for the vitality of flap within the first 12–24 h. The vitality and health are based on color, margin necrosis, and integrity of the flap which was confirmed superficial temporal artery pulse either manually or by Doppler. Flap sutures on the face were removed on the 6th post-operative day. Flap division, if necessary, was done after an average of 3 weeks. Follow-up was done for 4 months–12 months and on every follow-up visit, patients were questioned about the degree of satisfaction with speech, swallowing, and esthetics and the results were statistically analyzed and discussed.

Table 1: Cross-tabulation between the age distribution

Age group	No. of patients	Percentage
<30	2	8.0
31–40	4	16.0
41–50	7	28.0
51–60	5	20.0
>61	7	28.0

Table 2: Cross-tabulation between the site of tumor involvement

Site	No. of patients	Percentage
Cheek	9	36
Lower lip	5	20
Upper lip	3	12
Lower alveolus	2	8
Upper alveolus	2	8
Nose	2	8
Anterior part of tongue	1	4
Floor of mouth	1	4

Table 3: Cross-tabulation between sex distribution

Male	17
Female	8

Table 4: Cross-tabulation between stages of tumor involvement

Stage AJCC 2010	No. of patients	Percentage
I	3	12
II	11	44
III	7	28
IVa	4	16

RESULTS

Of 25 patients based on age distribution, 2 patients were age <30 years, 4 patients between 31–40 years, 7 patients between 41 and 50 years, 5 patients between 51 and 60 years, and 7 patients above 60 years [Table 1].

Of 25 patients based on site of tumor involvement, 5 patients had a tumor in the lower lip, 1 patient in the anterior part of tongue, 2 patients in the lower alveolus, 2 patients in the upper alveolus, 1 patient in the floor of mouth, 9 patients in cheek, 3 patients in the upper lip, and 2 patients in nose [Table 2].

Of 25 patients, 17 patients were males and 8 patients were females [Table 3].

Of 25 patients based on the stage of tumor involvement, 3 patient had Stage I, 11 patients had Stage II, 7 patients had Stage III, and 4 patients had Stage IVa [Table 4].

Table 5: Cross-tabulation adjuvant therapy

Adjuvant therapy	No. of patients	Percentage
Radiation	18	72
Chemoradiation	1	4
No adjuvant	6	24

Table 6: Cross-tabulation between types of primary surgery

Types of primary surgery	No. of patients	Percentage
Wide local excision	19	76
Hemimandibulectomy	2	8
Partial maxillectomy/palate alveolar resection	2	8
Marginal mandibulectomy	1	4
Partial glossectomy	1	4

Table 7: Cross-tabulation between the distribution of complications

Complications	No. of patients	Percentage
Flap necrosis	2	8
Hemorrhage from superficial temporal artery	1	4
Cosmesis	2	8
Altered forehead sensation	4	16
Partial or total loss of split-thickness skin graft	2	8
Need for another flap	2	8
Marginal loss	1	4
Partial loss	1	4

Of 25 patients, 18 patient had adjuvant radiation, 1 patients had chemo RT, and 6 patients had no adjuvant treatment [Table 5].

Of 25 patients, 19 patients had wide excision, 2 patients had hemimandibulectomy, 2 patients had partial maxillectomy/palate alveolar resection, 1 patient had marginal mandibulectomy, and 1 patient had partial glossectomy [Table 6].

Of 25 patients, 2 patients had flap necrosis, 1 had a hemorrhage from the superficial temporal artery which was managed successfully with flap salvage, 2 had cosmesis, 4 had altered forehead sensation, 2 had a partial or total loss of split-thickness skin graft (SSG), 2 needed another flap, 1 had a marginal loss, and 1 had a partial loss [Table 7].

DISCUSSION

The significance of reconstruction of maxillofacial/nasal and intraoral defects cannot be overemphasized in view of its unique position in a person's life (for esthetic and function). Reconstruction of facial defects is a challenge, which needs prompt creativity and innovation and demands strict adherence to the basic principles of reconstructive surgery and tissue transfer. This study was carried out to see the viability of forehead flap after reconstruction of the maxillofacial/nasal region and intraoral defects and to restore the function and physical form as close to nature as possible.

As forehead flap is locoregional flap, of maxillofacial region and easily done in two stage surgery. While donor site defects are also acceptable after the skin grafting, this study determined the efficacy and efficiency of the forehead flap in maxillofacial/nasal and intraoral defects. Of these 25 patients flaps, only 15 patients showed flap related complications. Anyhow, the total loss of flap leading to alternate flap was in only 1 case (4%). The success rate of the flap was thus 96%. This shows a higher success rate of forehead flap in maxillofacial region reconstruction and is a highly reliable flap considering viability and donor match.

This research matches with the study of other researchers like Yan *et al.*[12] on forehead flap, used for the reconstruction of basicranial and nasal facial defects after tumor dissection on 14 patients, there was partial necrosis only in 2 patients. The current study is near to this study, where partial necrosis was in 2 patients.

In the study of Cohen *et al.*,[13] forehead flap was infected with abscess formation in the tunnel, used to transfer the forehead flap to the oral cavity for the closure of the oral defect. He recommended a more direct route with a less dependent tunnel. In our study, we used tunneling in only 4 cases where needed. In the present study, we used forehead flap as lining purpose as well as the coverage of the solid structure like a bone graft or reconstruction plates for simultaneous reconstruction of mucosa and mandible. We experienced that the forehead flap has excellent adaptability to the transplanted bed, along with near-normal facial contour and tongue movements were not restricted.

Similarly, in the study of Millard,[14] he used forehead flap for immediate coverage of an iliac bone graft for simultaneous reconstruction of mucosa and mandible following radical excision of jaw malignancy. In his study, he found excellent results and the tongue movements were not restricted and facial mandibular contour was maintained in the patient who had immediate forehead procedure. Later, a successful functioning denture was fabricated for this patient.

The biggest drawback of the forehead flap is the prominent residual forehead donor site scar due to full-thickness skin graft. Although this is the universal rule of surgery that first, we have to preserve the function, then we must consider the element of cosmetics. Due to its exceptional reliability, versatility, relative technical simplicity, and usefulness of the flap in the maxillofacial area have preserved its role when other options failed. However, the difficult reality is that many head and neck patients fall into the lower end of socioeconomic spectrum and are uninsured so cannot afford the expenses of free tissue transfer, technically it is not feasible for every patient because of lack of resources, as well as cancer patients are usually from older age group, and are not very much concerned about their esthetics. That's why this flap is still very much popular and the donor site defect can easily be camouflaged in the females by an appropriate hairstyle. In the present study, donor site closure has been done with both SSG and, in some cases, by a full-thickness skin graft. For prevention of hyperpigmentation, sunblocks have been prescribed to avoid excessive sun exposure at least for the first 4–6 months after reconstructive surgery.

CONCLUSION

Reconstruction with forehead flap in maxillofacial/nasal region and intraoral defects provides natural building material precisely fitted to reconstruct maxillofacial defects to a condition as near to normal as possible. Forehead flap is a reliable technique for reconstruction of maxillofacial region defects. It is easy to rise and can provide coverage

for wide defects as far as the para mandibular and submandibular regions. Moreover, it does not require patient repositioning. Furthermore, it is a very reliable flap with lower complications and higher patient acceptability and also technically simpler to perform.

REFERENCES

1. Brown JS, Rogers SN, McNally DN, Boyle M. A modified classification for the maxillectomy defect. Head Neck 2000;22:17-26.
2. Grusovin MG, Coulthard P, Worthington HV. The efficacy of various bone augmentation procedures for dental implants: A cochrane systematic review of randomized controlled clinical trials. Int J Oral Maxillofac Implants 2006;21:696-710.
3. Mehta RP, Deschler DG. Mandibular reconstruction in 2004: An analysis of different techniques. Curr Open Otolaryngol Head Neck Surg 2004;12:288-93.
4. Mukerji R, Mukerji G, McGurk M. Mandibular fractures: Historical perspective. Br J Oral Maxillofac Surg 2006;44:222-8.
5. Schrag C, Chang YM, Tsai CY, Wei FC. Complete rehabilitation of the mandible following segmental resection. J Surg Oncol 2006;94:538-45.
6. Janis JE, Kwon RK, Attinger CE. The new reconstructive ladder: Modifications to the traditional model. Plast Reconstr Surg 2011;127:205S-12.
7. Huband M. Prosthetic rehabilitation. Dermatol Clin 2011;29:325-30.
8. Rohrich RJ, Griffin JR, Ansari M, Beran SJ, Potter JK. Nasal reconstruction--beyond aesthetic subunits: A 15-year review of 1334 cases. Plast Reconstr Surg 2004;114:1405-19.
9. Hunt JP, Buchman LO. The supraclavicular artery flap for lateral skull and scalp defects: Effective and efficient alternative to free tissue transfer. J Neurol Surg Rep 2014;75:e5-10.
10. Colletti G, Autelitano L, Tewfik K, Rabbiosi D, Biglioli F. Autonomized flaps in secondary head and neck reconstructions. Acta Otorhinolaryngol Ital 2012;32:329-35.
11. Baliarsing AS, Thorat TS, Gupta A. Flap selection in head and neck cancer reconstruction. Int J Otorhinolaryngol Clin 2013;5:63-76.
12. Yan Z, Fan Y, Ji W, Ye X, Shang J. One-stage reconstruction with the pedicle skin flap of forehead for defective tissue of head-neck tumors dissection. Lin Chuang Er Bi Yan Hou Ke Za Zhi 1999;13:254-6.
13. Cohen DJ, Jones RF, Engrav LH. Sepsis of the cheek over a subcutaneous forehead flap. Plast Reconstr Surg 1980;65:347-9.
14. Millard DR Jr. Total reconstructive rhinoplasty and a missing link. Plast Reconstr Surg 1966;37:167-83.

How to cite this article: Balasubramaniam R, Kumar PS. Versatility of Forehead Flap in Maxillofacial/Nasal and Intraoral Defects: A Retrospective Analysis. Int J Sci Stud 2020;7(12):107-111.

Source of Support: Nil, **Conflicts of Interest:** None declared.

Print ISSN: 2321-6379
Online ISSN: 2321-595X

Review Article

Novel COVID-19 Pandemic Threat: Systematic Approaches To Preventing and Controlling Transmission in Eye Care System in Developing Countries

Raj Lional[1], Heber Anandan[2], Prasad Jothi[3], J Mohamed Ali[4]

[1]Regional Medical Director, Department of Cornea and Refractive Surgery, Dr. Agarwal's Eye Hospitals, Tirunelveli, Tamil Nadu, India, [2]Senior Clinical Scientist, Department of Clinical Research, Dr. Agarwal's Eye Hospitals, Tirunelveli, Tamil Nadu, India, [3]Assistant Professor, Department of Microbiology, Kanyakumari Medical College and Hospital, Kanyakumari, Tamil Nadu, India, [4]Clinical Research Associate, Department of Clinical Research, Dr. Agarwal's Eye Hospitals, Tirunelveli, Tamil Nadu, India

Abstract

Background: 2019-novel coronavirus is a pandemic and major threat being how to avoid catching an infection.

Purpose: To develop a working protocol to prevent and control community transmission of novel and life-threatening corona viral strain (COVID 19) in a tertiary eye care system of a tier-three city in developing counties such as India and underdeveloped countries.

Methods: Prevention and control measures concerning staff training, working environment, staff health, patients, and outreach activities implemented and being practiced in our tertiary care ophthalmology hospital are focussed.

Results: Proper and adequate training imparted by a qualified immunologist in addition to continual updates on disease out breaking news and guidelines to the employees. Ways to limit transmission within and between patients and staff are discussed in conjunction with the disinfection of equipment and high- and low-risk areas in a more frequent manner. Outreach camps are stopped in the obedience of the authorized governing bodies.

Conclusion: This systemic approach developed based on our experience, and observational data will be useful in preventing transmission of this pandemic threat.

Key words: COVID-19, Ophthalmology, Pandemic

INTRODUCTION

Ever since its origin from Wuhan, China to Italy, and Spain and adjacent countries is being a major pandemic challenge for the human race.[1] On January 31, 2020, the World Health Organization (WHO) declared corona viral infection as a global medical emergency with due concern on developing countries such as India and underdeveloped countries which lack tools to contain the disease spread.[2]

Access this article online

www.ijss-sn.com

Month of Submission : 02-2020
Month of Peer Review : 02-2020
Month of Acceptance : 03-2020
Month of Publishing : 03-2020

The first confirmed case of novel coronavirus (nCoV) has been reported from Kerala where a student studying in Wuhan University, China, has been tested positive with the deadly virus.[3]

The Ministry of Health and Family Welfare is closely monitoring the emerging situation on 2019-nCoV in India on a daily basis. Between January 30, 2020, and February 3, 2020, MoHFW confirmed three cases of 2019-nCoV in Kerala. These patients are in stable condition and are being closely monitored in hospital isolation. Government of India (GoI) has issued travel advisories requesting the public to refrain from travel to China and that anyone with a travel history since January 15, 2020, from China will be quarantined on return.[4]

In this present situation, another challenge lies in the production and supply of protective masks and hand

Corresponding Author: Prof. Heber Anandan, Department of Clinical Research, Dr. Agarwal's Eye Hospitals, Tirunelveli, Tamil Nadu, India.

sanitizer which are highly in demand and resources appear limited.

This article focuses on control and prevention measures in tertiary eye care hospitals against nCoV with limited availability of resources to create a risk-free environment reduce the burden of transmission of a viral pathogen in this threatening coronavirus pandemic.

METHODS

This blueprint is developed using prevention and control measures implemented and being practiced at our tertiary eye care hospital concerning staff training, working environment, hospital workers, patients, and outreach activities. This is based on our clinical experience, observational data, and qualitative studies.

Training and Education

A special training session was organized for all our employees with an immunologist to provide adequate training on control and preventive measures. The immunologist emphasized on nature of the virus, virulence factor, transmission, public health concern, need for proper handwashing techniques, cleaning and disinfection of instruments, and touch areas. Newsletter, out breaking news from the WHO, ICMR, The Centers for Disease Control and Prevention, guidelines from GoI and Tamil Nadu State Government are circulated to employees for up-gradation of information toward corona infection.

Operating Environment

Our paramedical staff cleaned and disinfected slit-lamps and contact instruments with ethanol of over 80% concentration after every patient examination. Floors and walls are disinfected in more frequently than the routine practice. All the consultation cabins, nursing procedure rooms and patient waiting areas are fumigated with Aldasan 2000. 10 mL of the solution is mixed with 1 L of water and fumigated using fogger over a period of 20 min per room. We cleaned doors and handles and other high-risk touch areas with isopropyl alcohol (density 0.784) with a dilution of 1 mL in 1 L. Lift walls, stair railings are disinfected with isopropyl alcohol once in every 2 h.

Aerodesin 2000 is a mixture of 33 g of 1-Propanol; 18 g ethanol; and 0.5% acetone, which is used to clean equipment. Biomedical waste products should be disposed in a proper way respecting International Guideline.

Staff Health

Every employee is supplied with a high-quality protective mask to cover nose and mouth (3M/N95, ISO standard) with specific employee numbers and endorsement in the strap. We instructed them to wear at all times within hospital premises.

A special arrangement has been done to gas sterilize the masks every day. We use ethylene oxide 40 mg under 50°C for 4 h.

Hand sanitizer will be available on all floors at specified accessible spots and employees are encouraged to use them at least once every 15 min.

Employees are advised to inform their respective heads/managers immediately in case affected with symptoms of respiratory infection. Two employees, a driver and a pharmacist had minor upper respiratory changes were forced to undergo home isolation for 2 weeks.

The biometric attendance system was temporarily suspended instead, we are following conventional manual attendance register for administrative activities. All employees are advised to prevent contact with the nose and mouth after handing a patient.

All employees are encouraged to take adequate fluids, Vitamin C containing food and supplements and keep the immune system healthy.

Patient Care

All patients both new and review, along with attainders at the entrance of the hospital, were captured for the history of fever, non-contact temperature measurement, respiratory symptoms, and travel history in the past 2 weeks both domestic and international. Six Indian patients had international travel history and 26 had domestic travel history inter-state along with 13 overseas patients from the Maldives, of which surgical procedures have been done.

Figure 1: Sanitizer for all patients and attender coming to the hospital

Figure 2: Mask for patients and preventive suit for staffs

Figure 3: Preventive suit for ophthalmologists

Figure 4: Slit lamp protection sheet

We supplied masks, protective aids to them and monitored them through an isolated special tracking system with due precautions taken by the staff and medical team. Gloves and protective goggles were made mandatory in suspected cases [Figures 1-4].

Outreach

Community-based eye camps remain a backbone to feed cases into tertiary eye care hospitals in India. In this pandemic global situation, there is a strong question raised about whether to continue the eye screening and treatment camps. We conducted a focussed group discussion with clinicians, scientists and camp organizers, we got the majority of votes in favor of continuing camps rather than to stop them but in a controlled manner and due caution in prevention till we received a guideline from government regulatory authority. We incorporated COVID 19 awareness and precautionary measures into all the pamphlets and banners in a view to educate the public. In addition to this, we used a survey questionnaire for all the camp participants and bystanders regarding fever, respiratory symptoms, travel history both domestic and international.

CONCLUSION

In this nCoV pandemic scenario halting community transmission is the key factor to save people of the nation as no effective drugs or vaccines are yet available. This systemic approach developed based on our experience, and observational data will be useful in avoiding spread and overcoming this pandemic threat in tertiary eye care systems of developing counties such as India and underdeveloped countries.

REFERENCES

1. Li Q, Guan X, Wu P, Wang X, Zhou L, Tong Y, *et al*. Early transmission dynamics in Wuhan, China, of novel coronavirus-infected pneumonia. N Engl J Med 2020.
2. Statement on the Second Meeting of the International Health Regulations. Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV); 2005. Available from: https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov). [Last accessed on 2020 Feb 01].
3. First Case of Coronavirus Confirmed in India; Student Tested Positive in Kerala. Available from: https://www.businesstoday.in/current/economy-politics/breaking-coronavirus-reaches-india-first-confirmed-case-reported-in-kerala/story/394968.html. [Last accessed on 2020 Feb 01].
4. India Situation Report. Available from: https://www.who.int/india/emergencies/india-situation-report. [Last accessed on 2020 Feb 09].

How to cite this article: Lional R, Anandan H, Jothi P, Ali JM. Novel COVID-19 Pandemic Threat: Systematic Approaches To Preventing and Controlling Transmission in Eye Care System in Developing Countries. Int J Sci Stud 2020;7(12):112-114.

Source of Support: Nil, **Conflicts of Interest:** None declared.