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Interdisciplinary Management of Maxillary Anterior Teeth with External Root Resorption: A Case Report

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Abstract

Introduction: This is a case report showing interdisciplinary management of a tooth with external and cervical root resorption using mineral trioxide aggregate (MTA).

Case Report: A 35-year-old female with a complaint of pain in upper jaw with a history road traffic accident 8 year back. Non-surgical root canal therapy was performed with the use of calcium hydroxide and triple antibiotic paste as intracanal medicament. About 2% chlorhexidine solution was used as the final irrigant. MTA obturation was done in both central incisors; external cervical resorption in the left central incisor was repaired by reflecting the mucoperiosteal flap and sealing with MTA. The 3-month follow-up of the present case shows satisfactory results both clinically and radiographically.

Conclusion: Resorption cases has to be ruled out radiographically and clinically for successful management of these cases. Non-surgical and surgical treatment has been done hand in hand for management of this case.

Key words: Cervical root resorption, External root resorption, Mineral trioxide aggregate

INTRODUCTION

External root resorption occurs on the outer surface of the root, and the causes for this may vary. There are several types of external root resorption with the most common being external inflammatory root resorption. It may arise as a sequela of traumatic injury, orthodontic tooth movement, or chronic infection of the pulp or periodontal structures.^[1] Root resorption is a pathological process initiated by specific clastic cells which remove the organic and mineral components of dental hard tissues.^[2]

The major challenges associated with endodontic treatment of teeth with open apices due to resorption are achieving complete debridement, canal disinfection, and optimal sealing.^[3]

Recently, mineral trioxide aggregate (MTA) has emerged as a reliable material due to its biocompatibility, good sealing

property, and it encourages regeneration of periradicular tissues such as periodontal ligament bone and cementum.^[4] This is a case report showing management of maxillary central incisor with both cervical and external apical resorption with MTA obturation.

CASE REPORT

A 35-year-old female patient reported to the Department of Conservative Dentistry and Endodontics, Kannur Dental College, with a chief complaint of pain in the right upper front tooth. The patient had a history of trauma 8 years back in a road traffic accident. There was no relevant medical history.

On clinical examination, there was an Ellis Class II fracture on 11 and discoloration with respect to 21 [Figure 1].

Sinus tract was present in relation to 11. There was no mobility erythema, but tenderness on percussion was present. Both 11 and 21 negative responses (as compared to control tooth) were observed on thermal and electric pulp testing.

Intraoral periapical radiograph revealed a small, ill-defined radiolucent area involving the apical portion of the root of

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11 and 21 with blunt border and also radiolucency involving cervical third of 11 [Figure 2]. Based on the clinical and radiographic examination, we came to a diagnosis as follows:

- Chronic periradicular abscess and external apical root resorption of 11 and 21
- Ellis Class IV fracture with Heithersay's Class III cervical resorption of 11.

Taking into consideration the extent and severity of lesion, the treatment plan was decided as non-surgical root canal therapy with MTA obturation in both 11 and 21 and flap elevation and sealing of cervical resorption with the same.

The access cavity was prepared and working length of the tooth was determined [Figure 3]. Canals were cleaned and shaped with copious amount of percentage of sodium hypochlorite and vasoactive intestinal peptide. This was followed by irrigation with normal saline to remove any remnants of hypochlorite, and 0.2% chlorhexidine, latter canals were dried with absorbents points and calcium

hydroxide (R C Cal, Prime Dental Products, Kalher, Thane) as an intracanal medicament was placed in canals followed by a temporary restoration for 1 week. After 1-week, the patient was recalled and triple antibiotic paste was prepared by mixing ciprofloxacin 500 mg (Ciplox-500, Cipla Ltd., Sikkim, India), metronidazole 400 mg (Aristogyl, Aristo Pharmaceuticals Pvt. Ltd., Mumbai, India), and minocycline 100 mg (Minoz 100, Ranbaxy Laboratories Ltd., Solan, India), in tooth no. 11 and 12.

After 3 weeks, the patient was recalled, temporary filling was removed and canals were cleaned and dried. MTA, ProRoot MTA (Dentsply, Tulsa, Switzerland) was manipulated according to the manufacturer instructions. Both the central incisors were obturated with MTA; material was placed in the canals with amalgam carrier and was condensed vertically with hand pluggers [Figure 4].

For the management of cervical resorption, conventional full-thickness mucoperiosteal flap was elevated on 11



Figure 1: Pre-operative photograph



Figure 3: Working length determination

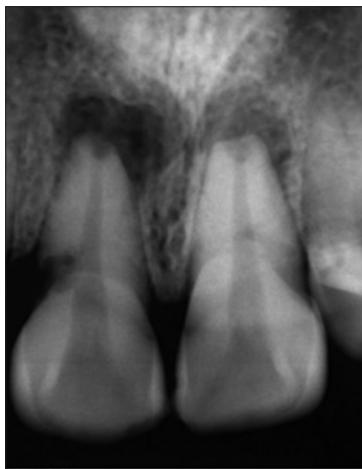


Figure 2: Pre-operative radiograph

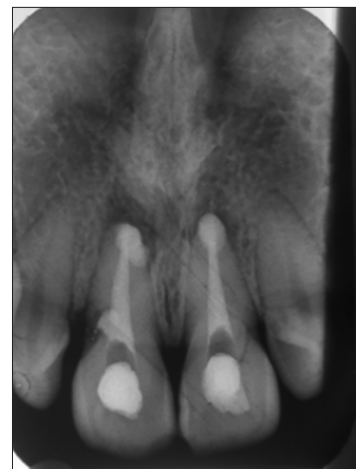


Figure 4: MTA obturation

under local anesthesia and MTA was placed and sutured [Figure 5-8].

Post-operative radiographs after 2 weeks [Figure 9] and 3 months [Figure 10] showed satisfactory healing.

DISCUSSION

External root resorption is one of the most difficult dental conditions to treat; attempting to perform endodontic therapy for every condition of external resorption is futile.^[5]

Cervical external resorption also called as invasive cervical resorption is a clinical term used to describe a relatively uncommon, insidious, and often aggressive form of external tooth resorption, which may occur in any tooth of permanent dentition. Invasive cervical resorption is defined as “a localized resorptive process that commences on the surface of root below the

epithelial attachment and the coronal aspect of the supporting alveolar process, namely, the zone of the connective tissue attachment.”^[6] If the defect is inaccessible in oral cavity but present in cervical third of tooth then orthodontic extrusion of tooth or apically positioned flap can be used, but this might give esthetically compromised results.^[7]

When the pathway of communication is opened between the root canal and the periodontium, it must be sealed with materials that preserve bacterial leakage, this material should be biocompatible and should favor regeneration of supporting structure.^[8]

A current trend in endodontic research is to explore various alternatives to gutta-percha to identify suitable filling materials that can provide greater resistance against coronal and apical leakage and thus protection from bacterial contamination.^[9] Development of new bioactive material such as MTA makes possible other therapeutic approaches including the obturation of root canal space



Figure 5: Local anesthesia



Figure 7: Placement of MTA



Figure 6: Elevation of flap



Figure 8: Suture placed

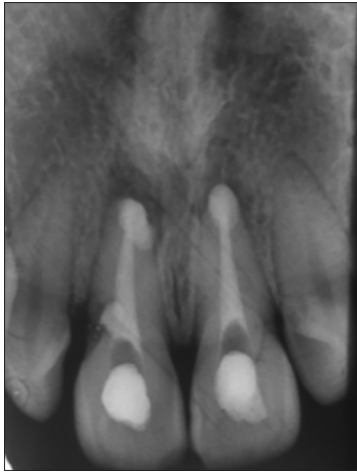


Figure 9: Follow up radiograph at 2 weeks

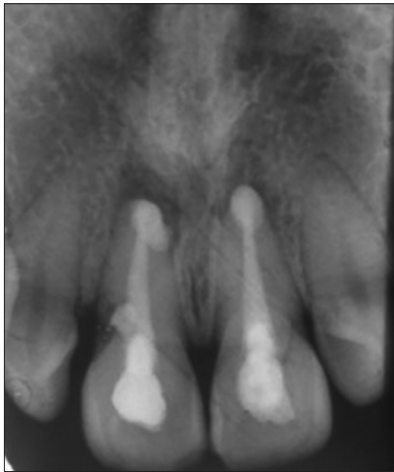


Figure 10: Follow up radiograph at 3 months

in complex cases of pathologic root resorption.^[10] One of the characteristics of bioactive material is its ability to form an apatite-like layer on its surface when it comes in contact with physiologic fluids *in vivo* or with stimulated body fluid *in vitro*, is MTA a bioactive material that is mainly composed of tricalcium and silicate. Investigation has shown that it can conduct and induct hard tissue formation; studies have illustrated the release of various ions from MTA.^[11] Antibacterial/antimicrobial activity of MTA seems to be associated with elevated pH. Tanomaru-Filho M *et al.* observed an initial pH of 10.2 for MTA rising to 12.5 in 3 h, it is known that pH level of 12.0 can inhibit most microorganisms including resistant bacteria such as *Enterococcus faecalis*.^[12]

Calcium hydroxide has been used for the management of external inflammatory root resorption due to its high alkalinity, which increases the pH of dentin by the diffusion of hydroxyl ions through the dentinal tubules.^[13] Conventionally, long-term calcium hydroxide has been recommended ranging from 6 to 24 months to allow the

formation of a hard tissue barrier.^[14] Calcium hydroxide has also been traditionally used for apexification of non-vital immature teeth.^[15]

Various studies have shown that triple antibiotic paste is beneficial in eliminating bacteria from infected dental tissues;^[16] metronidazole has a wide bactericidal spectrum against anaerobes while ciprofloxacin and minocycline are effective against bacteria resistant to metronidazole.^[17]

CONCLUSION

The present case was thus effectively managed using calcium hydroxide, triple antibiotic paste, and MTA. Calcium hydroxide inhibited the resorptive activity of the clastic cells and MTA formed the apical barrier, facilitating a three-dimensional obturation of the canal space.

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We thank the patient described for allowing us to share his details.

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Coloring Narrative Therapy for Hospitalization Patients of Hospice Palliative Care Wards without Special Psychological Test: A Case Report

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Abstract

Art therapy would help end-of-life care who hospitalized in hospice palliative care wards. This case report aims to examine Yeonmyeong (Prolongation of life) cure or spontaneous healing and so on have developed over the last 3 years. The case report provides an analysis of palliative care through coloring narrative therapy from torture and injection of ill treatment. Significant developments include the following: (1) The older persons who have chronic terminal cancers realize their here and now. (2) The patients have terminally accepted their end of life. (3) Their families were greeting adieu with their palliative care clients. In Korea, Yeonmyeong cure is approved by modern society patients and their families. Therefore, medical palliative care groups are thinking more well-being healing method for human being.

Key words: Approve of end-of-life, Coloring narrative therapy, Palliative care, Yeonmyeong cure

INTRODUCTION

Well-dying is a radical issue for modern society medical area nowadays. Yeonmyeong cure is a sensational issue of long-lasting life desire people. Many patients think that they will be survival recover beings in these days. Natural healing, that is to say, spontaneous healing means to save life from death through their metabolic immunity recovery in the forest nature or in the mountains. However, we are in basic end-of-life health-care environment. Hence, we think availability of end-of-life care. Therefore, we yield cost and quality of end-of-life care (The presbyterianism Church of Korea the 99th session general assembly hospital medical mission workshop p. 20). Human being is a holistic person, so hospice and palliative care need (p. 26).

Dying is a human and communal experience but is not a medical Event (2019 Korea Journal of Hospice Care, p.17).

CASE REPORT

Here, I will introduce end of life-related idioms. Euthanasia (-mercy killing) is contrast with passive euthanasia. We can see death with dignity, physician-assisted suicide, assisted dying, well-dying, natural death, advance euthanasia directives, and Medical Futility Law (2019 Korea Journal of Hospice Care, p. 10~11).

The other sayings as follows:

Uniform determination of death act. An individual who has sustained either

1. Irreversible cessation of circulatory or respiratory function, or
2. Irreversible cessation of all functions of the entire brain, including brain stem, is dead (2019 Korea Journal of Hospice Care, p. 6).

The Hospice palliative care is divided into holistic care, interrelated care, palliative care, and supportive care (The importance study on volunteer service and spiritual Care provider role for all-round care in hospice palliative care, p. 25).

I will show my patients' coloring therapy data. There are 6 types Palliative care. Table 1 shows hospice Palliative Care

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Steps of Coloring Narrative Therapy Results. The patient and his family are understood as these data.

DISCUSSION

View point of death in Won Buddhism is just seeing change and unchanged about death. They think that everyone has new started and has to prepare ahead in everyday life in Won Buddhism (Hospice Palliative Care and Clinical Art Therapy, p. 76(KOREAN Edition)).

This means that human life-death just like to Breath in and Breath out or asleep and awake, therefore like this life-death is not two sides directions but is one whole circle. Originally, there is no birth and death, the realized person knows this as change.

Like this, same is given to death and life value, therefore, death is life's basic origin and life is basic origin of death. That is to say, death is beginning from life and life is beginning from death.

In the truth aspects of one circle shape, there is not human death in fact. Death is physical body's change absent-to-disappear, so spiritual human is to exist eternally (p. 76). Death means not only flesh body appearing reality but also divided phenomena from life of disappearing body and flesh body.

Now let us examine the Philosophy of Hospice.

1. Hospice care and be behind a terminal patients, dying patients and their family. That is to say, hospice care unit is patients and their family
2. Hospice should help patients live as they can comfortable and full life
3. Hospice have to positively accept their life and accept death which is natural parts of life
4. Hospice is to be not lengthen or shorten of life but make full and abundant remnant life
5. Hospice helps to prepare death through advocacy and sufficient of needs such as physical, social, psychological, and spiritual needs by using all able satisfaction of patients and their families.

There are death stage theories.

1. Kubler-Ross death stages.
 - Denial

Denial stage patients' saying and behavior examples are as follows:

- Not serious speaking of symptoms like another person's matter.
- They turn the words promptly about speaking of death and never say about death.
- Publically they say "I don't believe it."
- Effort of non-medical therapy or healing through God.
- Don't asking of himself disease or symptoms.
- Anticipating of naturally disappearing symptoms and refusing of treatment.
- Don't recognizing of the radical change in body or appearance.
- Slightly saying of disease.
- Explaining of not yet die reason.

• Affirming of recover surely himself although he knows his disease.

- (2) Anger
- (3) Bargaining
- (4) Depression
- (5) Acceptance

2. Stage theory's Three Big Category

- Avoidance: shock, denial, distrust
- Confrontation: sadness, emotional reaction of loss
- Recovery: Returning of everyday life condition from sadness gradually.

Reaction of Death and Hospice care can be seen.

1. Fear
 - Fear of being unknown
 - Fear of loneliness
 - Fear of loss of family and friends
 - Fear of self-control ability loss
 - Fear of body loss and powerlessness
 - Fear of pain and suffering
 - Fear of identification loss
 - Fear of sadness
 - Fear of regression
 - Fear of cutting and corruption and burial

Table 1: Coloring narrative therapy outcome from hospice wards

Types	1 week	2 week	3 week	1 month	2 month	6 month	1 year
Recovery going out step			1				
Adieu saying step			1				
Nutrition absorbing step						2	1
Passing by step							
Don't accept their parents death						1	
Recognizing of their family's patient's death						1	

2. Depression and despondency
3. Anger and hostility
4. Sense of guilt and shame.

CONCLUSION

I have trained art therapy volunteer service since last 3 years in Wonkwang Hyodo Yoyang Hospital Hospice Palliative Care Wards. Here, I can classify as following types. We can see Table 1. The hospice palliative care results are as follows:

1. Recovery his health so goes out the hospital
2. Understanding of his life merits so takes his future life step of adieu
3. Continuously nutrition absorbing so keeps their lives together their family's care
4. According to the doctor's diagnostic decision so goes to future life with passing by
5. Patients' family recognizes their parents' health but they don't prepare to accept their parents' death and don't say their parents' death
6. Patients' family recognizes their patients' death so they say death.

These conclusions are used by time series investigation.

I read about moral problem related hospice. They are divided into eight types.

1. Autonomy
2. Veracity

3. Nonmaleficence
4. Beneficence
5. Confidentiality
6. Justice
7. Fidelity
8. Informed consent.

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Very Early (<2 h) Versus Early (12 h) Administration of Caffeine Citrate for Reducing Need for Mechanical Ventilation within 24 h of Life in Preterm Infants on Continuous Positive Airway Pressure

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Abstract

Background and Objective: In the caffeine for apnea of prematurity (CAP) trial, post hoc analyses have discovered reductions in respiratory and neurologic morbidities associated with earlier caffeine initiation (within 3 days). This study aims to compare the effects of early (<2 h) and late (12 h) initiation of caffeine in preterm neonates on continuous positive airway pressure (CPAP).

Study Design: A total of 36 neonates <32 weeks gestational age were randomized to receive intravenous caffeine citrate (20 mg/kg) before 2 h (early n = 19) or at 12 h of age (late n = 17). This was a pilot randomized controlled trial to determine the power needed to reduce the need for endotracheal intubation by 24 h of age. Other outcomes included the duration of respiratory support, duration of oxygen therapy, need for vasopressors, incidence of intraventricular hemorrhage, patent ductus arteriosus needing treatment, necrotizing enterocolitis, bronchopulmonary dysplasia, retinopathy of prematurity, sepsis, and mortality.

Results: There was no difference in the need for intubation ($P = 0.615$) or vasopressors ($P = 0.455$) by 24 h of age. Statistically significant reduction was noted in the total duration of CPAP support ($P = 0.003$). However, total duration of respiratory support ($P = 0.425$), total duration of mechanical ventilation days ($P = 0.237$), and oxygen days ($P = 0.145$) were favoring early caffeine group, which were not statistically significant. None of the babies in both the groups had apnea of prematurity. There was no difference in other outcomes.

Conclusion: This pilot study demonstrated the feasibility of conducting such a trial in very preterm neonates. We found that early caffeine administration was associated with statistically significant reduction in the duration of non-invasive respiratory support. Larger studies are needed to determine whether early caffeine reduces intubation, intraventricular hemorrhage, duration of respiratory support, and related long-term outcomes.

Key words: Airway pressure, Infants, Ventilation

INTRODUCTION

Respiratory distress syndrome can be successfully treated in very preterm infants with nasal continuous positive airway pressure (CPAP) beginning at birth.^[1] However,

many of these infants will fail CPAP and require endotracheal intubation and surfactant administration to achieve adequate gas exchange.^[2,3] Early use of caffeine as a respiratory stimulant represents a potential adjunctive therapy with CPAP to prevent intubation.

In the caffeine for apnea of prematurity (CAP) trial, infants in the caffeine group were able to discontinue positive pressure ventilation approximately 1 week earlier than the placebo group and had a significant reduction in their incidence of bronchopulmonary dysplasia (BPD).^[4] The average postnatal age of caffeine initiation in the CAP trial was 3 days. *Post hoc* analyses of the CAP trial,

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and retrospective studies performed by other groups, have discovered reductions in respiratory and neurologic morbidities associated with earlier caffeine initiation.^[5]

Few, small, observational studies have investigated the cardiovascular effects of caffeine in the neonate. Some have demonstrated transient decreases in cerebral and intestinal blood flow after a caffeine dose with no change in cardiac output.^[6] Others have shown increased blood pressure after a dose of intravenous caffeine.^[7,8] It is possible that these cardiovascular effects could be beneficial for early transitional circulation, especially in the premature infant who is prone to hypotension and cardiac dysfunction.

European centers have adopted a technique to administer surfactant during spontaneous breathing while receiving nasal CPAP (minimally invasive surfactant therapy).^[9] As part of this protocol, infants are given intravenous caffeine in the 1st h of age.^[10] Many centers have adopted the use of early caffeine as soon as infants have intravenous access along with antibiotics and fluids. However, this practice has never been demonstrated to be beneficial in a randomized controlled trial.

Recently, a pilot randomized controlled trial conducted at California comparing caffeine administration at 2 versus 12 h did not find any difference in need for intubation or vasopressors at 12 h of life.^[11]

Our center has a range of caffeine initiation from 1 to 24 h of age. We hypothesized that very early caffeine given in the first 2 h after birth to non-intubated preterm infants on nasal CPAP will be associated with a reduction in risk of intubation and inotrope support within the first 24 h of age, compared with caffeine administration at 12 h of age. Given the lack of previously published studies, our objective was to perform a pilot trial to determine the appropriate power for a larger study.

Study Design

This blinded, randomized pilot study was conducted in the Level III neonatal intensive care unit (NICU) at the Lokmanya Tilak Municipal General Hospital in Sion, Mumbai, between February 2018 and July 2018. Consent was obtained for infants within 1 h of birth after the baby was stabilized on CPAP. Any newborn delivered between 26 and 31^{6/7} weeks gestational age (GA) by the best obstetric estimates was eligible for inclusion. Exclusion criteria were one or more of the following: (1) Major congenital anomaly including airway anomalies, congenital diaphragmatic hernia, or hydrops, (2) known or a discovered major cardiac defect other than a patent ductus arteriosus (PDA), patent foramen ovale, or small ventricular septal defect, and (3) severe apnea or bradycardia in the first 10 min of age requiring emergent endotracheal intubation.

Eligible neonates were randomly assigned to receive intravenous caffeine citrate 20 mg/kg infused over 15 min within the first 2 h of age (early caffeine group) and at 12 h of age (late caffeine group). Subjects were randomized by stratification in blocks of 10 using a computer-generated block randomization schedule. Infants were intubated if they had PCO₂ >60 mmHg and pH <7.20 or FIO₂ >0.5 on CPAP or hemodynamic instability (mean arterial blood pressure <GA requiring two inotrope support).

A single-blinded echocardiogram was performed in the first 12 h of age using the Sonosite echocardiography machine. Measures of diameters of the PDA, shunt direction, left pulmonary artery end-diastolic velocity, and left atrial to aortic root ratio were collected on each examination done 12 h apart. Ultrasound head was performed on day of life 1, 3, and 7 for intraventricular hemorrhage diagnosis and assessment of the grade.

Relevant maternal and neonatal medical information was collected. Serial measurements of heart rate, mean arterial pressure, respiratory rate, and Silverman-Anderson score were done each hour. Normally distributed variables were analyzed with the independent samples *t*-test and non-parametric continuous outcome variables were analyzed with the Mann-Whitney *U*-test. Demographic data are presented as numbers and proportions for categorical variables or means with standard deviation for normally distributed continuous variables and medians for skewed distribution. Fisher's exact test and Chi-square test were used to analyze categorical outcome variables. Significance was set at *P* < 0.05. For statistics, IBM SPSS Statistics 21.0 (SPSS, Inc., Chicago, IL) functions were utilized.

RESULTS

A total of 36 subjects were enrolled. Nineteen subjects received early caffeine and 17 subjects received late caffeine. Figure 1 represents a flow diagram that quantifies participant progress through the trial. No parents who were approached for informed consent declined to participate, and no enrolled subjects were lost to follow-up.

There were no significant differences in maternal characteristics or delivery complications between the two groups [Table 1]. There was no statistically significant difference in need for ventilation within 24 and 72 h. No difference in need for inotrope support by 24 hours of life. Neonates who received early caffeine had a significant reduction in duration of CPAP (*P* = 0.003), but statistically non-significant reduction in duration of respiratory support (*P* = 0.425) and oxygen therapy (*P* = 0.145). Other morbidities were similar between the two groups [Table 2].

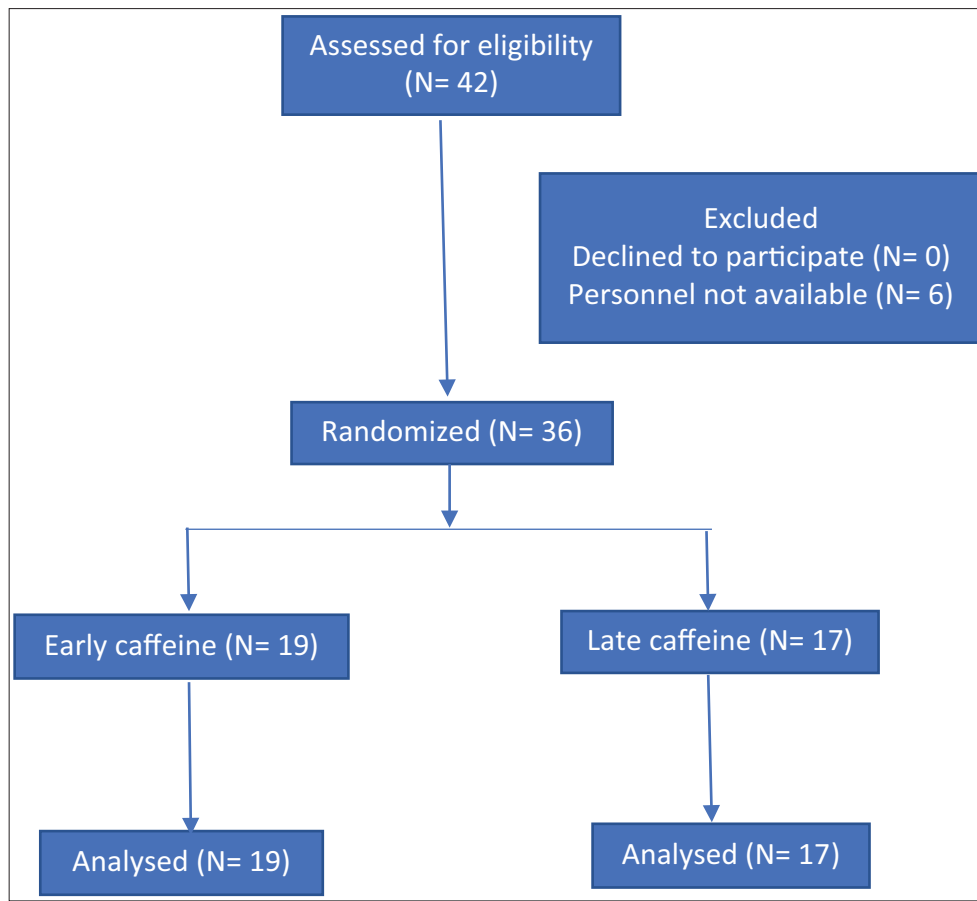


Figure 1: Tabular description

Table 1: Maternal characteristics

Characteristics	Early (n=19)	Late (n=17)	P-value
Maternal age (years)	28±2	29±2	0.802
Gravida/para (med)	2	3	0.516
Gestational age (weeks)	29.58±2	29.17±2	0.901
Birth weight (grams)	1198±374	1224±288	0.301
Male n (%)	11 (57.89)	9 (52.94)	0.765
Some antenatal steroids (%)	11 (57.89)	11 (64.70)	0.676
C-section deliver (%)	12 (63.15)	8 (47.05)	0.332
Premature rupture of membranes (%)	3 (15.78)	7 (41.17)	0.090
Pre-eclampsia (%)	6 (31.57)	2 (11.76)	0.153
Placental abruption (%)	1 (5.26)	2 (11.76)	0.481
GDM (%)	0 (0)	1 (5.26)	0.284
First surfactant administration	6 (31.57)	9 (52.94)	0.194
BMV (%)	4 (21.05)	4 (23.52)	0.858
Second surfactant administration	2 (10.52)	0 (0)	0.168

DISCUSSION

Caffeine's favorable efficacy and safety record in the NICU for the treatment of apnea of prematurity, and for preventing failed extubation, is well known.^[4,12-14] A potential new direction for caffeine therapy targets early administration for preterm neonates at risk for respiratory failure and cardiovascular insufficiency. Such an intervention should be feasible in most settings as

intravenous access is routinely achieved in these patients for provision of intravenous fluid and antibiotics. Infants managed initially on CPAP alone may take time to develop respiratory insufficiency and apnea. Waiting to give caffeine when these symptoms develop may not prevent the need for intubation.

This is the first randomized controlled trial of caffeine to compare timing of initiation of intravenous caffeine therapy in very preterm neonates. While our study did not demonstrate a difference in the need for endotracheal intubation at 24 h of age, we did see a trend for decreased duration of respiratory support, mechanical ventilation, and oxygen therapy. To detect 50% difference (from 30 to 15%), we would need at least 20 infants in each arm to adequately power for this outcome. Our primary hypothesis was based on the assumption that most intubation would occur in the first 24 h of age. Statistically non-significant reduction in the duration of respiratory support infants receiving early caffeine versus late caffeine group [Table 2], but need further study in a larger trial.

It is known that caffeine is a potent inhibitor of the vasodilator adenosine.^[15] This action may result in vasoconstriction of cerebral vessels or attenuation of

Table 2: Neonatal outcomes

Outcomes	Early (n=19)	Late (n=17)	P-value
Median Apgar score 1 min (IQR)	8 (7.8)	7 (6.8)	0.791
Median Apgar score 5 min (IQR)	9 (9.9)	9 (8.9)	0.438
Worst pH in 24 h	7.30±0.07	7.29±0.1	0.267
Worst base deficit in 24 h	-7.05±-2.7	-7.21±-2.6	0.879
Time of caffeine administration after birth	2	12	-
Peak PaCO ₂ in the first 24 h, mmHg	40.52±10.38	42.04±10.46	0.853
Required intubation by 24 h – n (%)	2 (10.52)	1 (5.88)	0.615
Required intubation by 72 h – n (%)	3 (15.78)	2 (11.76)	0.727
Required inotrope by 24 h – n (%)	4 (21.05)	2 (11.76)	0.455
CPAP duration (h)	24±16	60±58	0.003
Days of mechanical ventilation (h)	12.6±30.5	21.1±58.14	0.237
Days of total respiratory support (h)	52.5±65	81±111	0.425
Days of oxygen (h)	24±34	34.4±55	0.145
IVH (>3) – n (%)	0 (0)	2 (11.76)	0.124
HsPDA – n (%)	4 (21.05)	6 (35.29)	0.196
PDA requiring treatment – n (%)	4 (21.05)	5 (29.41)	0.563
NEC (Stage 2 or 3) – n (%)	1 (5.26)	0 (0)	0.337
Apnea of prematurity – n (%)	0 (0)	0 (0)	-
Apnea – n (%)	7 (36.84)	9 (52.94)	0.332
IVH any grade – n (%)	4 (21.05)	2 (11.76)	-
Oxygen at 36 weeks corrected age – n (%)	1 (5.26)	1 (5.88)	0.935
ROP requiring treatment – n (%)	0 (0)	0 (0)	-
CRP-positive EOS – n (%)	3 (15.78)	1 (5.88)	0.345
CRP-positive LOS – n (%)	0 (0)	1 (5.88)	0.284
Blood culture-proven EOS – n (%)	0 (0)	0 (0)	-
Blood culture-proven LOS – n (%)	2 (10.52)	3 (17.64)	0.906
Time to reach full feeds (days)	8.89±3.52	7.29±3.91	0.409
Survival (%)	18 (94.73)	15 (88.23)	0.766

CRP: C-reactive protein, LOS: Late-onset sepsis, EOS: Early-onset sepsis, IVH: Intraventricular hemorrhage, IQR: Interquartile range, ROP: Retinopathy of prematurity, CPAP: Continuous positive airway pressure, NEC: Necrotizing enterocolitis

adenosine-induced vasodilation that may occur during hypoxia or hypercarbia. Caffeine may, therefore, act in a similar mechanism to indomethacin, by decreasing the risk of reperfusion injury by limiting cerebral blood flow. Indomethacin has also demonstrated a transient decrease in cerebral saturations, but within 2 h of administration was shown to improve both blood pressure and superior vena cava flow.^[16] The protective effects for intraventricular hemorrhage (IVH) have only been demonstrated when given shortly after birth.^[16] Avoiding early fluctuations in cerebral blood flow may reduce morbidities, such as IVH, but this needs further study.

Interestingly, centers conducting similar retrospective studies of early (<3 days) versus late (>3 days) caffeine are reporting lower rates of IVH in the early caffeine-treated babies.^[17]

Patel *et al.* recently described their single center's experience with caffeine given before or after 3 days of age to preterm neonates 1250 g birth weight.^[18] In their retrospective study ($n = 140$), infants receiving early caffeine were significantly less likely to develop death or BPD (25 vs. 53%), BPD (24 vs. 51%), or a PDA requiring medical or surgical treatment (10 vs. 36%). These differences remained statistically significant even after adjustments for confounding variables. In addition, the median duration

of endotracheal intubation and mechanical ventilation was more than 2 weeks longer in the late caffeine group (6 vs. 22 days).^[18] A subsequent multicenter retrospective study of preterm infants with birth weights <1500 g ($n = 29,070$) also demonstrated significant associations between early caffeine initiation before 3 days of age and a reduced incidence of BPD, PDA treatment, and duration of mechanical ventilation.^[5] Meanwhile, those in the GA <24 weeks strata who received early caffeine and who survived had significantly lower BPD rates (43.7 vs. 67.1%) compared with late caffeine recipients. The incidence of late onset sepsis (21.2 vs. 24.5%) and inotropic support (21.6 vs. 31.6%) was also significantly less in the early caffeine group.^[5]

Lodha *et al.* with the Canadian Neonatal Network recently reported results from their multicenter retrospective study of caffeine initiation before or after 2 completed days of age in preterm infants GA <31 weeks ($n = 5517$). Positive outcomes associated with early caffeine in this study included fewer days of mechanical ventilation (2 vs. 4 days), a lower incidence of requiring high-frequency ventilation on day 2 (6.2 vs. 19.4%), a lower odds of having BPD at 36 weeks postmenstrual age (odds ratio [OR] 0.79, 95% confidence interval [CI] 0.64–0.96), and of surgically treated PDA (OR 0.58, 95% CI 0.42–0.8). Other outcomes

such as mortality, necrotizing enterocolitis, retinopathy of prematurity, neurological injury, and total length of hospital stay were not different. The median time of caffeine initiation in this study was 1 day of age in the early group and 4 days of age in the late group.^[19] These studies suggest that early caffeine, more so than caffeine *per se*, is associated with a reduction in time exposed to endotracheal intubation and positive pressure or mechanical ventilation, which, in turn, reduces the risk of developing BPD and possibly other associated complications.

While it is natural to assume that the respiratory and cardiovascular stimulant and vasoconstrictive effects of caffeine provide the pharmacologically plausible basis for these observed outcomes, recent animal studies indicate that caffeine can also ameliorate the inflammatory response and lung injury due caused by acute hyperoxia or intrauterine infection.^[20,21]

Our study has several limitations. First, since this was a pilot study, we were underpowered to achieve any differences in the outcome of reducing intubation. Second, given that our study included only non-intubated infants at birth, it is unclear whether early caffeine would have the same hemodynamic effects on potentially sicker intubated infants.

CONCLUSION

This pilot study demonstrated that conducting a prospective, randomized, placebo-controlled trial comparing early to late caffeine administration in very preterm neonates is feasible. We found that giving early intravenous caffeine administration to non-intubated, very preterm neonates resulted in reduction in total duration of respiratory support.

Larger prospective studies are needed to determine the effects of early caffeine on the need for intubation, IVH, and related long-term outcomes such as chronic lung disease and neurodevelopmental impairment.

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Audiological Profile in Auditory Neuropathy Spectrum Disorder – A Descriptive Study

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Abstract

Background: Auditory neuropathy, auditory dys-synchrony, and auditory neuropathy spectrum disorder (ANSND) are variable terms used to describe an auditory disorder seen in patients ranging in age from infants to adults. The prevalence of ANSD in deaf schoolchildren is 2.46% within the age range of 6–12 years. In children, they are detected by the presence of otoacoustic emissions (OAEs) in the absence of ABRs. In older age group, difficulty hearing in noise, fluctuating hearing, and speech perception performance not predicted by the level of residual hearing have been reported. The multitude of etiologies for ANSD results in heterogeneous group of patients – making the management strategies even more challenging. The common etiologies put forward are – prematurity, neonatal insult, genetic abnormality, ototoxic drugs, and head injury.

Aim of the Study: This study aims to study the audiological profile in ANSD in a tertiary care hospital and to study the etiology of ANSD cases.

Materials and Methods: A total of 42 patients attending the ENT Outpatient Department of Government Medical College, Kozhikode, with ANSD were included in the study. An ethical committee clearance was obtained before the commencement of the study. An ethical committee cleared consent form was used for the study. All ANSD patients were evaluated with a detailed history including perinatal and development history, ototoxic drug exposure, head trauma, neurodegenerative conditions, and family history. Following clinical evaluation which included general examinations, ENT examination, and central nervous system examination, an audiological evaluation, which included pure tone audiometry, speech audiometry, immittance evaluation, OAE, and auditory brainstem response, was done. Radiological investigation (magnetic resonance imaging brain with inner ear – focusing on any structural anomalies; cochlea, vestibulocochlear nerve, and internal auditory canal) was done. Patients were counseled regarding the rehabilitation options based on their audiological and radiological results and the need for follow-up was explained.

Observation and Results: A total of 42 patients attending the ENT Outpatient Department (OPD) of Government Medical College, Kozhikode, with ANSD were included in the study. Among the 42 patients, 21 (50%) were in the age group of 11–20 years followed by 13 patients who were between 0 and 10 years (30.95%). The remaining 8 were aged above 20 years (19.04%). The youngest patient was 10 months old and the oldest was aged 38 years with a mean age of 10.35 ± 2.10 years. There were 29 (69.04%) females and 13 (30.95%) males. 3/42 (7.14%) patients gave a history of exposure to ototoxic drugs such as streptomycin, gentamicin, and kanamycin, but never had a history of loss of hearing before that. History of premature birth was noted in 10 (23.80%) patients and the remaining patients did not show premature birth history. Among the 42 patients of this study group, 23 (54.76%) had low birth weight, of which 2/42 (4.76%) were <1.5 kg. 21/42 (50%) patients had birth weight above 1.5 kg. 10/42 patients (23.80%) gave a history of neonatal intensive care unit (NICU) admissions at the time of their birth.

Conclusions: The major risk factor identified in this study for ANSD was low birth weight with prematurity, NICU admissions, and viral infections having significant contributions. On audiological evaluation, hearing loss was of mild-to-moderate range with a low-frequency loss. There was no statistical correlation between pure audiometry values and speech audiometry which was a characteristic observation. OAEs were present in the majority of patients with absent cochlear microphonics (reverse polarity) and acoustic reflexes.

Key words: Auditory dys-synchrony, Auditory neuropathy spectrum disorder, Auditory neuropathy

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INTRODUCTION

Auditory neuropathy/auditory dys-synchrony/auditory neuropathy spectrum disorders (ANSNDs) describe a condition, in which patient's otoacoustic emissions (OAEs) are (or were at 1 time) present, and auditory brainstem responses (ABRs) are abnormal or absent.^[1] The first

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audiological report of ANSD was probably by Hinchcliffe *et al.*,^[2] Starr *et al.*^[3] introduced the term “neuropathy” after studying 10 patients with a unique set of auditory problems. In 2001, Berlin *et al.*^[4] introduced the term auditory neuropathy (AN)/auditory dys-synchrony to include those cases where no true neuropathy was apparent when the constellation of routine test results did not provide sufficient evidence to differentiate between synaptic dysfunction and “true neuropathy” of the cochlear nerve. Rance^[5] studied children with AN and reported that half of them had speech perception abilities like those of children with matched sensorineural hearing loss (SNHL) and had cortical evoked potentials. The other half did poorly in speech reception and lacked cortical responses. In the current terminology, ANSD is a disorder characterized by the disruption of the temporal coding of acoustic signals in the auditory nerve fibers, resulting in the impairment of auditory perceptions that rely on temporal cues.^[6] The prevalence accounts vary from roughly 1%^[7] to 10% in schools for the deaf and between 10% in newborns and 40% in hearing-impaired neonatal intensive care unit (NICU) graduates.^[3] Diagnosis usually needs a high index of suspicion. Although a detailed history might give a clue to some derangement, it is not uncommon to see patients diagnosed by audiological evaluation alone. On the one hand, patient’s will report with normal to severely compromised hearing and at the other extreme cases of ANSD presenting as treatment-resistant anxiety disorder can be seen.^[8] The late-onset ANSD can be a quite debilitating condition as the clients are perfectly normal till adolescence and suddenly exhibit auditory symptoms. This leads to poor communication among the peer groups and social isolation and decline in academic performance. All these lead to psychological issues such as stress depression and anxiety in persons with late-onset ANSD.^[9] There is no definite evidence to pinpoint to site of lesion in ANSD. It could be anywhere beyond the outer hair cells. It will very difficult to categorize the entity into cochlear or retrocochlear.^[10] There is no single test for the localization of the site of the lesion. In some cases, the damage might be to the inner hair cells; in other cases, the cause may involve damage to the auditory neurons that transmit sound information from the inner hair cells to the brain. Combinations of these problems might occur in some cases.^[11] Rance and Starr pointed out that presynaptic and postsynaptic disorders can cause an ANSD phenotype. The presynaptic disorders include inner hair cell dysfunction and/or loss and deficits in the neurotransmitter release from the inner hair cell-dendrite synapse. The postsynaptic disorders include unmyelinated dendritic nerve terminals dysfunction, axonal neuropathies, auditory ganglion cell disorders,^[12] demyelination disorders, auditory nerve hypoplasia, and auditory nerve conduction

block.^[12] Starr *et al.*^[3] suggested an etiological classification of ANSD based on this: Type I postsynaptic AN plus vestibular and peripheral neuropathies and Type II postsynaptic AN plus optic nerve disorders accompanying nuclear and mitochondrial mutations. Type III presynaptic AN plus inner hair cell and neurotransmitter disorder and Type IV auditory neuropathy unspecified where the affected sites are unknown.

Type of Study

This was a cross-sectional, descriptive, and analytical study.

Institute of Study

This study was conducted at Government Medical College and Hospital, Kozhikode.

Period of Study

This study was from January 2017 to June 2018.

MATERIALS AND METHODS

A total of 42 patients attending the ENT OPD of Government Medical College, Kozhikode, with ANSD were included in the study. An ethical committee clearance was obtained before the commencement of the study. An ethical committee cleared consent form was used for the study.

Inclusion Criteria

(1) Patients with a history and clinical examination suggestive of ANSD were included in the study. (2) Patients of all age groups were included in the study. (3) Patients of both the genders were included in the study.

Exclusion Criteria

(1) Patients who failed to complete audiological evaluation were excluded from the study. (2) Patients with a previous history of inflammatory diseases of the ears were excluded from the study. (3) Patients with uncontrolled diabetes and thyroid deficiencies were excluded from the study. All ANSD patients were evaluated with a detailed history including perinatal and development history, ototoxic drug exposure, head trauma, neurodegenerative conditions, and family history. Following clinical evaluation which included general examinations, ENT examination, and central nervous system examination, an audiological evaluation, which included pure tone audiometry (PTA), speech audiometry, immittance evaluation, OAE, and ABR was done. Radiological investigation (magnetic resonance imaging [MRI] brain with inner ear – focusing on any structural anomalies; cochlea, vestibulocochlear nerve, and internal auditory canal) was done. Patients were counseled regarding the rehabilitation options based on their audiological and radiological results and the need for follow-up was explained. All the data were analyzed with standard statistical methods.

Sample Size

The sample size was 42 (based on the previous hospital records and statistical analysis); $n = 4 pq/d^2$ wherein $p=60\%$, $q=100-60=40\%$, $d=15\%$ $n = 4 \times 60 \times 40/152$ and hence $n = 42$.

Working Strategy

(A) Patients were evaluated and diagnosed using the following methods: (1) Proper history and presenting complaints. (2) Intake of ototoxic drugs, associated neurodegenerative disorders or head injury was elicited. (3) Perinatal history and familial causes were noted. (B)(1) Patients were subjected to general examination and ENT examination, central nervous system examination – for any neurodegenerative causes. (2) Audiological evaluation including pure tone audiometry, speech audiometry, immittance evaluation, OAE, and ABR was done. (3) Radiological evaluation of the inner ear with MRI was done. (4) Following the study, the results were analyzed and rehabilitation was done.

OBSERVATION AND RESULTS

A total of 42 patients attending the ENT OPD of Government Medical College, Kozhikode, with ANSD were included in the study. Among the 42 patients, 21 (50%) were in the age group of 11–20 years followed by 13 patients who were between 0 and 10 years (30.95%). The remaining 8 were aged above 20 years (19.04%). The youngest patient was 10 months old and the oldest was aged 38 years with a mean age of 10.35 ± 2.10 years [Table 1]. There were 29 (69.04%) females and 13 (30.95%) males [Table 1].

Among the 42 patients, 41 (97.61%) had bilateral hearing loss and the remaining 1 patient had (2.38%) unilateral hearing loss and it was on the left side. None of the patients had hearing loss in their right ear [Table 2].

The incidence of tinnitus was observed in this study group and found that 30 (71.42%) of them did not complain of any tinnitus. Ten (23.80%) patients complained of tinnitus in their both ears and 2 patients (4.76%) had tinnitus in their right ear [Table 3].

Among the 42 patients, 36 (85.71%) had no complaints of vertigo and 6 (14.28%) had vertigo. All the 42 patients (100%) presented with poor speech discrimination (excluding children <5 years). Clarity of the speech was good in 25 (59.52%) of the patients. Clarity of the speech was poor in 17 (40.47%) of the patients [Table 4].

Examining the various etiologies that could possibly the causing ASND in this study, it was observed that

14 (33.33%) patients had a history of systemic viral infections before the onset of the disease. Of 14 patients with viral infections, 7 patients had suffered from viral parotitis (16.66%). The remaining 28/42 patients showed no history or ailment of viral infections before ASND disease [Table 5].

3/42 (7.14%) patients gave a history of exposure to ototoxic drugs such as streptomycin, gentamicin, and kanamycin, but never had a history of loss of hearing before that. History of premature birth was noted in 10 (23.80%) patients and

Table 1: The distribution of the patients according to their age groups and gender (n=42)

Age groups in years	Number (%)	Males (%)	Females (%)
0–10	13 (30.95)	3 (7.14)	10 (23.8)
11–20	21 (50)	7 (16.66)	14 (33.33)
21–30	5 (11.9)	2 (7.14)	3 (11.9)
Above 30	3 (7.14)	1 (2.38)	2 (4.76)

Table 2: The involvement of side of hearing loss in the study group (n=42)

Side of hearing loss	Number (%)
Unilateral	41 (97.61)
Bilateral	1 (2.38)
Right ear	42 (100)
Left ear	0 (0)

Table 3: The incidence of tinnitus in the study (n=42)

Tinnitus	Number (%)
Absent	30 (71.42)
Right ear	10 (23.8)
Left ear	2 (4.76)

Table 4: The incidence of vertigo, speech discrimination, and clarity of speech in the study (n=42)

Symptom	Present (%)	Absent (%)
Vertigo	36 (85.71)	6 (14.28)
Poor discrimination of speech	42 (100)	0 (0)
Clarity of speech	25 (59.52)	17 (40.47)

Table 5: The incidence of viral etiology in the study population (n=42)

Etiological factors	Number	Percentage
Viral infections-14		
Other than viral parotitis	7	16.66
Viral parotitis	7	16.66
Total		33.33
No viral infections	28	66.66

the remaining patients did not show premature birth history. Among the 42 patients of this study group, 23 (54.76%) had low birth weight, of which 2/42 (4.76%) were <1.5 kg. 21/42 (50%) patients had birth weight above 1.5 kg. 10/42 patients (23.80%) gave a history of NICU admissions at the time of their birth. 5/42 (11.9%) of the patients in this study had a history of head trauma. Consanguinity was observed in 5/42 patients gave a history of having born out of (11.9%) their parent's consanguineous marriage. Peripheral neuropathy was observed in 4/42 (9.50%) of the patients had peripheral neuropathy and 90.5% had no evidence of peripheral neuropathy. Of the 42 patients studied, only 1 had (2.38%) neurodegenerative disease – hereditary spastic paraplegia. To summarise the etiological factors playing a role in causing ANSD in patients of this study, it was observed that. Of the 42 patients studied, the major association was found with low birth weight (54.8%), followed by viral infection (33.3%), NICU admission (23.8%), and prematurity (23.8%). Some of them had more than one causative factor. The least common was neurodegenerative disease (2.4%). About 30.95% of them had no identifiable cause [Table 6].

On clinical examination of the ear, it was observed that 9 (21.42%) of the study participants had retracted (Grade I) tympanic membrane in both ears, whereas 78.6% had intact tympanic membrane in both ears. In the study population of 42 patients, 22 had moderate hearing loss (52.38%). Hearing loss was mild in 6 (14.28%) patients in their right ears [Table 7].

In the study population of 42 patients, 14 had moderate hearing loss (33.33%). Hearing loss was mild in 14 (33.33%) patients in their left ears [Table 8].

Looking at the pattern of pure tone audiometry and loss of hearing across the frequencies, it was observed that 90.4% had low-frequency type of loss and 4.8% had flat and the remaining 4.8% had high-frequency loss. High-frequency loss was noted in patient with hereditary spastic paraplegia. Analysis of the speech audiometry in the study subjects showed that all (100%) the ANSD ears had poor speech discrimination

score <25%. Speech reception threshold was more than 45% among the 38/42 (90.47%) of the patients. All (100%) of the patients with ANSD had poor correlation between PTA and speech audiometry, $P = 0.153$ (where P was significant at <0.05). Similarly, there was poor correlation between pure tone average and speech discrimination score with $P = 0.701$ (where P was significant at <0.05). Tympanometry studies of the patients with ANSD were carried out and it was analyzed that 39/42 (92.85%) had normal tympanograms (Type A) and the remaining 7/42 (7.14%) had C type of tympanogram. All the patients (100%) had absent acoustic reflexes on impedance audiometry. The study of OAEs in the present study showed that 36/42 (85.71%) had OAEs present in their right ears and 38/42 (90.47%) of the patients had OAEs present in their right ears. On the contrary, OAEs were absent in 6/42 (14.28%) of the right ears and 4/42 (9.52%) of the left ears. A study of cochlear microphonics was undertaken and it was observed that all (100%) of the patients had absent cochlear microphonics in both ears and a reverse polarity was also analyzed. Auditory brain stem response (ABSR) in the study population showed that all the patients showed threshold levels above 110 dB in all the left ears with prolonged latency periods. One patient had ABSR values in the right ear. MRI studies of all the patients were undertaken in this study and found that there was no inner ear abnormality noticed in all the patients (100%). Of the 42 patients studied, 37 (88.09%) of them were found eligible for amplification. In view of absent cochlear microphonics, cochlear implantation was not attempted in any of them. Rest of them 5/42 (11.90%) were comfortable without any rehabilitation options. Of 37/42 patients (88.09%), none of them found any significant benefit with amplification. Speech strategy was advised for them.

DISCUSSION

In the above descriptive study conducted at the Department of ENT, Government Medical College, Kozhikode, 42 patients with ANSD were analyzed for their symptoms, audiological evaluation, and radiological evaluation. The sociodemographic, clinical, and audiological

Table 6: The incidence of various risk factors in the study group (n=42)

Other etiological factors	Number	Percentage	Absent	Percentage
Ototoxic drugs	3	7.14	39	92.85
Premature birth	10	23.80	32	76.19
Low birth weight	23	<1.5 kg–02	19	45.23
	54.76%	>1.5kg–21		
		50		
NICU admission	10	23.80	32	76.19
Consanguinity	5	11.90	37	88.90
Peripheral neuropathy	4	9.52	38	90.47
Neurodegenerative disease	1	2.38	39	92.85

NICU: Neonatal intensive care unit

Table 7: The pure tone average values among the study group in their right ears (n=42)

Pure tone average	Number (%)
Minimal (16–25 dB)	5 (11.9)
Mild (26–40 dB)	6 (14.28)
Moderate (41–55 dB)	22 (52.38)
Moderate-to-severe (56–70 dB)	2 (7.14)
Severe (71–90 dB)	4 (9.52)
Profound (above 90 dB)	2 (4.16)

Table 8: The pure tone average values among the study group in their left ears (n=42)

Pure tone average	Number (%)
Minimal (16–25 dB)	4 (9.52)
Mild (26–40 dB)	14 (33.33)
Moderate (41–55 dB)	14 (33.33)
Moderate-to-severe (56–70 dB)	4 (9.52)
Severe (71–90 dB)	4 (9.52)
Profound (above 90 dB)	0 (0)

data were studied to determine the audiological profile of ANSD with an overview of etiology. Further, this study also assessed the various rehabilitation strategies available and the patient benefit with them. Among the study group, a total of 42 patients, majority were in the age group of <20 years (80.95%). This was consistent with the study of Berlin *et al.*,^[4] where 153 of 260 patients studied fell in the age group of <18 years. Of these, 69% were female and 31% were male, this was different from the study of Berlin *et al.* where the majority were males which were not considered significant in this study. This difference could be attributed to the large sample of the study by Berlin *et al.* (260 patients). All of them presented with hearing problems. Some had difficulty in understanding while others had difficulty in hearing. Majority of them (97.6%) had bilateral hearing problem and only one of them presented with unilateral hearing problem (left side). This was again consistent with the study of Berlin *et al.*^[4] where 92.69% had bilateral disease, whereas 07.31% had unilateral disease with the left side predominance (68.42%). While 14.3% of them had vertigo, 28.6% of them complained of tinnitus (4.8% involving the right ear alone). None of them found it debilitating in contrast with the study by Prabhu and Jamar^[13] where majority had moderate degree of functional impairment due to tinnitus. The study also concluded that no significant association between onset of hearing loss and tinnitus could be found. One of the characteristic observations was that all of the study participants had difficulty in speech discrimination, more aggravated in the background of noise. The severity of this varied, with one end showing speech discrimination abilities compatible with day-to-day activities and at the other end, we had people who presented with mask-like faces, completely oblivious of their environment. This observation was found

to be similar to those of Rance^[5] where speech perception ability of the ANSD group was found to be poorer than the matched normal and sensorineural group. In spite of poor speech discrimination, 59.5% had good clarity in speech. Of the 42 patients studied, 54.8% had a history of low birth weight, 33.3% had preceding viral infections, and 23.8% had prematurity and NICU admissions. Less than 15% of them had a history of consanguinity, head trauma, peripheral neuropathy, and ototoxic drug exposure and neurodegenerative diseases. Due to the multiple risk factors in many of them, there was considerable overlap in percentages. In 30.95%, no identifiable cause could be found. In the study by Berlin *et al.*,^[4] the major risk factors were hyperbilirubinemia (48%) and premature birth (47%), with only 7% having history of low birth weight. As genetic study was not done, the causation could not be attributed to these risk factors alone in the present study. Further, probing into the genetic workup might be needed for the same. In the category of low birth weight, 4.8% of patients were <1.5 kg with the lowest being 750 g. However, no significant association was found between birth weight and age of onset of symptoms. In a case report by Salvinelli *et al.*,^[14] preserved OAEs were seen in post parotitis patients in the presence of profound SNHL and abnormal ABR. It was attributed to the tropism of virus to the inner hair cells or sparing of outer hair cells due to difference in antigenicity. In our study, of the 33.3% having viral infection preceding the onset of symptoms, 50% had viral parotitis. However, contrary to the presentation in the report, all of them in our study had bilateral hearing problem. Although 23.8% of them had prematurity and NICU admission ranging from 10 to 28 days, no significant association was found with the onset of disease. Similar to the study by Unal and Vayisoglu,^[10] consanguinity, ototoxicity, and head trauma were also present in few people, with a history of consanguinity and head trauma in 11.9% and ototoxicity in 7.1%. On examination, 9.5% of them had peripheral neuropathy and one of them had neurodegenerative disease in the form of hereditary spastic paraplegia. The presence of Grade I bilateral retraction of tympanic membrane in 21.4% of them was not found to be statistically significant. Majority (78.6%) had normal external auditory canal and tympanic membrane findings. In pure tone audiogram, majority fell in the range of mild-to-moderate hearing loss with low-frequency type. This was consistent with the findings of Berlin *et al.*^[4] study, where 16.28% had mild-to-moderate hearing loss. A clinching factor here was poorly correlating PTA and speech audiometry. Speech audiometry becomes a reliable pointer here. Most of the time patients presented with difficulty in comprehension or poor academic performances. The discrepancy between the PTA and speech audiometry prompted us to probe deeper, thus unveiling the ANSD. A study conducted by Sinha *et al.*^[15] focuses on the importance of doing speech audiometry routinely by

highlighting a case of coexisting ANSD and conductive hearing loss, which without speech audiometry would have been managed as a case of otosclerosis. About 90.5% had speech reception threshold more than 45, implying the need for rehabilitation options. About 92.9% had normal tympanogram. The changes in tympanogram did not influence the disease status. All of them had absent acoustic reflexes. In the earlier days, the diagnostic factor in ANSD was the presence of OAEs and cochlear microphonics. However, as time progressed, it was found that the OAEs and cochlear microphonics need not always be present as evidenced by the study of Sharma *et al.*^[16] It was noted that in conditions where ANSD coexists with other pathologies (like noise-induced hearing loss), OAE could be absent, and it was also identified that the progressive form of ANSD could damage the outer hair cells. Here, OAEs were present in 85.7% of the right ears and 90.5% of the left ears. In the remaining patients, though no coexisting conditions were noted; all of them had complaints lasting for more than 5 years. Cochlear microphonics (reverse polarity) was found to be absent in all of them – depriving them of cochlear implantation. Reverse polarity was used to prevent the neural artifact. As cochlear response was noted to change polarity when the stimulus is inverted, neural responses do not change polarity. This was shown to uncover AN in the study by Berlin *et al.*,^[4] wherein ABR and cochlear microphonics were differentiated based on polarity change. All of them had abnormal ABR in the left ear. In the right ear, only one of them showed normal ABR. This was of the patient who presented with the left unilateral ANSD. MRI of the brain and inner ear detected no significant anomalies. Similar findings were also noted by Starr *et al.*^[3] As all of them did not show cochlear microphonics (reverse polarity), cochlear implantation was not tried in this study. Remaining options were amplification and speech strategy. The study by Berlin *et al.*^[4] noted that hearing aid had only very minimal benefit in minority of ANSD cases, as the underlying problem of difficulty in speech perception persisted. Moreover, it was argued that amplification modalities may damage the normal functioning outer hair cells, thus doing more harm than good. Many of them opted out of amplification as they were doing well in daily activities without any aids. About 88.1% of them were fitted with hearing aids, but none of them found it beneficial and thus was directed to speech strategies, the result of which needs to be assessed in further follow-up.

CONCLUSIONS

The major risk factor identified in this study for ANSD was low birth weight with prematurity, NICU admissions,

and viral infections having significant contributions. On audiological evaluation, hearing loss was of mild-to-moderate range with a low-frequency loss. There was no statistical correlation between pure audiometry values and speech audiometry which was a characteristic observation. OAEs were present in the majority of patients with absent cochlear microphonics (reverse polarity) and acoustic reflexes. Auditory brain stem response was found to be abnormal in all ears with ANSD. After assessing the patient profile, 37 of them were fitted with hearing aids. However, none of them showed any significant benefit, stressing on tailor-made rehabilitation strategies, and further researches into this.

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A Comparative Study between the Efficacy of Pre-incisional and Post-incisional Wound Infiltration of Bupivacaine for the Relief of Post-operative Pain

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Abstract

Introduction: Pain, the “fifth vital sign” is an unpleasant sensation localized to a part of the body. Post-operative pain has been widely studied, as it causes adverse psychological and physiological effects. Many anesthetic agents and techniques have been developed to minimize the post-operative pain. This study compares the effectiveness of two such techniques: Pre-incisional and post-incisional infiltration using bupivacaine as the anesthetic agent.

Materials and Methods: This prospective, randomized, non-crossover type, double-blind interventional study was conducted on 60 patients of either gender, aged 15–50 years, belonging to the American Society of Anesthesiologists Grades I and II undergoing lower abdominal surgeries. They were randomly divided into two groups: Pre-incisional and post-incisional infiltration groups and were monitored for up to 24 h postoperatively for the duration of analgesia and intensity of pain.

Results: The duration of post-operative analgesia was better in the pre-incisional infiltration group (540 min) compared to the post-incisional infiltration group (360 min). Similarly, the overall mean pulse rate, mean systolic blood pressure (SBP), and mean respiratory rate were lower in the pre-incisional infiltration group, indicating better post-operative pain relief.

Conclusion: Although both pre-incisional and post-incisional infiltration of bupivacaine are safe, pre-incisional infiltration provides better relief of post-operative pain.

Key words: Bupivacaine, Post-incisional, Post-operative pain, Pre-incisional, Visual analog scale

INTRODUCTION

Pain, the “fifth vital sign”^[1] is an unpleasant sensation localized to a part of the body. The word pain which causes majority of us shudder with fear is derived from the Greek word “poine” which means penalty or punishment.

In 1979, the International Association for the Study of Pain defined that pain is “An unpleasant sensory and emotional experience associated with actual or potential damage, or described in terms of such damages.”^[2] Post-operative pain

is associated with adverse psychological and physiological effect. The adverse physiologic effect of post-operative pain includes respiratory compromise from reflex splinting of respiratory and abdominal muscles, increased myocardial work and oxygen consumption, peripheral vasoconstriction, gastrointestinal and urinary dysfunction, impairment of muscle metabolism, and decreased physical activity.

Post-operative pain is maximum in the first 48 h. Various methods such as systemic narcotics, nonsteroidal anti-inflammatory drugs, neuraxial anesthetics techniques and nerve blocks, local anesthetic infiltration, epidural narcotics, and psychological methods which are employed to relieve pain during this period.

Topical infiltration of local anesthetics at the surgical site is a simple, easy, and attractive technique recommended for providing a longer post-operative pain-free period and decreased analgesic requirements.

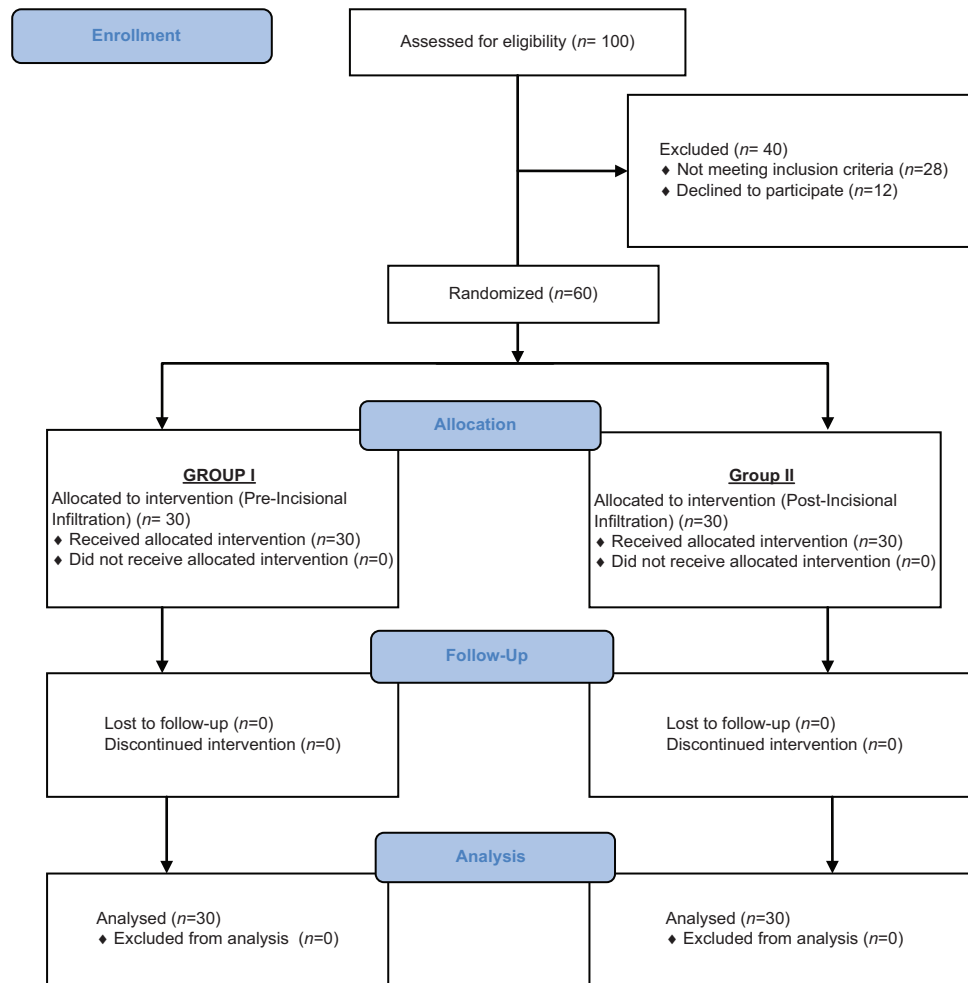
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Surgical incision provokes two kinds of modifications in the responsiveness of the nervous system: Peripheral sensitization and central sensitization. Peripheral sensitization is a reduction in the threshold of nociceptor afferent peripheral terminals. Central sensitization is an N-methyl-D-aspartate (NMDA) receptor-mediated activity-dependent increase in the excitability of dorsal horn neurons.^[3] This causes post-operative pain hypersensitivity state which manifests as an increase in the response to noxious stimuli and a decrease in the pain threshold. This leads to amplification and prolongation of post-operative pain. Infiltration of local anesthetics in the area of the skin before surgical incision pre-empts post-operative pain by preventing the establishment of peripheral and central sensitization

Therefore, this study was undertaken to compare the efficacy of pre-incisional and post-incisional wound infiltration of bupivacaine for post-operative pain relief in lower abdominal surgeries. The study compares the duration of analgesia, severity of pain, and demand for additional analgesics required for the first 24 h after the surgery in the above groups.

MATERIALS AND METHODS

This is a prospective, randomized, non-crossover type, double-blind interventional study, conducted in B. J. Medical College and Sassoon General Hospital, after obtaining permission from the Institutional Ethics Committee. This study was carried out on 60 patients belonging to either sex and ranging from 15 to 50 years of age, belonging to the American Society of Anesthesiologists Grades I and II, undergoing lower abdominal surgeries lasting for not more than 2 h under general anesthesia. A written informed consent was taken from all the patients.

Patients not providing consent, having a history of addiction, pre-medication with analgesic drugs, and psychiatric illness were excluded from the study. Routine investigations such as hemogram, urine for sugar and albumin, bleeding time, clotting time, blood sugar level, blood urea level, and serum electrolytes were done. Other investigations were carried out wherever necessary.

Patients were randomly divided into two groups of 30 patients each:

- Group I: Pre-incisional infiltration group
- Group II: Post-incisional infiltration group

20 ml of 0.25% bupivacaine was infiltrated 5 min before incision in Group I and after induction in Group II. The time of skin incision was taken as “zero” in both the groups.

The following parameters were monitored:

1. Time of infiltration
2. Time of incision
3. Vitals were monitored intraoperatively and up to 24 h postoperatively
4. Severity of pain: It was measured by visual analog scale (VAS) with 1 indicating “No Pain” and 10 indicating “maximum imaginable pain.” The scores were graded as
 - Mild: 1–3
 - Moderate: 4–6
 - Severe: 7–10
5. Requirement of analgesic (Inj. diclofenac sodium).

Statistical Analysis

The data were analyzed using SPSS software. The quantitative data were analyzed using “*t*-test” and the qualitative data were analyzed by Chi-square test. $P < 0.05$ was considered to be statistically significant.

RESULTS

Both the groups were comparable in terms of demographic variables and physical attributes. The mean duration of

surgeries was 108.67 ± 5.49 min in Group I and 106.67 ± 3.30 min in Group II. However, the difference was statistically not significant ($P = 0.09$).

The mean duration of analgesia (time for the requirement of the first dose of analgesic) was 9.1 ± 0.9 h in Group I and 5.7 ± 0.8 h in Group II, and this was statistically significant ($P < 0.0001$).

The mean analgesic requirement, in terms of injections of diclofenac sodium, in the post-operative period was 1.4 ± 0.5 in Group I and 2.0 ± 0.7 in Group II. However, the difference was statistically not significant ($P = 1$).

The mean pulse rate [Table 1], mean SBP [Table 2], and mean respiratory rate [Table 3] were overall significantly less in Group I as compared to Group II, from 8 h onward. The severity of pain, as measured by the VAS, was significantly less than Group I than in Group II [Table 4].

No incidence of adverse effects was noted in any group.

DISCUSSION

Physiologic studies have confirmed that a painful stimulus does not merely transmit a nociceptive signal to the central nervous system. It may trigger a complex cascade of physiological alterations in the somatosensory system, which lowers the dorsal horn neuron thresholds, sensitizing the peripheral and central pain pathways.^[4-6] The response

Table 1: Comparison of mean pulse rate in Groups I and II

Parameter	Group I (Mean±SD)	Group II (Mean±SD)	P-value	Statistical significance
Pre-operative	82.60±7.87	80.73±10.04	0.43	Not significant
2 h post-operative	78.27±3.43	78.70±4.37	0.67	Not significant
4 h post-operative	79.93±2.00	78.80±5.12	0.26	Not significant
6 h post-operative	76.70±3.61	77.87±4.42	0.27	Not significant
8 h post-operative	78.80±5.12	88.97±3.18	<0.0001	Significant
10 h post-operative	91.60±3.14	82.83±4.50	<0.0001	Significant
16 h post-operative	82.83±4.50	91.13±4.44	<0.0001	Significant
20 h post-operative	89.13±2.85	89.13±2.85	1.00	Not significant
24 h post-operative	91.13±4.44	100.43±5.97	<0.0001	Significant

SD: Standard deviation

Table 2: Comparison of mean systolic blood pressure in Groups I and II

Parameter	Group I (Mean±SD)	Group II (Mean±SD)	P-value	Statistical significance
Pre-operative	124.27±8.51	120.00±8.30	0.054	Not significant
2 h post-operative	115.27±6.23	113.87±7.31	0.43	Not significant
4 h post-operative	116.53±6.28	115.87±6.77	0.69	Not significant
6 h post-operative	120.13±5.48	117.93±5.55	0.13	Not significant
8 h post-operative	120.20±5.07	127.20±4.86	<0.0001	Significant
10 h post-operative	123.07±4.13	121.93±2.99	0.23	Not significant
16 h post-operative	115.87±6.77	123.07±4.13	<0.0001	Significant
20 h post-operative	125.27±2.90	125.27±2.90	1.00	Not significant
24 h post-operative	123.07±4.13	138.93±3.92	<0.0001	Significant

SD: Standard deviation

Table 3: Comparison of mean respiratory rate in Groups I and II

Parameter	Group I (Mean±SD)	Group II (Mean±SD)	P-value	Statistical significance
Pre-operative	15.87±1.38	14.87±1.59	0.01	Significant
2 h post-operative	13.33±0.61	13.13±1.01	0.36	Not significant
4 h post-operative	13.83±0.65	13.47±0.90	0.08	Not significant
6 h post-operative	13.33±0.61	13.67±0.84	0.08	Not significant
8 h post-operative	13.83±0.65	15.63±1.38	<0.0001	Significant
10 h post-operative	15.57±1.17	14.00±0.79	<0.0001	Significant
16 h post-operative	13.67±0.84	15.57±1.17	<0.0001	Significant
20 h post-operative	13.80±0.81	13.80±0.81	1.00	Not significant
24 h post-operative	15.57±1.17	16.90±1.06	<0.0001	Significant

SD: Standard deviation

Table 4: Comparison of mean visual analog scale scores in Groups I and II

Parameter	Mild (1–3)		Moderate (4–6)		Severe (7–10)		P value	Statistical significance
	Group I	Group II	Group I	Group II	Group I	Group II		
2 h post-operative	30 (100%)	30 (100%)	0	0	0	0	--	--
4 h post-operative	30 (100%)	30 (100%)	0	0	0	0	--	--
6 h post-operative	30 (100%)	30 (100%)	0	0	0	0	--	--
8 h post-operative	30 (100%)	5 (16.7%)	0	24 (80%)	0	1 (3.3%)	<0.0001	Significant
10 h post-operative	18 (60%)	5 (16.7%)	12 (40%)	23 (76.7%)	0	2 (6.7%)	<0.0001	Significant
16 h post-operative	10 (33.3%)	0	20 (66.6%)	27 (90%)	0	3 (10%)	<0.0001	Significant
20 h post-operative	5 (16.7%)	0	25 (83.3%)	25 (83.3%)	0	5 (16.7%)	<0.0001	Significant
24 h post-operative	0	0	30 (100%)	12 (40%)	0	18 (60%)	--	--

to subsequent or persisting painful stimuli may thereby be amplified, resulting in hyperalgesia, spontaneous pain, and allodynia. Pre-emptive analgesia intervention given before surgery may, therefore, prevent this sensitizing cascade, reducing the development and severity of post-operative pain.

The idea of pain was first introduced into clinical practice by Crile, in 1913,^[7] and further developed by Wall^[8] and Woolf^[9] Pre-emptive analgesia embodies the idea that the pain perceived after a tissue injury may be modified by an analgesic administered before the precipitating noxious stimuli. It further envisages the idea that the timing of the analgesic is critical in its efficacy (e.g., that a given dose administered preceding the stimulus is more effective than the same dose given afterward).

Post-operative pain can be eliminated or reduced by various analgesic drugs and techniques. Narcotics form the mainstay of analgesics for acute control of moderate-to-severe pain. They produce excellent analgesia but require extensive patient monitoring. In the post-operative period, when the patients are experiencing pain and are drowsy, narcotic administration possesses a potential risk of respiratory depression. This has led to research for analgesics that are devoid of opioid side effects with effective potency.

In this study, bupivacaine was used as an analgesic to compare the efficacy of pre-incisional infiltration with post-incisional infiltration to relieve post-operative pain.

The study groups were similar in terms of demographic variables and physical attributes.

Duration of Analgesia

In this study, the duration of analgesia (as determined by the requirement of rescue analgesia postoperatively) was 9.1 ± 0.9 h (540 min) in the pre-incisional infiltration group and 5.7 ± 0.8 h (360 min) in the post-incisional infiltration group.

This was similar to the study by Alsaif *et al.*,^[10] where the first analgesic request was made after 314.6 ± 76.7 min in the pre-incisional group and 207.0 ± 8.36 min in the post-incisional infiltration group. Thus, the duration of analgesia was more in the pre-incisional infiltration group than the post-incisional infiltration group.

Similarly, in the study by Divecha *et al.*,^[11] it was found that the duration of analgesia was longer in the pre-incisional infiltration group (7.5 ± 1.5 h) than in the post-incisional infiltration group (4.3 ± 1.7 h).

Total Analgesic Requirement

This refers to the total number of doses of injection of diclofenac sodium requirement in the first 24 h.

In this study, the mean requirement was lower in the pre-incisional infiltration group than in the post-incisional infiltration group. However, it was not statistically significant.

This was similar to the study by Olanipekun *et al.*,^[12] which found no significant difference in the mean analgesic (paracetamol) requirement in both the groups.

This was similar to the study by Alsaif *et al.*^[10] (pethidine) and Kato *et al.*^[13] (diclofenac sodium). Furthermore, in the study by Lohsiriwat *et al.*,^[14] it was found that both the total number of morphine injections and the amount of morphine used postoperatively in the pre-emptive group were less compared to the control group.

Pain Intensity

It was observed that the intensity of pain, as measured by the VAS score, was lesser in the pre-incisional infiltration group than in the post-incisional infiltration group. Mild (1–3) pain was seen 2 h postoperatively onward while moderate (4–6) and severe pain (7–10) were recorded 8 h postoperatively onward. There were no cases of severe pain in the pre-incisional infiltration group.

All the patients of the post-incisional infiltration group started experiencing moderate-to-severe pain from 16 h postoperatively onward. However, the same in the pre-incisional infiltration group started 24 h postoperatively onward.

Thus, overall control of pain was better in the pre-incisional infiltration group than in the post-incisional infiltration group, indicating better analgesia, up to 24 h postoperatively.

This was similar to the study by Alsaif *et al.*,^[10] where lower pain scores were observed in the pre-incisional group than in the post-incisional group, at the end of 30 min, 2 h, 4 h, and 24 h.

Similarly, the studies by Olanipekun *et al.*,^[12] Kato *et al.*,^[13] and Lohsiriwat *et al.*^[14] and found better analgesia in the pre-incisional infiltration group than in the post-incisional infiltration group.

Vital Parameters

The mean pulse rate was less in the pre-incisional infiltration group than in the post-incisional infiltration group, except at 4, 10, and 20 h postoperatively. This difference was clinically insignificant, but statistically significant from 8 h postoperatively onward (except at 20 h).

The mean SBP was more in the pre-incisional infiltration group than the post-incisional infiltration group up to 6 h postoperatively. However, the difference was clinically and statistically insignificant.

At 8 h, 16 h, and 24 h postoperatively, the mean SBP in the pre-incisional infiltration group was significantly

lower than the post-incisional infiltration group. At 24 h postoperatively, a sharp rise was observed in the mean SBP, which was both clinically and statistically significant.

The mean respiratory rate was less in the pre-incisional infiltration group than in the post-incisional infiltration group 6 h postoperatively onward, except at 10 and 20 h postoperatively. This difference was clinically insignificant, but statistically significant from 8 h postoperatively onward (except at 20 h).

All these parameters indicate better post-operative pain relief in the pre-incisional infiltration group than in the post-incisional infiltration group, which correlates with the interpretation of the VAS score.

Though existing studies did not measure the post-operative pain through the vital parameters, however, these results can be compared with the studies that measured the intensity of post-operative pain through VAS scores. Thus, the findings are in accordance with the studies by Alsaif *et al.*,^[10] Olanipekun *et al.*,^[12] Kato *et al.*,^[13] and Lohsiriwat *et al.*^[14] and where pre-incisional infiltration was found to provide better post-operative pain relief than post-incisional infiltration.

Adverse Effects

No adverse events of any kind were noted in the study, indicating that bupivacaine is safe as pre-incisional and post-incisional infiltration.

Most of the studies did not include any adverse effect profile.

In the study by Divecha *et al.*,^[11] where incidences of wound infection and hematoma were observed with ropivacaine. However, it was concluded that their sample size was inadequate to comment on the complication rates of wound infiltration.

Limitations

The study was limited by the outpatient department attendance of the patients requiring lower abdominal surgeries. Therefore, the results may not be generalized.

CONCLUSION

It can be effectively concluded from the study that though both pre-incisional and post-incisional infiltration of bupivacaine are safe (as evidenced by the lack of adverse effects), pre-incisional infiltration provides better analgesia and post-operative pain relief than the post-incisional infiltration, in terms of duration of analgesia, intensity of pain, and post-operative requirement of analgesic.

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Alteration in Serum Lipid Profile in Oral Squamous Cell Carcinoma

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Abstract

Background: Alteration in the pattern of serum lipid profile has been associated with a variety of cancers and precancerous conditions. Low levels of serum lipid serve as a prognostic marker in the early detection of oral precancerous and cancerous conditions because lipid plays an important role in new membrane biogenesis and maintains cell integrity.

Aim: The aim of our study is to evaluate the alteration in serum lipid profile in oral squamous cell carcinoma (OSCC) and compared it with control group.

Materials and Methods: A total of 80 subjects were selected from the Department of Oral Pathology and Microbiology, RUHS College of Dental Sciences, Jaipur (GDC-Jaipur). Among 80 subjects, 40 individuals were diagnosed with squamous cell carcinoma and other 40 individuals were taken in healthy control group selected randomly from other departments. The total parameters assessed include total cholesterol (TC), high-density lipoprotein cholesterol (HDL), low-density lipoprotein cholesterol (LDL), very LDL, and triglycerides (TGLs). Statistical analysis was carried out by Chi-square and one-way ANOVA test to evaluate parameters.

Results: There was a significant decrease in TC, HDL, and TGL in the oral cancer group as compared with the control group.

Conclusions: There was an inverse relationship between serum lipid profile and OSCC. The lower serum lipid status may be considered a useful prognostic biochemical indicator for initial changes occurring in the neoplastic proliferating cell.

Key words: Control group, Histologically diagnosed case of oral cancer, Serum lipid profile

INTRODUCTION

Oral cancer (OC) is the sixth most common cancer worldwide. Malignant neoplasms are major causes of fear, morbidity, and mortality all over the world. OC is one of the most mutilating diseases afflicting the humankind.^[1] In Southeast Asia, more than 100,000 new cases are reported every year. The main contributing cause of OC in India is the form of quid and smoking. It is most commonly preceded by clinically definable premalignant lesions and conditions. Around 0.3–25% of leukoplakia and 7–12% of oral submucous fibrosis cases will undergo malignant transformation.^[2]

In cancer, the newly proliferating cells would need many basic components well above the normal limits, used in physiological process. One such component is lipids which form major cell membrane components essential for various biological functions including cell division and growth of normal and malignant tissues. The increased requirement of lipids to fulfill the need of these new cells would be expected to diminish the existing lipid stores.^[3]

Altered lipid levels have been consistently associated with coronary heart disease and their relation to different cancers such as breast and colorectal has also been documented^[4] However, the reports on altered lipid levels in OC and pre-cancer are few and conflicting. With the above in mind, the present study was conducted to evaluate the implications of altered serum lipid profile in patients with OC. Hypolipidemia can be considered as one of the biochemical markers in early detection of cancer.^[5,6]

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Early detection of these lesions can dramatically improve the treatment outcome and prognosis in such patients. Thus, the development of newer diagnostic and predictive approaches that are safe, economical, and amenable to repeated sampling is imperative. Blood-based/serum-based tests offer the aforementioned advantages.

MATERIALS AND METHODS

Sources of Data

The present study was done in the Department of Oral Pathology and Microbiology, RUHS College of Dental Sciences, Jaipur. Forty patients with clinically and histopathologically proven oral squamous cell carcinoma (OSCC) were taken, the age group between 31 and 70 years. The study subjects comprised two groups as follows:

1. Group 1: OSCC
2. Group 2: Control group

Group 1 comprised 40 patients of OSCC in the age group of 20–70 years.



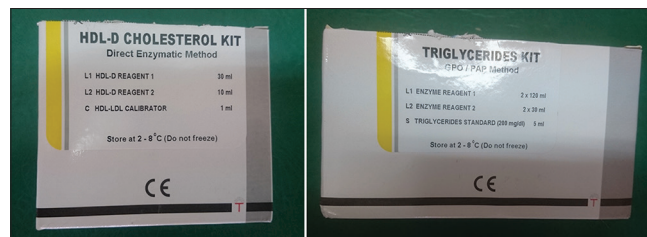
Diagnostic instruments



Centrifuged machine (Remi-C)

Inclusion Criteria

Patients clinically and histopathologically diagnosed with OSCC were included in the study.



Lipid profile kit



Stat Fax machine (3000)

Exclusion Criteria

The following criteria were excluded from the study:

- Patients with underlying systemic disease such as diabetes, hypertension, anemia, jaundice liver or kidney disorders, or other systemic diseases
- Patients on drugs that alter the lipid level

Group 2 (control group) comprised 40 healthy subjects in the same age group, sex matched with those of the OSCC group and with no deleterious oral habits and no associated oral lesions.

Materials

- a. 5 ml of blood sample of each individual
- b. Disposable syringe and needle
- c. Plain vial
- d. Centrifuged machine (Remi-C)
- e. Lipid profile reagent kit (coral clinical systemic)
- f. Micropipette and holder
- g. Semiautomatic biochemistry analyzer (Stat Fax-3000)

Methods

The selected patients were explained in detail about the study and the procedure they were subjected. A formal informed written consent was taken. Systemically and

detailed oral cavity examination of the patients were done. Histopathological examination was carried out in all the cases following incisional/excisional biopsy from the affected area of the oral cavity.

Under aseptic condition, in a selected individual with overnight fasting state, 5-ml of venous blood obtained using sterile disposable syringe and collected in a plain vial. Then, serum was separated by centrifugation in centrifuge machine at 3000 rpm for 10–15 min then use lipid profile reagent kit and analyzed for lipid profile.

Procedure

The serum was separated by centrifugation. The serum lipid profile was estimated using kits coral clinical system. Lipid analysis was done on a semiautomatic chemical analyzer (Stat Fax-3000) based on the spectrophotometric principle. By using an ultra violet - visible spectrophotometer, the serum lipid profile in the form of total cholesterol (TC), triglycerides (TGL) and high-density lipoprotein (HDL). Very low-density lipoprotein (VLDL) and LDLLDL were calculated using the formula given below.

- $VLDL = TG/5$
- $LDL = TC - VLDL - HDL$

Considering these curiosities, we aimed to estimate the serum lipid levels (TC, LDL, HDL, VLDL, and TGLs) in patients with OC and correlated the values with the control group patients. During the procedure, reagents preparation and stability like temperature maintained 37°C (room temperature) before analyzing the samples.

TC and TGLs

The serum cholesterol was estimated by taking three separate test tubes with, respectively, 10 µl of distilled water, 10 µl of sample, and 10 µl of cholesterol standard. 1 ml of cholesterol reagents were added to all three test tubes. The mixtures were mixed well and incubated at 37°C for 10 min. Measured the absorbance of the standard and test sample against the blank at 505 nm in the analyzer within 60 min.

HDL

Serum HDL cholesterol (HDL) two working reagents: Reagent-1 – 450 µl and reagent-2 – 150 µl are ready to use. Calibrator was prepared by adding distilled water 10 µl at room temperature (37°C). R-1 reagents were taken 450 µl in three test tubes with added 10 µl sample and calibrator, mixed well, and incubated at room temperature for 5–10 min. After added reagent-2, 150 µl mixed well and again incubated at room temperature for 5–10 min and read the absorbance of the calibrator and sample again blank at 578 nm wavelength in the analyzer.

RESULTS

Statistical Analyses

Statistical analyses were done using computer software (SPSS trial version 23 and primer). The qualitative data were expressed in proportion and percentages, and the quantitative data expressed as mean and standard deviations (SDs). The difference in proportion was analyzed using Chi-square test and the difference in means among the groups was analyzed using the Student's *t*-test for parametric data significance level for tests which were determined as 95% ($P < 0.05$).

Table 1: Distribution of the OSCC cases according to age group

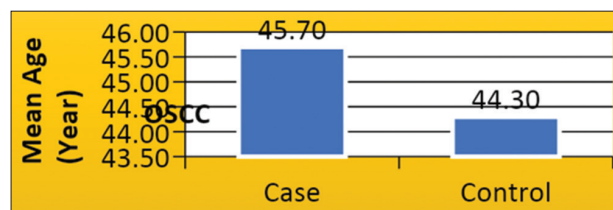
Age groups	OSCC case <i>n</i> (%)	Control <i>n</i> (%)	<i>P</i> -value LS
<40	14 (35)	18 (45)	0.65 NS
40–60	20 (50)	17 (42.5)	
>60	6 (15)	5 (12.5)	
Total	40 (100)	40 (100)	
Mean±SD	45.70 (12.89)	44.30 (12.11)	0.62 NS

OSCC: Oral squamous cell carcinoma, SD: Standard deviation, NS: Non-significant, LS: Least squares

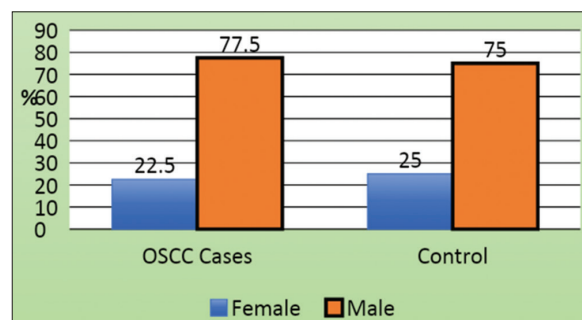
Table 2: Distribution of the OSCC cases according to gender

Gender	OSCC case <i>n</i> (%)	Control <i>n</i> (%)	<i>P</i> -value LS
Female	9 (22.5)	10 (25)	1.0 NS
Male	31 (77.5)	30 (75)	
Total	40 (100)	40 (100)	

OSCC: Oral squamous cell carcinoma, NS: Non-significant, LS: Least squares



Graph 1: Mean age among the oral squamous cell carcinoma cases



Graph 2: Distribution of the oral squamous cell carcinoma cases according to gender

Table 3: Comparison of serum lipid profile levels in the OC and control groups

Parameters assessed	Normal range	Control group (n=40)	OC cases (n=40)	P-value (statistically significant <0.005)
TGL (mg/dl)	<150	143.16±11.94	110.30±11.98	<0.001
TC (mg/dl)	150–230	203.24±9.54	186.34±12.31	<0.001
HDLc 9 mg/dl)	M: 40–60 F: 50–60	50.67±9.54	41.95±10.42	<0.001
LDLC (mg/dl)	100–160	134.24±16.86	125.61±10.88	>0.066
VLDLC (mg/dl)	4–40	20.79±6.96	28.83±5.86	>0.038

NO: Number of subjects, TC: Total cholesterol, TGLs: Triglycerides, HDLC: High-density lipoprotein cholesterol, LDLC: Low-density lipoprotein cholesterol, VLDLC: Very low-density lipoprotein cholesterol, *P value=0.05 – statistically significant, P value=0.05 – statistically not significant, OSCC: Oral squamous cell carcinoma, mg/dl: Milli-gram/deciliter

Table 4: Distribution of the OSCC cases according to TC (mg/dl)

TC mg/dl)	OSCC case n (%)	Control n (%)	P-value LS
150–230	40 (100)	40 (100)	
Mean±SD	186.34±12.31	203.24±10.51	<0.001 S

OSCC: Oral squamous cell carcinoma, SD: Standard deviation, TC: Total cholesterol

Table 5: Distribution of the OSCC cases according to TGL (mg/dl)

TGL (mg/dl)	OSCC case n (%)	Control n (%)	P-value LS
<150	40 (100)	31 (77.5)	
>150	0 (0)	9 (22.5)	
Total	40 (100)	40 (100)	
Mean±SD	110.3±11.98	143.16±11.94	<0.001 S

OSCC: Oral squamous cell carcinoma, SD: Standard deviation, TGL: Triglyceride

The Observations are Summarized

A total of 80 subjects were taken for the study including two groups as follows:

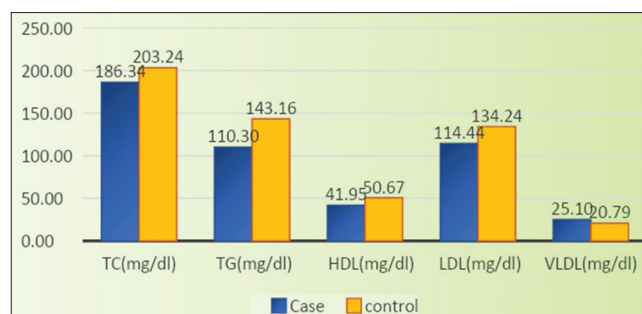
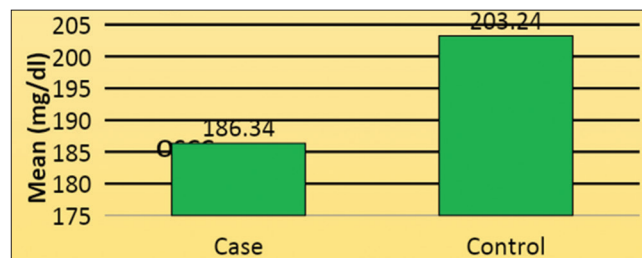
Among 40 subjects included in the present study Group 1, 31 (77.5%) were male and 9 (22.5%) were female, with an age range of 31–70 years. The OC and control groups were comparing.

Table 1 and Graph 1 shows the age distribution of the study population of oral cancer. Among 40 subjects, 17.5% (n = 7) of the patients were in the age group of <40 years, 65% (n = 26) in the age group of 40–60 years, and 17.5% (n = 7) in the age group of >60 years. The mean age of oral cancer patient was 45.70 years. Maximum numbers of oral cancer patients were in the age group of 41–60 years.

Among 40 subjects included in the present study, 31 (77.5%) were male and 9 (22.5%) were female, with an age range of 31–70 years. The OC and control groups were comparing. Distribution of cased according to gender groups is given in Table 2 and Graph 2.

Serum Lipid Profile in the OC and Control Group

The mean serum lipid profile values of the OC and control groups are represented in Table 3. *P* = 0.01 suggesting

**Graph 3: Comparison of serum lipid profile levels in the oral cancer and control groups****Graph 4: Mean value of total cholesterol (mg/dl) among the oral squamous cell carcinoma cases**

that, statistically, there was a highly significant reduction of mean serum TC, HDL, and TGLs in the subjects of OC as compared with the control group. The mean serum values of LDL and VLDL were reduced in the OC group as compared with the control group, but this reduction was not statistically significant.

In Table 3 and Graph 3, comparing the lipid levels of 40 OC patients with the standard reference values, we observed the mean ± SD of TC level as 186.34 ± 12.31 mg/dl (normal = 150–230 mg/dl), the mean ± SD HDL level as 41.95 ± 10.42 mg/dl (normal = 40–60 mg dl), and the mean ± SD TG level as 110.30 ± 11.98 mg/dl (normal = 150 mg/dl). The mean LDL level as 82.62 mg/dl (normal = 150 mg dl), the mean VLDL level as 15.33 mg dl (normal = 15–40 mg dl).

The mean serum TC, HDL, and TGL levels showed statistically significant reduction in the OC group as compared with the control group, whereas LDL and VLDL did not show a statistically significant reduction. In

the study, we also observed that 88% ($n = 32$) were using tobacco in the form of gutkha and quid and 12% ($n = 8$) in the form of without habit of tobacco.

Table 4 and Graph 4 showed the distribution of OSCC cases according to TC (mg/dl) level. The abnormality in TC level (<200 mg/dl) was observed with mean value of 186.34 mg/dl and SD ± 12.31 , which showed decrease in TC level in diagnosed case of OSCC. In the control group, the mean value of TC was 203.24 mg/dl with SD ± 10.51 . Statistically significant was found in TC level in OSCC diagnosed cases compared to the control group. Significant P value of total cholesterol <0.001 and standard normal range of total cholesterol followed 150–230 mg/dl.

Table 5 and Graph 5 showed the distribution of the OSCC cases according to TGL (mg/dl) level. The abnormality in TGL level (>150 mg/dl) was observed with mean value of 110.3 mg/dl and SD ± 11.98 which showed decrease

the TGL level in diagnosed case of OSCC. In the control group, the mean value of TGL was 143.16 mg/dl with SD ± 11.94 . Statistically significant was found in TGLs level in OSCC diagnosed cases compared to the control group. Significant P value of triglycerides < 0.001 , and standard normal range of triglycerides followed >150 mg/dl.

Table 6 and Graph 6 showed the distribution of the OSCC cases according to HDL (mg/dl) level. The abnormality in HDL level (40–60 mg/dl) was observed with mean value of 41.95 mg/dl and SD ± 10.42 mg/dl. Which showed decrease the HDL level in diagnosed case of OSCC. In the control group, the mean value of HDL was 50.67 mg/dl with SD ± 9.54 . Significant P value of HDL <0.001 , and standard normal range of HDL followed between 40–60 mg/dl [Graph 7].

DISCUSSION

Cholesterol and TGLs are important lipid constituents of the cell and are essential to carry out several vital physiological functions. Cholesterol is essential for the maintenance of the structural and functional integrity of all biological membranes. It is also involved in the activity of membrane-bound enzymes and is important for stabilization of the deoxyribonucleic acid (DNA) helix. Cellular uptake and regulation of cholesterol are mediated by lipoprotein receptors, especially located on the surface of the cells. For transport in plasma, TGL and cholesterol are packaged into lipoproteins, which are then taken up and degraded by cells to fulfill the demands for cellular function.^[7]

In some malignant diseases, blood cholesterol undergoes early and significant changes. Low levels of cholesterol in the proliferating tissues and in blood compartments could be due to the ongoing process of oncogenesis. The question arises whether hypolipidemia is a predisposing factor or result of cancer. However, earlier studies have reported that hypolipidemia may result due to the direct lipid-lowering effect of tumor cells or some secondary malfunction of the lipid metabolism or secondary to antioxidant vitamins.^[8,9]

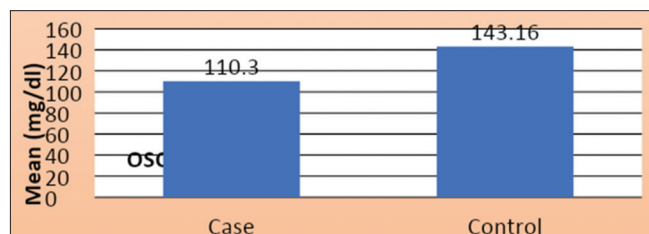
In our study, we observed the peak age incidence of patients mean age to be 45.7 years with SD ± 12.89 , which is in accordance with the observations reported by Sharma *et al.* (2018). This age-related incidence suggests that time-dependent factors result in the initiation and promotion of genetic events that result in malignant change and the diminished immune surveillance seen in the older age group.

Cholesterol is an essential constituent of lipoprotein fractions such as HDL, LDL, and VLDL. About 75% of

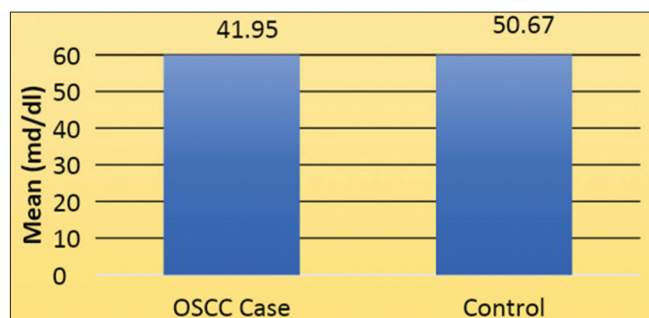
Table 6: Distribution of the OSCC cases according to HDL (mg/dl)

HDL (mg/dl)	OSCC cases <i>n</i> (%)	Control <i>n</i> (%)	<i>P</i> -value LS
High	1 (2.5)	10 (25)	
Low	20 (50)	10 (25)	
N	19 (47.5)	20 (50)	
Total	40 (100)	40 (100)	
Mean \pm SD	41.95 \pm 10.42	50.67 \pm 9.54	<0.001 S

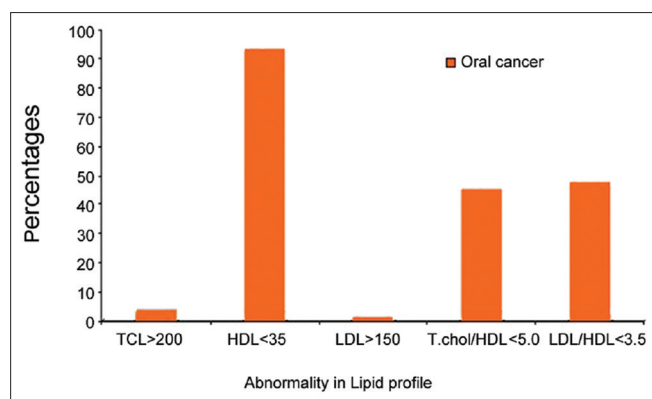
OSCC: Oral squamous cell carcinoma, SD: Standard deviation, HDL: High-density lipoprotein



Graph 5: Mean value of triglycerides (mg/dl) among the OSCC cases



Graph 6: Mean value of high-density lipoprotein (mg/dl) among the OSCC cases



Graph 7: According to Sherubin *et al.* (2013) abnormality of lipid parameters in oral cancer patients

the plasma cholesterol is transported in the form of LDL. Body cells sequester cholesterol from the LDL fraction of lipoproteins. LDL receptors are necessary for metabolizing circulating LDL levels and nearly 80% of the plasma LDL is cleared by LDL receptors. High activity of LDL receptors attributes for lowering the serum cholesterol levels.^[8,10]

In this study, we measured and compare the serum lipid profile value of 40 OC patients with the control group, significant reduction was found in the mean value. The mean value of TC, TGL and HDL Found to be decreased significantly. While mean value of LDL and VLDL were not found to significant. According to statistically significant taken value $P < 0.005$.

The several prospective and retrospective studies have shown an inverse association between blood lipid profile and different cancers. Lohe *et al.* (2010) have observed an inverse relationship between serum lipid profile and OC and oral pre-cancer.^[11,12]

Furthermore, some investigators have also found a relation of low serum cholesterol with increased risk of cancer occurrence and mortality. HDLC levels may be a useful indicator, reflecting the initial changes occurring in neoplastic conditions. A drastic reduction in levels of HDLC was observed in some study, which is in accordance with the previous reports stating that low HDLC is an additional predictor of cancer and it might be a consequence of disease that is mediated by utilization of cholesterol for membrane biogenesis of the proliferating malignant cells.^[13]

In our study did not reveal any significant difference between the two groups of LDL and VLDL Cholesterol same as in other studies. Furthermore, similar results were found for LDL cholesterol and VLDL cholesterol which were observed in a study conducted by Chawda *et al.* (2006).

Raste and Naik evaluated lipid profile in patients with carcinoma of breast, cervix, esophagus, colon, stomach, and leukemia and concluded that serum total lipids, cholesterol, and HDLC levels were significantly inversely associated with incidence of cancer, whereas TGL levels significantly elevated in cancer patients.^[2,14]

Possible Hypotheses for Hypolipidemia in Cancer and Pre-cancer^[3,15]

- Newly forming and rapidly proliferating malignant cells need many basic components such as lipids well above the normal physiological limits, leading to diminished lipid stores.
- Tobacco induces generation of free radicals and reactive oxygen species responsible for high rate of oxidation/peroxidation of polyunsaturated fatty acids, in turn, leading to increased utilization of lipids.
- Lower cholesterol levels before the detection of carcinoma may be due to underlying carcinoma process.
- Association of hypolipidemia with cancer may be secondary to other factors.
- May be due to increased membrane permeability to carcinogens induced by trans fatty acids.
- May be due to antioxidant vitamin therapy.
- Lipid peroxidation may play an important role in cancer development as lipid peroxidation product, malondialdehyde, may cross-link DNA on the same and opposite strands through adenine and cytosine. This may in theory contribute to carcinogenicity and mutagenicity in mammalian cells.

Lipid peroxidation may be induced by tobacco carcinogens that are known to produce reactive oxygen species and lipid peroxides.

Long *et al.* studied the lipid metabolism and carcinogenesis. To compare, preclinical cancer studies and clinical trials have revealed the crucial role of lipid metabolism in tumor growth and metastasis.^[3]

Lipid metabolism and cell survival or proliferation of cancer share certain common pathways involving numerous proteins as well as various cells, tissues, and organelles. Abnormalities in these pathways lead to tumor growth. Based on these findings, many drugs targeting lipid metabolism have been developed for cancer treatment. However, some inhibitors are able to inhibit cancer cell proliferation and tumor growth, but they induce cytotoxicity of normal cells as well. Thus, it is particularly important to develop a number of drugs with high specificities, thus decreasing toxicities. Abnormalities in these pathways lead to tumour growth. Based on these findings, many drugs targeting lipid metabolism have been developed for cancer treatment.^[15,16]

However, a detailed study of cholesterol carrying lipoprotein transport and the efficiency of the receptor system may help in understanding the underlying mechanisms of regulation of plasma cholesterol concentrations in cancer.

CONCLUSIONS

The results of our study show the evidence of statistically significant inverse relationship between the serum lipid profile values of TC, HDLC, TGL, and OC. The findings of this study suggest that serum lipid profile may be used as a biochemical indicator. The lower serum lipid status may be considered a useful indicator for initial changes occurring in the neoplastic cells. The result of our study strongly warrants an in-depth research on this aspect with larger samples and a longer follow-up to consider the low plasma lipid status in OC patients as a useful indicator to assess the course, prognosis, and treatment of the disease.

However, a detailed study of cholesterol carrying lipoprotein transport and the efficiency of the receptor system may help in understanding the underlying mechanisms of regulation of plasma cholesterol concentrations in cancer. Hence, the present findings strongly warrant an in-depth study of alterations in serum lipid profile patterns in patients with OC.

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Self-administration of MTP Pills and its Complications: An Observational Study

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Abstract

Background: Medical termination of pregnancy (MTP) has been legalized in India since 1971. MTP pills are well effective in the early weeks of gestation and safe only when used under medical supervision.

Aims and Objectives: The aim of the study was to find out the clinical presentations and complications following self-administration of MTP pills.

Materials and Methods: This was a retrospective observational study conducted at SMGS Hospital, Government Medical College Jammu from July 2018 to June 2019. Hundred patients were included in the study. Following factors were studied such as chief complaints, complications, treatment given, and blood transfusion.

Results: Majority (57%) of patients were aged between 30 and 39 years. About 66% were gravid three or more. Only 28% had taken the pill within prescribed gestational age limit for MTP, i.e., <7 weeks. Mid-trimester pill intake was encountered in 14% patients. About 41% presented with incomplete abortion. Anemia was present in majority of patients and blood transfusion was done in 38% patients. About 24% patients presented with life-threatening shock. Sepsis was present in 5% patients. Emergency laparotomy was required in 4% cases. Hysterotomy was done in 2% cases. Continuation of pregnancy was noted in 6% patients. Unintended pregnancy and limiting family size were main reasons for abortion 62% and 32%, respectively.

Conclusions: Unauthorized over-the-counter availability despite legal ban and ignorance of women have led to increased number of unsafe abortions. Increasing awareness among women regarding complications of unsupervised pill intake and easily availability of safe contraceptive methods can help control this health hazard.

Key words: Medical termination of pregnancy pill, Over-the-counter, Self-medication, Unsafe abortion, Unwanted pregnancy

INTRODUCTION

Unwanted pregnancy is a common problem worldwide. According to the World Health Organization (WHO), 19 million women worldwide undergo unsafe abortions annually and 18.5 million of these cases occur in developing countries. Mortality attributed to these unsafe abortions is around 68,000/year. In India, about 6.4 million abortions occur per year, and among these

56% are unsafe and responsible for 8–20% of all maternal deaths.^[1] When performed as per guidelines, medical abortion is a safe method of termination with success rate of 95–99%.^[2] Combination of mifepristone and misoprostol is commonly used drugs for medical methods of abortion. WHO recommends medical abortion using 200 mg of mifepristone followed by 800 µg of misoprostol vaginally or orally 24–48 h later for termination of pregnancy up to 9 weeks. WHO guidelines necessitate women requesting medical abortion to confirm pregnancy, estimate correct gestational age, and locate site of pregnancy, rule out contraindications, and it also recommends that the person or facility providing medical abortion should have back up facility in case of failed or incomplete abortion.^[3]

The guidelines for medical abortion in India have been prepared by the WHO in human reproduction, All India

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Institute of Medical Sciences, in collaboration with Ministry of Health and Family Welfare, Government of India and Indian Council of Medical Research according to which medical abortion is approved up to 7 weeks of pregnancy.^[4] Federation of Obstetrics and Gynaecological Societies of India recommends close monitoring of distribution of drugs that are used for medical abortion and that the medical profession and pharmaceutical industry should exercise due diligence in the promotion and usage of drugs that are used for medical abortion.^[5] As per the medical termination of pregnancy (MTP) law in India, abortion pills can only be prescribed by registered medical practitioner.^[6]

However, self-administration of abortion pills is rampant throughout the country due to over-the-counter availability of these drugs and complications are not uncommon due to this practice.

Aims

The objectives of this study were to evaluate the clinical presentation and complications following self-administration of MTP pills.

MATERIALS AND METHODS

A retrospective study was done in SMGS Hospital, Government Medical College Jammu in 1 year period from July 2018 to June 2019. Data were collected from medical records section. A total of 100 patients were included in the study.

Inclusion Criteria

Patients who had come after self-administration of the medical abortion pill were included in the study.

Data were collected from all patients regarding their age, parity, last menstrual period, presenting complaints, reason for abortion, time interval between pill intake and visit to hospital, investigation, and ultrasonography at time of admission, treatment given, management of complications and need for blood transfusion.

Analysis of data was done and results were tabulated.

RESULTS

During the study period of 1 year, 100 women had come after self-administration of medical abortion pills. The demographic profile of these women is shown in Table 1. The abortion pills were used by women of all ages. Majority of the women belonged to age group of 30–39 years. In our study, about 64% of the women were gravid three or more.

The gestational age at which an abortion pill was consumed is shown in Table 2. In this study, we found that only 28% of the women had taken the pill within the prescribed gestational age limit of up to 7 weeks. The majority (58%) had history of pill intake beyond 7 weeks gestation but within first trimester and 14% of the women had mid-trimester pill intake leading to increased complications. Majority of the patients (70%) attended the hospital between 0 and 14 days of pill intake. Three percent women presented beyond 1 month. Majority of patients (78%) had consumed the pill without prior ultrasonography to confirm the gestational age or localize the pregnancy. Unintended pregnancy, limiting family size, and failure of contraception were the main reasons for abortion by 62%, 32%, and 16%, respectively [Table 2].

Majority (41%) patients presented with bleeding per vaginam along with the passage of fleshy mass. About 24% patients presented with life-threatening shock. Prolonged irregular bleeding per vaginam was encountered in 14% patients. Continuation of pregnancy was reported by 6% women. About 5% women presented with sepsis [Table 3].

Table 4 shows the diagnosis of patients at admission. About 41% of patients presented with vaginal bleeding on and off and were diagnosed as incomplete abortion, whereas 24% patients presented with shock, 4% patients diagnosed as complete abortion, 13% as missed abortion, and 6% as continued pregnancy. All six patients with continued pregnancy had taken abortion pills after 9 weeks of gestation. There were 5 (5%) patients presented with high-grade fever, abdominal pain and vaginal bleeding were diagnosed as septic abortion. There were 4 (4%) patients diagnosed as ectopic pregnancy, and all of them underwent laparotomy. About 3 (3%) patients were diagnosed as hydatidiform mole.

Table 5 shows the severity of anemia and the need for blood transfusion in these women. Among these 100 women, 38% had varying severity of anemia, which was managed by blood transfusion. It was very alarming to see that 12% of women presented with very severe anemia which can sometimes be a life-threatening complication. There were 3% of patients who needed four or more units of blood transfusion.

Table 6 shows the treatment received by patients in the hospital. Suction and evacuation were performed in 68% of the patients. Blood transfusion was required in 38% patients and 72% were prescribed oral or intravenous iron therapy. Around 24% patients were presented in shock requiring urgent resuscitative management. Emergency laparotomy was required in 4% patients and in 2% hysterotomy was done. Cases of sepsis were managed by intravenous antibiotics.

Table 1: Demographic details of the patients (n=100%)

Parameters	% patients
Age (years)	
20–29	41
30–39	57
40–49	2
Gravida	
1	4
2	30
3	52
4 or >4	14

Table 2: Gestational age at pill intake, time interval intake of pill, and visiting to hospital, reasons cited for abortion

Parameters studied	% of patients
Gestational age at pill intake (weeks)	
<7	28
7–9	40
10–12	18
13–14	11
>14	3
Time interval (between pill intake and visit to hospital in days)	
0–7	38
8–14	42
15–21	13
22–28	4
>28	3
Ultrasonography before pill intake	
Yes	22
No	78
Reasons for abortion	
Unintended pregnancy	62
Limiting family size	32
Failure of contraception	16

Table 3: Chief complaints of patients presenting with the unsupervised intake of medical termination of pregnancy pill intake

Chief complaints	% patients
Heavy bleeding with passage of fleshy mass per vaginam	41
Shock	24
Irregular bleeding per vaginam	14
Pain abdomen	10
Continued pregnancy	6
Fever with pain abdomen and foul-smelling discharge per vaginam	5

DISCUSSION

Unsafe abortion is an important cause of increased maternal morbidity and mortality in developing countries. The advent of medical abortion pill was intended to protect women from complications. However, its widespread misuse, ignorance, and unawareness of complications

Table 4: Diagnosis at admission

Diagnosis at admission	% patients
Incomplete abortion	41
Complete abortion	4
Missed abortion	13
Continued live pregnancy	6
Septic abortion	5
Ectopic pregnancy	4
Hydatidiform mole	3
Shock	24

Table 5: Severity of anemia and need for blood transfusion

Severity of anemia	No.(%) patients
Very severe anemia Hb <4 g%	12
Severe anemia Hb 4–6.9 g%	26
Moderate anemia Hb 7–9.9 g%	28
Mild anemia Hb 10–10.9 g%	34
Blood transfusion	
One unit	16
Two unit	11
Three unit	8
Four unit	3

Table 6: Treatment received by the patients presenting with the unsupervised intake of medical termination of pregnancy pill

Treatment received	% patients
Management of shock	24
I/V antibiotics	5
Suction and evacuation	68
Blood transfusion	38
Laparotomy	4
I/V iron therapy	10
Oral iron therapy	62
Hysterotomy	2

I/V: Intravenous

of unsupervised intake on the part of women and easy over-the-counter availability of the pill have made this a public health hazard. In India, MTP act was passed in 1971 to prevent unsafe abortion with the aim of reducing the number of maternal morbidity and mortality due to unsafe abortion.^[6]

In our study, the majority of women were in the age group of 30–39 years. These results were consistent with Shivali *et al.*^[1] About 66% women were gravid three or more. These results were consistent with Shivali *et al.*,^[1] 77% women were gravid three or more in their study. Similar results were found in studies by Mishra^[7] (37%), Giri *et al.*^[8] (83%), and Kumari *et al.*^[9] (86.67%).

The safe upper gestational age limit for pill intake is up to 7 the weeks, as per MTP Act of India. The risk of complications associated with all forms of abortion

increases with gestational age. The risk is more if it is performed after first trimester even if performed under the best circumstances. In our study, only 28% of patients had taken the pill at the recommended gestational age, i.e., 7 weeks. In study by Shivali *et al.*,^[1] 26% patients had taken the pill up to 7 weeks of gestation. Similar results were reported by Mishra^[7] (37%). In our study, 58% patients had taken pill beyond 7 weeks but within first trimester and 14% of the women presented with mid-trimester pill intake leading to increased complications. Similar results were reported by Shivali *et al.*^[1]

Ultrasonography should be done before prescribing the pill for pregnancy localization and confirmation of the gestational age. However, our study only in 22% patients, prior ultrasonography was done and rest 78% patients had taken pill without prior ultrasonography. Ultrasonography was done in our hospital revealed diagnosis of missed abortion, ruptured ectopic pregnancy, and molar pregnancy in 13%, 4%, and 3% cases, respectively. These findings were similar to study by Shivali *et al.*,^[1] missed abortion (7%), ectopic pregnancy (5%), and molar pregnancy (3%).

About 80% of patients reported to the hospital between 0 and 14 days of pill intake, which is similar to study done by Shivali *et al.*^[1] (69%). Agarwal and Datta^[10] also found same result (76.6%). Four percent women presented to hospital after 1 month of pill intake. The main reasons for abortion were unintended pregnancy (62%), limiting family size (32%), and failure of contraception (16%). Shivali *et al.*^[1] also found similar results, unintended pregnancy (38%), limiting family size (36%), and failure of contraception (26%).

The most frequent complaint for admission was heavy vaginal bleeding along with a history of passage of fleshy mass, i.e., incomplete abortion. About 41% patients were diagnosed as incomplete abortion. The findings collaborate with other studies by Shivali *et al.*,^[1] Agarwal and Datta,^[10] and Thaker *et al.*^[11] where reported rates of incomplete abortion were 49%, 56%, and 70.2%, respectively. Suction and evacuation were required in 68% patients. In study done by Shivali *et al.*,^[1] suction and evacuation were done in 53% patients. This is similar to study done by Mishra^[7] and Kumari *et al.*,^[9] suction and evacuation were done in 46.5% and 50% cases, respectively. Method failure is said to occur in when women need surgical evacuation to complete the abortion. About 2–10% women would end up in surgical evacuation. However, in our study, this rate is very high which can be due to unsupervised pill intake by the women.

Varying degree of anemia was present in women in our study. About 26% of patients had severe anemia and

12% had very severe anemia requiring blood transfusion. In our study, 8% patients required 3 units of blood and 4 units were transfused in 3% of patients. These results were similar to another study done by Shivali *et al.*,^[1] Kumari *et al.*,^[9] i.e., 28% and 23.3%, respectively. More than half, i.e., 62% had mild-to-moderate anemia, for which oral or intravenous therapy was given. These results were similar to study by Shivali *et al.*^[1] About 24% patients presented with life-threatening shock requiring urgent resuscitation. In our study, continuation of pregnancy was reported in 6% women. The high incidence of continued pregnancy strongly points out to erroneous and incomplete dosing schedules with which the drug is prescribed by the unauthorized personnel. Serious life-threatening complications like sepsis are common in women undergoing unsafe abortions.^[12,13] In our study, 5% women presented with features of sepsis such as fever and pain abdomen. This is similar to the study by Shivali *et al.*^[1] (3%) and Agarwal and Datta^[10] (3.33%).

CONCLUSIONS

Medical abortion is safe and effective method of abortion when carried out under medical supervision. Unsupervised use of medical abortion pills was associated with many complications such as incomplete abortion, hemorrhage, ectopic pregnancy, and septic abortion. Hence, over-the-counter use of MTP pills should be restricted. Increasing awareness among women regarding complications of unsupervised pill intake and regarding availability and safety of various contraceptive methods can reduce the health hazard caused by unsupervised MTP pill intake.

Ethical Approval

The study was approved by the Institutional Ethics Committee.

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Umbilical Cord Milking Reduces Duration of Inotrope Support in Preterm Infants Less than 32 Weeks of Gestation, Born with Cesarean Section in Comparison to Delayed Cord Clamping

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Abstract

Objective: Very preterm infants commonly need inotrope support. We aimed to demonstrate that umbilical cord milking (UCM) would reduce the need for inotropes in preterm infants born with cesarean section in comparison to delayed cord clamping (DCC).

Study Design: We compared the need of inotrope support, in a pilot randomized controlled trial, among preterm infants <32 weeks' gestation receiving UCM ($n = 25$) in comparison to those who underwent DCC ($n = 24$).

Results: Baseline maternal and newborn characteristics were similar. There was a significant reduction in the total duration of inotrope support ($P = 0.004$) and total duration of respiratory support ($P = 0.021$) in babies undergoing UCM when compared to those undergoing DCC. Trend toward reduction in incidence of hemodynamically significant patent ductus arteriosus and intraventricular hemorrhage was noted in UCM group.

Conclusion: UCM significantly improved respiratory and hemodynamic stability in preterm infants <32 weeks' gestation without associated complications.

Key words: Gestation, Infants, Preterm

INTRODUCTION

Delayed cord clamping (DCC) is beneficial for preterm infants. A systematic review (2012), on the timing of umbilical cord clamping in preterm infants, demonstrated that DCC was associated with fewer infants requiring transfusion for anemia, lower incidence of intraventricular hemorrhage (IVH) (all grades) as well as necrotizing enterocolitis when compared with immediate umbilical cord clamping. Peak bilirubin levels were higher in infants

in the DCC group, but there was no statistically significant difference in the need for phototherapy between the groups.^[1] Recent systematic review by Fogarty *et al.* found that DCC (>30 s) reduced hospital mortality and reduced proportions of infants receiving blood transfusion by 10%.^[2] This growing body of evidence has led a number of professional organizations to recommend DCC in term and preterm infants.

An alternative to DCC is umbilical cord milking (UCM), in which the unclamped umbilical cord is grasped, and blood is pushed toward the infant several times before it is clamped. This procedure can be performed within 20 s. It has particular appeal for circumstances in which the 30–60-s delay in umbilical cord clamping may be too long, such as when immediate infant resuscitation is needed or maternal hemodynamic instability occurs.^[3] A recent meta-analysis of UCM in infants delivered at <33 weeks

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demonstrated that infants who undergo UCM have higher hemoglobin (Hb) and a lower risk for oxygen requirement at 36 weeks and IVH of all grades compared with those who undergo immediate cord clamping (ICC).^[4]

American College of Obstetricians and Gynecologists (ACOG) statement acknowledges that there are limited data indicating whether DCC performed during cesarean delivery (CD) can improve placental transfusion.

Aladangady *et al.* reported lower circulating red cell volume with DCC in neonates born by CD compared with vaginal delivery (VD). One could speculate whether more blood remains in the placenta when a neonate is delivered by CD because the anesthetic and surgical interventions interfere with the active contraction of the uterine muscles to expel the placenta.^[5]

A recent study of 154 infants delivered by CD, 75 were assigned to UCM and 79 to DCC. Neonates randomly assigned to UCM had higher superior vena cava flow and right ventricular output in the first 12 h of life. Neonates undergoing UCM also had higher delivery room temperature, blood pressure over the first 15 h, and urine output in the first 24 h of life. There were no differences between the 43 infants delivered by VD.^[6]

This is an area of active research, and several ongoing studies are needed to evaluate possible benefits of UCM compared with DCC, especially in babies born by cesarean section. Given that up to 90% of preterm infants are delivered by CD, there is a critical need to determine which therapy should be given to preterm infants delivered by CD.

Thus, this study is planned to evaluate whether UCM is better than DCC in reducing the need for inotrope support in very preterm infants born of cesarean section.

MATERIALS AND METHODS

Study Design

This pilot randomized controlled trial was conducted at Lokmanya Tilak Municipal tertiary care Hospital, Sion, Mumbai. The study was approved by the Institutional Review Board and was conducted between January 2018 and September 2018. The primary outcome needed for inotrope support within 24 h of delivery.

Objectives

The primary aim of the study was to determine, in comparison to DCC, whether UCM reduce the need for inotrope support in first 24 h of life, in preterm infants <32 weeks' gestation born of cesarean section. We also wanted to determine if UCM reduced the need for

transfusions, respiratory support, and mortality in offspring without adding complications.

Population

Pregnant women of <32-week gestation (dated by last menstrual period or earliest ultrasound) and undergoing cesarean section delivery were identified from the antepartum unit and labor room. Parents were approached and informed written consent was taken to enroll their newborn for randomization in either group. Entry criteria included newborns with the gestational age of 26 0/7–31 6/7 weeks born by cesarean section. Exclusion criteria included newborns requiring resuscitation, monochorionic multiples, placenta previa, abruptions, Rh sensitization, hydrops, life-threatening congenital anomalies, HIV, and hepatitis B surface antigen positive mothers.

Mothers were randomly assigned just before delivery by opaque, sealed envelopes. The obstetricians were made aware of the randomization by the neonatology team before delivery of the infant. Dichorionic twins received the random assignment separately. Using the timer in the delivery room one member of the team recorded and counted out loud the time elapsed from when the infant was delivered until the time the umbilical cord was clamped by the obstetrician in both arms of the study. Neonates who did not cry immediately after birth were excluded and ICC was performed.

Sample Size Calculation

The sample size was calculated based on the incidence of the need for inotrope support among preterm infants (<32 weeks) born in the prior 2 months. Taking into consideration an incidence of need for inotrope support of 60% to achieve a reduction to 26%, 28 patients in each group would be necessary for an alpha error of 0.05.

Intervention

UCM was performed by holding the infant at or ~20 cm below the level of the placenta. The cord was pinched as close to the placenta as possible and milked toward the infant over a 2-s duration. The cord was then released and allowed to refill with blood for a brief 1–2-s pause between each milking motion. This was repeated for a total of 4 times. After completion, the cord was clamped, and the neonate was handed to the neonatal team. DCC was performed by holding the infant at or ~20 cm below the level of the placenta and waiting for 45 s before clamping the cord. In both arms, infants were wrapped in the sterile Polydrape without drying, with head covered and were taken to radiant warmer. Neonates were managed as per labor room protocol of temperature stabilization and respiratory support.

Blinding was achieved by allowing only investigator, fellows posted in labor room and the obstetrician performing the intervention, to be aware of the allocation arm. No documentation of the intervention was made in the indoor case paper. The randomization cards assigned a subject identification number was kept by the investigator. Blinded echocardiograms and head ultrasounds were performed by a trained research fellow.

Outcomes

Primary outcome needed for inotrope support in the first 24 h of life. Monitoring of skin temperature, hemodynamic parameters (heart rate, capillary refill time, non-invasive blood pressure, and perfusion index), and respiratory system parameters (respiratory rate, distress score, and saturations) was done every hour for 24 h of life. Infant was provided with respiratory support anytime in the labor room and neonatal intensive care unit (NICU) as required. Newborns were provided inotrope support if (1) capillary refill time was more than 4 s or (2) non-invasive blood pressure revealed systolic or diastolic arterial pressure of less than lower 95th percent confidence limit as per gestational age given by Zubro's charts. Time of starting inotrope, drug, and dose and duration of inotrope support were documented.

Early echocardiogram (at 12 h) was performed with the Sonosite ultrasound system for detection of hemodynamically significant ductus arteriosus. Repeat echo was performed at 12 hourly intervals till 72 h. Measures of ductal diameter (narrowest diameter before entering in the left pulmonary artery), direction of flow, left pulmonary end-diastolic velocity, and left atrial to aortic root ratio were documented. Patent ductus arteriosus (PDA) was treated if it was hemodynamically significant.

All neonates were screened for a bedside head ultrasound at 24, 72 h, and 7 days to document evidence of IVH and it was graded as per Volpe's classification. Hb and hematocrit were documented at birth. Repeat screen was done if required during the NICU stay. Septic screen was done if sepsis was suspected. Initiation of feeding and escalation of feeds were decided by the treating physician. Time to reach full enteral feeds was noted. Any incidence of feeding intolerance was documented. Necrotizing enterocolitis was labeled according to modified bell's criteria.

Baby was monitored for icterus, peak bilirubin levels were documented, ad treatment (phototherapy) was offered as per NICE guidelines. All babies were screened for retinopathy of prematurity starting at 21 days of life (as per unit protocol). The requirement of oxygen at 36 weeks corrected for gestational age (bronchopulmonary dysplasia) was noted.

Babies underwent screening ultrasound at 28 days of life for assessment of periventricular leukomalacia. Number of blood transfusions till discharge or death and volume received per transfusion were documented. Babies were followed until discharge or death.

Statistical Analysis

We performed statistical analyses using SPSS Statistics version 23. Normally distributed continuous outcome variables were compared with the unpaired Student's *t*-test, and nonparametric continuous outcome variables were analyzed with the Mann–Whitney *U*-test. We based our sample calculations on the basis of previous data collection. Two-sided $P < 0.05$ was considered significant.

RESULTS

The baseline maternal, fetal, and newborn characteristics of UCM and DCC groups are summarized in Table 1, which shows no significant difference between groups.

Baseline maternal and newborn characteristics were similar. There was a trend in reduction of the need for inotrope support in UCM group (12%) as compared to DCC group (33.3%) ($P = 0.073$) with significant reduction in total duration of inotrope support ($P = 0.004$) in UCM group. Although there was no difference in need for respiratory support, there was significant reduction in total duration of respiratory support in babies undergoing UCM when compared to those undergoing DCC ($P = 0.021$). Trend toward reduction in incidence of hemodynamically significant PDA (31% in UCM group and 45.8% in DCC group) was noted ($P = 0.096$). Furthermore, reduction of incidence of IVH (any grade) was found in UCM group (12%) than those undergoing DCC (33.3%), this difference was not statistically significant. There was no statistically significant difference in Hb at birth, temperature on admission to NICU, incidence of polycythemia, requirement of partial exchange, incidence

Table 1: Baseline maternal and neonatal characteristics

Parameters	UCM (n=25)	DCC (n=24)	P-value
Maternal age (years)	29±4	28±3	0.75
Gestational age (weeks)	30±2	30±2	0.90
Birth weight (g)	1315±274	1272±269	0.58
Sex (male)	13 (52%)	14 (58.3%)	0.437
Pregnancy induced hypertension (n, %)	6 (24%)	5 (20.8%)	0.531
Diabetes (gestational or pre-gestational) (n, %)	2 (8%)	2 (8.3%)	0.680
LPV (n, %)	6 (24%)	5 (20.8%)	0.531
Some antenatal steroids (n, %)	21 (84%)	16 (66.66%)	0.141

Data are presented as mean±SD or expressed in percentages. UCM: Umbilical cord milking, DCC: Delayed cord clamping

of feed intolerance, peak bilirubin level, total duration of phototherapy, incidence of necrotizing enterocolitis, sepsis, total duration of NICU stay, and final outcome of death or discharge [Table 2].

DISCUSSION

Neonatal Resuscitation Program, WHO, and ACOG recommend DCC (>30 s) for all preterm babies at birth. A systematic review (2012) on timing of umbilical cord clamping in preterm infants, defined DCC as a delay of more than 30 s, with a maximum of 180 s. DCC was associated with fewer infants requiring transfusion for anemia (relative risk [RR], 0.61; 95% confidence interval [CI], 0.46–0.81), lower incidence of IVH (RR, 0.59; 95% CI, 0.41–0.85) as well as necrotizing enterocolitis (RR, 0.62; 95% CI, 0.43–0.90) compared with immediate umbilical cord clamping. Peak bilirubin levels were higher in infants in the DCC group, but there was no statistically significant difference in the need for phototherapy between the groups. Recent systematic review by Fogarty *et al.* including 18 RCTs, 2834 infants, found that DCC (>30 s) reduced

hospital mortality (RR 0.68; 95% CI 0.52–0.90) number needed to benefit being 33 also reduced proportions of infants having blood transfusion by 10%.^[2]

An alternative to DCC is UCM. Meta-analysis of seven randomized controlled trials of UCM in infants delivered at <33 weeks ($n = 501$) demonstrated that infants who undergo UCM have higher Hb and a lower risk for oxygen requirement at 36 weeks and IVH of all grades compared with those who undergo ICC.^[4]

Three trials of DCC that stratified by mode of delivery found no difference in hematocrit levels or tagged red blood cells in infants delivered by CD.^[7–9] The ACOG statement acknowledges that there are limited data indicating whether DCC performed during CD can improve placental transfusion.

Rabe *et al.* randomly assigned 58 neonates born at <33 weeks' gestation to UCM (4 times) or to a 30-s delay in cord clamping. Although they did not find any differences in outcomes, the infants treated with DCC had a lower CD rate (58% vs. 78%).^[10] Because a greater number of infants undergoing DCC were delivered by VD, the lower proportion of CD in this group may have reduced the difference seen between the two approaches.

Aladangady *et al.*^[5] reported lower circulating red cell volume with DCC in neonates born by CD compared with VD. One could speculate whether more blood remains in the placenta when a neonate is delivered by CD because the anesthetic and surgical interventions interfere with the active contraction of the uterine muscles to expel the placenta.

A recent study of a total of 197 infants (mean gestational age 28 weeks). Of the 154 infants delivered by CD, 75 were assigned to UCM and 79 to DCC. Of the infants delivered by CD, neonates randomly assigned to UCM had higher superior vena cava flow and right ventricular output in the first 12 h of life. Neonates undergoing UCM also had higher delivery room temperature, blood pressure over the first 15 h, and urine output in the first 24 h of life. There were no differences between the 43 infants delivered by VD.^[6]

Although there was no statistically significant difference in the primary outcome of need for inotrope support, our study demonstrated statistically significant reduction in total duration of inotrope ($P = 0.004$) and respiratory support ($P = 0.021$) with UCM compared with DCC.

Placental blood during UCM is directed toward the lungs during a time when there is a rapid fall in pulmonary

Table 2: Clinical variables of preterm infants in the delivery room and the NICU

Parameter	UCM (n=25)	DCC (n=24)	P-value
Birth Hb–(g/dL)	17.1±1.6	17.8±1.8	0.168
Hct (%)	53.3±5.8	54.9±5.8	0.32
Temperature on admission (degree C)	36±0.5	35.9±0.5	0.58
Respiratory support–n (%)	13 (52%)	12 (50%)	0.558
Duration of respiratory support (hours)	39±84	185±279	0.021
Surfactant–n (%)	8 (32%)	7 (29.2%)	0.538
Need for inotrope support within 24 h–n (%)	3 (12%)	8 (33.3%)	0.073
Duration of inotrope support (hours)	5.76±19	51±30	0.004
Polycythemia (Hct >65%)–n (%)	2 (8%)	4 (16%)	0.314
Partial exchange–n (%)	1 (4%)	2 (8.3%)	0.484
Need for transfusion–n (%)	5 (20%)	6 (25%)	0.469
PDA–n (%)	6 (31%)	11 (45.8%)	0.096
PDA requiring treatment–n (%)	6 (31%)	10 (41.6%)	0.155
Any IVH–n (%)	3 (12%)	8 (33.3%)	0.073
Severe IVH (Grade 3 and with PVHI)–n (%)	1 (4%)	2 (8.3%)	0.484
Feed intolerance–n (%)	1 (4%)	3 (12.5%)	0.289
Peak bilirubin value–(mg/dl)	13.8±2	14.7±2	0.42
Duration of phototherapy (days)	4 (16%)	3 (12.5%)	0.645
NEC any grade–n (%)	1 (4%)	1 (4.1%)	0.745
NEC Grade 3–n (%)	0	1 (4.1%)	0.490
Time to reach full feeds (days)	4±4	7±5	0.12
Sepsis–n (%)	4 (16%)	7 (29.1%)	0.224
Discharge–n (%)	23 (92%)	23 (95.8%)	0.516
Duration of hospital stay (days)	24±3	28±3	0.763

Data are presented as mean±SD or expressed in percentages. PDA: Patent ductus arteriosus, Hct: Hematocrit, Hb: Hemoglobin, DCC: Delayed cord clamping, NICU: Neonatal intensive care unit, IVH: Intraventricular hemorrhage, PVHI: Periventricular hemorrhagic infarction, NEC: Necrotizing enterocolitis

resistance, unlike any other period when volume is given which may have resulted in better respiratory transition. Pulmonary blood flow supplies most of the preload to the left ventricle improving left ventricular output providing hemodynamic stability which can explain reduction in need for inotrope support.

Although we did not see a statistically significant difference ($P = 0.073$) in IVH between groups, there is a definite trend in reduction of IVH in UCM (12%) versus DCC (33.3%). Because of improved hemodynamics in umbilical cord group during critical time period (<24 h), may prevent IVH from occurring by stabilizing the fluctuations in systemic blood flow that has been proposed as a mechanism for IVH. Lower incidence of hemodynamically significant PDA is also attributed to better respiratory transition and hemodynamic stability seen with UCM.

Studies have shown that low birth weight infants undergoing DCC are warmer than those undergoing ICC, possibly because of the warm placental blood entering the newborn.^[11] An additional advantage for UCM is the rapid time frame for UCM to occur. Theoretically, this should not only allow a minimal delay of resuscitation but also should prevent hypothermia in the operative field. The difference between the two groups in our trial was only 25 s, and as the baby was transferred after stabilization of temperature in the labor room, there was no difference in admission temperature among the two groups. UCM allows rapid placement of the newborn under the radiant warmer.

An important limitation of our trial was the lack of an ICC group. Because both DCC and UCM provide a placental transfusion regardless of the mode of delivery, it was expected that we would not see substantial differences in clinical outcomes. Because the recommendations by ACOG demonstrated that DCC improved clinical outcomes, we did not have equipoise to randomly assign infants to a third group that did not receive a placental transfusion.

Despite the concerns that UCM may provide a rapid bolus of blood, our data are consistent with other studies that found that UCM is beneficial with minimal risk. Placental blood during UCM is directed toward the lungs during a time when there is a rapid fall in pulmonary resistance. Concerns about rapid changes in venous pressure during cord milking were addressed in an early trial that demonstrated no greater increase in venous pressures with UCM compared with uterine contractions or a newborn cry during intact placental circulation. Therefore, UCM should no longer be considered experimental; rather, it is a proven intervention that ensures that premature newborns receive an adequate placental transfusion at birth.

CONCLUSION

UCM provides better hemodynamic and respiratory transition, as demonstrated by trend toward lesser need and a statistically significant reduction in duration of inotrope and respiratory support. Although not statistically significant, lesser incidence of IVH and hemodynamically significant PDA was noted among UCM group, in infants delivered by CD.

UCM should be considered as a beneficial option for preterm infants delivered by CD. Although more larger trials are needed to confirm our observations.

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AUTHORS' CONTRIBUTIONS

VVB conceived the study and contributed to its design, enrolled patients, retrieved, and analyze the data, and wrote the draft of the manuscript. JM retrieved and analyze the data. SK enrolled patients, retrieved, and analyze the data. PK enrolled patients, retrieved, and analyze the data.

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Retrospective Study of Pattern of Sexually Transmitted Infections in a Tertiary Care Center in South India

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Abstract

Introduction: Sexually transmitted infections (STIs) continue to be the major social and economic problems leading to considerable morbidity, mortality, and stigma in the developing world. Unprotected sex with an infected partner is the major risk factor for STIs and it further increases the risk of human immunodeficiency virus (HIV) infection. There is an immense need to understand the patterns of STIs prevailing in various regions of a country for proper planning and implementation of STI control strategies.

Aims and Objectives: The aims of the study were to the pattern of various STI in patients attending the sexually transmitted disease (STD) clinic of a tertiary care hospital in South India.

Materials and Methods: A retrospective study was done with the case records in the STD outpatient department, Coimbatore Medical College, Coimbatore, during the period from January 2014 to December 2018. The patient's data and laboratory results were compiled and studied.

Results: Of 2455, STI cases studied, there were 1127 male STI and 1281 female STI, and the male to female ratio is (1.1:1.2). There was 47 transgender with STIs. The most common complaint was vaginal and cervical discharge (27.04%) followed by syphilis (20.17%) and the least common complaint was non-herpetic ulcer (5.7%). In our study, 105 cases (4.27%) were found to be HIV positive.

Conclusion: In our study, the common STI found was cervical and vaginal discharge followed by syphilis. The combined approach of mass screening and behavioral changes in the population can decrease spread of STIs and HIV rapidly.

Key words: Cervical and vaginal discharge, Human immunodeficiency virus, Sexually transmitted infections, Syphilis, Transgender

INTRODUCTION

Sexually transmitted infections (STIs) continue to be the major social and economic problem leading to considerable morbidity, mortality, and stigma in the developing world.^[1] Unprotected sex with an infected partner is the major risk

factor for STI/human immunodeficiency virus (HIV) infection.^[2,3] STIs are infections that are commonly spread by sexual activity, especially vaginal intercourse, anal sex, and oral sex.^[4,5] Some STIs can be spread by non-sexual contact with donor tissue, blood, breastfeeding, or during childbirth.^[1] Many times STIs initially do not cause symptoms and are carried having a greater risk of passing the disease on to others.^[6,7] Symptoms and signs of STIs may include vaginal discharge, ulcers on or around the genitals, and lower abdominal pain. STIs can be transmitted to an infant before or during childbirth and may result in poor outcomes for the baby.^[1] More than 30 different bacteria, viruses, and parasites can be transmitted

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through sexual activity. Bacterial STIs include chlamydia, gonorrhea, and syphilis. Viral STIs include genital herpes, HIV/acquired immunodeficiency syndrome (AIDS), and genital warts. Parasitic STIs include trichomoniasis.^[1] Depending on the disease, some untreated STIs can lead to infertility, chronic pain, or death.^[8] However, the availability of baseline information on the epidemiology of STIs and associated risk behaviors is a bottleneck in designing, implementing, and monitoring targeted interventions.^[9-11]

MATERIALS AND METHODS

A retrospective study was done with analysis of the data collected from outpatient cards and laboratory records in our sexually transmitted disease (STD) outpatient department from January 2014 to December 2018. This study was done in the Department of Dermatology, Venereology, and Leprosy, Coimbatore Medical College, Coimbatore. It included persons having STI complaints, referral from integrated counseling and testing center and antiretroviral therapy center, referral from target intervention and nongovernmental organization. The recorded clinical history (sociodemographic features – age, sex, occupation, education, and marital status) and clinical examination findings were compiled. The results of rapid plasma reagin, *Treponema pallidum* hemagglutination assays, and HIV test were scrutinized in all cases. STIs were categorized into cervical and vaginal discharge, syphilis, genital ulcer disease herpetic and non-herpetic, lower abdominal pain, and genital wart. Other STIs are molluscum contagiosum, balanoposthitis, and scabies which were detected clinically. The data collected was analyzed statistically to know the clinic epidemiological profile.

RESULTS

A total of 2455 cases were found to have STIs in the 5 years study period from January 2014 to December 2018. The gender-wise distribution was analyzed in 2455 cases. There were 1127 male STI, 1281 females STI, male to female ratio is (1.1:1.2), and 47 transgender STI [Figure 1]. The majority of patients attending STI clinic was in the age group of 25–44 years. The most common STI found in our study [Figure 2] was cervical and vaginal discharge syndrome (27.04%), followed by syphilis (20.17%), other STI (14.41%), pelvic inflammatory disease (11.93%), herpetic ulcer (11.73%), genital wart (8.3%), and non-herpetic ulcer (5.7%).

Among the male patients [Figure 3], syphilis 32.12% (362/1127) was the most common STI, followed by

other STI 25.90% (292/1127), herpetic ulcer 18.45% (208/1127), genital wart 12.59% (142/1127), and non-herpetic ulcer 10.91% (123/1127).

Among the female patients [Figure 4], the most common STI was cervical and vaginal discharge 51.83% (664/1281), followed by pelvic inflammatory disease 22.87% (293/1281), syphilis 8.73% (112/1281), herpetic ulcer 6.245 (80/1281), genital wart 4.83% (62), other STI 4.05% (52/1281), and non-herpetic ulcer 1.40% (18/1281) cases.

Among the transgender [Figure 5], syphilis 76.59% (36/47) was the common STI followed by other STI 21.27% (10/47) and non-herpetic ulcer 1.1% (1/47).

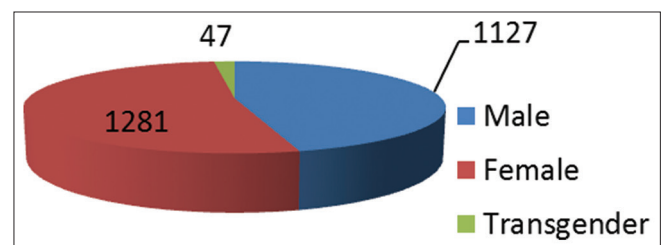


Figure 1: Male, female, transgender distribution

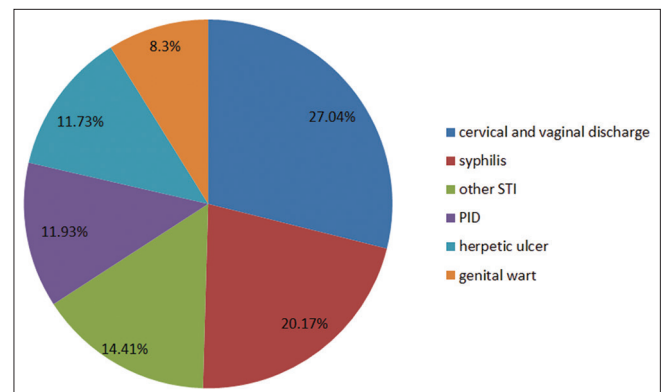


Figure 2: Sexually transmitted infection (January 2014–December 2018)

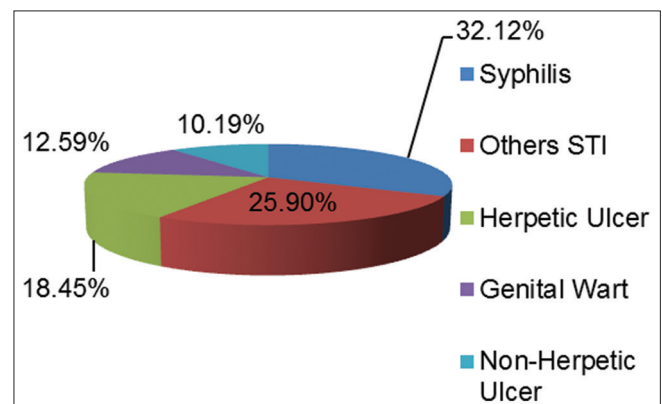


Figure 3: Sexually transmitted infection wise distribution: Male cases January 2014–December 2018

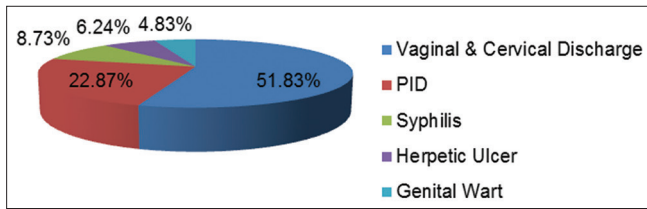


Figure 4: Sexually transmitted infection wise distribution: Female cases January 2014–December 2018

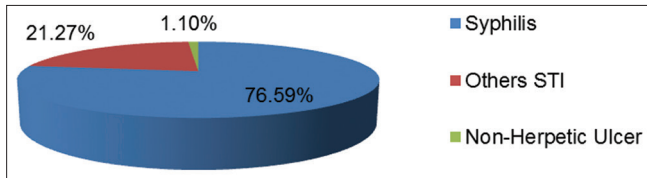


Figure 5: Sexually transmitted infection wise distribution: Transgender cases January 2014–December 2018

DISCUSSION

STI remains a global health problem of great magnitude. The pattern of STIs differs from country to country and from region to region. They are responsible for significant morbidity, infertility in both sexes, and economic loss to the family and increased susceptibility to HIV infection. STI contributes to fetal deaths, abortions, and the delivery of low birth weight babies.^[12] STI is not only a medical problem but also causes significant social stigma. Early diagnosis and appropriate treatment will definitely curb the transmission of HIV/AIDS. To achieve this, syndromic approach to STI management came into effect.^[13]

In our study, female STI (1281) cases were higher than the male STI (1127) cases. The male to female ratio was (1.1:1.2). Another study done in a tertiary care hospital in Chamba, Himachal Pradesh by Thapar *et al.*^[14] also showed similar observation that female cases outnumber the male cases at STI clinic, male to female ratio is 1:1.25.

The most common STI found in our study was cervical and vaginal discharge syndrome (27.04%) followed by syphilis (20.17%) and the least common is non-herpetic ulcer (5.7%). This was in contrast to the North-Eastern Indian study and study conducted at Medical College Trivandrum. In the North-Eastern Indian study,^[15] herpetic ulcer (38.1%) was the most common, followed by vaginal/cervical discharge (18.6%), urethral discharge (13.8%), and molluscum contagiosum (4.7%), while in a study at Medical College Trivandrum^[16] showed that the most common STD was syphilis (49.3%) followed by herpes genitalis (16.4%) and condyloma acuminata (11.1%).

In our study, bacterial STI (syphilis 20.75%) is higher than viral STI herpetic ulcer (11.73%) and genital wart (8.3%).

Another study in a tertiary care center in North India^[17] showed that syphilis had a rising trend in 2015. The study in West Bengal^[18] showed decrease in the prevalence of syphilis during 2004–2008 from 10.8% to 3.6%.

The important risk factors for STI found in our study are pre-marital exposures (love affairs, influence of friends, influence of alcohol, and monetary benefit) and extramarital exposure visit to the commercial sex workers. Comprehensive health education about STIs and HIV should be inculcated at the secondary school level. Media enlightenment campaigns about these STIs should also be emphasized. It is essential to spread awareness of the use of barrier methods of the contraception in the prevention of STI transmission.

CONCLUSION

The vaginal and cervical discharge was the most common STI followed by syphilis. HIV and STIs are perfect examples of epidemiologic synergy as they are core transmitters of each other. This can be controlled by promoting the strategies to reduce high-risk behavior, encouraging condom use, strengthening STI clinics and family health awareness programs and imparting sex education, and awareness regarding STI/HIV among the vulnerable population.

Limitation

Since this is a retrospective study and conducted in a tertiary care center, it does not reflect the current situation in the community. These results do not indicate the exact prevalence of STIs in the community as it is a hospital-based study.

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Magnetic Resonance Imaging in Evaluation of Avascular Necrosis of Femoral Head

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Abstract

Introduction: Avascular necrosis (AVN) of the femoral head is one of the common causes of pain and disability of hip. Impaired blood supply and increased intraosseous pressure are predominantly responsible for the necrotic process, which eventually results in collapse of the femoral head. Magnetic resonance imaging (MRI) is the preferred investigation for the evaluation of AVN.

Aims and Objectives: This study aims to assess the role of MRI in the evaluation of clinically suspected cases of AVN of hip and to describe the imaging features along with proper staging.

Materials and Methods: In this prospective study, 100 patients of all age groups with clinically suspected cases of AVN of femoral head were evaluated by MRI hip in the Department of Radiodiagnosis, Gandhi Medical College and Hamidia Hospital over a period of 1 year. Detailed history and associated risk factors were asked from all patients. MRI hip was then performed on 1.5 Tesla Hitachi ECHELON SMART - 523 MRI machine using the required protocol and sequences. The imaging findings were studied and proper staging was given.

Results: In our study of 100 cases of AVN, 132 femoral heads were involved (unilateral 68 and bilateral 32 cases). The most common risk factor associated was alcohol consumption. The most common quadrant of femoral head affected was anterosuperior (49.3%). The most common stage of AVN was found to be Grade III – 39.4% (Ficat and Arlet classification), Type C – 47% (Mitchell's classification), and Stage IIIC – 37.8% (Steinberg classification). MRI could detect early AVN in 50 femoral heads, in which radiographs were normal.

Conclusion: This study concludes that MRI is the modality of choice for diagnosing and staging AVN. Early diagnosis and appropriate treatment is associated with better outcome.

Key words: Avascular necrosis, Hip, Magnetic resonance imaging

INTRODUCTION

A normal hip joint is subjected to various stresses during daily activities of an individual. As it is one of the major weight-bearing joints of the body, its normal function is necessary for peaceful and enjoyable day-to-day life.

Avascular necrosis (AVN) of the femoral head is one of the common causes of painful hip in a young adult.

Impaired blood supply and increased intraosseous pressure are predominantly responsible for the necrotic process. The natural course of this disease is one of the relentless progressions with eventual collapse of the femoral head followed by secondary osteoarthritic changes in the hip.^[1] Bilateral presentation is frequently seen and males are more commonly affected. Contralateral hip may be affected in about 55% of the patients within 2 years.^[2]

Radiologic staging of the disease is of pivotal importance allowing the identification and risk stratification in pre-collapse stages, prognosis, adequate treatment planning, and post-operative follow-up.^[3] Diagnostic imaging modalities used in detecting AVN include conventional radiography, computed tomography, magnetic resonance imaging (MRI), and nuclear medicine hybrid techniques.^[4] Moreover, the increasing number of conservative or mini-invasive

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treatments has prompted the need of more advanced imaging techniques. MRI is considered the gold standard technique in the early stages of AVN with a sensitivity of more than 99%.^[5] It is non-invasive diagnostic test without the risk of ionizing radiation and provides valuable information in detecting early AVN due to its excellent soft tissue resolution and multiplanar imaging. Hence, the aim of our study is to diagnose AVN of femoral heads and to study the spectrum of imaging findings depicted on MRI for proper staging, which helps in subsequent treatment.

MATERIALS AND METHODS

The study is a prospective study on 100 patients with clinically suspected cases of AVN referred to the Department of Radiodiagnosis, Gandhi Medical College and Hamidia Hospital, Bhopal. The study was undertaken over a period of 1 year after taking written informed consent from all patients. A detailed history with a special emphasis on risk factors for AVN such as history of trauma, alcohol or steroid intake was asked. Relevant clinical notes and laboratory parameters for hemoglobinopathies were reviewed in all patients undergoing MRI for AVN.

Inclusion Criteria

The following criteria were included in the study:

1. Patients with clinically suspected case of AVN of hip with unilateral or bilateral hip pain
2. Patients of all age groups and both sexes.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with contraindication for MRI such as cardiac pacemakers, ferromagnetic metallic implants, cochlear implants, and aneurysmal clips
2. Patients with claustrophobia
3. Patients who refused consent.

MRI hip was performed on 1.5 Tesla MRI Hitachi ECHELON SMART - 523 machine with the help of dedicated surface coil. Patients were asked to lie in a supine position and both hips were scanned simultaneously using hip protocol. The sequences obtained were T1 weighted, T2 weighted, short-tau inversion recovery, proton-density fat saturation coronal with sagittal images, and T1-weighted and T2-weighted axial images. Based on MRI findings, modified Fiat and Arlet, Steinberg, and Mitchell classifications were determined in all the cases for staging of AVN.

RESULTS

In our study of 100 patients with clinically suspected case of AVN with hip pain, we observed the following results:

- The age range was from 10 to 74 years. The maximum number of cases, i.e., 28 was in the age group of 21–30 years [Table 1].
- There was a male predominance with 69 male patients and 31 female patients [Table 2].
- The most common risk factor for AVN was alcohol consumption seen in 46 cases (40%), followed by post-traumatic AVN cases 17 (17%), sickle cell disease associated with multiple bony infarcts was seen in 16 cases (16%), and idiopathic cases were 14, while six patients had a history of steroids intake and one patient had received radiotherapy [Table 3].
- The total number of femoral heads affected was 132, of which 68 cases were unilateral and 32 were bilateral [Table 4].
- The most common MRI findings in AVN of femoral head were abnormal focal subchondral signal abnormality (geographic pattern) which was seen in 72 patients. The other common MRI findings were bone marrow edema, double-line sign, subchondral cyst, subarticular collapse of femoral head, osteophytes, and joint effusion [Table 5].
- The most common quadrant of femoral head involved was the anterosuperior quadrant which was affected in 65 femoral heads (49.3%) [Table 6].
- According to Ficat and Arlet classification of AVN, of 132 femoral heads, Grade III was most commonly encountered which was present in 52 femoral heads (39.4%) [Table 7].
- According to Mitchell classification based on MRI signal characteristics within the center of the lesion, Type C (signal analogous to that of fluid) was the most common seen in 62 femoral heads (47%) [Table 8].
- According to Steinberg classification based on MRI findings, Stage IIIC was the most common stage seen in 50 femoral heads (37.8%) [Table 9].

DISCUSSION

In our prospective study of 100 patients with clinically suspected cases of AVN, 69 patients were male and 31 patients were female with male:female ratio of 2.2:1. The mean age of patients was 38.35 years which was similar to the study conducted by Reddy *et al.*^[6] where the mean age was 37.63 years. It was 35.3 in the study conducted by Kumar *et al.*^[7] and 47.5 years in the study by Gupta *et al.*^[8] Most of the patients in our study belong to the age group of 31–40 years which was similar to the study conducted by Kakaria *et al.*^[1] as risk factors for AVN such as alcohol and trauma occur more frequently in this age group. In our study, 46 patients gave a positive history of alcohol intake. In the study conducted by Kakaria *et al.*,^[1] 35% of patients gave a history of alcohol intake. The exact mechanism of

how alcohol leads to AVN is not known; however, several studies have concluded that excessive fatty substances are produced and get deposited in small blood vessels of bone. This blockage leads to decreased blood flow to femoral head causing bone death. Jacob *et al.*^[9] concluded that alcoholism-induced bone necrosis is caused by fat embolism linked to coexistent hyperlipidemia. Thus, alcohol intake can be considered as high-risk factor for the development of AVN.

In our study, a history of steroid intake was present in 6% of patients. In the study conducted by Reddy *et al.*,^[6] 6.67% of patients had a history of steroid use. Wu *et al.*^[10] in his study concluded fat hypertrophy, intravascular coagulation, and fat emboli as important risk factors of steroid-induced ischemic bone necrosis which may develop during initial 1 year of steroid intake.

In this study of 100 patients, unilateral AVN was seen in 68 patients while bilateral cases were 32; thus, the total number of femoral heads affected was 132. Unilateral AVN was mostly associated with a history of trauma.

Table 1: Age distribution

Age groups (in years)	Number of cases	Percentage
1–10	1	1
11–20	18	18
21–30	26	26
31–40	28	28
41–50	16	16
51–60	8	8
61–70	3	3

Table 2: Gender distribution in patients of AVN

Gender	Number of patients	Percentage
Male	69	69
Female	31	31

AVN: Avascular necrosis

Table 3: Risk factors for AVN

Risk factors	Number of patients (n=100)	Percentage
Idiopathic	14	14
Steroids	6	6
Alcohol	46	46
Trauma	17	17
Sickle cell disease	16	16
Radiotherapy	1	1

AVN: Avascular necrosis

Table 4: Unilateral versus bilateral AVN

Total number of patients having AVN	Number of patients having unilateral AVN	Number of patients having bilateral AVN	Number of femoral heads affected by AVN
100	68	32	132

AVN: Avascular necrosis

The most common quadrant of femoral head involved in our cases of AVN was anterosuperior, seen in 65 femoral heads (49.3%) followed by anteromedial compartment seen in 40 femoral heads (30.4%). Gabriel *et al.*^[11] in his study observed that MRI finding along the anterosuperior aspect of femur is specific for AVN. Nishii *et al.*^[12] in his study showed that the location and size of the lesion are the prognostic indicators of collapse and large necrotic lesions have likelihood to involve anterosuperior aspect of femoral head.

In our study, the most common MRI finding of AVN was focal subchondral abnormality seen in 92 femoral heads (69.7%), followed by diffuse marrow edema seen in 72 femoral heads (54.5%), double-line sign (55 femoral heads, 41.6%) which is seen on T2-weighted image and consists of inner bright line representing granulation tissue with surrounding dark zone representing adjacent sclerotic bone, subchondral cysts (42 femoral heads, 31.8%), subarticular collapse of femoral heads (24 femoral heads, 18.2%), osteophytes (15 femoral heads, 11.3%), and joint effusions (52 femoral heads, 39.4%). Sixteen patients of AVN with sickle cell disease were associated with multiple bone infarcts [Figure 1].

According to Ficat and Arlet^[13] classification of AVN, we observed that Grade I AVN (10 femoral heads, 7.5%) revealed diffuse marrow edema in the femoral head [Figure 2] and Grade II AVN (40 femoral heads, 30.4%) revealed focal geographical area of signal alteration in subchondral region of femoral head with double-line sign [Figure 3]. In the double-line sign, there is a combination of a hypointense peripheral border (sclerosis) and a hyperintense inner border (granulation tissue). Grade III AVN (52 femoral heads, 39.4%) revealed disruption of the normal contour of the femoral head with eventual cortical collapse [Figure 4]. Grade IV AVN (30 femoral heads, 22.7%) revealed subarticular collapse of femoral head associated with advanced degenerative changes of hip [Figure 5]. Thus, Grade III AVN was the most common seen in our studies. MRI was found to be highly sensitive in the evaluation of early AVN, i.e., Grade I and Grade II (10 and 40 femoral heads, respectively) which plain radiographs failed to detect.

Mitchell classification^[14] of AVN is divided into four stages based on MRI signal within the center of the lesion.

Table 5: MRI findings in AVN

MRI findings	Number of femoral heads	Percentage
Focal subchondral signal abnormality (geographic pattern)	92	69.7
Bone marrow edema	72	54.5
Subchondral cyst	42	31.8
Subarticular collapse of femoral head	24	18.2
Osteophytes	15	11.3
Joint effusion	52	39.4
Double-line sign	55	41.6

Double-line sign seen on T2-weighted sequence which consists of inner bright line representing granulation tissue and surrounding dark zone representing adjacent sclerotic bone. AVN: Avascular necrosis, MRI: Magnetic resonance imaging

Table 6: Distribution according to the location of lesion in femoral head

Location/quadrant	Number of femoral heads affected (n=132)	Percentage
Anterosuperior	65	49.3
Anteromedial	40	30.4
Anterolateral	5	3.7
Complete	22	16.6

Table 7: Distribution of AVN cases according to Ficat and Arlet classification

Grade	Number of femoral heads affected (n=132)	Percentage
Grade I	10	7.5
Grade II	40	30.4
Grade III	52	39.4
Grade IV	30	22.7

AVN: Avascular necrosis

Table 8: Distribution of AVN cases according to Mitchell classification (based on signal intensity within the lesion of femoral head)

Type	Total number of femoral heads affected (n=132)	Percentage
Type A	11	8.3
Type B	25	19
Type C	62	47
Type D	34	25.7

AVN: Avascular necrosis

- Stage A – Signals similar to fat
- Stage B – Signals similar to blood
- Stage C – Signals similar to fluid
- Stage D – Signals similar to fibrosis.

In our study, Stage C was the most common finding seen in 62 femoral heads (47%) [Figure 6] followed by Stage D comprising 34 femoral heads (25.7%) [Figure 7]. Stage A representing early disease and Stage D representing late disease. Similar findings were seen in a study conducted by Goyal *et al.*^[15]

Table 9: Distribution of AVN cases according to Steinberg classification of AVN based on MRI findings

Grade	Number of femoral heads affected (n=132)	Percentage
Grade IA	2	1.5
Grade IIA	6	4.5
Grade IIB	13	9.8
Grade IIC	15	11.7
Grade IIIA	1	0.7
Grade IIIB	7	5.4
Grade IIIC	50	37.8
Grade IVA	2	1.5
Grade IVB	1	0.7
Grade IVC	2	1.5
Grade VA	0	0
Grade VB	2	1.5
Grade VC	2	1.5
Grade VI	29	21.9

AVN: Avascular necrosis, MRI: Magnetic resonance imaging

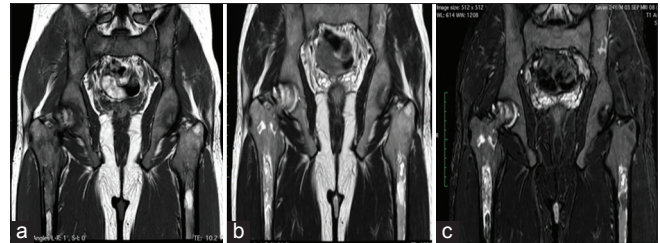


Figure 1: Case of sickle cell disease showing multiple bone infarcts in bilateral femur, associated with advanced stage of osteonecrosis in bilateral femoral heads. (a) T1 coronal. (b) T2 coronal. (c) Short-tau inversion recovery coronal

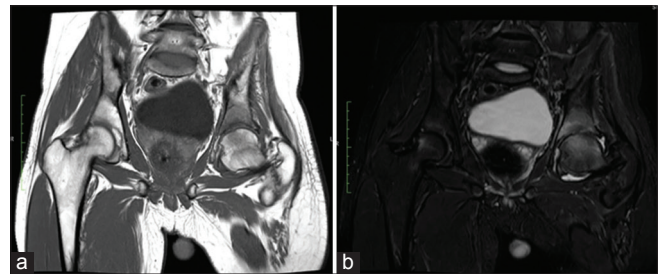


Figure 2: Case of Grade 1 avascular necrosis (Ficat and Arlet classification) of the left femoral head showing diffuse marrow edema. (a) T1 coronal. (b) Short-tau inversion recovery coronal

Steinberg *et al.*^[16] classified AVN from Stage 0 to Stage VI based on the imaging findings and further quantified the extent of involvement of hip as follows:

- Stage 0 – Normal radiograph, normal bone scan
- Stage I – Normal radiograph, abnormal bone scan/MRI
- Stage II – Sclerosis and/or cyst formation in femoral head
 - a. Mild: <15% head involvement
 - b. Moderate: 15–30%
 - c. Severe: >30%

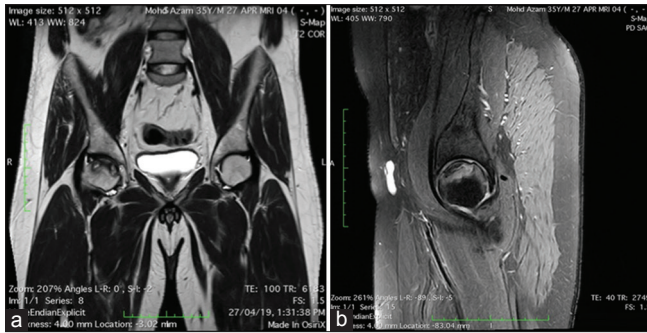


Figure 3: Case of Grade II avascular necrosis (Ficat and Arlet classification) showing focal subchondral area of signal alteration in anterosuperior quadrant of the right femoral head with double-line sign (seen on T2-weighted sequence and consists of inner bright line representing granulation tissue and surrounding dark zone representing sclerosis). (a) T2 coronal. (b) Proton-density (fat sat) sagittal

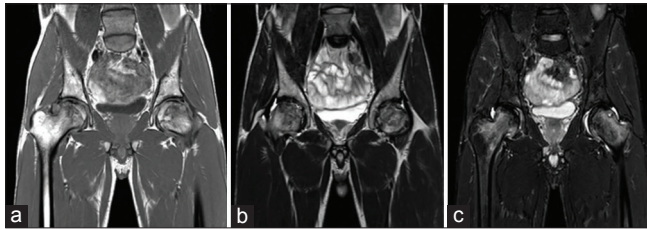


Figure 4: Case of bilateral avascular necrosis. Grade III (Ficat and Arlet classification) showing irregular articular surface of bilateral femoral heads with altered marrow signals and adjacent short-tau inversion recovery (STIR) hyperintense marrow edema. (a) T1 coronal. (b) T2 coronal. (c) STIR coronal

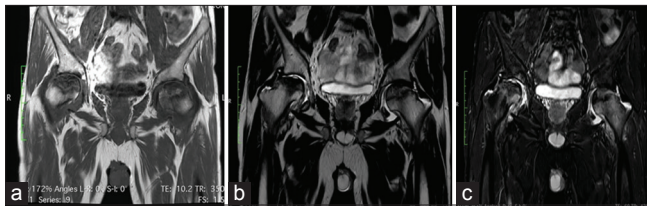


Figure 5: Partial collapse of the right femoral head and geographic area of altered signal intensity in the left femoral head noted, which is appearing hypointense on coronal T1- and T2-weighted images with adjacent short-tau inversion recovery (STIR) hyperintense marrow edema. Findings are suggestive of Grade IV avascular necrosis (AVN) on the right side and Grade II AVN on the left side (Ficat and Arlet classification) associated with bilateral hip joint effusion. (a) T1 coronal. (b) T2 coronal. (c) STIR coronal

- Stage III – Subchondral collapse (crescent) without flattening
 - a. Mild: <15% of articular surface
 - b. Moderate: 15%–30%
 - c. Severe: >30%
- Stage IV – Flattening of femoral head without joint space narrowing
 - a. Mild: <15% of surface has collapsed and depression is <2 mm

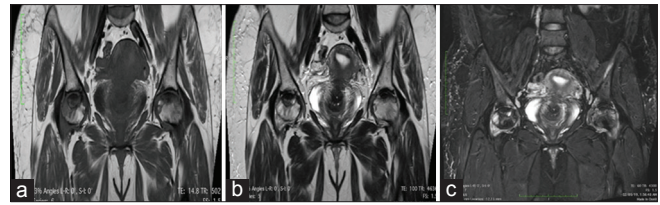


Figure 6: Coronal images showing hyperintense signal on T2-weighted images and hypointense signal on T1-weighted images within the necrotic foci in the right femoral head, suggestive of Type C avascular necrosis (Fluid and Mitchell's classification). (a) T1 coronal. (b) T2 coronal. (c) Short-tau inversion recovery coronal



Figure 7: Coronal images showing hypointense signal on T1- and T2-weighted images in the left femoral head suggestive of Type D avascular necrosis (fibrosis and Mitchell's classification). (a) T1 coronal. (b) T2 coronal. (c) Short-tau inversion recovery coronal

- b. Moderate: 15%–30% collapsed or 2–4 mm depression
- c. Severe: >30% collapsed or >4 mm depression
- Stage V – Flattening of femoral head with joint space narrowing as for Stage IV plus estimate of acetabular involvement
 - a. Mild
 - b. Moderate
 - c. Severe
- Stage VI – Advanced degenerative changes of hip joint.

In our study, Stage IIIC was the most common seen comprising 50 femoral heads (37.8%) followed by Stage VI (29 femoral heads, 21.9%). Four patients showed acetabular involvement. It was also observed that if the lesion is seen involving <30% of femoral head then there is low risk of collapse, if lesion is seen involving between 30% and 50% then there is moderate risk of collapse, and if >50% involvement is seen then there is high risk of collapse of femoral head. Thus, collapse is directly proportional to femoral head involvement; similar findings were also seen in the studies done by Beltran *et al.*^[17]

CONCLUSION

MRI has distinct advantage over other modalities in being radiation free, non-invasive, excellent soft tissue contrast, multiplanar imaging capability, and high sensitivity in detecting osteonecrosis of femoral head. We diagnosed a large number of patients with early AVN where radiographs were normal and also detected AVN on contralateral hip in patients with advanced stage. Thus, MRI is the modality of choice for staging of AVN which helps in early and accurate treatment of the patients.

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Prospective Study on Effect of Submucosal Alcohol Injection in Cases of Rectal Prolapse in Infants and Children

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Abstract

Purpose: The purpose of the study was to study the impact of sclerosing agent in cases of rectal prolapse in infants and children.

Materials and Methods: A total of 200 cases of diagnosed rectal prolapse in infants and children attending a tertiary care of West Bengal were included in the study for the effect of submucosal injection of alcohol from a period of August 2016 to July 2018. 1.5–2 ml of alcohol was linearly injected in three sites (two laterals and one posterior).

Results: All 200 cases were followed at 3 months interval for a period of 2 years. One hundred and twenty-one patients (60.5%) had a duration of prolapse for 3–6 months. Forty-six patients (23.0%) had prolapse for more than 8 months and 33 (16.5%) patients had prolapse for more than 1 year. One hundred and ninety-one (90.5%) patients responded to a single injection. Five patients (2.5%) required the second injection. Four (2%) patients with age more than 10 years did not respond to the treatment. Twenty-five patients had fecal soiling for a period of 10–12 days. No infectious complication and no recurrence were observed.

Conclusion: 2–5 ml of ethyl alcohol (96%) is effective for the treatment of rectal prolapse. The duration of rectal prolapse had no deleterious effect on treatment; however, patients with age more than 10 years did not respond to sclerosing agent, probably due to different etiology.

Key words: Ethyl alcohol, Rectal prolapse, Sclerosing agents

INTRODUCTION

Rectal prolapse is a very agonizing condition for the child and parents depending on severity of the disease.^[1] It has two clinical variants, one being less severe responds to conservative treatment after a few weeks. The other variants are comparatively more severe persisting for several weeks or months.^[1] A good many number of treatment modalities are available, including injection of sclerosing agents. From available clinical resources, alcohol is used as a sclerosant only in few reports and its effect on prolonged rectal

prolapse and its follow-up has not been investigated in the eastern part of India.^[2] Lack of available clinical results in prolonged rectal prolapse treated with submucosal alcohol injection of ethyl alcohol attracted our attention to this study.

MATERIALS AND METHODS

A total of 200 consecutive patients in 1–12 years of age, clinically diagnosed with rectal prolapse were recruited in our study between August 2016 and July 2018. The institutional ethics committee clearance and informed content of the parents were taken. All cases of rectal prolapse were treated in our center by injection of 96% ethyl alcohol. Rectal prolapse associated with other congenital anomalies such as imperforate anus bladder exstrophy, cystic fibrosis, and neurological causes was excluded from the study. The children underwent conservative treatment for 6 weeks

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before alcohol injection. Prior pre-anesthetic checkup was done. All patients were admitted on day before the procedure. The procedure was carried after bowel preparation under general anesthesia. All patients were subjected to anorectal manometry before the procedure to exclude the specific cause. Data pertaining to age, sex, episodes of injection, complications, and recurrence were documented.

The clinical procedure was in lithotomy position under general anesthesia. The left index finger was introduced into the rectum. A spinal needle number 19 or 21 was mounted onto a syringe. The needle was inserted from the mucocutaneous junction and advanced submucosally in full length, while the index finger palpated the needle. During withdrawing the needle, 1.75–2 ml of alcohol was injected linearly in three sites (two lateral sites and one posterior site). Patients were discharged with analgesia, but with antibiotics for 5–7 days. Follow-up was carried out on days 7, 14, and 30 and then every 3 months for 1 year.

RESULTS

Of 200 patients, 144 (72%) were male and 56 (28%) were female. All patients were treated for rectal prolapse with the injection of ethyl alcohol. Two hundred cases (144 males and 56 females) had a mean age of 2.5 years (range: 1–12 years). The minimum follow-up was 12 months. Anorectal manometry and sweat chloride test were normal in all the patients. According to the duration of prolapse, the patients were divided into three groups.

In Group I, 121 cases had a duration of rectal prolapse for 3–6 months, Group II had 46 cases more than 8 months, and Group III had 33 cases of rectal prolapse, respectively [Table 1].

Table 1: Cases of rectal prolapse with different durations

Group	I	II	III
Number of cases	n=121 (60.5%)	n=46 (23%)	n=33 (16.5%)
Duration	3–6 months	More than 8 months	More than 1 year

One hundred and ninety-one (90.5%) patients had good response to a single injection (90.5%). Four patients (2.0%) required the second injection. Four (2.0%) patients had no response after the second injection and were treated by other procedures [vide Table 2]. The age of patients who did not respond was more than 10 years, and the duration of the prolapse was 6, 8, and 12 months. Twenty-five cases (16.4%) developed fecal soilage for few days. Four patients presented with constipation for 2–3 days. No infectious complications occurred and no recurrence was observed after the post-operative follow-up at 1 year.

DISCUSSION

The sex incidence in our study was 2.5:1 toward male which is different from earlier study conducted by Corman *et al.*^[2] (1:1) and Chan *et al.*^[6] (1.8:1). The mean age of our patients was 2 years and 5 months that are similar to other reports.

Qvist *et al.*^[1] described two types of rectal prolapse according to the severity and need for surgery.

- Type I with less severe form with response to the conservative treatment within 1–8 weeks
- Type II with more severe form and may continue for several weeks or months; this required surgical intervention.

All our patients were treated for 8 weeks after the onset of their disease to ensure that the conservative treatment has failed.

Maximum patients were from suburban and rural areas and their parents believed that this will regress spontaneously. This belief was the cause of delay in seeking of medical attention in our patients. A good many number of sclerosant have been used in the treatment of rectal prolapse. Kay and Zachary^[3] and Dutta and Das^[4] used 9–15 ml of 30% saline pararectally with the success rates of 78.4% and 83.4%, after the first injection and 94% and 96.7% after the second injection.

Wyllie^[5] used 8–10 ml of 5% phenol in almond oil with the success rates of 91% after the first injection and 100%

Table 2: Cure rate of rectal prolapse with different durations of the disease

Group	I	II	III
Number of cases responding to sclerosant	121	46	33
Duration of prolapse (months)	3–6 months	More than 8 months	More than 1 year
Total number of cases, n=191 (90.5%)			
Response to single injections	115	41	30
Response to two injections	2	2	1
Total number of cases, n=5 (2.0%)			
No response	2	1	1

after the second injection. Chan *et al.*^[6] used 1 ml/kg of 50% dextrose in water and other agents with the success rates of 64% after the first injection and 84% after the second injection. The failure percentage (16%) after the second injection was probably due to the involvement of secondary rectal prolapse.

We found only one report, in which alcohol was used as the sclerosing agent. Malyshev and Gulin^[7,8] used (up to 35 ml) ethyl alcohol (70%) in 353 cases with the cure rates of 96% after the first injection and 98% after the second injection. All the above-mentioned authors, except for Wyllie, had injected the agents submucosally and pararectally. However, we injected the agent only submucosally. Our success rates after the single injection were 90.5% and after the second injection were 94%.

We used 5.25 ml (1.75 ml in each site) in children <3 years and 6 ml in older children. In the above-mentioned reports, the duration of rectal prolapse was not defined. Five patients in our report (2.5%) required two injections and four patients did not respond to the second injection.

The cure rates in our patients were 90.5% after the first injection and 94% after the second injection, in spite of a prolonged duration. Qvist *et al.*^[1] concluded that a duration of more than 8 weeks requires operation. In our study, all patients responded to the sclerosing agent in spite of the prolonged rectal prolapse and no infection was noted, whereas failure was observed in four cases after 1 year. Soiling in our patients was probably due to mucosal edema and not due to damage to the sphincter because we did not inject the sclerosing agent pararectally. Constipation (observed in four patients) was probably due

to the infiltration of the sclerosing agent outside the rectal wall at the level of the sciatic nerve.

CONCLUSION

It is noted that the submucosal injection of ethyl alcohol with smaller amounts (4–6 ml) is effective in prolonged rectal prolapse. It appears that the response to this treatment was not related to the site, amount of agent, type of agents, and duration of disease. However, the secondary causes in older children despite several anatomic variants in early childhood rectal prolapse are the main reasons for the failure of alcohol injection. All the patients with rectal prolapse beyond early ages should be evaluated for the secondary causes such as chronic constipation, neuromuscular disorders, scleroderma, Hirschsprung's disease, rectal polyp, cystic fibrosis, and parasites.^[7]

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A Comparative Study between Standard Weight-Based Technique and Pinna Size-Based New Technique for Classic Laryngeal Mask Airway Size Selection in Pediatric Population

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Abstract

Introduction: The laryngeal mask airway (LMA) is a non-invasive supraglottic airway device designed to maintain the airway, which sits outside of and creates a seal around the larynx. In clinical practice, the most commonly used method for size estimation is the weight-based method. However, this may not be suitable due to lack of standardization in pediatric patients, emergencies, overweight, etc. Therefore, this study was undertaken to evaluate the efficacy of the new pinna size-based method for the estimation of LMA size.

Materials and Methods: A total of 100 pediatric patients, aged under 15 years, undergoing ambulatory surgeries, belonging to American society of anesthesiologists (ASA) Grades I and II, were randomly divided into two groups: Weight-based and Pinna size-based estimation. Parameters such as number of attempts and change of size required were monitored.

Results: LMAs were inserted in both the groups in the first attempt. However, LMAs needed to be exchanged in 2% of cases in Group A and in 16% of cases in Group B.

Conclusion: Pinna size-based estimation for the size of LMA is a convenient and feasible alternative to the traditional weight-based estimation.

Key words: Auricle size, Children, Laryngeal mask airway, Pinna size, Weight-based estimation

INTRODUCTION

The laryngeal mask airway (LMA) is a supraglottic airway device designed to maintain the airway, which sits outside of and creates a seal around the larynx. It is relatively non-invasive as compared to endotracheal intubation and in scenarios where endotracheal intubation is not mandatory, LMA has emerged as a formidable choice over endotracheal intubation.^[1] Compared with the face

mask, the LMA allows for a more “hands-free approach” to airway management.^[2] In difficult airway management, LMA can bypass obstruction at supraglottic level and allow rescue oxygenation and ventilation, provided that mouth opening is sufficient.^[3]

The LMA Classic is a first-generation supraglottic airway device, with the largest evidence base for efficacy and safety, and is considered the benchmark against which newer LMAs are judged.^[1]

For proper use of the LMA, the main criteria are selection of appropriate size, the method of insertion, and inflation of the cuff. The LMA is available in different sizes ranging from 1 to 6. Sizes over 4 are used for the adult population, with LMA size 4 being appropriate for an adult female and size 5 for an adult male with a body weight not exceeding

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100 kg. Sizes of 3 or less are for the pediatric population. However, the selection of the correct size in children remains difficult due to a lack of standardization of weight-based and age-based methods for sizing. In clinical practice, the most commonly used method for size estimation is the weight-based method.^[4]

However, this may not be suitable in many patients due to the wide range for each category of weight. The development of the oropharyngeal cavity and the tissues surrounding the upper airway (bone and soft tissues) is linearly related to the age and the height independently of the sex or weight of a child.^[5] An endotracheal tube size is said to be approximately equal to the size of the little finger of a child. Although this estimation may be difficult and unreliable, it provides a rough approximation of the size of the tube required. No similar method exists for rough estimation of the required LMA size.

LMA in Children

The LMA has formed a very important part of the airway management of adults and, now, children. Early trials of the pediatric LMA note that the design was a scaled-down version of the adult LMA and not anatomically designed for children. Moreover, it was clear that the range of available sizes was inadequate. Since then, improvements in the design and availability of suitable sizes (from the smallest size 1 for wt. 0–5 kg to the older child, size 3 of weight 50 kg), together with favorable clinical experiences have led to the increasing use of LMA in children. As the LMA can be inserted easily without the use of muscle relaxants and provides a secure airway, it is increasingly used where a face mask was previously used. It is seen to replace the tracheal tube in a lot of situations as its use with controlled ventilation has also become accepted practice.

Therefore, this study was undertaken to assess the feasibility of using external ear (pinna) size of the child, as a proxy for the required size of LMA and compare the results with the standard weight-based technique.

MATERIALS AND METHODS

This prospective, randomized study was undertaken after approval from the Institutional Ethics Committee. A total of 100 patients in the age group of 1–15 years undergoing ambulatory surgeries such as circumcision, open herniotomies, anal dilatation, urethral dilatation, laparoscopic appendicectomy, laparoscopic hernia repair, diagnostic laparoscopy, belonging to American society of anesthesiologists (ASA) Grades I and II, and whose parents willing and able to understand the risk of surgery and anesthesia were included in the study. Patients belonging to ASA Grade II or higher, ex-preterm infants,

emergency cases, and patients with a history of hiatus hernia and decreased pulmonary or chest wall compliance, patients with a history of obstructive sleep apnea, asthma, congenital heart disease, obesity, mental retardation, or recent history of respiratory tract infection were excluded from the study. A written informed consent was obtained from the parent. The patients were randomly divided into two groups:

- Group A – Weight-based LMA selection
- Group B – Pinna size-based LMA selection

Pre-anesthetic checkup was done and routine investigations performed. Patients were kept overnight fasting. The external ear was measured with a ruler in the vertical and horizontal dimensions. If the external ear fell between two sizes of LMA, larger size was considered. LMAs one size larger and one size smaller were available for exchange if the approximation was incorrect. I.V line was secured. Premedication was given: Midazolam 0.03 mg/kg i.v, ketamine 0.5 mg/kg i.v, and glycopyrrolate 4 mg/kg i.v. After confirming adequate baseline saturation, the child was pre-oxygenated. Induction was done with propofol 2 mg/kg, fentanyl 2 mg/kg i.v, and muscle relaxant in the form of atracurium 0.5 mg/kg i.v. Airway was secured with the selected classic LMA. Correct placement of device was confirmed. Patients <20 kg were induced on Jackson Rees circuit and patients >20 kg were induced on closed circuit. After induction, patients were maintained on closed circuit with oxygen, air, and desflurane (3–8%) or oxygen, air, and sevoflurane (1–3%). All patients received air:oxygen (50:50). Ventilation was controlled to maintain normocapnia. End-tidal concentration of each anesthetic combination (volatile drug and air) was maintained at approximately 1.3 minimum alveolar anesthetic concentration (MAC) until the end of surgery, when spontaneous recovery of neuromuscular function was confirmed and all anesthetics were discontinued. Ventilation was continued at the same fresh gas flow until the return of a cough reflex. Each patient's LMA was removed when there were a cough and gag reflex, grimace, and purposeful movements.

Statistical Analysis

Analysis was done by SPSS. The data were analyzed using Chi-square test. $P < 0.05$ was considered to be statistically significant.

RESULTS

Both the groups were comparable in terms of demographic variables and physical characteristics. The gender-wise distribution of Groups A and B is shown in Table 1. However, the difference was statistically not significant ($P = 0.401$).

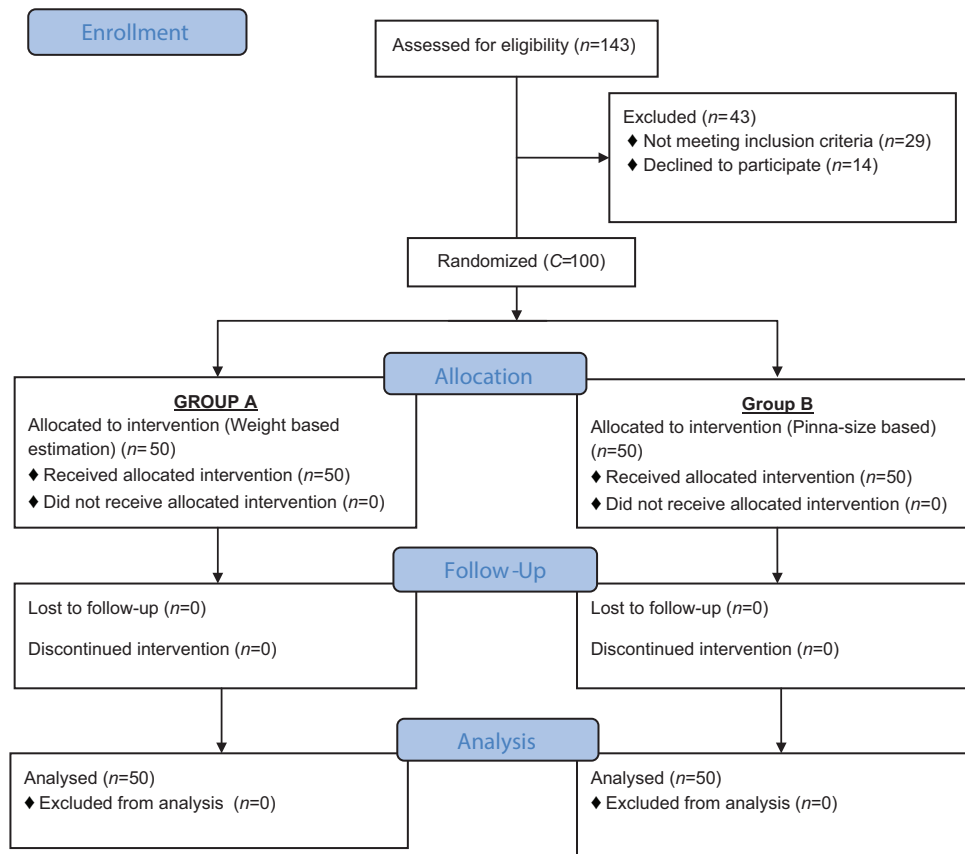


Table 1: Gender-wise distribution of the study population in Groups A and B

Parameter	Group A (%)	Group B (%)	P-value	Statistical significance
Male	44 (88)	41 (82)	0.401	Not significant
Female	6 (12)	9 (18)		

The requirement for changing the LMA tube due to incorrect estimation of size was greater in Group B than in Group A [Table 2], and this difference was statistically significant ($P = 0.014$).

DISCUSSION

Before the introduction of LMA Classic by Dr. Brain, the choices of airway management were either face mask or tracheal tube. In the past 25 years with the development of various supraglottic airway devices, the armamentarium for airway management has increased. However, for the proper use of these airway devices, size selection is of utmost importance. Insertion of correct size of airway is required for its appropriate use. At present, weight-based method is commonly used worldwide for Classic laryngeal mask airway (CLMA) size selection. The best evidence requires a randomized controlled trial comparing a new method against the established one, properly powered to

detect clinically relevant differences in clinically important outcomes. Such studies in children are very rare.

LMA Classic is a first-generation supraglottic airway device, whose usage in children is well established in both routine and difficult airway management. It has the largest evidence base for efficacy and safety and is the benchmark by which other supraglottic airway devices are evaluated.^[1]

The LMA is used widely by anesthesiologists for a variety of elective cases and is part of the difficult airway algorithm of the ASA.^[6] It is now a standard device in many ambulances and emergency departments and estimating the correct size, especially for children, can be beneficial.

Therefore, this study was conducted to assess the feasibility of using pinna/auricle size for the assessment of size of LMA in children, as an alternative to the traditional weight-based assessment.

Both the groups were similar in terms of demographic variables and physical characteristics.

All the cases were successfully intubated in the first attempt in both the groups. However, the estimation of the LMA size based on pinna size was found to be accurate in 84% of the cases, while the traditional weight-based method was

Table 2: Group-wise distribution of the requirement of changing of LMA in Groups A and B

Parameter	Group A	Group B	P-value	Statistical significance
Change of LMA required	1 (2)	8 (16)	0.014	Significant
Change of LMA not required	49 (98)	42 (84)		

found to be accurate in 98% of the cases. Thus, in the study, the pinna-based method was found to be feasible with 84% success rate. It may be used as an alternative to the traditional weight-based method, especially in cases of overweight patients and emergencies, where the weight-based estimation may be erroneous or comparatively time consuming.

The results of a number of attempts, success rate for correct estimation of the size of LMA by pinna size-based method, and conclusions were similar to the following studies:

- According to the study by Haliloglu *et al.*,^[7] auricle size-based Proseal laryngeal mask airway (PLMA) selection showed good correlation with the body weight-based method, with a success rate of 90% in the first attempt. They also concluded that the weight-based method tended to overestimate the size of PLMA
- According to the study by Zahoor *et al.*,^[8] success rate with pinna size method was 93%. For 11 of the 14 failures, the ear size-based estimation led to an underestimation of the required LMA size and a half-size larger LMA was finally chosen. Tonsillar hypertrophy and light anesthesia were the other causes of failure. Hence, this method could be used as an additive method to the existing standard methods
- In the study by Ravi *et al.*,^[9] the first attempt success in PLMA placement in pinna group was found to be 93.07%. They successfully concluded that pinna-based size selection of PLMA can be used as an alternative method to weight-based size selection in age groups between 6 months and 12 years of age
- Gallart *et al.*^[10] compared the traditional weight-based method for the estimation of size of LMA with a novel method using combined width of patient's index, middle, and ring fingers, as the best estimate for size of LMA. They argued that a new valid and practical approach for the estimation of LMA size in children is required as an alternative in the cases where the weight of the patient is unknown or in emergency situations or in cases where weight is borderline and accurate estimation of LMA size may not be possible. They found "excellent agreement" between both the methods, with disagreement of only one size in 22%

of cases. In such patients, the weight was a borderline value that would indicate a change in the size of the LMA using the classic method

- In the study by Weng *et al.*,^[11] a comparison was done traditional weight-based estimation and the new thyromental distance-based estimation. They found that the weight-based technique tended to choose an oversized LMA for overweight patients. This may lead to many foreseeable adverse consequences such as increased number of attempts for the placement of LMA, inadvertent injury to the soft tissues of oral cavity and throat, leakage, and insufficient ventilation. They found thyromental distance-based method to be better in terms of positive pressure ventilation, facilitating device placement, and reliable pharyngeal sealing.

Limitations

The study was limited by the OPD attendance of the pediatric patients undergoing ambulatory surgeries. Therefore, the results may not be generalized.

CONCLUSION

Thus, it is be effectively concluded from the study that pinna size-based estimation for the size of LMA required in children can be considered as a convenient alternative to the traditional weight-based estimation and needs to be explored further.

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Diverse Presentation of Intraventricular Colloid Cysts – A Tale of Eight Cases

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Abstract

Introduction: Colloid cysts are one of the benign intracranial tumors most commonly occurring in the rostral part of the third ventricle. These may present with varied spectrum of clinical features that poses challenges in clinical diagnosis. The presentation may range from being asymptomatic to simple headaches, seizures, and even sudden death. Most of the symptoms can be attributed to the development of obstructive hydrocephalus. Chemical or aseptic meningitis is unusual complication posing complicating differential diagnosis. We describe eight such cases with wide variety of symptoms.

Materials and Methods: We present a case series of eight cases of the third ventricle colloid cysts presented at our institute. Age of the patients ranged from 15 to 55 and five of them were females. All the clinical features were recorded from each one of them. Computed tomography and magnetic resonance imaging were used to diagnose the condition. Four of them underwent excision of the cyst in single stage either by open or endoscopic approach. Two patients underwent preliminary ventriculoperitoneal shunt done in the view of poor neurological status and craniotomy and excision was done in later stage. In one patient bedside external ventricular drain was inserted for emergency decompression of ventricles. One patient is under serial radiological follow-up.

Results: Eight cases that we observed had wide variety of symptoms. Six patients had chronic headache with progressive severity, and four of them had nausea with vomiting, three patients had seizures. The cysts in two patients were discovered accidentally, during the evaluation of seizures in one patient and others in evaluation of traumatic head injury. One elderly patient had presented with psychiatric symptoms, drop attacks along with the features of normal pressure hydrocephalus. One teenage patient presented with sudden deterioration and went into cardiac arrest even after emergency decompression of ventricles done. Seven of them underwent surgery and one of them succumbed. The surgery improved health in all other seven patients.

Conclusion: Colloid cysts may present with a wide range and beyond expected neurological manifestations. The severity or rapid clinical deterioration does not exactly correlate with depending on the site, size of the cyst. Leaking cysts with chemical meningitis may further complicate the diagnosis. Hence, early diagnosis and surgery with complete removal of cysts offer better clinical outcomes in those patients.

Key words: Colloid cyst, Obstructive hydrocephalus, Sudden cardiac arrest, Surgical removal, Third ventricle

INTRODUCTION

In 1858, Wallmann first reported on colloid cysts. In 1921, Dandy succeeded in complete resection of a colloid cyst through a transcortical-transventricular approach. Colloid

cyst is one of the benign lesions constituting nearly 15–20% of intraventricular tumors.^[1,2] In most of the cases, these are solitary and sporadic and rarely familial forms are documented.^[3-5] They usually occur in the anterior and anterosuperior part of the third ventricle.^[6,7] In all the five cases of described here, a solitary colloid cyst of the third ventricle was the common pathology. However, they differed in their clinical presentation. Various symptoms are characteristic of colloid cysts that may be detected incidentally for unrelated symptoms or due to specific problems caused by the cyst itself. These are often the result of different forms of hydrocephalus as well as irritation of major important centers around the third ventricle.^[6,8-10] In

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addition to headache, nausea, and vomiting, the symptoms may also present as disorders of consciousness, psychiatric symptoms, and even sudden death.

CASE REPORTS

We present a case series of eight cases of the third ventricle colloid cysts presented at our institute. The patient's demographic details, symptoms, radiological findings, and management are tabulated [Table 1].

Case 1

A 36-year-old male, headache, nausea, and vomiting, and two episodes of seizures, on computed tomography (CT) brain, there was hyperdense lesion in 3rd ventricle with features of hydrocephalus. On magnetic resonance imaging (MRI), lesion was 11*15 mm hypointense on T1 and T2 [Figure 1]. Patient underwent endoscopic excision of the colloid cyst. Post-operative period was uneventful.

Case 2

A 46-year-old female presented with nausea and vomiting for a few days followed by sudden deterioration in consciousness. On CT Brain, there was hyperdense lesion occluding both foramen of Monro, causing obstructive hydrocephalus. On MRI, the lesion was 20*23 mm which was non enhancing on contrast [Figure 2]. The patient underwent right ventriculoperitoneal shunt followed by transcranial excision.

Case 3

A 54-year-old male presented with headache, nausea, and vomiting with altered behavior and features of normal pressure hydrocephalus and drop attacks. MRI brain showed 25*23 mm T1 and T2 hypointense lesion with classic DOT sign [Figure 3]. The patient underwent endoscopic excision of cyst. The patient is asymptomatic now.

Case 4

A 40-year-old female presented with chronic headache and seizures. During evaluation, MRI brain showed 24*30 mm contrast-enhancing lesion in rostral part of 3rd ventricle with classic DOT sign [Figure 4]. The patient underwent transcranial excision of the cyst. The cyst was glistening white with soft and gelatinous consistency [Figure 5]. The post-operative period was uneventful.

Case 5

A 30-year-old female admitted with head injury. On CT brain, there was hyperdense lesion in 3rd ventricle without feature of hydrocephalus. On MRI, it was 6*6 mm colloid cyst [Figure 6]. The patient is asymptomatic. She is on periodic follow-up.

Case 6

A 45-year-old female admitted with headache, nausea, and vomiting. On MRI brain 15*18 mm contrast-enhancing

Table 1: Case reports: The clinical features, radiology, and treatment

Cases	Age	Sex	Clinical features	Computed tomography scan	Magnetic resonance imaging	Size	Procedure
Case 1	36	Male	HA, N/V, seizures	Hyperdense lesion at ant part of third ventricle	T1 hyper, T2/T2 flair hypointense lesion	15×11 mm	Endoscopic excision
Case 2	46	Female	HA, N/V, altered sensorium	Hyperdense lesion in rostral third ventricle occluding both the foramen of Monro	T1 hyper, T2/T2 flair hypointense and contrast non-enhancing lesion	20×23 mm	Right ventriculoperitoneal shunt followed by transcranial excision
Case 3	54	Male	HA, N/V, psychiatric symptoms, f/o NPH, and drop attacks	Hyperdense lesion at ant. part of third ventricle near right foramen of Monro	T1 iso, T2/T2 flair hypointense with classical "DOT" sign	25×23 mm	Endoscopic excision
Case 4	40	Female	Seizures, chronic headache	Hyperdense lesion at rostral part of third ventricle	T1hyper, T2/T2 flair hypointense lesion with "DOT" sign	24×30 mm	Transcranial excision
Case 5	30	Female	No symptoms	Hyperdense lesion at ant. part of third ventricle near left foramen of Monro	T1 iso, T2/T2 flair hypointense lesion	6×6 mm	Periodic observation
Case 6	45	Female	HA, N/V, seizures	Not available	T1 iso, T2 hypo, contrast enhancing lesion	15 × 18 mm	Endoscopic excision
Case 7	35	Female	HA	Hyperdense lesion in rostral third ventricle occluding both the foramen of Monro	T1 iso and T2 hyperintense lesion at rostral 3 rd ventricle	20×13 mm	Right ventriculoperitoneal shunt followed by transcranial excision
Case 8	15	Male	Sudden deterioration	Hyperdense lesion in third ventricle with obstructive hydrocephalus	Could not be taken	22×26 mm	External ventricular drainage

HA: Headache, N/V: Nausea and vomiting

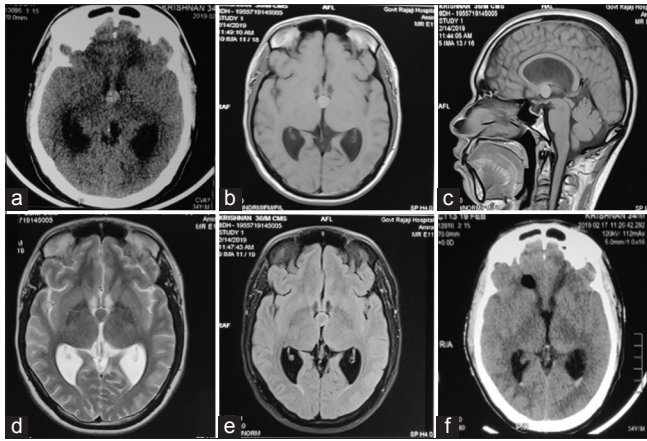


Figure 1: (a) Plain computed tomography (CT), axial view shows hyperdense lesion in third ventricle, (b and c) hyperintense lesion in T1 axial and sagittal planes, (d and e) hypointense on T2 and flair images, and (f) post-operative CT exhibiting complete removal of the cyst

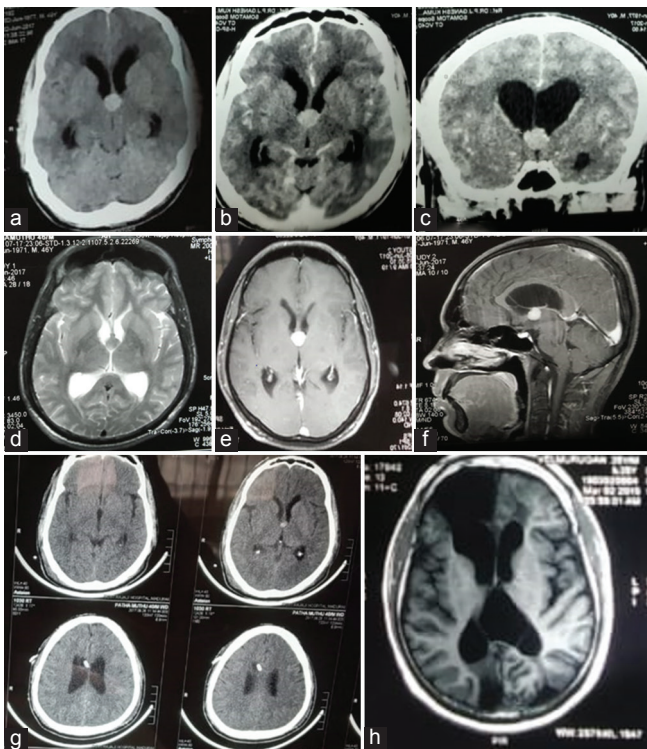


Figure 2: (a) Plain computed tomography (CT), axial view shows hyperdense lesion in third ventricle, (b and c) hyperdense lesion in contrast-enhanced CT axial and coronal planes, (d) hypointense on T2, (e and f) T1 contrast, axial, and sagittal show hyperintense lesion. (colloid cysts usually does not take up contrast) post-operative: (g) Successful decompression of ventricles after VP shunt (Stage 1), and (h) post-operative magnetic resonance imaging shows complete removal of the cyst (Stage 2)

lesion in 3rd ventricle [Figure 7]. Endoscopic excision of the cyst was done. On histopathology, it showed feature of colloid cyst. Postoperatively, the patient is doing well without any major morbidity.

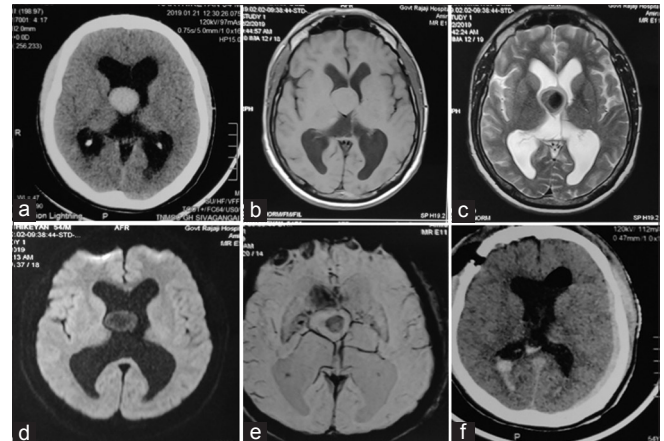


Figure 3: (a) Hyperdense lesion on computed tomography axial, (b) isodense lesion on T1 image, (c) classical "DOT" sign on T2 magnetic resonance imaging, (d) no diffusion restriction on diffusion-weighted images, (e) no blooming on SWI, and (f) post-operative images show complete excision of tumor

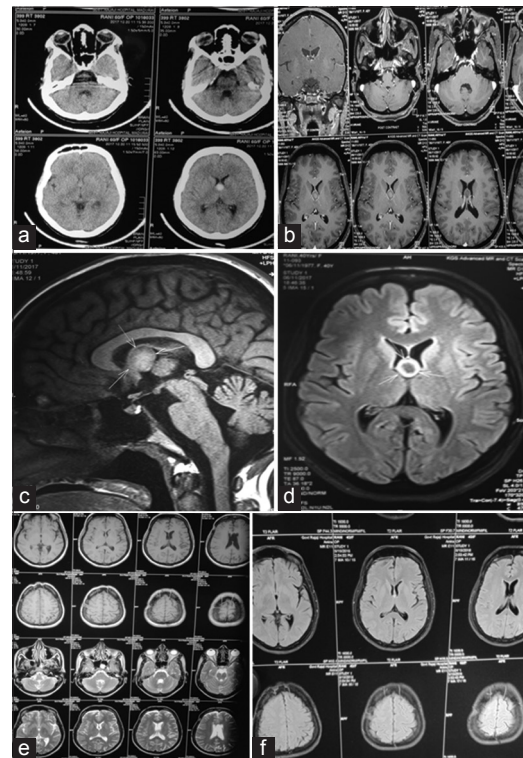


Figure 4: (a) Hyperdense lesion in plain computed tomography brain, (b) contrast-enhancing lesion in rostral third ventricle, (c) hyperdense lesion on plain magnetic resonance imaging (MRI), (d) "DOT" sign on flair MRI post-operative: (e and f): MRI brain after complete excision of lesion

Case 7

A 35-year-old female presented with chronic headache with papilledema. On CT brain, there was hyperdense lesion in 3rd ventricle, causing obstructive hydrocephalus. An emergency right VP shunt was done to decompress the ventricles. On MRI, there was 20*13 mm hyperintense

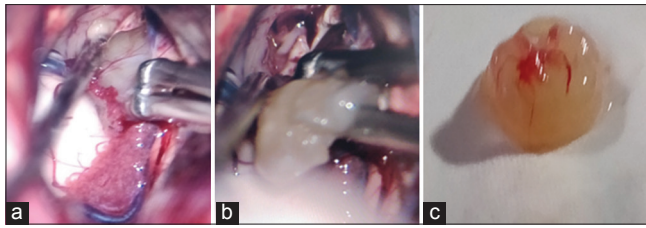


Figure 5: Intraoperative images: (a) Colloid cyst seen after opening third ventricle, (b) excision of the cyst, and (c) colloid cyst specimen removed

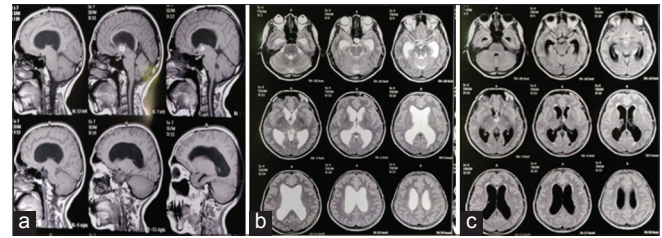


Figure 8: (a) Magnetic resonance imaging shows hyperdense lesion in third ventricle in T1, (b) hypo in T2, (c) contrast-enhancing lesion in rostral third ventricle

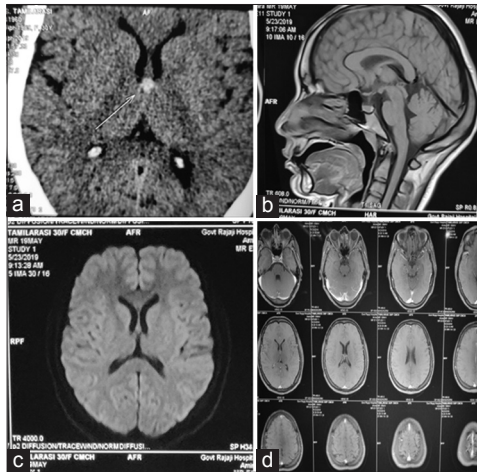


Figure 6: (a) Plain computed tomography, axial view shows hyperdense lesion in third ventricle. (b) MRI brain plain in sagittal section shows tiny iso intense lesion on T1, (c) Diffuse restriction on diffusion-weighted images, (d) tiny contrast-enhancing cyst

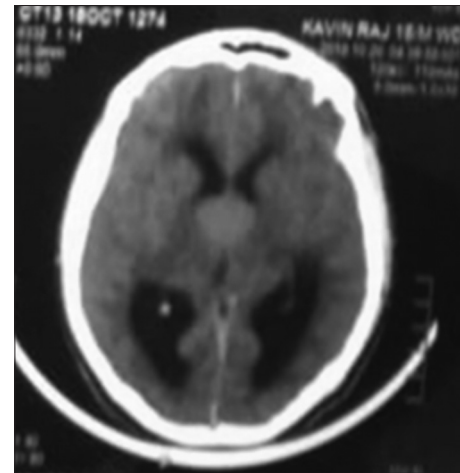


Figure 9: Computed tomography brain of 15-year-old boy shows hyperdense colloid cyst in third ventricle with obstructive hydrocephalus. Patient died due to sudden cardiac arrest

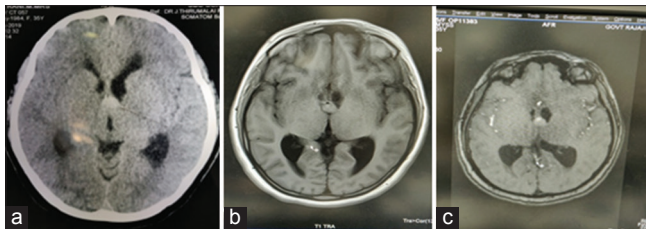


Figure 7: (a) Plain computed tomography, axial view shows hyperdense lesion in third ventricle. (b) Hyperintense lesion in T1, (c) contrast-enhancing

lesion in rostral part of 3rd ventricle [Figure 8]. Later patient underwent transcranial excision of the cyst.

Case 8

A 15-year-old young boy, presented with sudden unconsciousness. On CT brain there was hyperdense lesion in 3rd ventricle, causing obstructive hydrocephalus [Figure 9]. An emergency bedside external ventricular drainage was done, but he went into sudden cardiac arrest and succumbed to death.

Seven of them underwent surgery and one of them succumbed. The surgery improved health in all other

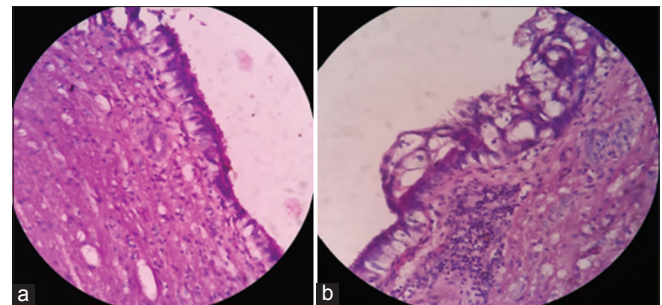


Figure 10: (a) Microscopic images show cyst wall lined by ciliated columnar cells with mucin and (b) vacuolated cytoplasm is noted

seven patients. Histopathology in all cases showed ciliated columnar epithelium with mucin and vacuolated cytoplasm characteristic of colloid cysts [Figure 10].

Observation

Of eight cases in our study, five patients were in the age group of 30–40 and two above 40 and 15-year-old young patient. Among them five were females. Headache was the most common symptom and was present in six patients. Most of the time, it was chronic headache varying in severity.

Five of six patients complained of holocranial headache. Five cases had nausea and vomiting which was more in early morning with severe headache suggestive of raised intracranial pressure. Psychiatric symptoms along with features of normal pressure hydrocephalus patient and drop attacks were reported in one patient. Three patients had presented with seizures, and one among them was incidentally found while evaluating for seizures. Cyst was incidentally detected in one patient while evaluating for head injury without any preceding symptoms. One young patient had rapid deterioration with sudden cardiac arrest [Table 2].

Two of the above cases underwent transcranial approach and two underwent endoscopic total excision of the cyst in a single stage. Two cases required emergency cerebrospinal fluid (CSF) diversion in the view of deteriorating neurological as well as clinical status; hence, right ventriculoperitoneal shunt was done followed by transcranial excision of the cyst in the second stage once patient improved. Post-operative period was uneventful in all these cases and was discharged and being followed up. One of the asymptomatic cases with small colloid cyst is under serial clinic radiological observation and one case, a young 15-year-old presented with sudden deterioration in unconscious state. Cardiopulmonary resuscitation was initiated immediately, and bedside external ventricular drain was placed since he was unfit for major surgery, but patient died due to sudden cardiac arrest.

DISCUSSION

Colloid cyst of third ventricle is a pathological condition which constitutes around 2% of brain tumors and most commonly occurring in third to fifth decade. About 80% of the patients with colloid cyst reported in literature are aged 30–60 years. Approximately 15–20% of all intraventricular masses are colloid cysts. Colloid cysts develop in the rostral aspect of the third ventricle in the foramen of Monro in 99% of cases, and despite their benign histology, they may carry high risks and neurologic complications, with a mortality reported from 3.1% to 10% in symptomatic

cases or 1.2% in total.^[11,12] Although these tumors are considered congenital, their presentation in childhood is rare (the youngest reported case involved a 2-month-old infant). The increased use of computed tomography (CT) and magnetic resonance imaging (MRI) has resulted in an increased number of patients being diagnosed.

Colloid cysts are often found incidentally, but when symptomatic, they present with obstructive hydrocephalus and paroxysmal headaches. These headaches are typically due to raised intracranial tension and are severe in early mornings. Other symptoms are gait disturbances, short-term memory loss, nausea, vomiting, and behavioral changes.^[12] Sudden loss of tone in lower limbs with falls and without loss of consciousness (drop attacks) has been reported in few cases. In addition, symptoms similar to normal-pressure hydrocephalus (e.g., dementia, gait disturbance, and urinary incontinence) have been associated with the presentation of colloid cysts. One of the studies shows that 8% of asymptomatic patients with a colloid cyst of the third ventricle eventually became symptomatic;^[13] however, a different study found 34% of symptomatic patients presented to a hospital with acute deterioration and in some cases sudden death.^[14] Pollock *et al.* described the four most important factors associated with cyst-related symptoms^[13] such as younger patient age, cyst size, ventricular dilation, and increased cyst signal on T2-weighted MRI.

In some instances, due to sudden blockage of foramen of Monro and resulting obstructive hydrocephalus causes sudden loss of consciousness and, if not intervened at the right time, results in death due to herniation. Another theory which explains sudden death in patients with colloid cysts is that the acute neurogenic cardiac dysfunction (secondary to the acute hydrocephalus) and subsequent cardiac arrest. The risk of sudden death remains difficult to predict. Cyst size and extent of ventricular dilatation do not seem to predict for acute deterioration.^[15] One of our patients had similar rapid deterioration and died due to sudden cardiac arrest.

Due to the wide range of symptomatology, the imaging modalities such as CT and MRI remain the mainstay tool

Table 2: Spectrum of clinical variation

Cases	Headache	Nausea/vomiting	Psychiatric symptoms	Seizures	Altered mentation	Sudden deterioration	Feature of NPH	Drop attacks
Case1	✓	✓		✓				
Case2	✓	✓			✓			
Case3	✓	✓	✓				✓	✓
Case4	✓			✓				
Case5								
Case 6	✓	✓		✓				
Case 7	✓	✓			✓			
Case 8						✓		

for diagnosis.^[16,17] The diverse appearance on imaging depends on the composition of the cysts.^[17,18] Cysts with a high content of cholesterol and protein are hyperdense on plain CT, hyperintense on T1-weighted, and hypointense on T2-weighted MRI sequences.^[16-18] An intracystic low T2 “DOT” is a common MRI feature of colloid cysts of the third ventricle. The hyper density noted in CT scan depends on the solidity of the contents of colloid cyst. In all our patients, CT scan showed hyperdense lesion which was evident also during the operation. The cysts were filled with gelatinous and dense content. Colloid cysts do not take up contrast either on CT or on MRI. This is not a feature of most of the colloid cysts.^[18,19]

Surgery remains mainstay of treatment in colloid cysts. The three approaches most commonly used are the transcortical approach, the interhemispheric transcallosal approach, and the endoscopic approach. In few cases, stereotactic drainage/aspiration has been used, but failure to achieve complete aspiration remains major drawback in this technique. Furthermore, the recurrence rate is high because the cyst wall is usually retained. The endoscopic approach also carries a higher rate of incomplete cyst resection, which may increase recurrence rates. Microsurgical resection through either the transcortical-transventricular or transcallosal approach is still considered the criterion standard for treatment of symptomatic patients with colloid cysts.^[20] In one of the studies, the authors conclude that every attempt must be made to completely remove the cyst wall and contents.^[21] Rarely, subfrontal lamina terminalis approach may be used.^[22,23] The likelihood of complications is higher in those cysts, which are rapidly increasing (bleeding into cyst) and in large cysts.^[14,24,22,25] If the patient is clinically unstable and not fit for surgery, emergency ventricular drainage is indicated and bilateral ventricular drainage plays the role. If there is no neurological deterioration and patient is clinically fit, CSF diversion is not indicated because enlarged ventricles can facilitate the surgical approach.

Patients in whom asymptomatic colloid cysts are diagnosed can be cared for safely with observation and serial neuroimaging. If a patient becomes symptomatic, the cyst is enlarging, or hydrocephalus develops, prompt neurosurgical intervention is necessary to prevent the occurrence of neurological decline from these benign tumors.^[9] In our study, one such asymptomatic patient is in regular clinicradiological follow-up.

CONCLUSION

Colloid cyst of third ventricles, even though benign, may present with a wide variety of symptoms irrespective of patients age, size, or location and also carry high risk of

clinical and neurological deterioration due to sudden onset hydrocephalus thus posing a great challenge in diagnosing and treating this unique condition. CT and MRI remain the best diagnostic tool until now. In this study, we encountered eight such cases in 1 year and each case has surprised and challenged us with its presentation. A solid clinical acumen is necessary in diagnosing and treating such cases for it can be cured completely with appropriate surgical approach.

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A Prospective Comparative Clinical Study on Repair of Paraumbilical Hernias with Mayo's and Mesh Techniques and their Postoperative Complications

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Abstract

Background: "Paraumbilical hernia" occurs through Linea Alba either above or below umbilicus. The current trend is to use a mesh for the repair irrespective of the size. The conventional suture method of Mayo's is also being practiced in various centers. An attempt is made in this study to compare both the methods especially in relation to their post-operative complications in the long-term follow-up.

Aim of the Study: The aim of the study to study and compare Mayo's method and use of mesh technique in the surgical management of repair of paraumbilical hernias in relation to their post-operative complications.

Materials and Methods: A cross-sectional prospective clinical study was conducted in the Department of General Surgery of Malabar Medical College Hospital, Modakkallur. Atholi, Kozhikode, Kerala, wherein 58 patients undergoing surgery for paraumbilical hernia were included in the study. The patients were assigned to these groups using random numbers from www.randomizer.org. The patients belonging to Group A were subjected to Mayo's operation and Group B were subjected to Mesh technique. All the patients were asked thorough history taking followed by investigations of surgical profile before undertaking the surgery. All the patients were followed up from day 1 postoperatively for 2 years.

Observations and Results: A total of 58 patients with paraumbilical hernia were divided into 2 equal groups comprising of 29 each. The mean age in Group A was 43.65 ± 4.10 years and in Group B was 44.60 ± 3.20 years. There were 18 females and 11 males in Group A and 17 females and 12 males in Group B. The patients belonging to the age group of 33–62 years were 21/29 (72.41%) in group A and 23/29 (79.31%) in Group B. There was no statistical significance in the incidence among the two groups as $P = 0.153$ (P taken significantly at <0.05). The male to female ratio in Group A was 1:1.63 and 1:1.41 in Group B. Pain was complained in the post-operative period in 19/29 (65.51%) patients in Group A and 16/29 (55.17%) patients in Group B. Hematoma was observed in 5/29 (17.24%) patients in Group A and 7/29 (24.13%) patients in Group B. Seroma was observed in 4/29 (13.79%) patients in Group A and 3/29 (10.34%) patients in Group B.

Conclusions: In a follow-up of 2 months to years, among the procedures used classical Mayo's repair had 4/29 recurrences and 1/29 were noted in patients underwent mesh repair. Even though Mayo's repair for paraumbilical has been the procedure of choice in many centers, but the tension-free mesh repair has an advantage of having no recurrences and can be used in the presence of bigger defect and weaker abdominal muscle tone, thus showing a superior and favorable procedure than Mayo's repair.

Key words: Hernia mesh, Hernia, Laparoscopic hernia repair, Mayo's operation, Paraumbilical hernia, Umbilical hernia

INTRODUCTION

Hernia is defined as a bulging of the part of the normal contents of the abdominal cavity through a weakness in the

abdominal wall.^[1] Paraumbilical hernia is a type of ventral hernia occurring through Linea Alba either superior or inferior to the umbilicus. Ventral hernias constitute one of the common hernias of adulthood especially in women in the ratio of 3:1.2.^[2] The development of paraumbilical hernia is a multifactorial and complex process, typically supraumbilical in location.^[3] In 90% of the patients, paraumbilical hernias occur as acquired defects as a direct result of increased abdominal pressure, especially in multiparous women, obese individuals, elderly people, patients with emphysema, and asthma-related diseases.^[4] Paraumbilical hernias are a common surgical problem

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consisting of 10% of all primary hernias.^[5-7] The sac of the hernia may contain preperitoneal fat, omentum, or small intestine mostly, but sometimes a combination of these structures also may herniate.^[8] The most common symptom making the patient to visit the surgeon is pain in the swelling.^[9] As the incidence of complications such as incarceration and strangulation is more common with ventral hernias and elective surgery remains the choice of treatment.^[10] In Mayo's repair, attempts at widening the hernia defect in transverse direction cut more aponeurotic fibers and favors recurrence at lateral extremities of the repair. Recurrence often occurs much earlier than expected and has been reported to occur in the first few post-operative months (Mair, 1945).^[11] It was believed that the wide area of contact between upper and lower fascial sheets would promote strong adhesion between them and ensure a good repair. The use of mesh to repair the hernia defect, either open or laparoscopic, is widely used now a day.^[12,13] The recurrence rates have come down drastically with the use of a tension-free mesh technique when compared to Mayo's tissue repair.^[14,15] In this context, the present study was conducted to study and compare Mayo's method and use of Mesh technique in the surgical management of repair of paraumbilical hernias in relation to their post-operative complications.

Type of the Study

This was a cross-sectional prospective comparative study.

Period of the Study

The study was from January 2016 to December 2018.

Institute of the Study

This study was conducted at Malabar Medical College Hospital, Modakkallur. Atholi, Kozhikode, Kerala.

MATERIALS AND METHODS

A cross-sectional prospective clinical study was conducted in the Department of General Surgery of Malabar Medical College Hospital, Modakkallur. Atholi, Kozhikode, Kerala, wherein 58 patients undergoing surgery for paraumbilical hernia were included. An Institutional Ethical Committee Clearance was obtained before the commencement of this study. An ethical committee cleared consent form was used for the study.

Inclusion Criteria

(1). Patients aged above 12 years and below 72 years were included in this study. (2). Patients with paraumbilical hernia alone were included in this study. (3). Patients presenting with *de novo* paraumbilical hernia or with its complications were also included in this study. (4). Patients with paraumbilical hernia with complaints of pain were

included in this study. (5). Patients who had hernia of small and medium size; 3–8 cm diameter were included in this study. (6). Patients of both sex groups were included in this study.

Exclusion Criteria

(1). Patients aged below 12 years and above 72 years were excluded from the study. (2). Patients uncontrolled hypertension, diabetes mellitus, and other allergic asthma were excluded from the study. (3). Patients with debilitating diseases or immunodeficiency diseases were excluded from the study. (4). Patients having large and recurrent, cirrhosis of liver, ascites, and carcinoma were excluded from the study. A total of 57 patients were divided into two groups. Group A consisted of 29 patients and Group B consisted of 28 patients. The patients were assigned to these groups using random numbers from www.randomizer.org. Patients belonging to Group A were subjected to Mayo's operation and Group B were subjected to mesh technique. All the patients were asked thorough history taking followed by investigations of surgical profile before undertaking the surgery. The traditional Mayo repair consisted of a vertical overlap with adjacent aponeurotic structures. The incision in the aponeurosis was extended longitudinally on either side of the hernia defect. The hernia sac was encircled and excised from the edges of the fascia. The sac was transected from the base of the umbilicus. All the patients were followed up from day 1 postoperatively for 2 years. An observation was made in relation to the post-operative symptoms and complications such as pain, fever, wound infection, hospital stay, analgesic requirements, quality of life, and recurrence. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

Among the 58 patients in this study with paraumbilical hernia were divided into two equal groups comprising of 29 each. The mean age in Group A was 43.65 ± 4.10 years and the mean age in Group B was 44.60 ± 3.20 years. There were 18 females and 11 males in Group A and 17 females and 12 males in Group B. Overall there were 35/58 (60.34%) females when compared to 23/58 (39.65%) males. $P = 0.041$ (P taken significantly at <0.05). Patients belonging to the age group of 33–62 years were 21/29 (72.41%) in Group A and 23/29 (79.31%) in Group B. There was no statistical significance in the incidence among the two groups as $P = 0.153$ (P taken significantly at <0.05). The male to female ratio in Group A was 1:1.63 and 1:1.41 in Group B [Table 1].

The most common symptom of clinical presentation in both the groups was swelling (Group A – 18/29

[62.06%] and Group B – 16/29 [55.17%]) followed by pain (Group A – 14/29 [48.27%] and Group B 16/29 [55.17%]). The most common complication was irreducibility (Group A – 4/29 [13.79%] and Group B 3/29 [10.34%]) followed by intestinal obstruction and ulceration (Group A – 2/29 [6.89%] and Group B 3/29 [10.34%]) [Table 2].

During the surgery, the size of the defect in Linea Alba was measured and tabulated in Table 3. There were 17/29 (58.62%) patients with 2–4 cm defect in Linea Alba in Group A and 14/29 (48.27%) in Group B. The defect was 5–7 cm in 11/29 (37.93%) patients in Group A and 14/29 (48.27%) in Group B [Table 3].

The complaints during the post-operative period and complications in both the groups were tabulated in Table 4. Pain was complained in the post-operative period in 19/29 (65.51%) patients in Group A and 16/29 (55.17%) patients in Group B. Hematoma was observed in 5/29 (17.24%) patients in Group A and 7/29 (24.13%) patients in Group B. Seroma was observed in 4/29 (13.79%) patients in Group A and 3/29 (10.34%) patients in Group B. Wound infection was observed in 2/29 (6.89%) of Group A and Group B patients. The period of return to normal activity was 10–21 days

(mean 14.73 days) in Group A and 10–18 days (mean 12.16 days). All the patients were followed up for 2 years. There were 4/29 (13.79%) cases of recurrence in Group A and 1/29 (03.44%) recurrence in Group B [Table 4].

DISCUSSION

In the present study, 58 patients were included with paraumbilical hernia that underwent two types of common procedures. The study was a cross-sectional and prospective one. Paraumbilical hernia is common in the 4th–5th.^[16] In this study, the mean age of occurrence in Group A was 43.65 ± 4.10 years and the mean age in Group B was 44.60 ± 3.20 years. In a similar study conducted by Daudpoto, Shahid Mirani, and others, it was observed that the majority of patients were above the age of 40 years^[17] and in a report by Berger *et al.*^[18] the mean age was 42.7 with standard deviation.^[12] Paraumbilical hernia is reported commonly in women than men.^[19] In the present study, the incidence of paraumbilical hernia was more common females than males with a male to female ratio of 1:1.41. Overall, there were 35/58 (60.34%) females when compared to 23/58 (39.65%) males. The $P = 0.041$ (P taken significantly at <0.05). The explanation given is that fat tissue deposition varies according to gender contributing hernia in a major way.^[20] The most common symptom of clinical presentation in both the groups was swelling (Group A – 18/29 [62.06%] and Group B – 16/29 [55.17%]) followed by pain (Group A – 14/29 [48.27%] and Group B – 16/29 [55.17%]). The most common complication was irreducibility (Group A – 4/29 [13.79%]

Table 1: The demographic data of the study group (n=58)

Observations	Group A–29	Group B–29	P-value
Age			
12–22	02	01	0.148
23–32	03	02	
33–42	06	07	
43–52	11	12	
53–62	04	04	
63–72	03	03	0.132
Gender			
Male	18	17	
Female	11	12	0.153
Incidence 33–72 years group	72.41%	79.31%	
Male to female ratio	1:1.63	1:1.41	0.110

Table 2: The incidence of symptoms and complications in the study groups (n=8)

Complaints	Group A–29%	Group B–29%
Swelling	18 (62.06)	16 (55.17)
Pain	14 (48.27)	16 (55.17)
Abdominal distension	03 (10.34)	02 (06.89)
Constipation	03 (10.34)	04 (13.79)
Vomiting	01 (03.44)	02 (06.89)
Complications		
Ulceration	02 (06.89)	03 (10.34)
Irreducibility	04 (13.79)	02 (06.89)
Intestinal obstruction	02 (06.89)	03 (10.34)
Strangulation	01 (03.44)	02 (06.89)

Table 3: The size of the defect in Linea Alba per operatively (n=58)

Size	Group A–29 (%)	Group B–29 (%)
2–4 cm	17 (58.62)	14 (48.27)
5–7 cm	11 (37.93)	14 (48.27)
>7 cm	01 (03.44)	01 (03.44)

Table 4: The incidence of postoperative complaints and complications in the study group (n=58)

Post-operative complaints and complications	Group A–29 (%)	Group B–29 (%)
Pain	19 (65.51)	16 (55.17)
Use of analgesic doses in 1 week		
3–6	09 (31.03)	11 (37.93)
7–10	13 (44.82)	15 (51.72)
>10	07 (24.13)	03 (10.34)
Hematoma	05 (17.24)	07 (24.13)
Seroma	04 (13.79)	03 (10.34)
Wound infection	02 (06.89)	02 (06.89)
Mesh extrusion	–	02 (06.89)
Recurrences	04 (13.79)	01 (03.44)

and Group B – 3/29 [10.34%]) followed by intestinal obstruction and ulceration (Group A – 2/29 [6.89%] and Group B – 3/29 [10.34%]). In a similar study by Courtney *et al.*^[9] it was observed that the most common symptom was swelling complained by their patients in 67.18% followed by pain in 49.30%. There were 17/29 (58.62%) patients with 2–4 cm defect in Linea Alba in Group A and 14/29 (48.27%) in Group B. The defect was 5–7 cm in 11/29 (37.93%) patients in Group A and 14/29 (48.27%) in Group B. In a study by Abdul Qayoom *et al.*^[17] who classified the size of the hernia defects to 2–4 cm; were found in (63–78%) of the cases and 4–6 cm; and were found in (21–36%) patients. Wassenberg *et al.*^[21] typed the hernia defects to small size (1–2 cm); were found in (62.5%) and medium defects (2–4 cm); and were found in (37.5%) patients. In the present study, pain was complained in the post-operative period in 19/29 (65.51%) patients in Group A and 16/29 (55.17%) patients in Group B. Hematoma was observed in 5/29 (17.24%) patients in Group A and 7/29 (24.13%) patients in Group B.

Seroma was observed in 4/29 (13.79%) patients in Group A and 3/29 (10.34%) patients in Group B. Wound infection was observed in 2/29 (6.89%) of Group A and Group B patients. The period of return to normal activity was 10–21 days (mean 14.73 days) in Group A and 10–18 days (mean 12.16 days). All the patients were followed up for 2 years. There were 4/29 (13.79%) cases of recurrence in Group A and 1/29 (03.44%) recurrence in Group B. The occurrence of seroma may be explained by the fact that onlay techniques require subcutaneous dissection to place the meshes, which lead to devitalization of the tissue. The incidence of seroma in the study by Abdul Qayoom *et al.*^[17] was nearly similar to our study (13.79%). However, the incidence of seroma was <5% in a study by Bessa *et al.*^[22] chronic pain was not found in this study subjects. A review of literature shows that the recurrence rate was lower after mesh repair than that after Mayo's operation (1% vs. 11%) in a 64-month mean post-operative follow-up by Arroyo *et al.*^[4] In a retrospective clinical series of 100 patients, the recurrence rates for the suture and mesh repair groups were 11.5% and 0%, respectively ($P = 0.007$).^[23] There are certain limitations to this study such as the study design which is weak regarding question of better surgery that has to be addressed. Secondly, the sample size is small.

CONCLUSIONS

The study reflects the clinical aspects, surgical techniques, and the related post-operative complications of the commonly used surgical procedures for paraumbilical hernia. These are most common in elderly females, with

swelling followed by pain being the chief presentation, irreducibility is the common complication. In a follow-up of 2 months to years, among the procedures used classical Mayo's repair had 4/29 recurrences and 1/29 were noted in patients underwent mesh repair. Even though Mayo's repair for paraumbilical has been the procedure of choice in many centers, but the tension-free mesh repair has an advantage of having no recurrences and can be used in the presence of bigger defect and weaker abdominal muscle tone, thus showing a superior and favorable procedure than Mayo's repair.

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Renal Doppler Indices in Chronic Liver Disease and its Role in Predicting Hepatorenal Syndrome

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Abstract

Introduction: Hepatorenal syndrome (HRS) is the most serious complication of renal dysfunction in patients with chronic liver disease (CLD). Renal arterial vasoconstriction may persist for weeks, even months before an increase of blood urea nitrogen or serum creatinine values can be discovered.^[1] Duplex Doppler ultrasonography of the kidneys is an easy and non-invasive method to assess blood flow and arterial vascular resistance as a parameter for vasoconstriction.^[2-4] Intrarenal resistive index (RI) may be superior to serum creatinine levels as an indicator in patients with liver cirrhosis for the detection of patients at risk for the development of HRS.

Objective: The objective of the study was to correlate renal Doppler indices with serum creatinine levels in various stages of CLD and to determine its role in predicting the risk for developing HRS in patients of CLD.

Materials and Methods: Grayscale, color flow, and duplex Doppler ultrasonography were performed in patients of CLD, which were divided into four groups with increasing clinical severities. Their serum creatinine level was compared with renal Doppler indices in various groups of increasing severity.

Results: Most common cause of CLD in our study population was alcoholism (62%). About 65% of cases show irregular liver surface, and irregular liver surface is significantly higher in Groups II, III, and IV versus Group I. Heterogeneous, homogenous, and fatty echo texture were showed by 78%, 11%, and 11%, respectively. Mean peak systolic velocity and end-diastolic velocity in our study are 33.99 cm/s and 11.55 cm/s, respectively. Mean pulsatility index in cases was 1.17. In our present study, RI level was significantly higher in cirrhotic patients, and there is a significant association between RI and study groups. As the severity of liver disease of group increases, the RI value also gets elevated.

Conclusion: Intrarenal RI seems to be a helpful predictor to identify a subgroup of CLD patients with a higher risk of developing kidney failure or HRS, which can translate into the early initiation of treatment for impending HRS.

Key words: Chronic liver disease, Hepatorenal syndrome, Resistive index

INTRODUCTION

Renal dysfunction often develops in patients with chronic liver disease (CLD). The impairment of kidney function is caused by severe renal arterial vasoconstriction due to complex changes in systemic hemodynamics. Hepatorenal syndrome (HRS) is the most serious complication of renal dysfunction in patients with CLD and is associated with extremely short survival time.

Renal arterial vasoconstriction may persist for weeks, even months before an increase of blood urea nitrogen or serum creatinine values can be discovered.

Duplex Doppler ultrasonography of the kidneys is an easy and non-invasive method to assess blood flow and arterial vascular resistance as a parameter for vasoconstriction. The arterial resistance index is the most widely used parameter to estimate the arteriolar vascular resistance.

The resistive index (RI) can be used to assess vascular resistance through a simple analysis of the Doppler waveform. The normal value of RI is 0.50–0.70 and is measured at the arcuate arteries or interlobar arteries. To define the prognostic value of RI measurement for renal function impairment in patients with different stages of CLD

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more precisely, we analyzed intrarenal arterial resistance index in patients with CLD and correlated it with serum creatinine level which indicates severity of renal function decline.

MATERIALS AND METHODS

Source of Data

This is a hospital-based prospective cross-sectional study of sample size 100 subjects, conducted at the Department of Radiodiagnosis and Imaging, Gandhi Medical College and Hamidia Hospital, Bhopal. The study population include patients with CLD referred to our department for radiological assessment from various Departments of Gandhi Medical College and Hamidia Hospital, Bhopal. The study period was performed between March 2017 and September 2018.

Plan of Study

All the patients were referred to our department for ultrasound from various Departments of Gandhi Medical College and Hamidia Hospital, Bhopal. On the basis of their clinical profile, 100 cases are divided into four groups—CLD patient without ascites, with mild ascites, with moderate ascites, and with gross/refractory ascites. Twenty-five controls were taken for comparison. No financial burden was incurred on the patient. Ethical clearance was taken from Ethics Committee of Gandhi Medical College, Bhopal.

Inclusion Criteria

All patients of age more than 18 years who have sonographic evidence of CLD and patients willing to cooperate for the study were included in the study.

Exclusion Criteria

Emergency, trauma, and post-operative patients, patients with diabetes, hypertension, or nephrotoxic drug intake were excluded from the study. Patients with acute infections, malignant diseases, nephropathies, and pathomorphological findings in ultrasound include decreased kidney size, reduction of renal parenchymal width, and significant renal parenchymal hyperechogenicity. Patients unwilling to cooperate in the study were excluded from the study.

Instrumentation

All examinations were performed using ultrasound and color Doppler Machine Philips, GE, and Esaote of our department using convex 3.5–5 MHz array transducer and 11–12.5 MHz linear transducers.

Statistics Analysis

Descriptive statistical analysis was performed with Statistical Analysis System version 9.2 for windows and SPSS Complex Version 21.0 for windows, Inc., Chicago, USA, with Microsoft Word and Excel being used to generate graphs and tables. Results are presented as Mean \pm standard

error of mean and in number (%). Chi-square test used to find the significance of study parameters on categorical scale between two and more groups.

Methodology

The patient was explained complete details about the study. Consent form in a local language containing all information about study was given to the patient. Once a patient satisfied the inclusion criteria, a thorough workup of patients was done by history taking, clinical examination, laboratory investigations, grayscale sonography findings, and renal Doppler examination. All patients subjected to detailed history of CLD, especially bleeding tendency, ascites, jaundice, and encephalopathy. Direct ultrasonographic and Doppler examination of the patient was done in the radiology department.

The patients examined in supine, oblique, both side lateral decubitus, and occasionally prone position using a combination of subcostal and intercostals approach. After obtaining an optimum B mode, color flow and duplex Doppler activated and the values of Doppler indices measured in the interlobar arteries. At least three satisfactory blood flow velocity waveforms were obtained and employed for statistical analysis of the average from three waveforms. No significant differences between the left and right interlobar arteries were observed, and therefore the mean value of both was taken [Figures 1-4].

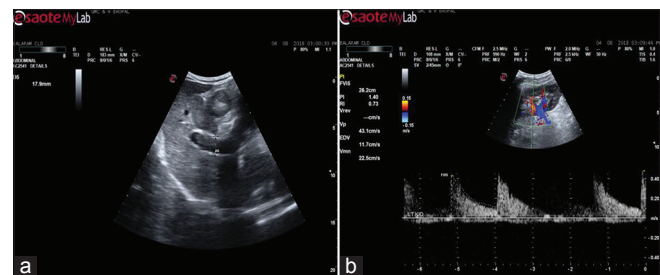


Figure 1: Grayscale ultrasound image shows coarsened liver echotexture, dilated portal vein in a patient of chronic liver disease without ascites (left). Color Doppler ultrasound image shows left kidney normal in size, shape, and echotexture showing raised resistive index in intersegmental artery in same patient (right)

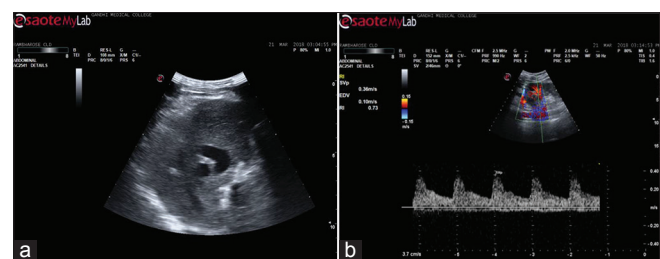


Figure 2: Grayscale ultrasound image shows coarsened liver echotexture, dilated portal vein in a patient of chronic liver disease with mild ascites (left). Color Doppler ultrasound image with right kidney showing raised resistive index in intersegmental artery in same patient (right)

The RI was calculated as the difference between peak systolic velocity (PSV) and end-diastolic velocity (EDV) divided by PSV. The pulsatility index (PI), defined as the difference between peak systolic and end-diastolic flow divided by the mean maximum flow velocity was determined using calculation software. A mean value was calculated for the Doppler indices for both kidneys and was correlated with serum creatinine level. Data are collected, and system analyzed, and statistical tests applied.

OBSERVATIONS AND RESULTS

In our study of 100 cases of CLD, the main burden of the disease was between 51 and 60 years. Study shows that CLD is common in both sexes with male predominance (74%). Out of total 100 cases, 62% were alcoholic, 10% were chronic cases of hepatitis B and C. About 5% of cases were of non-alcoholic fatty liver disease, which includes patients of metabolic syndrome, as shown in Graph 1.

Ultrasonographic hepatomegaly was seen in 19% cases, and it was shrunken in 16%, signifying that in CLD, one may have an enlarged to a fibrosed liver depending on severity and chronicity of underlying disorder. About 65% of cases show irregular liver surface, while 35% shows smooth

surface. The irregular surface is significantly higher in Groups II, III, and IV. No difference was found between Groups III and IV. About 78% and 11% of cases showed heterogeneous and homogenous echotexture, respectively, in our study. About 11% showed fatty echotexture.

In our study, portal vein was dilated in 46% cases as compared to control, where it was dilated in only 4% case. The mean portal vein diameter in cases was 14.17 mm.

In our study, ultrasonographic splenomegaly was seen in 65% cases with mean spleen size and was 14.01 cm. Spleen size is significantly higher in cases than controls, $P < 0.001$ as computed by unpaired *t*-test.

Mean PSV and EDV in the case group in our study was 33.99 cm/s and 11.55 cm/s, respectively. Mean PI in cases was 1.17 as compared to control group where mean is 0.98. PI is significantly higher in cases than controls, $P = 0.049$.

RI was significantly higher in non-ascitic patients with liver cirrhosis than in control subjects (16% vs. 4%) and in mild ascitic patients compared to non-ascitic patients (24 vs. 16%), in moderate ascitic patient group compared to mild ascitic group (36% vs. 24%), and gross refractory ascitic patient group as compared to moderate ascitic patients (52% vs. 36%), as shown in Figures 1-4. Hence, there is a significant association between RI and study groups. As the severity of liver disease of group increases, the RI value also gets elevated, $P < 0.001$ as computed by Chi-square test, as depicted by Table 1.

In our present study, serum s creatinine level was significantly higher in cases as compared to control group (25% vs. 4%). Furthermore, as severity of disease increases, serum creatinine level also keep on increasing non-ascitic liver disease patients (12%), mild ascitic patient (20%), moderate ascitic group (24%), and refractory ascitic group (44%) with $P < 0.001$ as computed by Chi-square test, as depicted in Table 2.

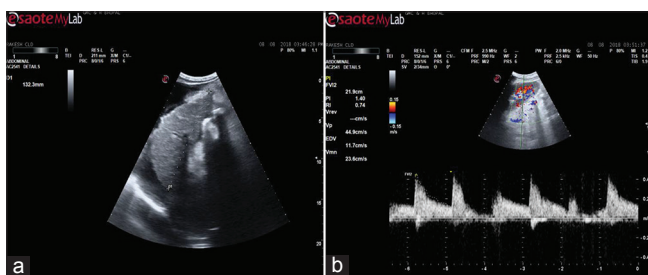


Figure 3: Grayscale ultrasound image shows small irregular, nodular liver showing dilated portal vein in a patient of chronic liver disease with moderate ascites (left). Color Doppler ultrasound image shows right kidney with significantly raised resistive index in intersegmental artery (right)

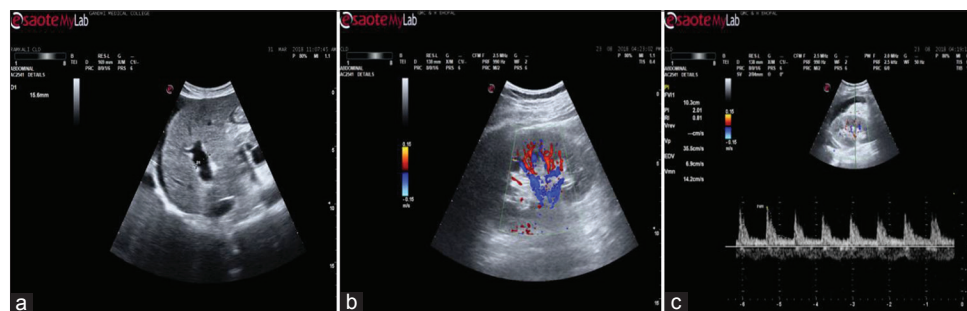
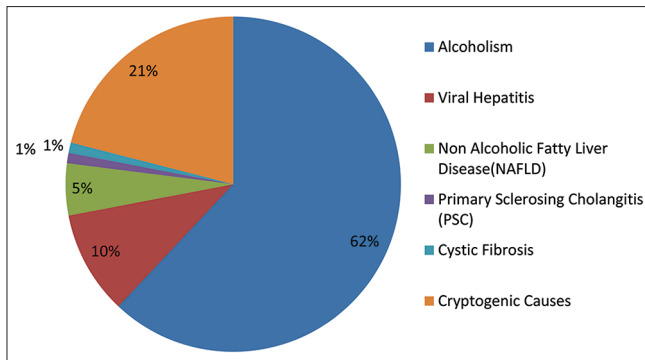


Figure 4: Grayscale ultrasound image shows small irregular, nodular cirrhotic liver showing dilated portal vein and gross ascites in a patient of chronic liver disease with refractory ascites (left). Color Doppler (middle) and pulse Doppler (right) ultrasound image shows normal kidney showing normal vascularity, however showing significantly raised resistive index in intersegmental arteries in the same patient



Graph 1: Causes of chronic liver disease in study groups

Correlation of RI with serum creatinine – there was no significant correlation noted between RI and serum creatinine in case Group I, correlation coefficient -0.186 , $P = 0.374$ with a moderate significant relationship between RI and creatinine levels in case Group II, correlation coefficient -0.658 , $P < 0.001$. There is a strong significant relationship between RI and creatinine levels in case Group III, correlation coefficient -0.719 , $P < 0.001$. Furthermore, a strong significant relationship between RI and creatinine levels in case Group IV, correlation coefficient -0.739 , $P < 0.001$, as depicted by Graphs 2-5.

Hence, as severity of disease progresses, correlation between serum creatinine level and renal RI becomes more and stronger.

DISCUSSION

Our study is aimed to calculate the renal RI by renal Doppler study and to correlate it to the serum creatinine level in various progressive stages of CLD patients. By this study, we can predict the risk of developing renal failure in these CLD patients and prevent development of HRS by early and timely intervention. HRS is a functional form of acute kidney failure seen in patients with acute liver failure or CLD in absence of any other identifiable cause of renal failure.

In the present study, we used indices of color Doppler ultrasound for diagnosis of renal failures in progressive stages of CLD patients. It is a non-invasive assessment of blood flow in renal vasculature.

AGE

The mean age of cases was 44 years. Since controls were age-matched, there was no significant difference between the age group distribution of cases and controls, $P = 0.452$ as computed by Chi-square test. The main burden of the disease was between 51 and 60 years.

Table 1: RI category distribution of various study groups

Group	RI-category		Total	P value
	Elevated	Normal		
Case Group I				
Count	4	21	25	<0.001
% within GRP	16.0	84.0	100.0	
Case Group II				
Count	6	19	25	
% within GRP	24.0	76.0	100.0	
Case Group III				
Count	9	16	25	
% within GRP	36.0	64.0	100.0	
Case Group IV				
Count	13	12	25	
% within GRP	52.0	48.0	100.0	
Control				
Count	1	24	25	
% within GRP	4.0	96.0	100.0	
Total				
Count	33	92	125	
% within GRP	26.4	73.6	100.0	

RI: Resistive index

Table 2: Creatinine category distribution of various study groups

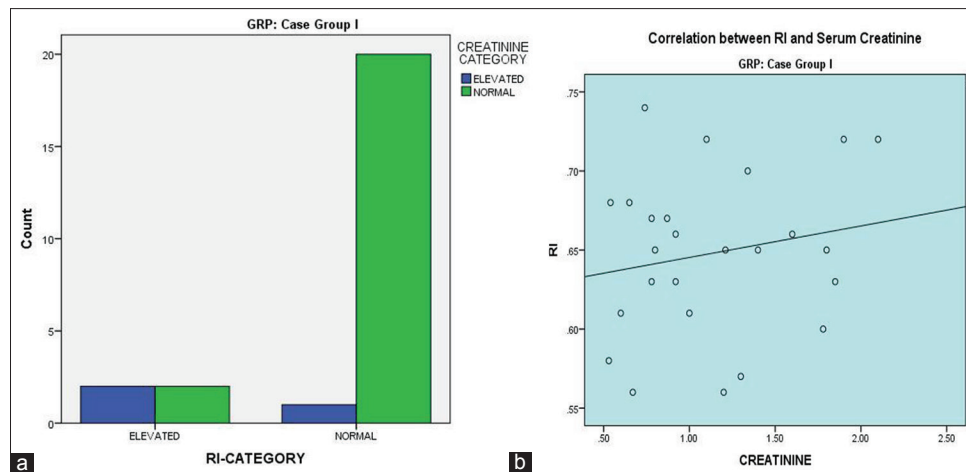
Group	Creatinine Category		Total	P value
	Elevated	Normal		
Case Group I				
Count	3	22	25	
% within GRP	12.0	88.0	100.0	
Case Group II				
Count	5	20	25	
% within GRP	20.0	80.0	100.0	<0.001
Case Group III				
Count	6	19	25	
% within GRP	24.0	76.0	100.0	
Case Group IV				
Count	11	14	25	
% within GRP	44.0	56.0	100.0	
Control				
Count	1	24	25	
% within GRP	4.0	96.0	100.0	
Total				
Count	26	99	125	
% within GRP	20.8	79.2	100.0	

Gender

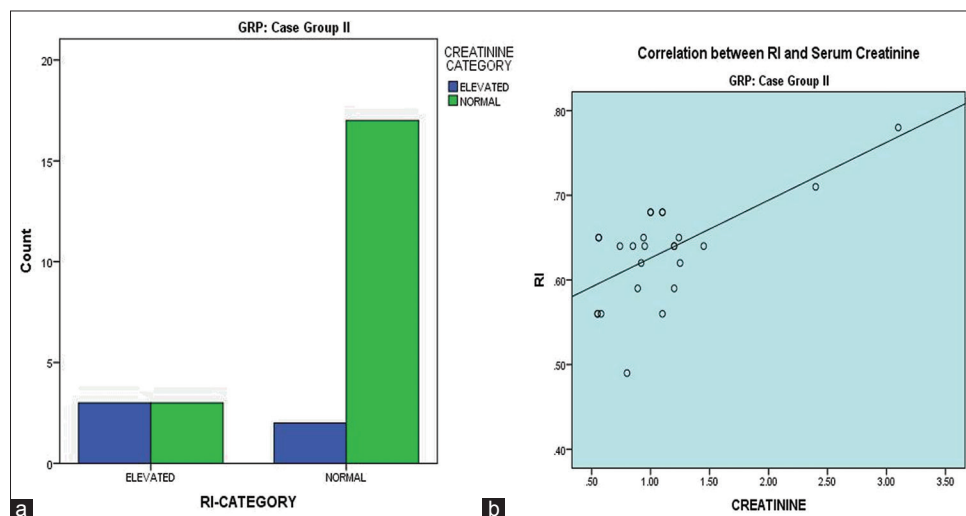
Out of total cases, 26% were female and 74% were males. This study shows that CLD is common in both sexes with male predominance similar to that reported internationally.^[5,6] No significant difference between the gender distribution of cases and controls, $P = 0.534$ as computed by the Chi-square test.

Etiology of CLD

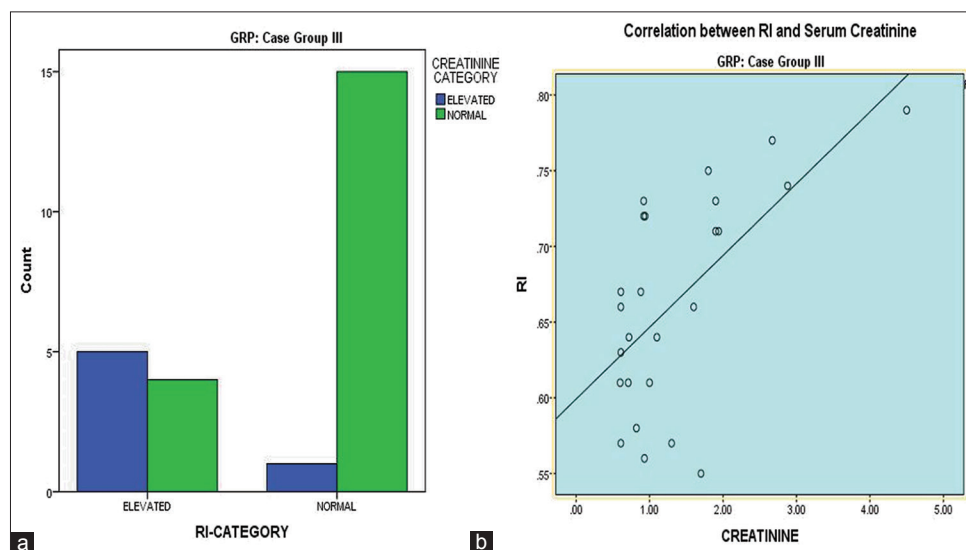
In our study, out of a total 100 cases, 62% were alcoholic, 10% were chronic cases of hepatitis B and C. About



Graph 2: (a and b) Correlation between resistive index and creatinine in the study Group I



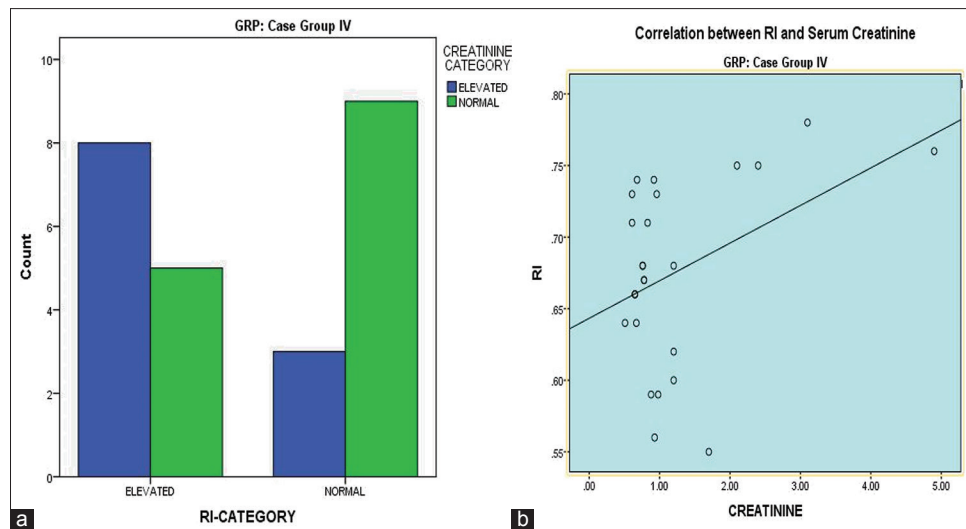
Graph 3: (a and b) Correlation between resistive index and creatinine in the study Group II



Graph 4: (a and b) Correlation between resistive index and creatinine in the study Group III

5% of cases were of non-alcoholic fatty liver disease, which includes patients of metabolic syndrome (diabetes

insipidus, hypertension, and hyperlipidemia, obesity, etc.). The leading causes worldwide of CLD are hepatitis B



Graph 5: (a and b) Correlation between resistive index and creatinine in the study Group IV

virus, hepatitis C virus, and alcohol. Other causes of CLD are viral hepatitis (hepatitis B and D, cytomegalovirus, and Epstein–Barr virus), toxoplasmosis, schistosomiasis, inherited and metabolic disorders, drugs, toxins, etc.^[7]

Liver Span

In our study, ultrasonographic hepatomegaly was seen in 19% cases and it was shrunken in 16%, signifying that in CLD, one may have an enlarged to a fibrosed liver depending on severity and chronicity of underlying disorder. These findings are similar to the work of Hanif *et al.*^[8] The most reliable measurement is sagittal dimension from the dome to the tip of the right lobe taken at the midclavicular line. If this exceeds 15.5 cm, the liver is enlarged.

Liver Surface/Edge

In our study, 65% of cases show irregular liver surface, while 35% shows smooth surface. The irregular surface is significantly higher in Groups II, III, and IV versus Group 1 and control. Group I is higher than control. No difference was found between Groups III and IV. The control group showed no irregularities of liver edges. However, a study done by Mahjabeen *et al.* showed 32% and 68% of cases for irregular and normal liver edge, respectively.^[9]

Liver Echotexture

Although, coarsening of hepatic parenchymal echotexture were subjective signs, 78% and 11% of cases showed heterogeneous and homogenous echotexture respectively in our study. 11% showed fatty echotexture. Weickert *et al.* conducted a prospective study on 100 patients by doing their ultrasound before biopsy also following the similar parameters laid down in our study. Results showed that ultrasound examination was sensitivity of 55% and specificity of 86%.^[10]

Portal Vein Diameter

A significant difference between the portal vein diameter category distribution of cases and controls noted, $P < 0.001$ as computed by Chi-square test. In our study, portal vein was dilated in 46% cases as compared to control, where it was dilated in only 4% case. Mean portal vein diameter in cases was 14.17 mm whereas in control was 12.3 mm.

Spleen Size

In our study, ultrasonographic splenomegaly was seen in 65% cases and 8% of controls. The mean spleen size was 14.01 cm in cases and 11.28 cm in controls. Spleen size is significantly higher in cases than controls, $P < 0.001$ as computed by unpaired *t*-test. The incidence of splenomegaly in patients with hepatic cirrhosis varies in published reports from 32% to 42%. In a study by Liebowitz,^[11] 17 among 50 patients with cirrhosis who died with bleeding esophageal varices, the spleen weighed more than 350 g in 28.

PSV

Mean PSV in the case group in our study is 33.99 cm/s while it is 30.56 cm/s in control group. No significant difference was found between PSV in cases and controls as computed by unpaired *t*-test ($P = -0.197$).

EDV

Mean EDV in our study case group was 11.55 cm/s, whereas in it was 11.72 cm/s in control group. No significant difference was found between EDV in cases and controls as computed by unpaired *t*-test ($P = -0.872$).

PI

Mean PI in cases was 1.17 as compared to control group where mean is 0.98. PI is significantly higher in cases than controls, $P = 0.049$.

In Italy, Sacerdoti *et al.*^[12] reported that the PI was significantly higher in non-ascitic cirrhotic patients than in control patients, in ascitic patients than in non-ascitic patients, in ascitic patients not treated with diuretics than in non-ascitic ones and in ascitic patients treated with diuretics than in those not treated. The PI was significantly higher in Child-Turcotte-Pugh Classes B and C patients than in Class A patients.

The normal mean PI is approximately 0.96 ± 0.10 for healthy subjects in a study by Mehnaz.^[13]

Serum Creatinine

In our present study, serum creatinine level was significantly higher in cases as compared to control group (25% vs. 4%). Significant difference between the creatinine category distribution of cases and controls, $P = 0.023$ as computed by Chi-square test. Also as severity of disease increases, serum creatinine level also keep on increasing- non ascitic liver disease patients (12%), mild ascitic patient (20%), moderate ascitic group (24%) and refractory ascitic group (44%) with $P < 0.001$ as computed by Chi-square test. Platt *et al.*^[1] performed a long-term follow-up of 180 patients with cirrhosis without azotemia, showing that despite similar severity scores, the outcome for HRS, and renal dysfunction were significantly worse in patients with initially elevated RI values. Within the group of 76 patients with $RI \geq 0.70$, 55% developed kidney dysfunction and HRS, whereas only 6% (6/104) of the subjects with normal $RI < 0.70$ developed kidney dysfunction at the end of follow-up ($P < 0.01$).

RI

Doppler ultrasound measurement of renal RI is a useful index to quantify renovascular resistance in cirrhotic patients before HRS develops. HRS is the outcome of vasoconstrictor systems^[14,15] (i.e., the renin-angiotensin system, the sympathetic nervous system, and arginine vasopressin) on the renal vasculature, in an attempt to ameliorate the intense underfilling of the arterial circulation. Thus, there is a drop in renal perfusion and glomerular filtration rate with intact tubular function. The RI provides us with an easy non-invasive tool to detect this deterioration in renal function as well as being a prognostic indicator.

RI values measured in interlobar-arcuate arteries are expected to show the most consistent results. No significant difference between the left and right kidney was found in our groups either. Concerning variability in RI measurement average a number of at least three measurements in one kidney to obtained a single representative value.^[16] Therefore, one representative value averaged from three measurements in one region appears to be sufficient to assess the RI in a patient.

On the basis of previous studies, intrarenal RI of 0.70 was considered as a threshold value is indicative of increased renal vasoconstriction.^[17-19]

In our present study, RI level was significantly higher in cirrhotic patients (32%) than in control subjects (4%). Significant difference was found between the RI category distribution of cases and controls, $P < 0.001$ as computed by Chi-square test. In addition, the RI was significantly higher in non-ascitic patients with liver cirrhosis than in control subjects (16% vs. 4%) and in mild ascitic patients compared to non-ascitic patients (24 vs. 16%), in moderate ascitic patient group compared to mild ascitic group (36% vs. 24%), and gross refractory ascitic patient group as compared to moderate ascitic patients (52% vs. 36%). Hence, there is a significant association between RI and study groups. As the severity of liver disease of group increases, the RI value also gets elevated, $P < 0.001$ as computed by the Chi-square test.

The correlation between increased RI and azotemia seems to confirm the role of vasoconstriction in the pathogenesis of cirrhotic kidney disease.^[13] However, intrarenal arterial RI values were already significantly increased in the group of non-ascitic cirrhotic patients and even higher in ascitic patients than in control subjects. Thus, RI measurement seems to identify renal vasoconstriction at an earlier time than elevated serum creatinine values.

In 2002, Bardi *et al.*^[8] found out that RI in patients with HRS was significantly higher (≥ 0.70) compared to the normal subjects in his study. Platt *et al.*^[1] measured intrarenal resistance, in 180, cirrhotic patients without kidney dysfunction. The mean initial RI in patients who subsequently developed the HRS was 0.77 ± 0.05 . Kastelan *et al.*^[17] investigated RI in 46 cirrhotics divided into three groups, those with cirrhosis and normal renal function, cirrhosis with renal dysfunction without HRS, and cirrhosis with HRS. They found that RI (≥ 0.70) was significantly increased in the cirrhotic patients with HRS compared to the other two groups. Götzberger *et al.*,^[20] in their study, found the average RI levels in patients with liver cirrhosis and creatinine of 1.0 ± 0.4 were 0.77.

There is no doubt, therefore, of the usefulness of the RI in predicting HRS in cases of established cirrhosis and which can translate into the early initiation of treatment for impending HRS. Elevated RI values are more commonly seen in patients with advanced stages of liver cirrhosis but can be regularly found in patients with clinical stages Child A or B. Therefore, the renal RI can play an additional role in evaluating the severity and prognosis of the disease. Platt *et al.*^[1] performed a long term follow-up of 180 patients with cirrhosis without azotemia showing that, despite

similar Child-Pugh scores, the outcome for HRS and renal dysfunction was significantly worse in patients with initially elevated RI values. Within the group of 76 patients with $RI \geq 0.70$, 55% developed kidney dysfunction and even 26% HRS, whereas only 6% (6/104) of the subjects with normal $RI < 0.70$ developed kidney dysfunction at the end of follow-up ($P < 0.01$).

Intrarenal RI seems to be a helpful predictor to identify a subgroup of patients with higher risk of developing kidney failure or HRS. Follow-up studies are required to quantify the prognostic value of elevated RI.

Correlation of RI with Serum Creatinine

There was no significant correlation noted between RI and serum creatinine in case Group I, correlation coefficient -0.186 , $P = 0.374$ with a moderate significant relationship between RI and creatinine levels in case Group II, correlation coefficient -0.658 , $P < 0.001$.

There is a strong significant relationship between RI and creatinine levels in case Group III, correlation coefficient -0.719 , $P < 0.001$. There is a strong significant relationship between RI and creatinine levels in case Group IV, correlation coefficient -0.739 , $P < 0.001$.

Hence, as severity of disease progresses, correlation between serum creatinine level and renal RI becomes more and stronger.

We conclude that the evaluation of intrarenal RI appears to be easy to perform, non-invasive method providing only with low costs for the assessment of early renal impairment in patients with liver cirrhosis due to increased vasoconstriction which is at higher risk of developing manifest renal failure.

CONCLUSION AND RECOMMENDATION

HRS is a functional renal failure seen in patients with acute liver failure or CLD in the absence of any other identifiable cause of renal failure. It is primarily a diagnosis of exclusion. HRS carries a grim prognosis: Mortality is high, with median survival is 3–6 months.

In our present study, creatinine level was significantly higher in cases as compared to control group. Also as severity of disease increases, serum creatinine level also keep on increasing-non-ascitic liver diseased patients, mild ascitic patient, moderate ascitic group and refractory ascitic group.

RI level was also significantly higher in cirrhotic patients than in control subjects. Similarly, the RI was significantly

higher in non-ascitic patients with liver cirrhosis than in control subjects and in mild ascitic patients compared to non-ascitic patients in moderate ascitic patient group compared to mild ascitic group and gross refractory ascitic patient group as compared to moderate ascitic patients. Hence, there is a significant association between RI and study groups. As the severity of liver disease of group increases, the RI value also gets elevated.

Intrarenal RI seems to be a helpful predictor to identify a subgroup of CLD patients with higher risk of developing kidney failure or HRS, which can translate into the early initiation of treatment for impending HRS. Longitudinal studies with carefully follow-up are necessary to corroborate and expand the above findings.

We conclude that the evaluation of the intrarenal RI appears to be an easy to perform, non-invasive method providing only with low costs for the assessment of early renal impairment in patients with liver cirrhosis due to increased vasoconstriction. The intrarenal RI may play an additional role in evaluating the severity and prognosis of liver disease. This may help in identifying subgroups of cirrhotic patients who need more intense monitoring. However, this needs further validation in larger cohorts with long-term follow-up as well as we need to elucidate the optimal cutoff values of RI for diagnosing renal impairment. Intrarenal RI may be superior to serum creatinine levels as an indicator in patients with liver cirrhosis for the detection of patients at risk for the development of HRS.

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Clinical Presentation and Management of Urethral Strictures: A Retrospective Study

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Abstract

Introduction: Male urethral stricture (US) disease is a common condition which results in narrowing or obliteration of the urethral lumen and may involve any segment of the urethra from the urethral meatus to the bladder neck.

Aim: This study aims to study the clinical presentation and management of US.

Materials and Methods: In this retrospective study, 200 patient's data were analyzed. Stricture characteristics, investigations, treatment, and complications were recorded.

Results: In this study, 190 (95%) males and 10 (5%) females were included in the study. The mean age of onset of USs was 51 ± 7.28 years. The most common site of the occurrence of male US was the bulbar urethra (80 patients). Endoscopy optical internal urethrotomy was done in 60 patients and dilatation was done in 40 patients and 30 patients needed buccal mucosal graft.

Conclusion: The US is a common disease that accounts for a considerable amount of morbidity and cost to the health-care system. Proper diagnosis and repair of the strictures are essential along with the appropriate imaging modality to prevent the risk of renal failure and to reduce morbidity.

Key words: Management, Stricture, Urethra

INTRODUCTION

Urethral stricture (US) is the narrowing of the urethra, the canal that carries urine from the bladder through the penis and through the urethral meatus (opening at the tip of the penis). The US can be caused by an infection, instrumentation, injury, or non-infectious urethritis.^[1] USs profoundly impact the quality of life and result in bladder calculi, infections, fistula, sepsis, and even renal failure. The incidence of USs is estimated to be 200–1200 cases per 100,000 people and the incidence sharply increases in men >55 years of age. Female USs usually occur in postmenopausal age group due to hormone deficiency (distal urethral stenosis). Untreated USs can end up in a variety of complications such as thick-walled trabeculated

bladder (85% incidence), acute retention (60%), prostatitis (50%), epididymo-orchitis (25%), periurethral abscess (15%), and bladder or urethral stones (10%).^[2]

Strictures can be divided into anterior and posterior types, which differ in their location as well as pathogenesis. In a retrospective study of strictures, it was found that 92.2% were anterior strictures with 46.9% occurrence in the bulbar urethra and 30.5% occurrence in the penile urethra. About 9.9% of them were both penile and bulbar strictures while 4.9% were pan-USs.^[3] US is characterized by changes in the extracellular matrix of urethral spongiosal tissue.^[4] Normal connective tissue is replaced by dense fibers and there is a decrease in the ratio of Type III to Type I collagen.^[5] The terms US and urethral stenosis are both different. Stricture is used to define the narrowing of the urethral lumen that is surrounded by corpus spongiosum that is the urethral meatus through the bulbar urethra, whereas urethral stenosis is the narrowing of the posterior urethra due to trauma which is not enveloped by corpus spongiosum that is the membranous urethra through the bladder neck/prostate junction. As most of the affected patients are of the younger age group, this disease has a significant

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amount of life ramifications compared to other urological diseases.^[6] Apart from a compromise in the quality of life, USs also impose significant treatment expenditure to the patients.

Aim

This study aims to study the clinical presentation and management of US.

MATERIALS AND METHODS

This retrospective study was conducted in the Department of Urology at Tirunelveli Medical College Hospital for 3 years from 2015 to 2018. Patients diagnosed with US disease were included in the study. Patient's details were collected such as age, gender, stricture characteristics, investigations, treatment, and complications which were recorded. The data were presented as frequency and percentage.

RESULTS

A total of 200 patients were observed, of which 190 (95%) were male and 10 (5%) were female [Figure 1]. The mean age of onset of USs was 51 ± 7.28 years and a higher incidence (42%) was noticed in the 25–35 years age group. This concurs with the fact that US is more common in young males. The primary cause of US was observed to be post-inflammatory (77.5%) and the rest 22.5% were due to trauma [Figure 2]. The most common site of the occurrence of male US was the bulbar urethra (80 patients) followed by membranous urethra (60 patients) and penile urethra (35 patients). Ten patients had prostatic US and one was in the fossa navicularis [Figure 3]. These findings are also in accordance with literature. Regarding treatment of US, around 70 patients needed excision and anastomosis of the strictured urethra. Endoscopy optical internal urethrotomy was done in 60 patients and dilatation was done in 40 patients and 30 patients needed buccal mucosal graft [Figure 4]. No significant complication was observed in this study, but 20 patients had recurrence, 15 had infection, and 10 had bleeding postsurgically [Figure 5].

DISCUSSION

The prevalence of US in younger men is 200 in 100,000 and >600 in 100,000 in older men according to an estimate by the United States.^[2] The incidence was 0.9% in 2001 according to the data by Medicare with increasing incidence after 65 years of age.^[7] The etiology of USs can be iatrogenic, idiopathic, inflammatory (gonorrhea or lichen sclerosis), or traumatic.^[8] Idiopathic and iatrogenically induced USs

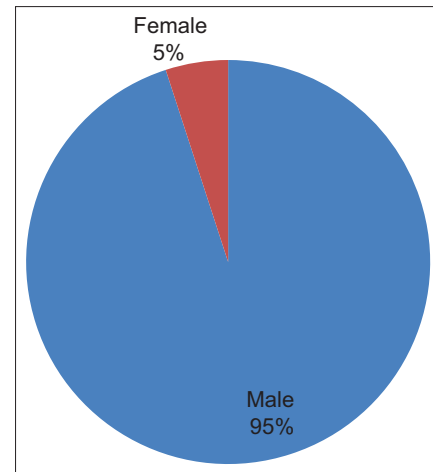


Figure 1: Gender incidence of urethral strictures

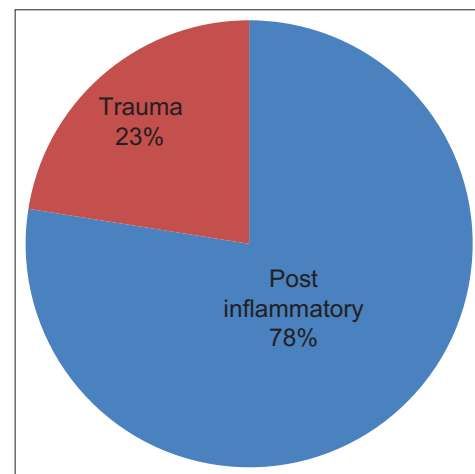


Figure 2: Etiology of urethral stricture

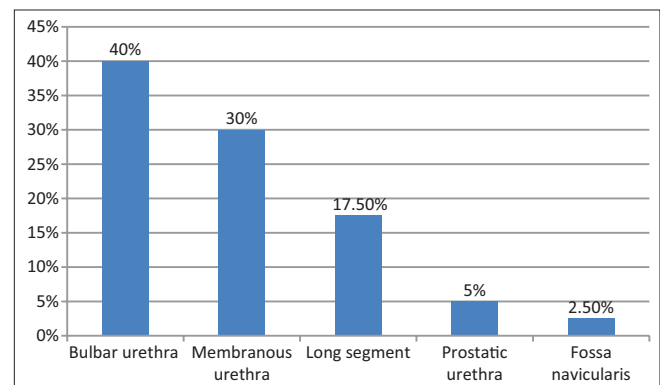


Figure 3: Site of urethral stricture

are the most common and account for about 33% of the patients while inflammatory and traumatic USs account for about 15% and 19%, respectively. Urethral stenosis is not well categorized. Idiopathic strictures occur in the bulbar urethra more frequently and can be due to childhood trauma or a congenital anomaly or due to tissue ischemia in older patients.^[9] Idiopathic stenosis of the posterior urethra

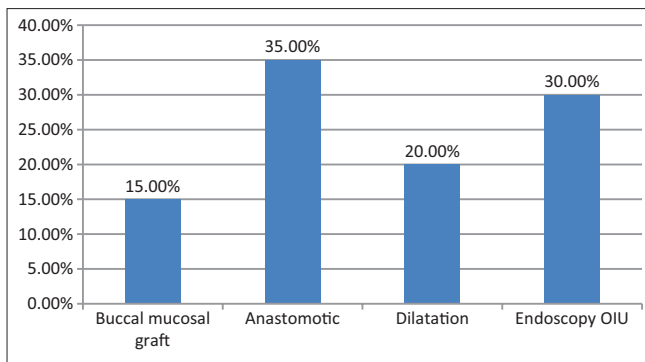


Figure 4: Treatment modalities used

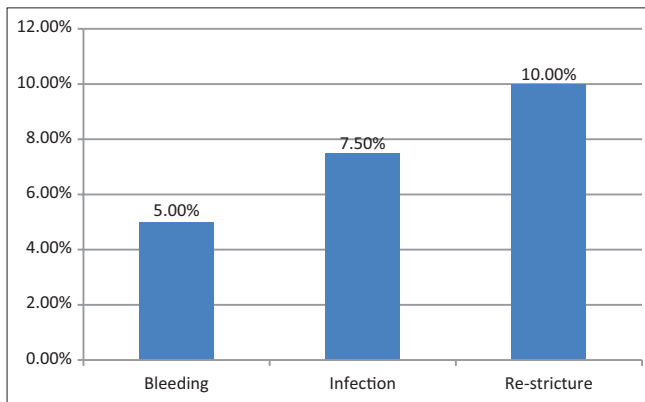


Figure 5: Complications of urethral stricture

is less common. Iatrogenic strictures occur from the region of meatus to the bladder neck and occur mostly in the penile urethra which can be a complication of hypospadias surgery in youngsters or a complication of transurethral surgery or long-term use of urethral catheters in older men.^[10] Posterior urethral stenosis can be due to trauma or intervention for the same.^[11]

Histological evaluation of a US shows changes in the extracellular matrix of the urethral spongiosal tissue where the normal connective tissue is replaced by dense fibers and a decrease in the ratio of Type III to Type I collagen fibers.^[4,5] This is accompanied by changes in nitric oxide synthesis in the urethral tissue and a decrease in the smooth muscle to collagen ratio.^[12] The anterior US following trauma or infection results in spongiofibrosis where the corpus spongiosum becomes fibrosed narrowing down the urethral lumen. Extensive fibrosis can involve the tissues outside the corpus spongiosum.

The symptoms of US include obstructions in voiding, straining while urinating, feeling of incomplete bladder emptying, and a weak stream. Recurrent urinary tract infection, prostatitis, epididymitis, bladder stones, and hematuria may also be present. Palpation of the anterior urethra to identify the depth of the scar tissue is necessary

and urinalysis should be done to rule out infections. Uroflowmetry studies might be performed to identify the voiding pattern and the presence of post-void residual volume. Retrograde urethrography (RUG) and voiding cystourethrography (VCUG) are performed to know the location, length, and severity of the US. Usually, there is narrowing of the urethral lumen at the stricture site and dilation of urethra proximal to the stricture site. If the RUG and VCUG are not informative, a cystoscopy can be performed through the meatus or by suprapubic cystostomy to know the location and elasticity of the strictured urethra. USG determines the degree of spongiofibrosis.^[13,14] Intraoperative USG with hydrodistension when the patient is under anesthesia enables accurate evaluation of anterior strictures and dispenses the need for an additional pre-operative evaluation. To ensure the stability of the stricture and to allow maximum stricturing at the time repair, it is advised to avoid the use of urethral catheters at least 6 weeks before the procedure. At times, suprapubic cystostomy can be done before 6–12 weeks before the repair to divert infected urine in case of urethral abscess or fistulas.

Urethral dilation, internal urethrotomy, and urethroplasty are done to repair US. In this study, anastomotic urethroplasty was done in 70 patients and resulted in a good prognosis. Urethral dilatation, endoscopy, and urethroplasty substitution were the other treatment modalities adopted. Complications were observed in 45 patients with the chief complication being stricture recurrence (10%) followed by infection and bleeding. Studies say that repeated urethrotomy procedures are not clinically effective and long-term high success rates are reported with urethroplasty (85–90%). The limitations of this study are its retrospective nature and the small study population. Future studies must focus on a more elaborate nature of the presentation of USs, their treatment, and associated complications.

CONCLUSION

The US is a common disease that accounts for a considerable amount of morbidity and cost to the health-care system. Proper diagnosis and repair of the strictures are essential along with the appropriate imaging modality to prevent the risk of renal failure and to reduce morbidity. In this study, the various etiologies, types of occurrence, treatment, and complications associated with US have been discussed. Urethroplasty is observed to be a definitive treatment option for US and 20 cases of failed US repair have been reported. The success rate for a repeat urethroplasty or urethrotomy was not included in this study. Further work in this regard is needed for a more comprehensive understanding of the reasons for failure

and appropriate treatment options for US. Numerous controversies still exist in this area and future studies must address these issues.

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Fetomaternal Outcome in Gestational Diabetes Mellitus at a Tertiary Care Hospital

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Abstract

Introduction: Gestational diabetes mellitus (GDM) is a common medical problem that results from an increased severity of insulin resistance as well as impairment of the compensatory increase in insulin secretion. GDM has profound effects on fetomaternal outcome.

Aims and Objectives: This study aims to evaluate the impact of GDM on pregnancy and fetal outcome.

Materials and Methods: The present study was a prospective observational study. The screening was done by glucose challenge test and 3 h, 100 g glucose tolerance test. The study population was divided into two groups, cases and controls. All the patients were followed up for maternal complications, fetal complications, mode of delivery, and neonatal complications.

Results: A total of 350 randomly selected pregnant females who met the inclusion criteria were subjected to oral glucose challenge test. Of 350 women, 22 women were found to have GDM and were compared with non-GDM patients. GDM patients had significantly higher percentage of pregnancy-induced hypertension (13.6% vs. 2.6%, $P = 0.031$), polyhydramnios (22.7% vs. 4.3%, $P = 0.004$), urinary tract infection (40.9% vs. 14.5%, $P = 0.003$), and excess weight gain (36.4% vs. 6.3%, $P = 0.001$). GDM patients had higher cesarean deliveries in 13 (59.1%) and assisted vaginal deliveries in 2 (9.1%) as compared to non-GDM (110 [36.3%] and 6 [2%], $P = 0.006$, respectively). Among the fetal outcome, GDM patients had higher macrosomia (31.8% vs. 8.3% in non-GDM group [$P = 0.003$]), neonatal convulsions (18.2% vs. 2.3% in non-GDM group [$P = 0.003$]), respiratory distress (22.7% vs. 3.3% [$P = 0.002$]), and neonatal intensive care unit admission (72.7% vs. 12.9% [$P = 0.001$]).

Conclusion: GDM is associated with both maternal and fetal complications, most notably macrosomia leading to increased cesarean section rate and instrumental deliveries.

Key words: Fetomaternal outcome, Gestational diabetes mellitus, Glucose challenge test, Oral glucose tolerance test

INTRODUCTION

Gestational diabetes mellitus (GDM) is a common medical problem that results from an increased severity of insulin resistance as well as impairment of the compensatory increase in insulin secretion. Pregnancy, in essence, serves as a metabolic stress test and uncovers underlying insulin resistance. GDM represents a high-risk factor in pregnancy.^[1] GDM has profound effects on fetomaternal outcome.

Effects of diabetes on the mother^[2] include pre-eclampsia 10–25%, chorioamnionitis, postpartum endometritis, postpartum bleeding, and increased incidence of cesarean section. Effect of gestational diabetes on the fetus^[2] includes hypoglycemia, hyperviscosity syndrome, hyaline membrane disease, macrosomia, hypocalcemia, apnea and bradycardia, traumatic delivery, and congenital malformations. Effect of pregnancy on diabetes^[3] includes as follows: More insulin is necessary to achieve metabolic control, progression of diabetic retinopathy and nephropathy, and cardiomyopathy.

Aims and Objectives

The aims of this study were as follows:

1. To evaluate the impact of GDM on pregnancy outcome
2. To compare the pregnancy outcome in GDM group and non-GDM group.

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MATERIALS AND METHODS

The present study was conducted in the Department of Obstetrics and Gynaecology, Sher-i-Kashmir Institute of Medical Sciences (SKIMS), Soura, Srinagar, over a period of 1½ years, i.e., August 2014–January 2016. Patients with risk factors were divided into two groups, i.e., cases – positive for screening test and controls – negative for screening test.

Inclusion Criteria

The following criteria were included in the study:

1. Pregnant women between 24 and 28 weeks of gestation irrespective of the age and parity with risk factors such as overweight, history of diabetes mellitus in the first degree relatives, previous history of macrosomic baby or congenital malformations, history of instrumental difficult deliveries, and polyhydramnios.
2. Informed consent.

Exclusion Criteria

The following criteria were excluded from the study:

1. Women having diagnosed glucose intolerance before pregnancy
2. Women with a history of GDM in the previous pregnancy in whom abnormal blood sugar persisted after delivery
3. Women with a history of cardiac, respiratory, renal, and hepatic diseases or on drugs such as corticosteroids and progestogens.

Detailed history, physical examination, and routine investigations were carried out. All the subjects who fulfilled the inclusion criteria were screened for GDM. The screening was done by GCT in the patients with risk factors for GDM using 50 g of oral glucose. The women found positive on screening test were subjected to 3 h, 100 g glucose tolerance test. The glucose tolerance was assessed according to Carpenter and Coustan criteria.

The study population was divided into two groups, cases and controls. All the patients were followed up for maternal complications (pregnancy-induced hypertension [PIH], hydramnios, urinary tract infection (UTI), antepartum hemorrhage, and excessive weight gain), fetal complications (preterm birth, intrauterine fetal death, fetal macrosomia, malpresentation, intrauterine growth retardation, and stillbirth), mode of delivery (vaginal, cesarean, or assisted vaginal delivery), and neonatal complications (macrosomia, congenital malformation, convulsions at birth, respiratory distress syndrome, Apgar score 1 min and 5 min, and neonatal intensive care unit [NICU] admission).

Statistical Analysis

The recorded data were compiled and entered in a spreadsheet (Microsoft Excel) and then exported to

data editor of SPSS version 20.0 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics of data including the mean and standard deviation for numerical variables and the percentages of different categories for categorical variables were obtained. Frequency distribution tables and bar charts were used for data presentation. Student's independent *t*-test was employed for parametric data and for non-parametric data, Chi-square or Fisher's exact test, whichever appropriate, was used. $P < 0.05$ was considered statistically significant.

RESULTS

This study was carried out at the Department of Gynaecology and Obstetrics of SKIMS, Srinagar. A total of 350 randomly selected pregnant females who met the inclusion criteria were subjected to oral glucose challenge test. Of 350 women, 22 (6.3%) women were found to have GDM. Of 350 patients, 25 patients were lost in various stages of follow-up. A percentage comparison was made for various demographic parameters and outcome of GDM between the two groups. GDM patients had significantly higher percentage of PIH (13.6% vs. 2.6%, $P = 0.031$), polyhydramnios (22.7% vs. 4.3%, $P = 0.004$), UTI (40.9% vs. 14.5%, $P = 0.003$), and excess weight gain (36.4% vs. 6.3%, $P = 0.001$), as shown in Table 1. In the current study, normal delivery occurred in 7 (31.8%), cesarean deliveries in 13 (59.1%), and assisted vaginal deliveries in 2 (9.1%) as compared to non-GDM in whom normal deliveries were 187 (61.7%), cesarean deliveries were in 110 (36.3%), and assisted vaginal deliveries were in 6 (2%) ($P = 0.006$). The main indication for cesarean in GDM group was fetal distress and macrosomia. Macrosomia was found in 31.8% deliveries of GDM group as compared to 8.3% in non-GDM group ($P = 0.003$). There was a strong correlation between neonatal convulsion and GDM. Women with GDM had 18.2% of neonates with convulsion as compared to 2.3% in non-GDM group ($P = 0.003$), the main cause being hypoglycemia. The difference was highly significant. There were 22.7% of neonates with respiratory distress in GDM group as compared to 3.3% in non-GDM group ($P = 0.002$). A strong correlation was observed between NICU admission and GDM 72.7% as compared to non-GDM women 12.9% ($P = 0.001$). There was no significant difference in with respect to stillbirths (4.5% vs. 0.7%, $P = 0.19$), preterm births (9.1% vs. 4.3%, $P = 0.267$), and mean Apgar score (8.39 vs. 8.78, $P = 0.45$) [Table 2].

DISCUSSION

The present study was undertaken to find pregnancy and fetal outcome of GDM in patients at risk for GDM at SKIMS Maternity Hospital, Srinagar. The study was

Table 1: Maternal complications associated with GDM

Hypertension	GDM		Non-GDM		P-value
	n	% age	n	% age	
Present	3	13.6	8	2.6	0.031
Absent	19	86.4	295	97.4	
Total	22	100	303	100	
Hydramnios					
Present	5	22.7	13	4.3	0.004
Absent	17	77.3	290	95.7	
UTI					
Present	9	40.9	44	14.5	0.003
Absent	13	59.1	259	85.5	
Excessive weight gain					
Present	8	36.4	19	6.3	<0.001
Absent	14	63.6	284	93.7	

GDM: Gestational diabetes mellitus, UTI: Urinary tract infection

Table 2: Fetal outcome

Observations	GDM, n (%)	Non-GDM, n (%)	P-value
Preterm delivery	2 (9.1)	13 (4.3)	0.267
Intrauterine death	1 (4.5)	5 (1.7)	0.346
Malpresentation	5 (22.7)	14 (4.6)	0.006
Stillbirth	1 (4.5)	2 (0.7)	0.190
Macrosomia	7 (31.8)	25 (8.3)	0.003
Apgar score	8.39	8.78	0.45
Neonatal convulsions	4 (18.2)	7 (2.3)	0.003
Respiratory distress	5 (22.7)	10 (3.3)	0.002
NICU admission	16 (72.7)	39 (12.9)	0.001

NICU: Neonatal intensive care unit, GDM: Gestational diabetes mellitus

conducted in 350 patients taken by simple random sampling.

Maternal Complications

PIH

The prevalence of PIH was higher in GDM group in this study 13.6% as compared to non-GDM group where it was 2.6%.

Buchanan *et al.*^[4] reported the prevalence of hypertension 2.7% in GDM versus 1.1% non-GDM group. Kjos and Buchanan^[5] reported that there was increased incidence of hypertensive disorders in females with GDM and that the data were more convincing for an association with pre-eclampsia. The Fourth International Conference on GDM observed double the risk of hypertensive disorders in females with GDM as compared to normal women. Weijers *et al.*^[6] founded that women with GDM had higher rates of PIH as compared to control group. Kvetny *et al.*^[7] reported that pre-eclampsia was found in 15.5% of women with GDM as compared to 1% in non-GDM group.

Hydramnis

In this study, hydramnios was present in 22.7% of women with GDM as compared to 4.3% of non-GDM group.

Griffin *et al.*^[8] reported that hydramnios, stillbirths, abortions, and PIH were founded more in women with GDM. Sermer *et al.*^[9] reported that untreated cases of GDM were complicated with hydramnios PIH and operative deliveries.

UTIs

In this study, UTI occurred in 40.9% of women with GDM as compared to 14.5% in non-GDM group.

Forsbach *et al.*^[10] reported that GDM was complicated with toxemia in 18%, polyhydramnios in 10%, and UTI in 6%.

Excessive weight gain

In this study, excessive weight gain was seen in 36.4% of women with GDM as compared to 6.3% in non-GDM group. Weight gain of more than 1 kg/month in the second trimester and 2 kg/month in the third trimester is considered excessive.

Jindal *et al.*^[11] concluded in their study that 32% of women with GDM had excessive weight gain in pregnancy as compared to 1.7% in non-GDM group. Owen *et al.*^[12] reported that gestational glucose intolerance represents a pathological continuum affected by numerous factors, especially gestational age, maternal weight, and maternal age. Naylor *et al.*^[13] reported that as the weight gain occurs outside normal limits, the glucose intolerance also increases.

Fetal Complications

In the present study, GDM mothers had 9.1% preterm deliveries as compared to 4.3% in non-GDM, intrauterine death in 4.5% in GDM as compared to 1.7% in non-GDM group. Malpresentation was seen in 22.7% of women with GDM as compared to 4.6% in non-GDM group. Fetal macrosomia was present in 31.8% of women with GDM as compared to 8.3% in non-GDM group.

Jindal *et al.*^[11] observed preterm deliveries 12% versus 1.7%, intrauterine deaths 12% versus 1.7%, stillbirth 4% versus 1.3%, fetal macrosomia 36% versus 7.3%, and malpresentations 16% versus 6% in GDM and non-GDM group, respectively. Buchanan *et al.*^[4] reported that preterm deliveries were 10.4% in GDM group versus 7.5% in non-GDM group. Weeks *et al.*^[14] found that when compared with controls, GDM patients were at increased risk for macrosomia (26% vs. 11%), cesarean section (9% vs. 2%), and fetal loss up to 15%. Coustan *et al.*^[15] reported that fetal macrosomia occurred in about 50% in untreated patients, 36% in women on diet control, and only 7% in women on diet control plus insulin.

Mode of Delivery

In the current study, 13 of 22 women with GDM (59.1%) had their pregnancy terminated by lower segment cesarean sections (LSCS), normal delivery in 7 (31.8%), and assisted vaginal delivery in 2 (9.1%), whereas in non-GDM group,

the percentages were 36.3%, 61.7%, and 2% for LSCS, normal, and assisted vaginal delivery, respectively.

Weeks *et al.*^[14] observed that the rate of cesarean section approached to 37% in GDM group. de Veciana *et al.*^[16] reported the rate of cesarean section with GDM approached to 40–50%. Buchanan *et al.* reported the rate of cesarean section to be 24.9% in GDM group. Sermer *et al.*^[9] observed that higher cesarean section rate was founded in mothers with increasing weight, age, and body mass index. Kjos and Buchanan^[5] reported that mere knowledge that mother has GDM or has been treated with insulin increases the chance of cesarean section.

Neonatal Complications

In the current study, 7 of 22 (31.8%) women delivered large-sized macrosomic babies, i.e., more than 4 kg. The result was compared with the studies conducted by de Veciana *et al.*^[16] observed that macrosomia occurred in 15.45% of pregnancies complicated by diabetes. Coombs *et al.* observed that macrosomia occurred in 29% of patients and was associated with higher postprandial glucose levels. Hod *et al.*^[17] in their serial studies reported macrosomia in 18% of infants as a neonatal complication. Jindal *et al.*^[11] observed that macrosomia occurred in 32% versus 6.8% in GDM positive group and GDM negative group, respectively. Buchanan *et al.*^[4] observed that macrosomia occurred in 9.3% of patients with GDM. Fourth Metzger and Coustan^[18] on GDM reported that macrosomia is significantly more common in the offsprings of women with GDM.

In the present study, mean Apgar score in GDM patients at 1 min was 7.96 and at 5 min was 8.39 as compared to non-GDM group where it was 8.25 and 8.78, respectively. The difference was not statistically significant. There were no congenital malformations seen in this study. Neonates with convulsions at birth were 18.2% in GDM versus 2.3% in non-GDM group and respiratory distress in 22.7% of GDM versus 3.3% in non-GDM group.

Hod *et al.*^[17] observed that neonates with convulsion were 5.3% in GDM group as compared to 4.9% of controls and respiratory distress syndrome was 1.3% as compared to 1% in controls. Persson and Hanson^[19] observed that GDM is associated with increased risk of fetal macrosomia, birth trauma, convulsion, hyperbilirubinemia, and respiratory distress syndrome. Jindal *et al.*^[11] observed that respiratory distress syndrome was 4% versus 0.09%, hypoglycemia 4% versus 0%, and congenital malformations 8% versus 0.9% in GDM and non-GDM group, respectively.

CONCLUSION

GDM is associated with both maternal and fetal complications, most notably macrosomia leading to increased cesarean section rate and instrumental deliveries.

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Antenatal Ultrasonogram Detection of Fetal Urinary Tract Dilatation – Evaluation to form Guidelines for Postnatal Risk Stratification and Treatment Plan: A Single-center Study

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Abstract

Introduction: The incidence of antenatally detected genitourinary abnormalities is on the rise. Although this has led to earlier interventions and better prognosis, there is a lack of standardization and uniformity in the diagnosis of urinary tract dilatation (UTD) which has resulted in more confusion than before regarding the management. Entities such as “prominent pelvis,” “pelviectasis,” and “hydronephrosis” have been used without any objective criteria which lead to unnecessary and extensive postnatal evaluation.

Aim: This study aims to study the imaging features of those infants with antenatally diagnosed fetal urinary tract dilation and to standardize the protocol for postnatal follow-up and management.

Materials and Methods: A prospective study of 72 mothers who were antenatally diagnosed with fetal UTD were enrolled for the study and postnatal follow-up done by imaging with ultrasound, voiding cystourethrogram, and intravenous urogram.

Results: Among the 72 enrolled cases of 24 were categorized under UTD A1, nine children were managed conservatively with regular follow-up. Those categorized under UTD P1, six cases had normal postnatal scans at the 1st week of life and at 1 month, of which three cases had transient hydronephrosis and two had partial pelviureteric junction obstruction (PUJO). Of 14 children with intermediate-risk dilation UTD P2, 11 children had complete PUJO, two had partial PUJO, and one had bilateral vesicoureteric reflux (VUR), of which patients with complete PUJO required pyeloplasty and the rest needed only observation. Among the 20 neonates with UTD P3 high-risk dilation, 10 cases of posterior urethral valve, six cases of complete PUJO, one case of obstructive megaureter, one case of VUR, one case of bilateral ureterocele, and one case of non-neurogenic bladder, all of which required surgical intervention except in case of VUR.

Key words: Fetal pyelectasis, Hydronephrosis, Pelviureteric junction obstruction, Urinary tract dilatation

INTRODUCTION

Hydronephrosis refers to the dilatation of the renal collecting system, regardless of the etiology. While pyelectasis or pelviectasis refers to the dilated renal pelvis, the term caliectasis is used when there is a dilatation of renal

calyces. Earlier days, the clinical scenario of septicemia due to hydronephrosis associated with urinary tract abnormalities such as posterior urethral valve (PUV) was a common entity in pre-ultrasonogram era which is not much encountered nowadays because majority of them are detected during antenatal scans. The early demonstration of hydronephrosis provides an opportunity to preserve renal function by decompressing the obstructed collecting system immediately after birth and also timely treatment of recurrent urinary tract infections with antibiotic prophylaxis.^[1]

Prenatal diagnosis of fetal urinary tract dilatation (UTD) improves perinatal management and the prognosis

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thereafter. The primary objective of prenatal ultrasound is to describe the pathology as accurately as possible, to exclude associated malformations, and to screen for parameters predictive of poor renal function, bringing up the necessity for a multidisciplinary perinatal approach.

In the era of ultrasound advancement, the incidence of antenatally detected abnormal renal sonogram is on the rise. Although this has led to earlier intervention and better prognosis in a subset of newborns, lack of standardization and uniformity in diagnosis of UTD has resulted in more confusion than before regarding the management. Another major problem is the subjective use of terminologies such as “prominent pelvis,” “pelviectasis,” and “hydronephrosis” without any objective criteria which lead to unnecessary and extensive postnatal evaluation.

The signs of functioning of the fetal metanephric kidney are seen as early as 9–12 weeks of gestation. Tubular reabsorption and functioning of Henle’s loop begin by 14 weeks of gestation. The rate of fetal urine production relatively increases by 10 times as the gestational age progresses from 20 weeks to 40 weeks.^[2] This results in total increase in fetal urinary output by 3-fold during 20–25 weeks and about 2-fold between 30 weeks and 40 weeks.^[3]

While imaging the fetal renal pelvis by ultrasonogram, numerous physiological factors have been taken into account. The extent to which the fetal bladder is distended and maternal hydration status during the time of sonographic study is also vital in demonstrating fetal pyelectasis.^[4] There is a relative decrease in the size of the anteroposterior (AP) diameter of the fetal renal pelvis when the fetal bladder is empty and shows variability depending on the volume of the fetal bladder.^[5]

Nephrogenesis continues up to 36 weeks of gestation and at birth in full-term infants, but nephron formation continues even after birth in preterm infants.

Normally, fetal kidneys are visualized as oval, hyperechoic structures lateral to the upper lumbar spine at around 13–14 weeks of gestation. Following the production of urine, the fetal urinary bladder can also be demonstrated. Due to the cyclical pattern of filling up of the urinary bladder of the fetus and voiding, the bladder has to be visualized at least once during an entire 20 min scan during the second-trimester anomalies scan.^[6] The kidneys are more echogenic than the liver and pancreas until 17–18 weeks of gestation. Beyond 20 weeks of gestation, there is decrease in the echogenicity, along with appearance of corticomedullary differentiation, the differentiation being more marked after 28 weeks. Even though there is a gradual increase in the kidney size,^[7] the ratio of the renal and abdominal circumferences remains constant which is approximately

0.27–0.30. Usually, renal calyces, ureters, and the urethra are not sonographically visualized under normal circumstances.

Transvaginal sonography has also been recommended as a useful technique to demonstrate the fetal kidneys, particularly during the early weeks of gestation.^[8]

US is considered abnormal when the following features are encountered: AP diameter of the renal pelvis over 7 mm (when the fetal bladder is empty), variable dilatation patterns, dilated calyceal system, dilatation of ureter more than 3 mm, thickened pelvic wall, megacystis, loss of renal corticomedullary differentiation, contracted kidney, features of renal dysplasia, decreased amount of amniotic fluid, and pulmonary hypoplasia.^[9] According to a recent study, if the urinary tract appears normal in at least two serial ultrasonograms, one during the 1st and another at the 6th week in the postnatal period, there is usually no demonstrable abnormality in voiding cystourethrogram (VCUG).^[10]

Apart from routine ultrasonogram, in our institution, VCUG or micturating cystourethrogram and intravenous urogram (IVU) were done for assessing the excretory function and level of obstruction as indicated in patients in whom prenatal imaging has shown evidence of abnormality in urinary collecting system.^[11] It has been recommended that VCUG should be done only when postnatal renal sonographic findings are abnormal.

Many etiologies have been attributed to neonatal UTD which includes structural pathology and reflux-related abnormalities. Some of the commonly reported structural and non-structural causes of fetal hydronephrosis in newborns and infants, majority of which includes physiological hydronephrosis as in extrarenal pelvis and transient hydronephrosis, pelviureteric junction obstruction (PUJO), vesicoureteral reflux (VUR), PUV megaureter, megacystis, ureterocele, multicystic kidney disease, and duplex moiety. Identification of non-significant fetal hydronephrosis is clinically important so as to decide the appropriate timing of investigations. When physiological and transient causes are excluded, PUJO and VUR are the major urinary tract abnormalities which require further imaging workup and surgical intervention.^[12]

Appropriate timing of postnatal evaluation depends on abnormality which is likely to be associated with pyelectasis. In general, when there is an urgent need for immediate neonatal investigations as indicated in bilateral gross hydronephrosis, dilated single functioning kidney, PUV, and duplex moiety with obstructive features. In such cases, the VCUG and IVU are performed under antibiotic coverage. In neonates with mild to moderate dilation, imaging is ideally done after 4 weeks as there is possibility of spontaneous resolution within 2 to 3 weeks. Prophylactic

Table 1: Normal values for urinary tract dilatation (adopted from multidisciplinary consensus on the classification of prenatal and postnatal urinary tract dilatation, Journal of Pediatric Urology [2014] 10, 982–989)

Ultrasound findings	Time at presentation		
	16–27 weeks	>28 weeks	Postnatal (>48 h)
Anteroposterior renal pelvis diameter	<4 mm	<7 mm	<10 mm
Calyceal dilatation			
Central	No	No	No
Peripheral	No	No	No
Parenchymal thickness	Normal (subjective)	Normal (subjective)	Normal (subjective)
Parenchymal appearance	Normal (echoes/CMD/cortical cyst)	Normal (echoes/CMD/cortical cyst)	Normal (echoes/CMD/cortical cyst)
Ureter	Normal (dilatation)	Normal (dilatation)	Normal (dilatation)
Bladder	Normal (wall thickness/ureterocele/posterior urethra dilatation)	Normal (wall thickness/ureterocele/posterior urethra dilatation)	Normal (wall thickness/ureterocele/posterior urethra dilatation)
Oligohydramnios	No	No	NA

CMD: Corticomedullary differentiation, NA - Not applicable

Table 2: UTD risk stratification: Prenatal presentation for UTD A1 (low risk) and UTD A2–3 (increased risk). (Adopted from multidisciplinary consensus on the classification of prenatal and postnatal UTD, Journal of Pediatric Urology [2014] 10, 982–989)

Prenatal presentation			
16–27 weeks	>28 weeks	16–27 weeks	>28 weeks
APRPD 4–7 mm	APRPD >7 mm	APRPD >7 mm	APRPD >10 mm
Central or no calyceal dilatation		Peripheral calyceal dilatation	
Parenchymal thickness normal		Parenchyma thickness abnormal	
Parenchymal appearance normal		Parenchyma appearance abnormal	
Ureters normal		Ureters abnormal	
Bladder normal		Bladder abnormal	
No unexplained oligohydramnios		Unexplained oligohydramnios	
UTD A1		UTD A2–3	
Low risk		Increased risk	

UTD: Urinary tract dilatation, APRPD: Anteroposterior renal pelvis diameter

antibiotics are used based on the clinical symptoms. In our institution, antibiotics were given only when VUR was demonstrated.

The possibility that a neonate will have significant postnatal renal abnormality is proportional to the severity of the antenatal hydronephrosis. In fact, the third-trimester imaging features usually predict the severity better. Although no direct relationship could be established between extent of dilatation and functioning of the kidney, assessment of the degree of dilation is primarily used as the main parameter. Features of hyperechoic renal parenchyma with the presence of cortical cysts are indicative of renal obstructive

dysplasia and probabilities of deteriorating renal function.^[13] Based on the degree of antenatal hydronephrosis we can identify the possible etiology. Marked hydronephrosis is suggestive of Pujo which accounts for 10 percent of the cases with fetal hydronephrosis. 50 percent of those with mild hydronephrosis are identified to have transient hydronephrosis and physiological hydronephrosis. 20 percent of the those with mild dilation have extrarenal pelvis and 15 percent of them have VUR. About 80% of cases resolve spontaneously of the second-trimester pyelectasis is seen in either *in utero* or during the 1st year of life.^[14] Since majority of antenatally detected uropathies have shown the potential to resolve spontaneously, surgery is performed only after a period of observation. Nowadays, only 5–10% of cases require surgical intervention. Surgical indications are often correlated with the progression of dilatation *in utero* on sequential examinations. Only 10–30% of fetal pyelectasis in reported series proves to be related to VUR postnatally.^[15]

Aim

This study aims to study the imaging features of infants with antenatally diagnosed renal abnormalities to form guidelines for the management of these infants and to standardize the parameters related to fetal UTD based on the recommendations given by the multidisciplinary consensus group held in Linthicum, Maryland, USA, in March 2014.

MATERIALS AND METHODS

This prospective study was conducted in the Department of Radiodiagnosis and Pediatric Surgery and Urology, Coimbatore Medical College and Hospital from August 2013 to January 2015.

Demographic, clinical, and laboratory data of all consecutive mothers whose antenatal scans showed sonographic renal abnormalities were prospectively collected for this study. Based on antenatal sonogram findings, three categories were formed based on the extent of UTD. The infants were then evaluated in the postnatal period both clinically in the department of pediatric surgery and with ultrasound in the department of radiodiagnosis, respectively, and classified into two risk groups. Infants in each group were evaluated on a specific set of investigations particular for that group. (The classification into various risk groups is based on the consensus conference held in Linthicum). All the infants were managed according to their postnatal diagnosis and followed up for a period of 1 year. The data collected were evaluated and the results were analyzed to form purposeful guidelines that could help in postnatal management of infants with antenatally diagnosed renal abnormalities.

Exclusion Criteria

Mothers who had antenatal scan elsewhere and came for postnatal follow-up were excluded from the study. Antenatal sonograms with multiple anomalies, chromosomal anomalies, and genitourinary anomalies other than UTD such as ectopic kidneys, ovarian cyst, and Mullerian structure abnormalities were excluded from the study.

Description of Risk Stratification

The risk stratification that we used in our study was proposed by a multidisciplinary consensus group that constituted experts from eight societies with special interest in the management of fetus and infants with UTD.^[1] The normal antenatal and postnatal sonographic values are given in Table 1. The AP renal pelvis diameter (APRPD) was measured in transverse plane with spine at 12^o clock position and calipers at widest portion of intrarenal pelvis. The APRPD was graded as mild (4–7 mm), moderate (7–10 mm), and severe (>10 mm) for gestational age between 16 and 27 weeks. For >28 weeks, grading is mild (7–10 mm), moderate (10–15 mm), and severe (>15 mm). Based on antenatal findings, two risk groups are formed, namely, UTD

A1 and UTD A2–3, as shown in Table 2. The classification is based on the presence of the most concerning feature.

Similarly, postnatal presentation is divided into three risk groups, namely, UTD P1 – low risk, UTD P2 – intermediate risk, and UTD P3 – high risk, as shown in Table 3.

RESULTS

The number of mothers enrolled in the study between August 2014 and January 2016 was 72. All these mothers had two antenatal scans one in the second trimester (16–27 weeks) and another in the third trimester (>28 weeks). The risk stratification was applied to both the trimester scans and any progression in severity between the 2nd and 3rd trimester were noted. Of the 72 cases, 6 were excluded due to anomalies other than UTD listed in Table 4 and 42 cases had high-risk dilatation UTD A2–3. Twenty-four cases had low-risk dilatation UTD A1.

Among the 24 cases of UTD A1, three cases had low-risk dilatation only in the first trimester and became normal in the second-trimester scan. Six cases who had UTD A1 in both the first and second trimester also had normal postnatal scans at the 1st week of life and at 1 month and are under observation. Among the eight children with UTD P1, six had transient hydronephrosis and two had partial PUJO which was managed conservatively with regular follow-up.

Six neonates had UTD P1 low-risk dilatation, of which three had transient hydronephrosis which resolved and three had partial PUJO which were kept under observation. Among the 14 cases with UTD P2 intermediate-risk dilatation, 11 had complete PUJO, one had partial PUJO, one had bilateral VUR, and one had PUV which were managed as required. In the high-risk group UTD A2–3, there were 42 cases. Six neonates had UTD P1 low-risk dilatation, of which three had transient hydronephrosis which resolved and three had partial PUJO which were kept under observation. Among the 14 cases with UTD P2 intermediate-risk dilatation, 11 had complete PUJO,

Table 3: UTD risk stratification: Postnatal presentation for UTD P1 low risk, UTD P2 intermediate risk, and UTD P3 high risk. (Adopted from multidisciplinary consensus on the classification of prenatal and postnatal UTD, Journal of Pediatric Urology [2014] 10, 982–989)

Postnatal presentation		
APRPD	APRPD	APRPD
10–15 mm	>15 mm	>15 mm
Central calyceal dilatation	Peripheral calyceal dilatation	Peripheral calyceal dilatation
Parenchymal thickness normal	Parenchymal thickness normal	Parenchymal thickness abnormal
Parenchymal appearance normal	Parenchymal appearance normal	Parenchymal appearance abnormal
Ureters normal	Ureters abnormal	Ureters abnormal
Bladder normal	Bladder normal	Bladder abnormal
UTD P1	UTD P2	UTD P3

UTD: Urinary tract dilatation, APRPD: Anteroposterior renal pelvis diameter

one had partial PUJO, one had bilateral VUR, and one had PUV which were managed as required.

Twenty neonates with UTD P3 high-risk dilatation were the group that required earlier intervention. It included 10 cases of PUV, six cases of PUJO, one case of obstructive megaureter, one case of VUR, one case of bilateral

ureterocele, and one case of non-neurogenic bladder. In this group, 19 cases required surgical intervention [Table 5].

DISCUSSION

Fetal urologic abnormalities encompass a spectrum of disease processes that present a challenge for both the pediatric urologist and obstetrician. Knowledge of the specific conditions will help with prenatal counseling, determination of the need for therapeutic intervention *in utero* versus early delivery, postnatal evaluation, and management of these conditions. Prenatal diagnosis of renal abnormalities opens new and exciting vistas in postnatal management and benefits of fetal ultrasonography (USG) are increasingly evident.

Among the 24 cases of UTD A1, three cases had low-risk dilatation only in the first trimester and became normal in the second-trimester scan.^[16] These cases were subjected

Table 4: Number of patients in each risk group

Category	Number of patients
Total number of antenatal patients	72
Patients with UTD A1 low risk	24
Patients with UTD A2–3 high risk	42
Number of cases excluded	06
Ectopic kidney (2)	
Multicystic kidney disease (1)	
Horseshoe kidney (1)	
Duplex system (1)	
Extrarenal pelvis (1)	

Table 5: Evaluation of antenatal high-risk group UTD A2–3

Antenatal risk stratification (>28 weeks)	Postnatal risk stratification	Number of patients	Postnatal evaluation	Final diagnosis	Management
UTD A2–3	Normal	2	Only USG at 1 week	Normal	Observation
UTD A2–3	UTD P1	3	Only USG at 1 week and 1 month	Transient hydronephrosis which disappeared	Observation
UTD A2–3	UTD P2	3	USG, MCU, DTPA	Partial PUJO	Observation
		1	Only USG at 1 week and 1 month	Partial PUJO	Observation
		11	USG, MCU, DTPA	Complete PUJO	Pyeloplasty
		1	USG, MCU, DMSA	Bilateral Grade 2 vesicoureteric reflux	Observation
UTD A2–3	UTD P3	1	USG, MCU, DMSA, UDS	PUV	Fulguration
		10	USG, MCU, DMSA, UDS	PUV	Fulguration
		6	USG, MCU, DTPA	Complete PUJO	Pyeloplasty
		1	USG, MCU, DTPA	Obstructive megaureter	Ureterostomy
		1	USG, MCU, DMSA	Vesicoureteric reflux	Observation
		1	USG, MCU, MRI spine, DMSA, UDS	Non neurogenic bladder	Bilateral ureterostomy
		1	USG, MCU	Bilateral ureterocele	Ureterocele deroofing

UTD: Urinary tract dilatation, MCU: Micturating cystourethrogram, DTPA: Diethylenetriaminopentaacetic acid, DMSA: Dimercaptosuccinic acid, PUJO: Pelviureteric junction obstruction, MRI: Magnetic resonance imaging, USG: Ultrasonography

Table 6: Evaluation of antenatal low-risk dilatation UTD A1

Antenatal risk stratification		Postnatal risk stratification	Number of patients	Postnatal evaluation	Final diagnosis	Management
2 nd trimester	3 rd trimester					
UTD A1	Normal	Normal	3	Only USG at 1 week	Normal	Observation
UTD A1	UTD A1	Normal	6	Only USG at 1 week and 1 month	Normal	Observation
UTD A1	UTD A1	UTD P1	6	Serial USG	Transient hydronephrosis which disappeared	Observation
			2	USG, MCU, DTPA	Partial PUJO	Observation
			1	USG, MCU, DMSA	Bilateral Grade 2 vesicoureteric reflux	Observation
UTD A1	UTD A1	UTD P2	1	USG, MCU, DMSA, UDS	PUV	Fulguration
			3	USG, MCU, DTPA	Partial PUJO	Observation
			1	USG, DTPA	Complete PUJO	Pyeloplasty
UTD A1	UTD A1	UTD P3	1	USG, DTPA	Complete PUJO	Pyeloplasty

UTD: Urinary tract dilatation, MCU: Micturating cystourethrogram, DTPA: Diethylenetriaminopentaacetic acid, DMSA: Dimercaptosuccinic acid, PUJO: Pelviureteric junction obstruction, USG: Ultrasonography

to only one ultrasound scan in the postnatal period after 1 week of life and all three had normal scans. These three children do not need any further evaluation and are under follow-up.^[17] Six cases who had UTD A1 in both the first and second trimester also had normal postnatal scans at the 1st week of life and at 1 month and are under observation.

Out of five children with UTD P2, one had bilateral VUR, three had partial PUJO, and one had complete PUJO which required surgery and the rest needed only observation. Only one case had UTD P3 and that patient was diagnosed with PUJO and managed with pyeloplasty.^[18] In the high-risk group UTD A2–3, there were 42 cases. Two fetuses had progressive UTD from UTD A1 in the second trimester to UTD A2–3 in the third trimester. Among the 42 cases, two neonates had normal postnatal scan that was followed up with a USG at 1 month. Six neonates had UTD P1 low-risk dilatation, of which three had transient hydronephrosis which resolved and three had partial PUJO which were kept under observation. Among the 14 cases with UTD P2 intermediate-risk dilatation, 11 had complete PUJO, one had partial PUJO, one had bilateral VUR, and one had PUV which were managed as required [Table 6].^[19]

Twenty neonates with UTD P3 high-risk dilatation were the group that required earlier intervention. It included 10 cases of PUV, six cases of complete PUJO, one case of obstructive megaureter, one case of VUR,^[20] one case of bilateral ureterocele, and one case of non-neurogenic bladder. In this group, 19 cases required surgical intervention.

CONCLUSION

Antenatally diagnosed renal abnormalities are frequently encountered and there is no proper protocol in postnatal therapeutic management of these conditions. Postnatal management of these infants should be determined before birth.

Evaluating every child with prenatal sonogram renal abnormalities results in the cost-related burden on the health-care resources. Not evaluating any child with prenatal sonogram renal abnormalities could avoid these initial costs but might delay the diagnosis of significant uropathies such as PUV and, consequently, incur higher

long-term health and financial costs. The ultimate purpose of the study is to avoid two risks to avoid unnecessary, prolonged postnatal follow-up and delayed diagnosis.

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Effectiveness of Slow Breathing on Blood Pressure and Quality of Life in Patients with Hypertension: A Randomized Trial

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ABSTRACT

Background: Hypertension constitutes a significant cardiovascular burden globally. Non-pharmacological interventions are highly sought either as an adjunct or primary means of managing hypertension. Slow breathing (SB) is one of such approach which gains attention in recent times due to its multiple physiological benefits in lowering blood pressure (BP). However, there is a gap in literature testing the ability of SB training on quality of life (QOL) of hypertensive (HT) patients.

Aim of the Study: This study aims to find out the effectiveness of SB on reduction of BP and improvement in the health-related QOL in HT patients.

Materials and Methods: It was a randomized, open, and parallel-group trial design carried out at the Outpatient Department of Medicine in Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, Tamil Nadu, India. The study consists of 60 HT patients assigned equally to either study or control group. The study group was trained with SB training for 4 weeks, whereas no specific treatment was given for controls.

Results: The mean drop in systolic BP (SBP) for the study group was 14.24 ± 3.30 mmHg, whereas the mean drop was only 5.28 ± 2.26 mmHg for controls. The mean drop in diastolic BP (DBP) was 6.20 ± 2.69 mmHg for the study group, whereas it was only 3.12 ± 2.05 mmHg for controls. There was significantly higher drop in systolic as well as DBP in the study group. Likewise, the World Health Organization QOL-BREF (WHOQOL-BREF) was improved to 10.79 ± 5.47 in the 0–100 scale for the study group, whereas the mean improvement in the WHOQOL-BREF for control was 5.95 ± 0.01 in the 0–100 point scale.

Conclusions: It was concluded that 4 weeks of SB training were effective in reducing BP and improving QOL in patients with HT.

Key words: Breathing training, High blood pressure, Hypertension, Non-pharmacological measures, Quality of life, Slow breathing

INTRODUCTION

Hypertension (HT) is an important cause of premature death globally.^[1] In India, HT accounts for substantial mortality and morbidity and ranks one of the tops in the world.^[2] The Government of India in association with Registrar General of India had carried out the prevalence

of risk factors of cardiovascular diseases including HT in the District Level Household Survey-4 and it found that the prevalence of HT in India is 25.3%.^[3] It further states that there is convergence of rural-urban and rich-poor difference in its prevalence.^[3,4] Non-pharmacological therapy plays a key role either as a first-line management or adjuncts to drug therapy in the management of various stages of HT.^[5,6] One of such approach which gains popularity in the recent times is practice of slow breathing (SB). As the name implies, SB involves slowing of respiratory rate (RR) to 10 or less with high tidal volume. There are multiple physiological benefits of SB in controlling blood pressure (BP), which includes enhancement of slowly adapting pulmonary stretch receptors,^[7] improvement in the baroreceptor sensitivity,^[7-11]

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and reduced sympathetic^[11,12] and chemoreceptor activity.^[13] Recent evidence support that it has favorable changes in blood gases, particularly lowering of partial pressure of carbon dioxide to produce long-term changes in BP.^[13,14] HT is a chronic disorder and, therefore, apart from the regular physiological evaluation such as magnitude of BP and associated comorbidities, the self-assessment of quality of health is vital in better estimating the health condition. It is well reported that the self-evaluation of health status by the patient superiorly predicts the disease severity and death than most of the available objective measures.^[15] In majority of the previous studies, the effectiveness of SB with respect to various physiological measures has only attempted, the vital parameter of health-related quality of life (HRQOL) is neglected. Further, SB is performed by interactive breathing device (IBD) in most of the previous work.^[16-18] The IBD is limited in its availability and it is expensive. To overcome those gaps, in the present work, HRQOL is used as one of the primary outcome measures along with BP monitoring. The SB is trained by recorded auditory command in the present investigation. The World Health Organization QOL-BREF (WHOQOL-BREF) is a tool of selection to estimate HRQOL. The rationale for choosing the WHOQOL-BREF is that it specifically evaluates QOL which is the missing element in most of the assessment scales. Further, the WHOQOL-BREF is designed in such a way that it is beyond cultural variation and it best suits to international community. Therefore, the aim of the present investigation is to find out the effectiveness of 4 weeks of SB training on BP and QOL in patients with HT by listing the following research hypothesis. Null hypothesis (H_0): 4 weeks of SB are not effective in reducing BP and improving QOL in HT. Alternating hypothesis (H_1): 4 weeks of SB are effective in reducing BP and improving QOL in HT.

MATERIALS AND METHODS

Trial Design

This was an open, parallel-group, and randomized clinical trial.

Participants

Final stage, 60 HT patients were selected and randomly assigned to either experimental or the control group. Allocation to the study group was done by blocked randomization method. The block size was 4 and hence through six ways allocation was performed and it was carried out by a third person, a physiotherapist to maintain allocation concealment.

The study was ethically approved by the Institutional Human Ethics Committee of RMMC and H, Annamalai University, Chidambaram, Tamil Nadu.

Sample Size Estimation

Sample size was estimated with the level of significance of 5%, that is, $z_{\alpha/2} = 1.96$, power of 80%, that is, $z\beta = 0.84$, standard deviation of 10 mmHg and clinically significant improvement of 10 mmHg. Therefore, the sample size was 30 in each group.

Selection Criteria

Age between 30 and 60 years, both genders were included in the study. Joint National Committee-7 (JNC-7) of pre and Stage I HT was only chosen as they were the most suitable for SB, medication with calcium channel blockers with same drug and constant dosage for at least 2 weeks before the onset of the study were only chosen better to avoid the drug influence of autonomic nervous system; patients without history of cardiovascular diseases, transient ischemic attack, and stroke were not selected; patients doing regular exercise and involved in other forms of treatment were excluded from the study.

Settings

This study was conducted at the Outpatient Department of Medicine, Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, Tamil Nadu, India.

Allocation Process

The patients were allotted to the corresponding groups using blocked randomization method [Figure 1].

Intervention

The study purpose and procedure were explained. Patients were instructed to relax in a chair for 15 min before the commencement of pre-evaluation. Thereafter, BP evaluation was carried out and the response of self-administered HRQOL questionnaire was obtained. The experimental group was instructed about SB and a prior practice was given.

SB

It involves 4 s of inspiration and 6 s of expiration.^[11] The recorded auditory command was used as a cue to provide breathing training.^[19] The constant, repeated command of inhalation and exhalation was used as means of SB. Therefore, breathing rate was reduced to 6 breaths/min and it was performed for ½ h in succession. The practice was carried out for 5 days in a week for 4 consecutive weeks.^[16,19] Patients were told to avoid breath holding during the training and if they were not able to follow the breathing sequence during the course of training, they were instructed to do normal breathing until they were returning back to the sequence of SB. It was practiced under the supervision of physiotherapists for 2 days in a week and for remaining 3 days, practice was carried out in patients home. Home complaints were monitored and evaluated by the self-adherence rating scale.^[20] Those who had 7 or more in the

numerical rating scale of 10 were only taken for analysis.

For the control group, SB was not given but was instructed to take regular course of antihypertensive (HT) pills prescribed by the physician. They were followed up once in a week for the total period of 4 weeks to ascertain that there was no change in the current treatment regimen.

Outcomes

Primary

- (i) Systolic BP (SBP) and diastolic BP (DBP)
BP was recorded in an arm supported table with a backrest chair in a sitting position. Feet were

completely placed in a floor. Monitoring was done for 3 times with the interval of each of 5 min. The average of the last two measures was taken as final BP reading. The measurement was carried out by the standard mercury sphygmomanometer.

- (ii) WHOQOL-BREF^[21]

It consists of 26 questions. It evaluates QOL with respect to four domains, namely, physical health, psychological, social relationship, and environmental. The raw scores in each domain were transformed into the scores of 0–100 scale and the overall score was calculated by finding the mean of all the four domains. It is a 5-point Likert's scale with 5 denotes maximum and 1 denotes least score. The score of

Assessed for Eligibility (n=70)

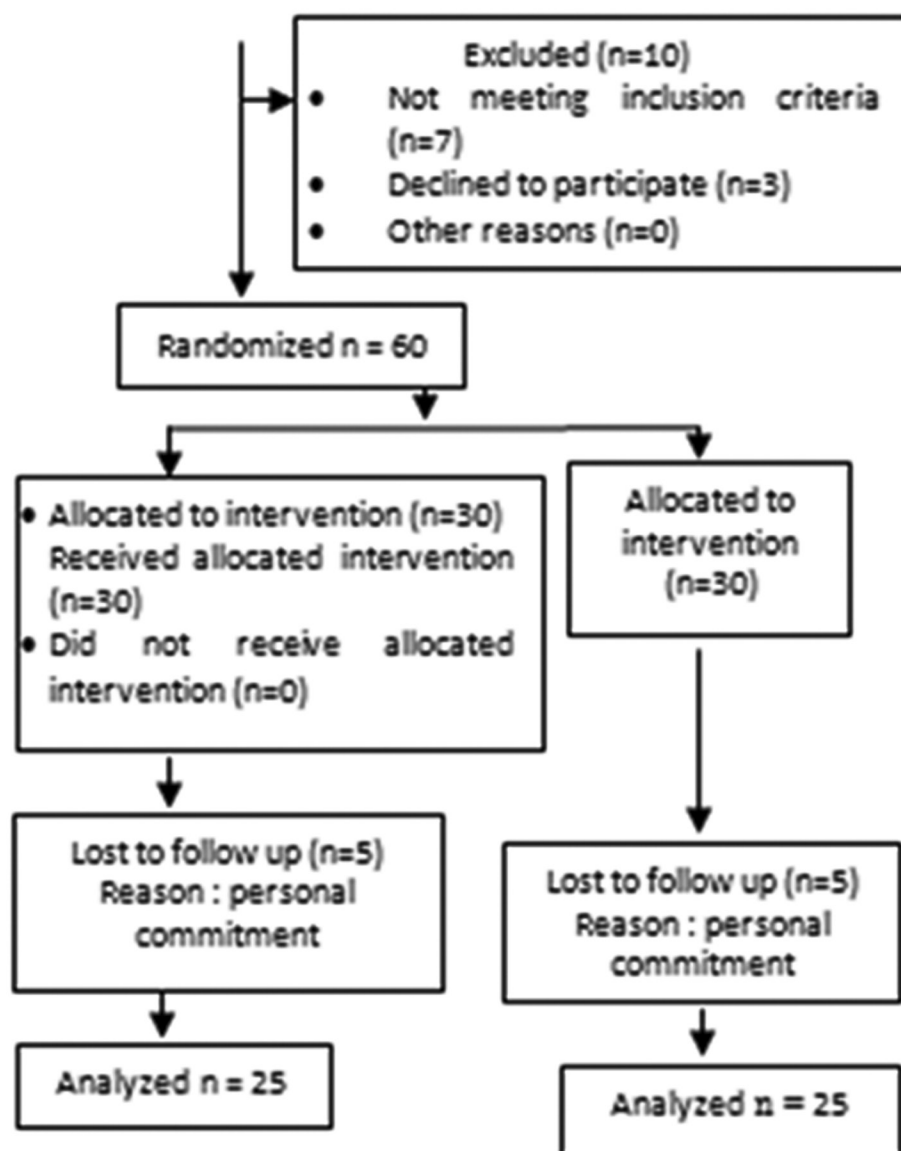


Figure 1: Patient allocation flow diagram

question number 3, 4, and 26 was reversed as they were negatively phrased items. As the domain scores were scaled in positive direction, higher scores represent higher QOL and vice versa.

Secondary

(i) Pulse rate (PR)

PR was evaluated by handheld pulse oximetry.^[22] It was recorded thrice with an interval of 5 min each and the average of the last two measures was considered as final value.

(ii) RR

It was evaluated by EMMA Capnometer.^[23] The patients were told to breath normally for few breaths in a handheld Capnometer. The extrapolated RR was displaced in the screen. It was recorded thrice with an interval of each of 5 min and an average of the last two measures was taken as final value.

Statistical Analysis

Basic characteristic findings were tested for homogeneity using independent sample “*t*” test. Within-group before and after intervention, comparison was carried out by the paired sample “*t*” test. The mean difference of pre- and post-values of the outcomes was compared between groups using independent sample “*t*” test. The parametric test was selected because the distribution of the data was normal and the unit of measurement was in interval scale. The entire statistical analysis was carried out by the Statistical Package for the Social Sciences (SPSS-21).

RESULTS

The anthropometric measures such as age, gender, and body mass index were homogenous between groups at the baseline. Likewise, the outcomes such as SBP, DBP, PR, RR, and WHOQOL-BREF were homogenous between groups at the start of the study [Table 1].

The post-values of the outcomes are shown in Figure 2. It is inferred that post-values of vital parameters such as BP, PR, and RR were comparatively lower in the study group.

It is inferred from Table 2 that there was a significant reduction in BP, PR, and RR in the study group following treatment. In controls, significant reduction was observed in SBP, PR, and RR following the study period, but reduction in DBP was statistically insignificant. The WHOQOL-BREF was significantly improved following treatment in the study group. Likewise, it has improved significantly after the study period in controls.

Between-group comparisons of outcome [Table 3] show that there was significantly higher improvement in all the outcomes (SBP, DBP, PR, RR, and WHO-BREF) in the study group when compared to controls.

The individual domain scores of all the four aspects of the WHOQOL-BREF were shown comparatively higher improvement in the study group [Table 4].

DISCUSSION

In the current study, SBP was reduced to 14.24 ± 3.30 mmHg for the study group which is well above the clinically significant improvement. The present work methodology is similar to the study done by Swarnalatha,^[19] who also demonstrated a significant

Table 1: Basic characteristic of the study patients

Parameters	Study		Control		“P”
	M	SD	M	SD	
Age (years)	44.72	8.04	43.48	8.81	0.606
Gender (male/female) %	60	40	56	44	0.622
Body mass index	24.89	2.67	25.60	2.40	0.322
Systolic blood pressure (mmHg)	145.64	8.05	144.0	8.59	0.50
Diastolic blood pressure (mmHg)	94.96	8.19	91.96	4.12	0.06
Pulse rate (beats/min)	84.8	7.39	86.36	8.88	0.50
Respiratory rate (breaths/min)	17.08	2.41	16.36	1.84	0.24
WHOQOL-BREF	56.56	11.81	57.05	9.69	0.87

M: Mean, SD: Standard Deviation, P: Probability value, WHOQOL-BREF: World Health Organization quality of life-BREF

Table 2: Within-group comparison of outcomes following treatment

Outcomes	Study				Control			
	M	SD	“t”	“P”	M	SD	“t”	“P”
Systolic blood pressure	-14.24	3.30	21.52	0.001	-5.28	2.26	7.47	0.001
Diastolic blood pressure	-6.20	2.69	11.51	0.001	-3.12	2.08	1.10	0.278
Pulse rate	-3.52	3.57	4.92	0.001	-0.40	1.80	3.36	0.003
Respiratory rate	-3.08	1.03	14.84	0.001	-0.80	1.19	9.86	0.001
WHO-BREF	10.79	5.47	1.66	0.001	3.07	3.47	4.42	0.001

M: Mean, SD: Standard Deviation, P: Probability value, t: Test statistics, WHO-BREF: World Health Organization-BREF

Table 3: Difference in the outcome between groups following treatment

Outcomes	MD	SD. error	“t”	“P”
Systolic blood pressure	-8.96	0.801	11.17	0.001
Diastolic blood pressure	-3.08	0.68	4.52	0.001
Pulse rate	-3.12	0.80	3.89	0.001
Respiratory rate	-2.28	0.31	7.22	0.001
WHOQOL-BREF	7.72	1.29	5.95	0.001

MD: Mean difference, SD. error: Standard error, P: Probability value, t: Test statistics, WHOQOL-BREF: World Health Organization quality of life-BREF

reduction in BP following 4 weeks of training, but mean arterial pressure was used as outcome rather than SBP and DBP. Elliot *et al.*^[18] had also demonstrated a significant reduction in systolic and DBP following 180 min of training over 8 weeks in SB. The magnitude of improvement was also similar to the present work, the mean drop in SBP was 15 mmHg and DBP was 5 mmHg. In the present work, on an average, there were 8.96 ± 0.801 mmHg of higher SBP reduction which was observed in the study group when compared to controls. The magnitude of improvement on an average was 3.08 ± 0.68 mmHg for DBP in the study group than in controls. Therefore, there was considerable degree of improvement in BP which was observed in the study group. There was a significant drop in PR and RR which were noted in the study group following training. However, the mean drop was 3.52 ± 3.57 beats/min and 3.08 ± 1.03 breaths/min for PR and rater, respectively. Even though these two parameters were reduced following training, drop was less in magnitude. Hence, apart from the reduction in sympathetic nervous system activity, there could be other factors influencing BP drop following training. It was suggested that SB training causes positive influence of long-term control of BP by altering blood gases, particularly lowering the carbon dioxide which ultimately increases renal excretion of sodium and drop in BP.^[14,16] Cardiac output and total peripheral resistance are the important factors influencing BP. As there was not much change in PR,

SBs ability in lowering peripheral resistance could be the factor in BP reduction. Activation of slowly adapting pulmonary stretch receptors by the practice of SB positively influences peripheral resistance by causing vasodilatation of the peripheral arteries.^[14]

QOL was significantly improved following SB in the study group. The degree of improvement was 10.79 ± 5.47 in the 0–100 scale of the WHOQOL-BRIEF. Therefore approximately 11% improvement was noted in the current health related QOL in the study group following training and which was found to be a improvement. Further, the improvement in QOL was significantly higher in the study group than in controls. On an average, there were $7.72 \pm 1.29\%$ higher improvements in QOL for the study groups when compared to controls. The influence of SB on QOL is not yet studied and the positive result of the current findings could add a great value to the present work. The WHOQOL-BREF has four domains, namely, physical, psychological, social relationship, and environmental. On analyzing each domain, the degree of improvement was much greater in physical and psychological domains in the study group. There was a significantly higher improvement in all the domains following training in the study group when compared to controls. Subjective evaluation of well-being is equally important to physical measures in evaluating the treatments. Hence, SB can be an effective adjunct in managing hypertension. In the present work, SB was trained by recorded auditory command, which is a simple means of doing SB. In the majority of previous work, SB was trained by special device which is costly and limited in availability.^[14,16,17]

Table 4: Comparison of individual domain scores of the WHO-BREF between groups

Domain	M D	SD. error	"t"	"P"
Domain-I (psychological)	9.88	2.10	4.70	0.001
Domain-II (physical)	9.24	2.39	3.86	0.001
Domain-III (social relationship)	4.20	2.29	1.82	0.07
Domain IV (environmental)	7.28	1.50	4.83	0.001

MD: Mean difference, SD. error: Standard error, P: Probability value, t: Test statistics, WHO-BREF: World Health Organization-BREF

Limitation and Recommendations

The outcomes such as arterial carbon dioxide, baroreceptor sensitivity, renal measures, and heart rate variability can be included in the future endeavor to analyze in depth the influence of SB on these measures. The estimation of frequency and duration of SB training needs to be

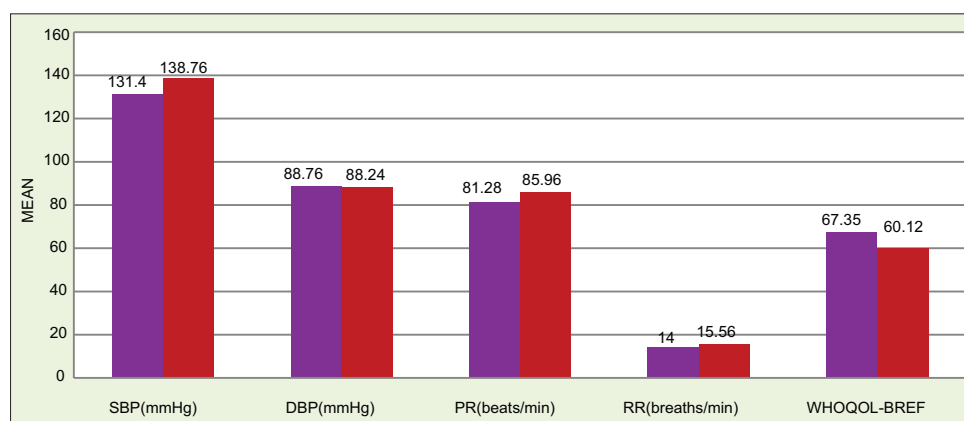


Figure 2: Post-outcomes

evaluated extensively to find out the optimal threshold of the SB training.

CONCLUSIONS

Four weeks of SB significantly improves BP and health-related QOL in patients with hypertension. It is suggested that SB is an effective adjunct in managing hypertension and could be incorporated with regular course of medication for the effective BP control.

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Evaluation of Maxillary Central Incisor and Canine Exposures in Resting Position of the Maxillary Lip for Determining the Anterior Level of Occlusal Plane

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Abstract

Introduction: The exposure of the maxillary anterior teeth affects the anterior level of occlusal plane, esthetics, and speech. Previous data suggests approximately 2 mm of exposure of the maxillary central incisors in the resting position of the maxillary lip.

Aim: This study aimed to evaluate the relationship between the vertical position of the maxillary central incisors and canines and the maxillary lip in Indian dentulous subjects according to age, sex, and lip length.

Material and method: A total of 540 (272 male and 268 female) Indian adults between 21 and 60 years of age were included in the study. The exposures of the maxillary central incisors and canines were measured using a ruler with the maxillary lip in the rest position. Additionally, the maxillary lip length of each subject was also measured.

Result: Data were analyzed using analysis of variance and Student's t-test. The tooth exposure was inversely proportional to lip length. Statistically significant differences in the exposures of the maxillary central incisors and canines were observed between the age groups 20-30 years and 30-40 years and 40-50 years for maxillary central incisors. However, no significant differences were observed between the age groups 50-60 years for maxillary central incisors and between 40-50 years and 50-60 years for maxillary canines.

Conclusion: Maxillary central incisor exposure is highly variable while maxillary canine exposure showed lesser variations with age, sex, and lip length.

Key words: Canine exposure, Incisor exposure, Lip length, Occlusal plane

INTRODUCTION

An esthetic and appealing smile is the requirement of most patients. Hence, anterior teeth have become the focus of

attention for both patients and dentists. The anterior teeth play a key role in speech, incision of food, and definitely, esthetics. Replacement of one or two missing maxillary anterior teeth using adjacent teeth as abutments is not difficult. However, when the maxillary anterior teeth, all maxillary teeth, or all teeth are missing, the determination of the relative positions of the anterior teeth becomes a subjective decision.

Landa laid specific guidelines for the vertical positioning of the maxillary central incisors and clarified that 0 mm–2 mm of the incisal edge should be visible below the maxillary

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lip.^[1] Sharry instructed that “for a patient with an average length of the upper lip, 1–2 mm of the occlusion rim should be seen when the lip is at rest. For a patient with a short upper lip, perhaps, 5–6 mm of the occlusion rim would be seen.”^[2] Ellinger *et al.* suggested that for a normal lip, the occlusion rim should extend just below the resting lip position and proposed variations in guidelines for short or long lips.^[3] Boucher and Payne used phonetics to determine the position of the maxillary anterior teeth.^[4,5] Heartwell recommended that the vertical length of the maxillary occlusion rim in the anterior region should extend approximately 2 mm below the relaxed lip.^[6]

Vig and Brundo found a gradual decrease in the amount of maxillary central incisor exposure with an increase in age, accompanied by a gradual increase in the exposure of mandibular anterior teeth.^[7] Ahmed described that a decreasing amount of maxillary teeth exposure and increasing amount of mandibular teeth exposure can be seen from Caucasians to Asians to Blacks.^[8] Misch performed a pilot study on Caucasian dentulous patients and concluded that the range of maxillary central incisor exposure was wide, and the use of an average dimension as a guide may not be accurate in clinical practice.^[9]

Therefore, the purpose of the study was to investigate the effect of lip length, age, and sex on the exposure of maxillary central incisors and canines in the resting position of the maxillary lip in the Indian population.

MATERIALS AND METHODS

This clinical observational study was planned with 540 Indian adults (272 were male and 268 were female) aged between 21 and 60 years. The participants were recruited from patients visiting the department of prosthodontics of a dental college. All subjects had Angle’s Class I occlusion, without crowding or spacing between the anterior or posterior teeth. Patients were excluded if they had a history of trauma or plastic surgery associated with the lips, undergone orthodontic treatment, prostheses in the anterior region, mobile or extruded anterior teeth, and/or moderate-to-severe wear of the maxillary anterior teeth.

Table 1: The overall mean exposures of the maxillary central incisors and canines

Sex	Maxillary central incisors		Maxillary canines	
	Mean (mm)	Range (mm)	Mean (mm)	Range (mm)
Male	2.27	–2 to 7	–0.22	–3 to 2
Female	3.00	–2 to 8	0.07	–3 to 2



Figure 1: Measurement of maxillary central incisor exposure

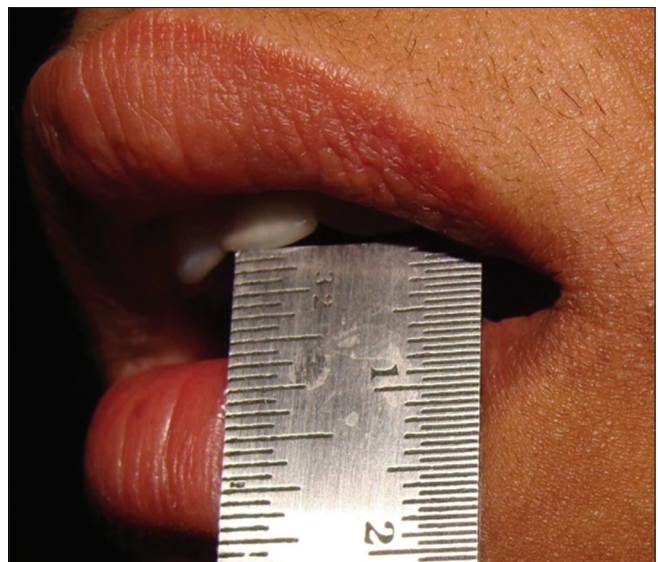


Figure 2: Measurement of maxillary canine exposure

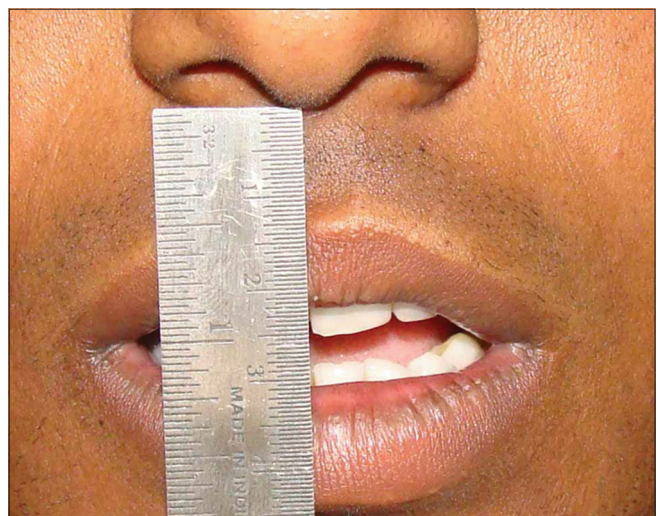


Figure 3: Measurement of maxillary lip length

Each subject was asked to sit upright in a chair with the head unsupported. Measurements were made by an examiner

Table 2: The exposures of the maxillary central incisors and canines according to lip length in male and female subjects

Lip length (mm)	Number of observations	Maxillary central incisors			Maxillary canines		
		Mean (mm)	Standard deviation	Range (mm)	Mean (mm)	Standard deviation	Range (mm)
Male							
10–15 (short)	30	5.06	1.21	2.5 to 7	0.86	1.19	–1 to 2
16–20 (medium)	178	2.38	1.69	–2 to 5	–0.20	1.07	–3 to 2
21–25 (medium)	66	1.01	1.37	–2 to 4	–0.74	0.94	–3 to 1
Female							
10–15 (short)	38	5.34	1.64	0 to 8	1.26	0.72	–1 to 2
16–20 (medium)	160	3.07	1.06	0 to 5	0.21	0.88	–2 to 2
21–25 (medium)	70	1.68	1.93	–2 to 4	–0.72	1.15	–3 to 1

using a handheld millimeter ruler. Each subject was asked to say “emma” so that the mandible and lips attained their respective rest positions. The lower lip was parted and using the millimeter ruler, the vertical distance from the inferior margin of the vermilion border of the maxillary lip in repose to the incisal edge of the right maxillary central incisor was measured [Figure 1].

Thereafter, the vertical distance from the inferior margin of the vermilion border of the maxillary lip in repose to the tip of the right maxillary canine was measured [Figure 2]. Similarly, the exposures of the left maxillary central incisor and canine were recorded. When the incisal edge/canine tip was above the inferior border of the maxillary lip, the exposure was recorded as a negative value. The maxillary lip length of each subject was also measured from the base of the columella to the lower margin of the vermilion border of the maxillary lip [Figure 3].

The exposures of the maxillary central incisors and canines on both sides of the arch were averaged, and the mean values of maxillary central incisor and canine exposures for each subject were used for further analysis. The obtained data were categorized for male and female subjects according to age groups as follows: 21–30, 31–40, 41–50, and 51–60 years. The obtained data for maxillary lip length were categorized according to the lip lengths as follows: Short, medium, and medium lip lengths for lip lengths of 10–15 mm, 16–20 mm, and 21–25 mm, respectively.

The exposures of the maxillary central incisors and canines in different age groups and in patients with different lip lengths were compared between male and female subjects using the analysis of variance (ANOVA). $P < 0.05$ was considered statistically significant.

RESULTS

The overall mean exposure and range of exposure of the maxillary central incisors and canines in the rest position of the maxillary lip in both male and female subjects are shown

Table 3: Results of one-way ANOVA for lip length groups

P-value	Maxillary central incisors	Maxillary canines
Male	<0.000	<0.000
Female	<0.000	<0.000

ANOVA: Analysis of variance

in Table 1. The overall mean exposures of the maxillary central incisors and canines in male subjects were 2.27 mm and –0.22 mm, respectively. The mean exposures of the maxillary central incisors and canines in female subjects were 3.00 mm and 0.07 mm, respectively.

The mean exposure, standard deviation, and range of exposure of the maxillary central incisors and canines in the rest position of the maxillary lip in male and female subjects according to their lip length are shown in Table 2. With the increase in lip length, the exposures of the central incisors and canines decreased in both male and female subjects. The exposures of the maxillary central incisors and canines [Table 3] showed statistically significant difference between the age groups in male and female subjects.

The mean exposure, standard deviation, and range of exposure of the maxillary central incisors and canines in the rest position of the maxillary lip in male and female subjects according to their age groups are shown in Table 4. The mean exposures of both maxillary central incisors and canines in male and female subjects decreased with increasing age from 20 to 60 years.

In this study, the overall mean exposures of the maxillary central incisors and canines were greater in female subjects than that in male subjects. The mean exposures of the maxillary central incisors and canines decreased from 5.06 mm to 1.01 mm and 0.86 mm to –0.74 mm, respectively, as the lip length increased from 10 mm to 25 mm in male subjects. The mean exposures of the maxillary central incisors and canines decreased from 5.34 mm to

Table 4: The exposures of the maxillary central incisors and canines according to age groups in male and female subjects

Age groups (Years)	Number of observations	Maxillary central incisors			Maxillary canines		
		Mean exposure (mm)	Standard deviation	Range of exposure (mm)	Mean exposure (mm)	Standard deviation	Range of exposure (mm)
Male							
21–30	76	3.10	1.98	–2 to 7	0.02	1.01	–2 to 3
31–40	68	2.63	1.75	–1 to 6	–0.19	1.14	–3 to 2
41–50	68	2.00	1.93	–2 to 5	–0.33	1.22	–3 to 2
51–60	62	1.38	1.68	–2 to 5	–0.40	1.14	–3 to 2
Female							
21–30	74	3.95	1.62	–1 to 8	0.58	1.09	–2 to 2
31–40	64	3.34	1.25	0 to 7	0.20	0.89	–2 to 2
41–50	70	2.80	1.63	–1–5	–0.01	1.08	–3–1
51–60	60	1.93	1.97	–2 to 4	–0.46	1.21	–3 to 1

Table 5: Comparison between male and female groups for the exposures of maxillary central incisors and canines

Age groups	P-value	Inference
Maxillary central incisors		
20–30 years	0.004	Significant difference
30–40 years	0.038	Significant difference
40–50 years	0.010	Significant difference
51–60 years	0.100	Non-significant difference
Maxillary canines		
20–30 years	0.002	Significant difference
30–40 years	0.029	Significant difference
40–50 years	0.102	Non-significant difference
51–60 years	0.767	Non-significant difference

1.68 mm and 1.26 mm to –0.72 mm, respectively, as the lip length increased from 10 mm to 25 mm in female subjects.

The results [Table 5] demonstrated that there was a statistically significant difference in the maxillary central incisor and canine exposures between the age groups 20–30 years and 30–40 years and in the maxillary central incisor exposure between 40 and 50 years. However, no significant differences were observed between the age groups 50 and 60 years for maxillary central incisor exposure and 40–50 years and 50–60 years for canine exposure.

DISCUSSION

The anterior level of the occlusal plane should be accurately determined. Limited studies have provided the average values for the accurate determination of the anterior level of occlusal plane in both male and female patients of all age groups according to the maxillary lip length and race of the patient.^[1–6] Hence, this study was conducted to investigate the effect of lip length, age, and sex on the exposure of maxillary central incisors and canines in the resting position of the maxillary lip in the Indian population. The

rest position of the lip is determined when the lips are slightly parted and the teeth are out of occlusion with the perioral muscles relatively relaxed. In the static position, the following four factors influence the tooth exposure: Lip length, age, race, and sex.^[7]

The results suggest that exposure of the maxillary central incisor is similar between male and female subjects after 50 years of age while exposure of the maxillary canine is similar between male and female subjects after 40 years of age in the studied population.

The tooth display was inversely proportional to lip length. This result suggests that the exposure of both maxillary central incisors and canines should be altered according to the lip length in both male and female patients.

From Tables 4 and 5, it can be proposed that the exposures of maxillary central incisors in male and female subjects decrease with age, and clinically negligible change occurs after the age of 50 years. In contrast, the exposures of canines in male and female subjects decrease faster with age, and clinically negligible change occurs after the age of 40 years.

The results of this study suggest that the exposure of maxillary central incisors shows greater variation according to age and lip length, in both male and female subjects, compared to the exposure of maxillary canines. Hence, the use of the maxillary central incisors as a guide for positioning the anterior level of occlusal plane may not be predictable. In addition, limited changes in canine exposure occur according to age and lip length, in both male and female subjects. Hence, the anterior level of occlusal plane can be established in a more predictable manner using canine exposure as guide. However, further long-term prospective studies are required to validate the results of this study.

This study is not without limitations. Subjects included in the study were from a single relatively small area to be representative of the entire Indian population. The limited sample size and manual method of measurements restrict the generalization of the study results. Further studies, targeting a larger population, or large multicenter studies should be performed for providing insights into this vast topic.

CONCLUSION

This study showed that the mean exposures of maxillary central incisors and canines were greater in female subjects than that in male subjects. The exposures of the maxillary central incisors and canines decreased as the lip length increased from 10 mm to 25 mm in male and female subjects. Maxillary canine exposure decreases till 40 years of age and shows few changes till the age of 60 years while the maxillary central incisor exposure decreases till 50 years of age and limited changes occur till the age of 60 years. As reported, the maxillary central incisor exposure in the resting position of the maxillary lip is highly variable, while the maxillary canine exposure tended to show lesser variations with age, sex, or lip length.

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