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Case Report

Orbital Prosthesis – A Case Report

Anuja Baburao Kunturkar[1], Vivek Choukse[2], Shalvika Subodh Khavnekar[1], Ranjeet Gandagule[3], Kulbhushan Ganesh Mante[1], Prathana Nitin Borikar[1]

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Abstract

For the patient's cosmetic and psychological recovery, an orbital prosthesis is a good option to surgical reconstruction. It needs to be attractive, robust, lightweight, affordable, and most crucially, retentive. A case of orbital damage that required surgery and was then followed by orbital exenteration has been detailed in a clinical report with an explanation of prosthetic rehabilitation. The patient's psychological and mental health were intended to be improved as well as their appearance, thanks to the orbital prosthesis. The procedures used and the addition of the patient's own hair to the eyelashes significantly improved the esthetics. The purpose of the orbital prosthesis was to improve the patient's psychological and mental health while restoring his or her esthetics.

Key words: Eye prosthesis, Maxillofacial prosthesis, Orbital exenteration, Prosthetic eye

INTRODUCTION

The primary organ of sight is the eye. They play a crucial part in facial expression as well.[1] Loss of an eye or a disfigured eye has a far-reaching impact on an individual's psyche. In addition, it affects one's social and professional life.[2] The loss or absence of an eye may result from a congenital defect, irreparable trauma, a painful blind eye, sympathetic ophthalmia, or the need for histologic confirmation of a suspected diagnosis.[3]

Rehabilitation of various maxillofacial defects is a time-consuming, complex, and overwhelming task requiring a patient-specific design and technique. Human face disfigurement involving loss of an eye enhances physical and emotional challenges.[4] The surgeon frequently performs extreme surgeries, such as orbital exenteration, to treat malignancies or chronic, progressive disorders that do not respond to any form of conservative therapy.[5] The associated psychological effect of these defects on the patient requires immediate management and rehabilitation intervention by a team of specialists.[6]

An orbital prosthesis is a potentially cost-effective and conservative substitute for surgical restoration for the patient's emotional and esthetic recovery as well as for the preservation of the orbital cavity. Therapy planning and therapy selection are influenced by the patient's post-operative status as well as social and economic circumstances.[7] Ocular prosthesis may be either readymade (stock) or custom made. Fabrication of a custom ocular prosthesis allows for a range of variations during construction.[8]

An orbital prosthesis should have good esthetics, be durable, lightweight, affordable, and most significantly, be retentive. The type of fabrication material and retention depends on the patient's cosmetic requirements, the size and extent of the defect, the type of lifestyle, the financial situation, etc.[9] The custom-made ocular prostheses achieved intimate contact with the tissue bed enabling an ideal fit.[10]

Polysiloxane, room-temperature vulcanized (RTV) silicones, high-temperature vulcanized silicones, silphenylenes, chlorinated polyethylene, polyvinyl chloride, and polyurethane are examples of recent materials. RTV silicones are the materials that are utilized the most frequently.[9]

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Figure 1: Extraoral photographs

CASE REPORT

A 42yr old female-year-old female patient reported in the Department of Prosthodontics and Maxillofacial Prosthetics, Dr. HSRSM Dental College and Hospital, Hingoli, Maharashtra, with a chief complaint for the rehabilitation of her left eye which had been resected *en bloc* because of trauma and subsequent persistent infection. Examination showed a completely healed ocular socket. There was no pain or discomfort in the defect region. Definite bony undercuts were found on the superior and inferior borders of the socket which ultimately aided in retention of the prosthesis.

A master impression of the defect and non-defect side was made once the patient was at ease and sitting comfortably in an upright position, the impression extending 3 cm beyond the desired eventual prosthesis borders, which were defined before making the impression. Petroleum jelly was used as a lubricant for the eyebrow and for the anophthalmic socket after careful inspection, and the iris and pupil diameters on the unimpaired side were measured using a pair of vernier calipers.

Step 1

Extraoral photographs of the patient were taken in frontal left and right lateral views (Figure 1).

Step 2

Preliminary impression was made with alginate and plaster of the anophthalmic region (Figures 2-4).

Step 3

Cast was fabricated; later, fabrication of the wax pattern was made on the cast with proper orientation (Figure 5).

Step 4

The wax pattern along with the eye shell was checked in the patient's site. Proper measurements were made using the graphic tracers (Figures 6-9).

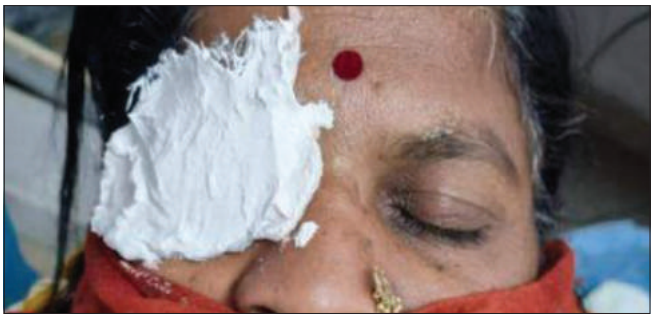

Figure 2: Primary impression made with alginate

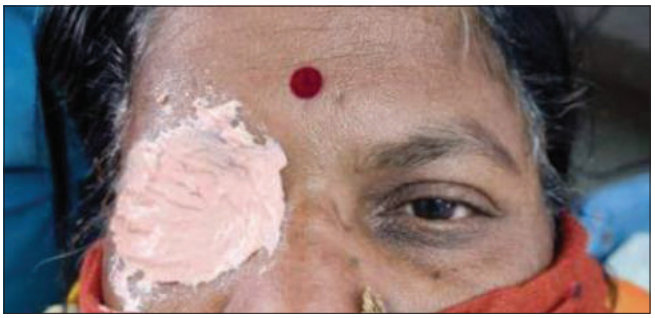

Figure 3: Primary impression made with alginate

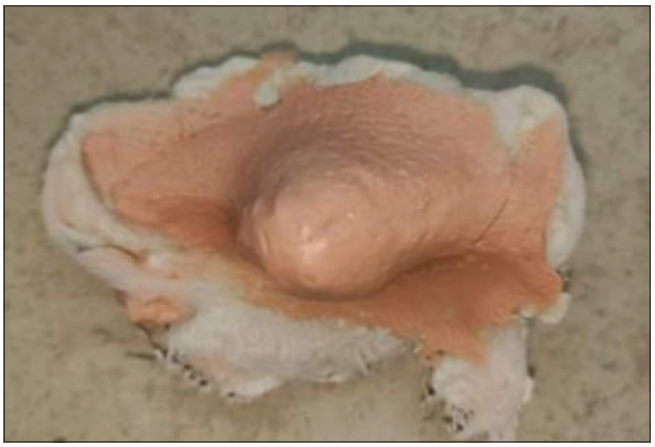

Figure 4: Primary impression made with alginate

Step 5

A final impression of the anophthalmic site was made with the elastomeric impression materials (Figures 10-13).

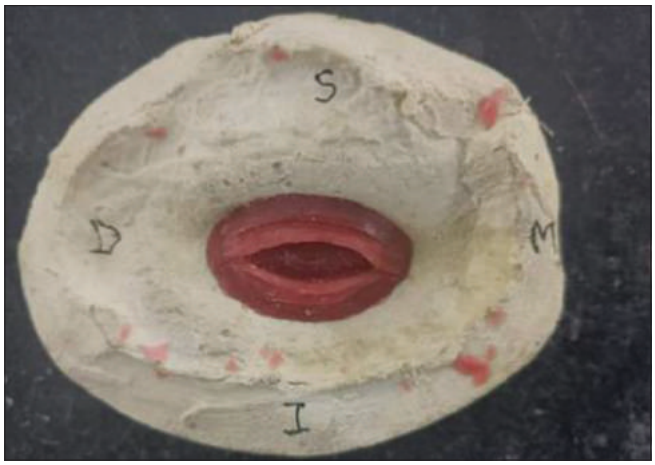

Figure 5: Primary cast with waxup

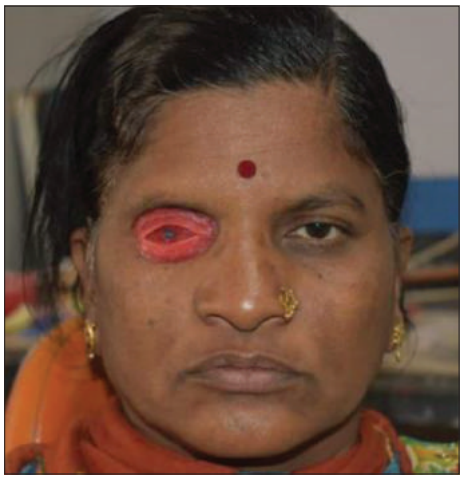

Figure 6: Wax trail in position

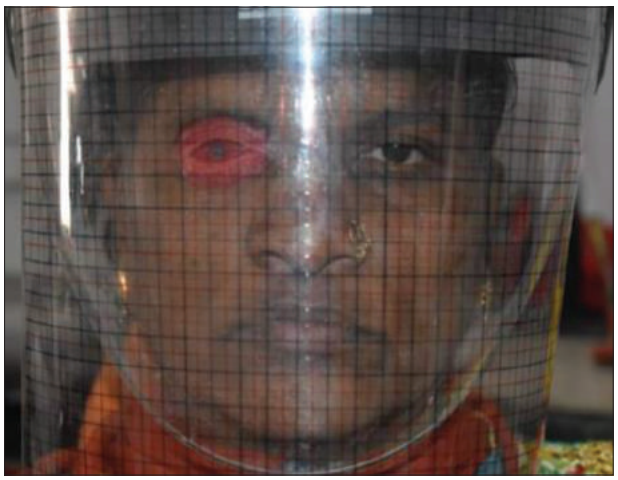

Figure 7: Iris positioning

Figure 8: Frontal view iris positioning in patient

Figure 9: Lateral view

Figure 10: Final impression with light body and putty

A master cast was obtained with orientation (Figure 14).

Step 6

Dewaxing was done with the help of eye shell stabilizer followed by proper shade matching with the help of stains mixed in silicone material and was made of the patient's skin tone with the help of the neighboring eye taken as a guide (Figures 15-18).

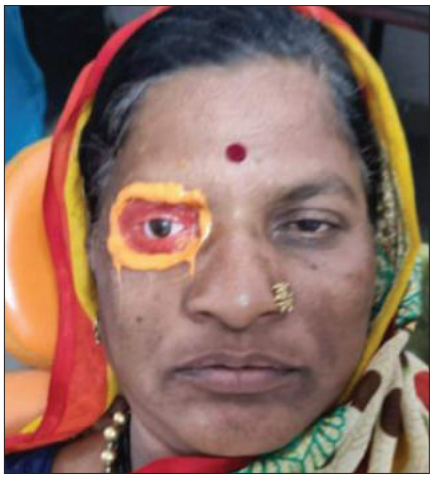

Figure 11: Final impression with light body and putty

Figure 12: Final impression with light body and putty

Figure 13: Final impression on removal

Step 7

After the complete set of the material, the prosthesis was taken out of the mold. False eyelashes were attached to the prosthesis (Figures 19 and 20).

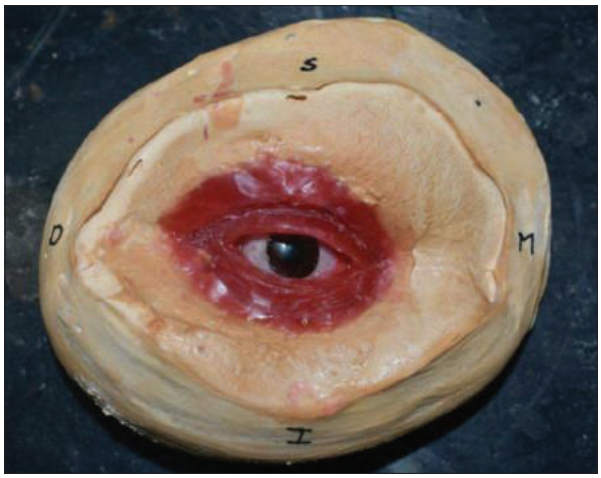

Figure 14: Iris positioning on cast

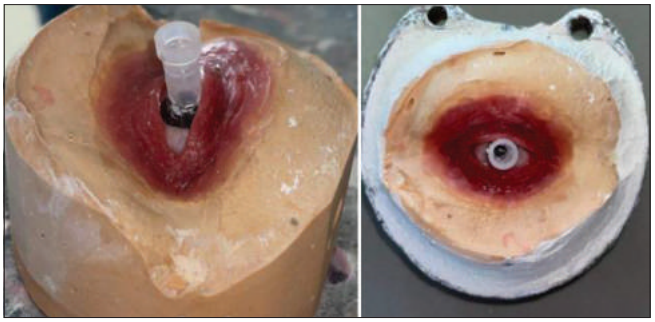

Figure 15: Flasking

Figure 16: Dewaxing

Step 8

The prosthesis was then tried in the patient (Figures 21 and 22).

An appropriate eyeglass frame was selected to mask the margins of the prosthesis (Figure 23).

The pre and post-operative photographs of the patient were recorded (Figures 24 and 25).

Home care instructions were given. The patient was instructed home care of the prosthesis, cleaning with soap

Figure 17: Packing

Figure 18: Packing

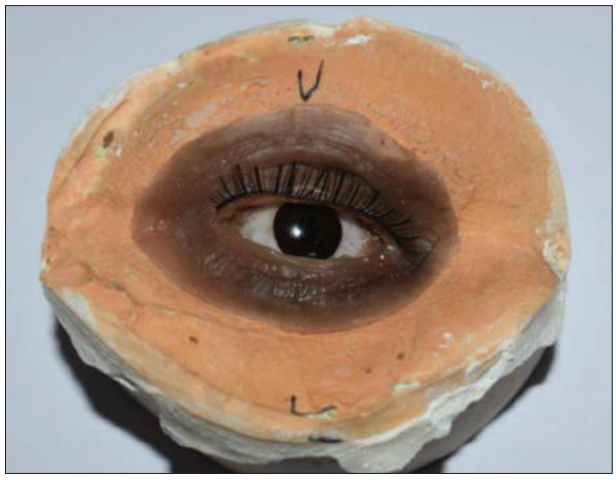

Figure 19: Final prosthesis

and warm water once per day. Removing the prosthesis during sleep and keeping it in a refrigerator at night to prolong the life span of the silicone should be advised. The patient was asked to report on a 6 monthly to yearly basis for evaluation of the prosthesis condition.

Figure 20: Final prosthesis

Figure 21: Final prosthesis lateral view

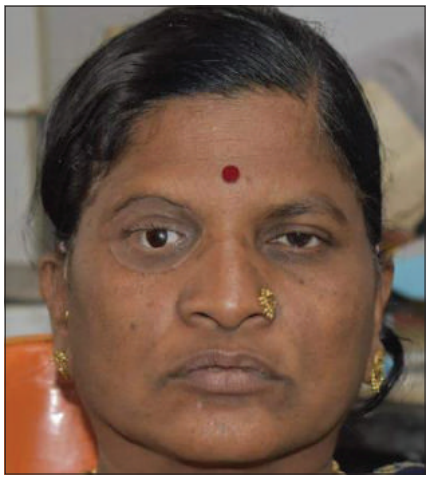

Figure 22: Final prosthesis frontal view

DISCUSSION AND CONCLUSION

Following surgical removal of an organ, prosthetic rehabilitation is the preferred course of care for individuals with a significant facial deformity of the maxillary-orbital complex. If a split-thickness graft is used to fill the deficiency, the prosthesis will be more tolerable and retain its shape better.

Figure 23: Final prosthesis frontal view

Figure 25: Final Prosthesis photograph

Figure 24: Pre-prosthetic photograph

A practitioner can treat a patient who needs a personalized ocular prosthesis using a variety of effective ways. Conventionally retained orbital prostheses are useful, trouble-free, cost-effective, and successful, even though implant-retained ocular prosthesis plays a significant part in the success of treatment. Utilizing adhesive, securing the prosthesis to eyeglasses, or cutting into both hard and soft tissue can help keep the device in place.

The silicone eye prosthesis offered the benefits of being lightweight, having superior esthetics than acrylic prosthetics, and having a realistic look. However, as the prosthesis obtains retention through anatomic undercut, the application of adhesive was not necessary. As a result, the likelihood of an allergic reaction to adhesives was reduced in this instance because more tissue came into contact with the prosthesis.

The use of spectacle was optional for the patient but it was not used specifically as the method of retention for the present patient as he was comfortable with the prosthesis.

The fabrication of the maxillofacial prosthesis is a labor-intensive, artistic process that takes time. Successful prosthetic rehabilitation depends on having a maxillofacial prosthesis that is well-retained, simple to use, and detachable.

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Review Article

Robotics: A Next-Generation Technology in Prosthodontics

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Abstract

The use of robots is increasing in a number of medical specialties, including dentistry, to minimize manual labor and improve the accuracy of procedures. Artificial intelligence and robotics are next-generation technologies that are opening new avenues of growth and exploration for prosthetic dentistry. This article focuses on the applications and advances of robotics in prosthodontics to date. Robotic interventions in prosthodontics are primarily used for the design and fabrication of complete dentures and to support surgical procedures related to dental implantology. In both cases, significant advances have been made that allow procedures to be performed with high success rates and a higher degree of accuracy. The use of robots significantly reduces the time required for each procedure. However, the use of such sophisticated and uniquely designed robots for various prosthetic treatments must be strictly supervised by a qualified dentist. Clinical judgement and professional competence are essential.

Key words: Dental implants, Prosthetic dentistry, Robots, Teeth arrangement, Yomi system

INTRODUCTION

Prosthodontics has been constantly changing and proving that it can adapt to changing requirements. Education, research, and practice of prosthetic dentistry is influenced by the development of newer concepts, technologies, and materials. One of these developments has been the introduction of robots in prosthetic dentistry.[1]

As a result of advances in laboratory technology, biomaterial science, clinical procedures, and multidisciplinary research, prosthodontics has undergone continuous change. Probably, more than any other dental specialty, prosthodontics has demonstrated the ability to evolve in response to changing needs, and it will likely continue to do so.[2]

Playwright Karel Capek first used the word "robot" in his 1921 play Rossom's Universal Robot. The Czech word "robota," meaning forced labor is the origin of the word "robot." In his 1950 science fiction novel I robot, author Isaac Asimov first introduced the interdisciplinary field of engineering and science known as robotics. The Robot Institute of America describes a robot as "a reprogrammable, multifunctional manipulator designed to move materials, parts, tools, or specialized equipment through various programmed motions to accomplish a variety of tasks." Robots can not only increase worker productivity by taking on repetitive, tedious, and dangerous tasks that humans cannot do, but they can also perform tasks that humans are incapable of doing.[1]

Robotic systems are not intended to replace human surgeons but are designed as intelligent surgical tools. They help improve the accuracy, standard, and safety of surgical procedures. Their ability to provide a communication link between preoperative surgical plans and the operating room is perhaps their most valuable capability. Even though all the necessary technologies have been developed and can be easily adapted, robotics in dentistry is still in its infancy. Robots are mainly used in dental implantology and partial and full dentures for tooth arrangement in prosthodontics.

With the advancement of robotics and artificial intelligence theory and the urgent needs of prosthodontics and

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orthodontics, a new type of medical robot has emerged, such as a robot in prosthodontics. Robots in prosthetics can perform the following tasks: Making full or partial dentures and performing dental implantation. The software of the expert system for prosthetics incorporates the extensive knowledge and skills that experienced dentists and dental technicians have acquired over the years.

The fabrication of full or partial dentures as well as dental implants is then made possible by robotics in prosthetics. Robotics in prosthodontics is a completely new application for this technology. Research on robots in prosthetics will also represent a theoretical and technological advance. In addition to realizing the quantification of full or partial dentures, dental implantology, and the development of prosthodontics, their successful application will also represent an advance in relative fundamental theory.[3]

ROBOTS IN THE DENTAL INDUSTRY

Dental Patient Robots

It was discovered that dental patient robots, also known as phantom heads because they only have a simple functional cephalic region and a tooth arrangement, are very different from real patients. Robotic dental patients were first proposed in Japan.[3]

Show Hanako

In order to create a lifelike robot that behaved exactly like a human in its gestures and responses, Showa University collaborated with the robotics company TMSK in the nation's capital. This helped the dental students learn more effectively.[4]

Geminoid DK

The first robot in a series based on characters from countries other than Japan is called Geminoid DK. These remote-controlled robots, known as geminoids, can copy different head motions and facial expressions by using cutting-edge motion capture technology.[4]

Simroid Robot

The Nippon Dental University Kokoro created the Simroid robot, which is used to instruct dentists. It is an improvement over the 2007 robot Simuloid, which was less effective. This robot was created to give dentists emotional feedback, particularly regarding pain and discomfort. It also responds to questions and commands and rates and evaluates the patient's treatment.[4]

DIFFERENT APPLICATIONS

A Tooth Arrangement Robot for Complete Denture

The most important step in the manual, traditional fabrication of complete dentures is to insert the artificial teeth into a dental cushion in the correct position and direction. This work can only be done effectively by specialized dentists and trained technicians. Robotic fabrication of denture systems has now replaced the traditional method. The size of the teeth, the positioning and alignment of the individual teeth in relation to each other, and the curvature of the dental arch differ significantly in complete dentures. The flexibility of a robot is an advantage as it can be configured to fabricate complete dentures.[3]

The Canadian company CRS Robotics Corporation manufactured a robotic system with a single manipulator (Figure 1) and 6 degrees of freedoms (DOFs). This system was then modified to fabricate full dentures (Zhang *et al.*, 2001; Song *et al.*, 2001).

The main components of the system include a CRS robot, an electromagnetic gripper, a computer, a central control system with robot control software for planning and executing movements, a prosthetic base, a light source, and a photosensitive adhesive (Wang and Li, 2001).[3] Robotic arm of the typical CRS robot system is shown in Figure 2.

The robotic system's three-dimensional virtual tooth-arrangement software helps create the patient's medical history data, expert-drawn jaw, and dental arch curves according to the patient's mandibular arch parameters, and dental arch curve adjustments. Once the designed dentitions are displayed in three dimensions, a virtual observation environment is provided and each tooth position can be changed interactively. The robot control software handles the calibration of the tooth arrangement, the initial positioning of the robot, the generation of control data for the tooth arrangement, and the general control of the robot. The maximum load capacity of this robot system is 3 kg; the maximum speed is 4.35 m/s; and the positioning repeatability is 0.05 mm. In the production of a complete prosthetic system for patients, this system was used after its modification. The system is based on the use of a unique photosensitive substance that hardens when illuminated. In this system, standard teeth are selected and implanted in fixed positions by a robot. However, it was found that the system had difficulty accurately gripping and manipulating the artificial teeth.

As a result, better robotic systems with more DOF were developed. An advanced system with 84 DOF and 14

independent tooth manipulators on the dental arch curve was developed as a result of further research (Zhang *et al.*, 2008). The manipulators could move along the tooth tail in either direction to change the position of the tooth on the dental arch. The tooth could be adjusted in position along the X, Y, Z, lingual, rotational, and near-far-mid axes using a tooth arrangement helper with 6 DOF (three rotations and three movements).[5]

This robot can assume any position in the area of the artificial teeth, which solved a number of problems with the previous robot. The fact that this system is driven by 84 independent motors complicates its control, which reduces its efficiency.[3]

Subsequently, 14 independent manipulators, a tooth arc generator, and a sliding path mechanism were used to create a significantly improved robotic system for the 50 DOF tooth arrangement as shown in Figure 3 (Zhang *et al.*, 2011; Zhang *et al.*, 2010). The dental arch curve generated by the dental arch generator corresponds to that in the patient's oral cavity.

The dental arch generator is controlled by the glide path mechanism. The 14 independent manipulators can move along their own tails to compensate for the rotation of each tooth, just like the 84 DOF robotic system. These manipulators each have 3 DOFs, two rotations and one movement, so they can position each tooth in the Z, lingual and near-far-mid directions. Two parallel, rotating vertical rods are located under each manipulator to provide the additional 3 DOFs needed to adjust the tooth in the X, Y and rotational directions. This type of adjustment has helped reduce the system's motor requirements to 50, improving system efficiency. This 50 DOF robotic system for tooth adjustment is simpler and easier to control than previous generation systems and produces a complete denture in as little as 30 min. The system's repeatable positioning accuracy is 0.07 mm for a single manipulator and 0.1 mm for the entire robotic system.[3] The robotic system for total denture fabrication has made great strides in efficiency, but the process still relies heavily on manual labor. The main obstacles to widespread use of the system are its high cost and lack of knowledge about its operation.[3] Virtual prototype for tooth-arrangement robot of Cartesian type is shown in Figure 4.

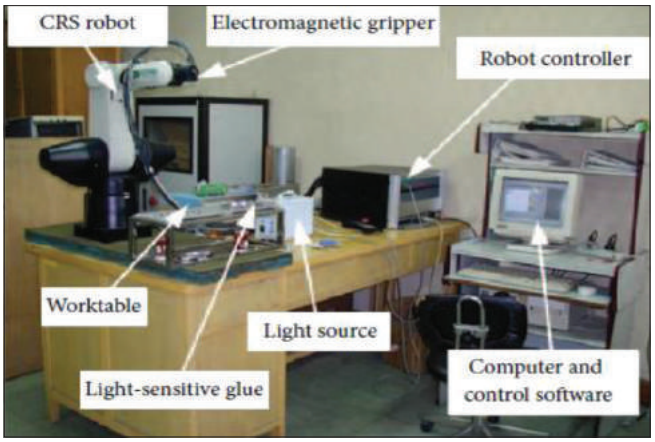

Figure 1: Single manipulator tooth-arrangement robot system for complete denture

Figure 2: Robotic arm of the typical CRS robot system

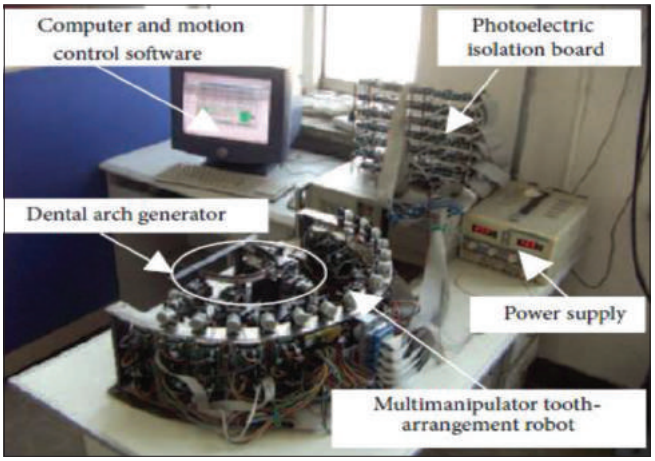

Figure 3: 50 degrees of freedom multimanipulator tooth-arrangement robot system

ROBOTS FOR DENTAL IMPLANT SURGERY

Robotic surgery for dental implants, once found only in science fiction, is now a reality. Robotic systems are not intended to replace human surgeons, but to be used as intelligent surgical tools that help improve the accuracy, quality and safety of surgical procedures. Ecole des Mines de Paris in France and Umea University have developed a robotic workbench for dental implants that covers the entire surgical spectrum from preoperative planning to

Figure 4: Virtual prototype for tooth-arrangement robot of Cartesian type

the operating room. The robot is expected to perform the following tasks in implantology: preoperative 3D reconstruction, path pre-planning and intraoperative image navigation in real time. The structure of the robot should accommodate flexible, image-guided insertion angle and position adjustment in the limited working space.[1]

Developed by Neocis Inc. in the USA and approved by the FDA in 2017, the Yomi robotic system for dental implantology is the first robotic system for dental implantology available on the market.

Preoperative planning and surgical navigation are the two main components of robotic dental surgical systems (Figure 5). Based on the data provided by the patient computed tomography, surgeons have a different perspective in the preoperative planning system. An infrared light-based navigation camera is used by the surgical navigation system to determine where to place the surgical tool. These robots, which continuously track the patient's movements and take control of the drill as the dentist approaches the tissue, can help the surgeon achieve good accuracy. To help the surgeon avoid potential errors, the system continuously monitors the patient.

With the help of monitoring and real-time 3D graphics, the dental procedure can be planned immediately and performed without delay in the dental clinic. Benefits of using these robots include faster healing times and generally safer procedures for dentists as they drill with greater precision. On September 22, 2017, a robotic dentist placed two dental implants in a woman in Southern China, performing the first ever fully automated dental

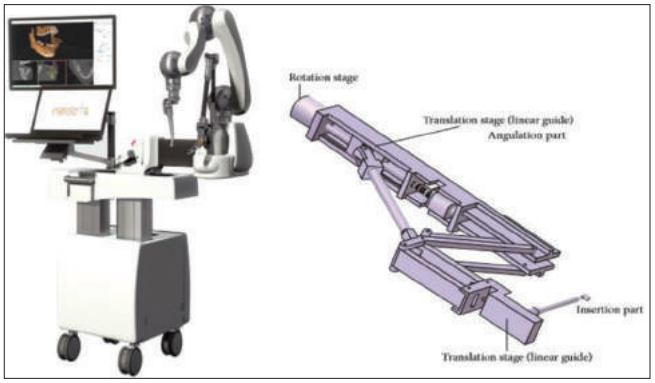

Figure 5: Yomi dental implantology robotic system

Figure 6: World's first fully automated dental implant robotic surgery

implant surgery shown in Figure 6. The entire procedure was supervised by human doctors who did not directly intervene.[1]

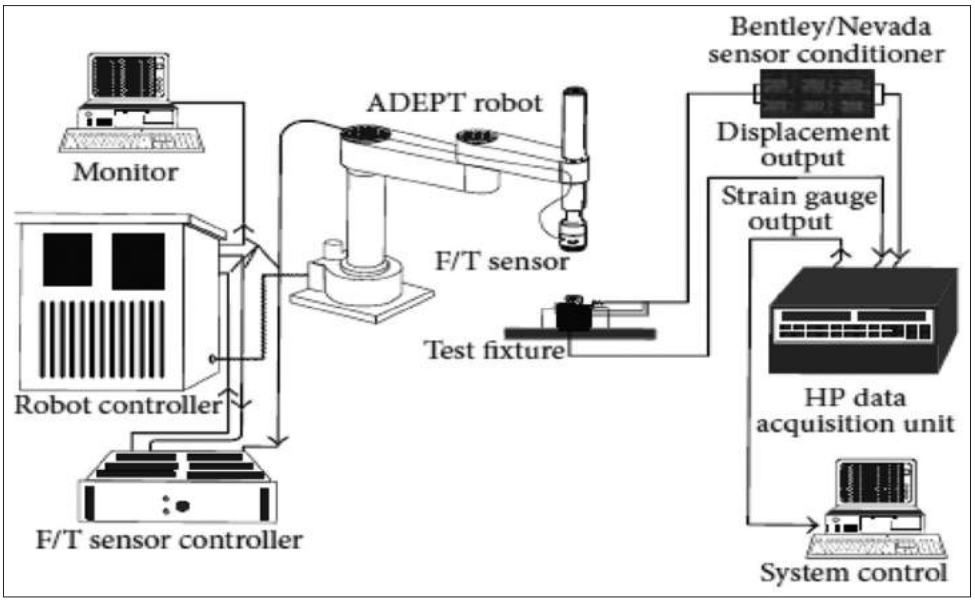

Figure 7: Measurement system for mastication force after dental implantology

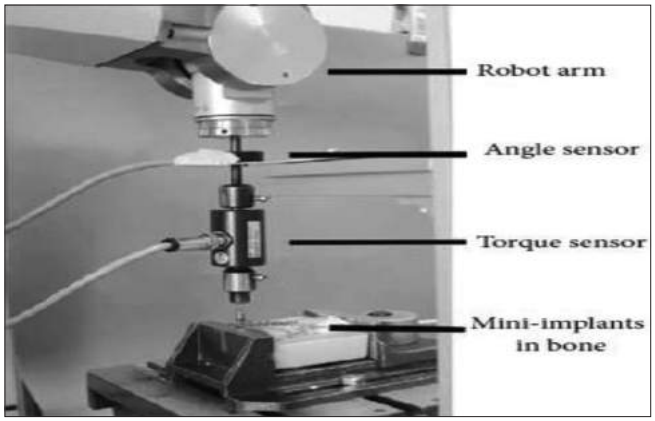

Figure 8: Implant surgery system constructed by the University of Duesseldorf

Robot-assisted Surgical Template Fabrication

Compared to traditionally manufactured surgical guides, robotic-assisted surgical guide manufacturing has led to better clinical outcomes. Robotically fabricated surgical guides can fully control the trajectory of the implant, are less expensive, minimally invasive, and reduce the likelihood of human error in clinical practice.[1]

Dental Masticatory Robots

A robot that can perform at least some specific human masticatory functions is called a "masticatory robot" There are numerous instruments and devices for measuring human masticatory movements. These devices and machines are not sufficient to simulate the full range of complicated movements and functions that occur during mastication. This paved the way for realistic and controllable robotic replication of jaw movements for a variety of applications, including dental education, jaw simulation, and speech therapy. The Dento Munch robotic simulator is an example of a dental masticatory robot. It is a 6 DOF robot for dental test simulations. It consists of the compliance module and artificial jaws. The jaws have been recreated to resemble a human lower and upper jaw with artificial teeth. They can be applied to dental components such as individual teeth, crowns, bridges or an entire denture to simulate the wear of materials and test the effectiveness of the bridge.[1] Measurement system for mastication force after dental Implantology is shown in Figure 7.

The Mouth Training Robot

Robots from the Waseda-Yamanashi (WY) series have been created for the training of temporomandibular joint (TMJ) disorder patients. During a training session for opening the mouth, this robot is used to open and close the patient's mandible. The WY-5 and WY-6 versions are the most sophisticated. The WY-5 robot measures the biting force coming from the patient by using three translational components of the force. A doctor robot with two DOFs (for open/close and forward/backward movements) or three DOFs (for open/close, forward/backward, and right/left movements) remotely controls the robot. The WY robot incorporates muscular EMG measurements to track any changes in the patient's jaw muscle and evaluate robotic therapy.[1]

Waseda Jaw (WJ) Series Robots

In order to comprehend the patient's mastication movement and resistance forces during jaw opening and closing training, the WJ robot is used as a patient robot. TMJ dysfunctions may also be assessed for and treated with the aid of this robot. These robots implement artificially produced clenching and grinding trajectories and have

three DOFs, two artificial TMJs, and two TMJs. Eleven artificial muscle actuators (AMA) that each consist of a set of DC motor, encoder, wire, and force sensor power the robot. The AMA was created to mimic the forces generated during muscle contraction. The motor pulls the opposite end of the tendon, which is attached to one end of the robotic mandible.[1]

Robots for Treating TMJ Disorders

Waseda University in Japan created the oral-rehabilitation robot known as Waseda Asahi Oral-rehabilitation robot No. 1 (WAO1). It is made up of a body with a headrest, two 6 DOF arms with plungers, a control box, a computer, and an automatic massage trajectory generation system with virtual compliance control. By pressing or rubbing a plunger whose motion is automatically computer-controlled, this robot system massages the patient's face. The WAO1 is the first robot that massages a patient's facial tissues, mastication muscles (masseter and temporalis), and saliva-producing oral structures, such as the parotid gland and duct. As a result, it may be used to treat TMJ disorder and dry mouth.[1]

Speech Robots

This was created in 2005 at the Canadian province's university. The two TMJs: one at each end of the jaw are driven by two 3-DOF parallel manipulators. It has been designed to examine how jaw movements affect how we perceive and comprehend face-to-face communication.[1]

Humanoid Practice Robot

The ethical difficulty of using human subjects for clinical training in dental education is a major barrier. Humanoid practice robots were introduced to address this problem. These robots can be mounted on a dental chair and are full-body models. Through computer control, they behave like actual patients and can mimic the gestures and speech of a real patient. When the students receive dental training, they may end up performing ineffective operational procedures, and these reactions, such as pain response, emesis reflex, cough reflex, and irregular pulse, simulate accidents that may happen during treatment. Simroid is a type of humanoid training robot.[1]

Microrobotized Dental Implant Surfaces

In comparison to conventionally treated implant surfaces, microrobotized dental implant surfaces can be used to achieve a higher bone-to-implant ratio and improved biomechanical fixation between the bone and implant.[1]

Nanorobots

Producing robots at or close to the microscopic scale of a nanometer, 1 nm is equal to one millionth of a millimeter, is known as nanorobotics. Nanoimpression material with nano-filler is available for use in prosthetic dentistry. To improve polyvinylsiloxane's flow, reduce the number of voids, and thus provide more precision in the recorded impression and better model pouring, nanofillers are incorporated into the material. Nano robots can also be used in cosmetic dentistry for dentition re-naturalization procedures. They remove outdated amalgam fillings and recreate teeth using biological materials that are identical to the original teeth.[1] Implant surgery system constructed by the University of Duesseldorf is shown in Figure 8.

ROBOTIC ADVANTAGES

1. Greater accuracy and precision.
2. Stable and durable, allowing for continuous use without rest.
3. Capable of correctly processing and evaluating quantitative data introduced into the system.
4. A reduction in surgical errors.

ROBOTIC DISADVANTAGES

1. Lack of situational judgement renders them unable to use any qualitative data.
2. Robotic operations require more resources and have challenging learning curves.
3. There is a high demand for dexterity.

FUTURE REQUIREMENTS

Research into the use of robots in prosthetic dentistry has advanced, but it is not yet finished. In order to optimize the robotic systems with accuracy within the constrained space of the oral cavity, more high-quality research and improvisation are required, according to the state of the art of robot application in prosthodontics. To grasp and precisely position the artificial teeth, a tooth-arrangement robot also needs improvements in sensor and control techniques as well as a highly effective and coordinated control algorithm. Future research for dental implantology robots must concentrate on real-time acquisition, feedback of drilling depth and implant force, and registration between intraoperative navigation image and preoperative reconstruction image. One of the key technologies for controlling the robot's motion in prosthodontics is human-computer interaction. A type of software for human-computer interaction should be created to provide operators with humanization input and feedback to streamline the operation.

CONCLUSION

Although still in its infancy, the use of robots in prosthetic dentistry is no longer speculative. To maximize the

benefits of this great innovation, high-quality research is needed in this era of rapidly evolving ideas and technologies. In the coming years, robotic assistance in prosthetic dentistry will continue to be a hotly debated topic. Under the guidance of an experienced dentist, the use of sophisticated and customized robots helps to improve the accuracy and precision of various prosthetic treatments. However, it is impossible to completely eliminate human intervention. Clinical judgement and professional expertise are essential. Based on their experience and skill, artificial intelligence cannot replace an experienced dentist. In addition to doctors, patients must also be convinced to accept this technology for the benefit of humanity. Within a short time, the use of this artificial intelligence in the diverse field of prosthetic dentistry will be an everyday reality and the subject of intense discussion.

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Original Article

First Dorsal Metacarpal Artery Flap: A Reliable Choice for Thumb Reconstruction

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Abstract

Introduction: Soft-tissue defects of the thumb are very debilitating and require a good durable coverage to give a functional thumb to the patient. Lots of options are available for thumb reconstruction. In this study, we focused on the first dorsal metacarpal artery (FDMA) flap to cover the defects.

Materials and Methods: A prospective study of 7 patients who presented with thumb injury over the period of 2 years is managed with islanded FDMA flap along with treatment for associated injuries and is subsequently evaluated for outcome and followed up to 3 months.

Results: We are able to cover the defects easily in all patients without any undue tension. All flap survived, one developed distal margin necrosis and one developed epidermal loss, and both were managed with dressings. Donor site was covered with split-thickness skin graft and wound over the dorsum was closed primarily.

Conclusion: With careful dissection, FDMA flap is easy to harvest. It provides reliable, durable, and sensate cover with minimal donor site morbidity.

Key words: FDMA flap, Thumb defect, Reconstruction

INTRODUCTION

During the evolution what humans got is specialized function of the thumb, which aid in grasping and lots of other functions. Soft-tissue defects of the thumb are very debilitating and result in more loss of function than injury to any other finger.[1] Hence, soft-tissue defects of the thumb not only required coverage but also we must ensure that a patient gets a functional thumb.

Lots of options are available to reconstruct the defects such as Moberg's flap, Littler's neurovascular island flap, cross finger flap, pulp tissue transfer of toe, and other small free flaps. In this study, we focused on the first dorsal metacarpal artery (FDMA) flap for thumb reconstruction and its outcomes.

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FDMA flap was first described by Hilgenfeldt in 1961 and Holevich in 1963 as a peninsular flap with preservation of skin over the pedicle.[1] In 1979, Foucher and Braun described it as an island flap.[2,3]

The FDMA is a constant vessel arising from the radial artery. The artery is located deep in the first dorsal web space overlying the ulnar half of the first dorsal interosseous muscle. Venous drainage of the flap is through two venae comitantes that are in connection with large cutaneous superficial veins in the first intermetacarpal space.

MATERIALS AND METHODS

This prospective study was performed at our institution from January 2021 to April 2023; during this period, 7 patients presented with soft-tissue defect of the thumb. They all are evaluated and planned for FDMA flap.

Surgical Technique

Out of 7 patients, 6 are done under regional anesthesia and one under general anesthesia. Tourniquet was used in all patients. The first thorough debridement was done.

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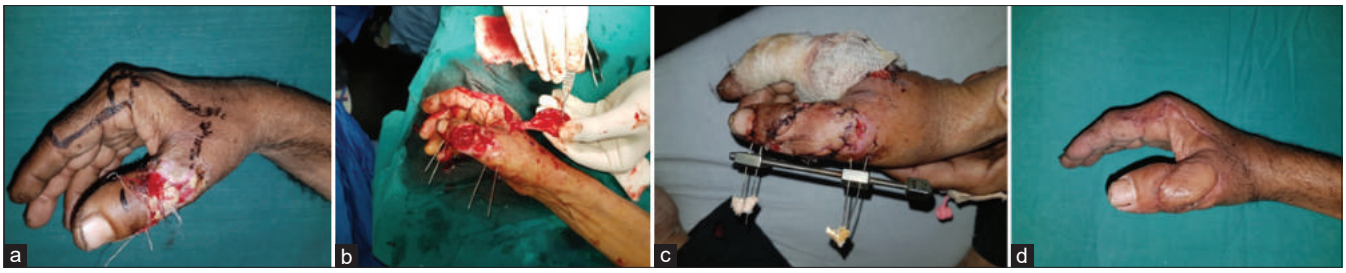


Figure 1: (a) defect over the dorsum of RT thumb with flap markings, (b) intraoperative bony fixation with flap elevation, (c) after 7th post-OP day, (d) after 3 months with good aesthetically appearing flap

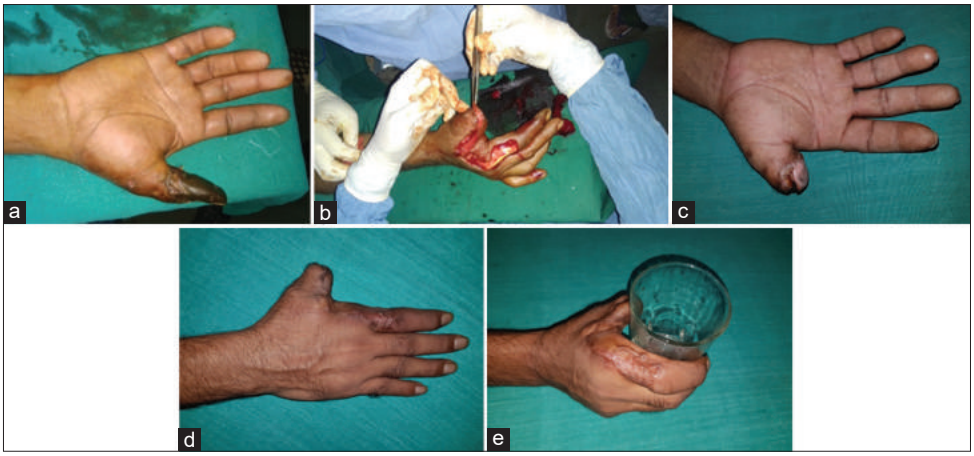


Figure 2: (a) RT distal thumb gangrene, (b) after distal amputation and flap elevation, flap easily reached the distal margin and covered the defect, (c) distal margin necrosis, (d) well-healed flap and donor site after 3 months, (e) patient is able to hold glass and do his routine work

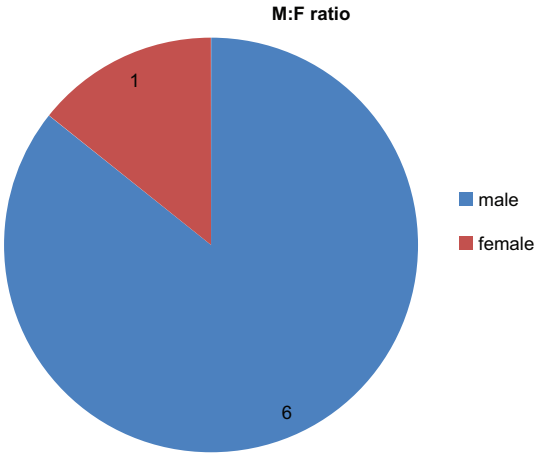
Associated bony injuries are fixed properly. Then, size of defect is measured and extrapolated on the dorsum of the index finger. Planning in reverse was done to ensure the flap reaches and cover whole the defect easily and tension free. Then, incision is placed first over the dorsum of index finger and flap is elevated from distal to proximal and carefully above the paratenon of extensor tendon and dissection continues once we reached the proximal limit, then a lazy S incision is placed over dorsum of the hand. Dermal flap is raised on both the side of the incision. Next flap is lifted and dissection continues proximally carefully dissecting the pedicle. At this stage, one can see the first dorsal interossei muscle and we include some fibers in the muscle to ensure that no damage was done to pedicle. Once flap is elevated, tourniquet was released and flap is check for bleeding. Then, a subcutaneous tunnel was made and flap is transferred to defect site and insetted. Donor site is covered with split-thickness skin graft (STSG) and incision over dorsum is closed primarily. Dressing was done. Post-operatively, hand elevation is done for 48 h. All patients were discharged after graft dressing on the 5th post-operative day. Sutures were removed on 10–14th post-operative day. This was followed by a course of physiotherapy for 6 weeks in all patients. The patients were instructed to come for post-operative follow-up every month for 3 months. All patients were evaluated for the occurrence of early post-operative complications in terms of flap necrosis, hematoma, infection, wound dehiscence, and graft loss.

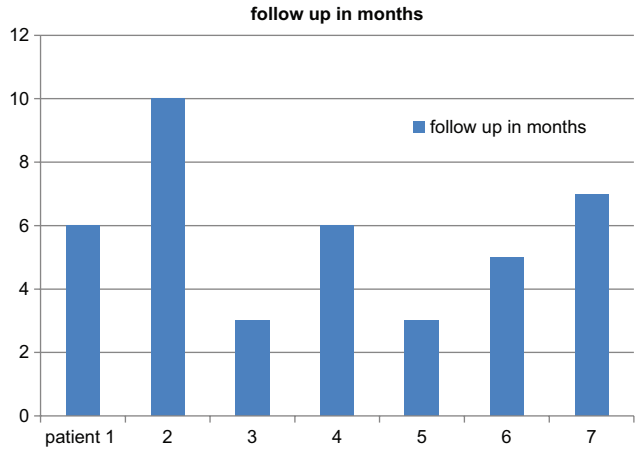
RESULTS

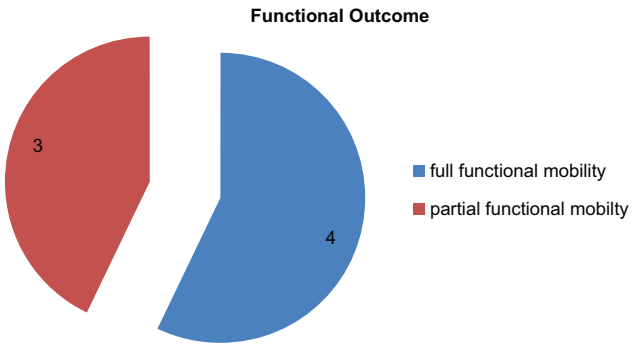
During this period, seven 1st dorsal metacarpal artery island flaps were used for the reconstruction of complex post-traumatic soft-tissue thumb defects in seven cases with an average age of 39.4 years. The subject data and outcomes are summarized in Table 1. The flap sizes ranged from 21 × 13 mm to 31 × 22 mm (mean 25.8 × 17.1 mm). Five flaps survived completely and one had distal flap margin necrosis that was treated conservatively and healed by secondary intention, and one had distal half epidermal loss, which again manages by dressings. All the recipient and donor areas were healed uneventfully. The mean follow-up period was 5.7 months (range 3–10 months). The functional outcome, four had full functional recovery while 3 had partial owing to underlying bony injury. They were pleased with the cosmetic appearance of the flap and donor site.

Table 1: Clinical data

Age/sex	Flap Size(mm)	Flap site	Associated injury	complication	Functional recovery	Follow-up (months)
45 y/M	26×13	Rt dorsal	Nil	Nil	Full	6
50 y/M	24×14	Lt dorsal	Nil	Nil	Full	10
26 y/M	29×18	Rt dorsal	NIL	Nil	Full	3
55 y/M	31×22	Rt dorsal	IP Jt disruption and tendon injury	Nil	Partial	6
7 y/F	21×13	Rt dorsal	IP Jt disruption	Distal half epidermal loss	Partial	3
45 y/M	29×21	Rt volar	Distal amputation	Distal margin necrosis	Partial	5
48 y/M	21×19	Rt volar	Nil	Nil	Full	7







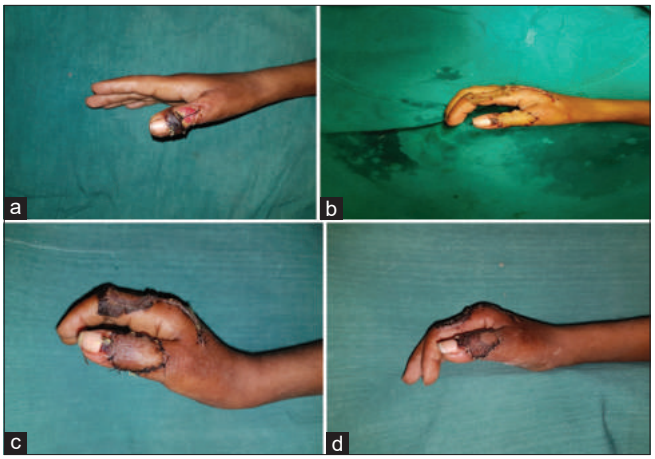


Figure 3: (a) right thumb dorsal defect, (b) immediate post-OP after flap inset, (c) 7th post-OP day, (d) after 3 weeks

Case 1

A 55-years-old male presented with a history of road traffic accident, resulting in defect over the dorsum of right thumb with IP Jt disruption, he was managed with distraction and FDMA flap, and has good post-operative recovery with partial functional outcome owing to joint injury, and nonetheless, he was able to do his routine work.

Case 2

A 45-years-old male presented with partial amputation of RT thumb at IP Jt, initially managed with replantation, which eventually fail. Later on, distal amputation of RT thumb and coverage with FDMA flap was done. He has good recovery and able to do his routine work.

Case 3

A 7-years-old female presented with defect over the dorsum of the right thumb along with thumb IP Jt disruption, and the patient was treated with FDMA flap and K-wire fixation of IP Jt was done [Figures 1-3].

DISCUSSION

Lots of options are available to reconstruct the thumb defects such as Moberg's flap, Littler's neurovascular island

flap, cross finger flap, pulp tissue transfer of toe and other small free flaps and groin flap, abdominal and other distant flaps. All the above-mentioned options have their merits and demerits. Local flaps offer superior esthetic results due to the replacement "like with like" tissue.[4]

In this study, we focused on FDMA flap and its outcomes. We were able to cover the defect in all the patients, without any undue tension. Five out of seven flaps survived completely. One developed distal margin necrosis, which was managed with dressing and other developed loss of epidermal tissue over distal half of the flap, which was again managed with dressing.

Ghoraba and Mahmoud,[5] in their study of 15 flaps, 14 flaps survived completely while one developed distal necrosis and they also managed it with dressings. Satish and Nema[6] used 9 FDMA flaps to cover post-traumatic thumb defects and found that the mean flap size was 33.3 × 19.4 mm and only one flap had partial necrosis that healed without secondary procedure.

As compared to groin and abdominal flap, FDMA flap has many advantages as it is a single-stage procedure with minimal donor site morbidity and also we need not to immobilize the hand in awkward position and also stiffness of joints occurring as a result can be avoided.

Donor site is covered with STSG, which heals without any complication and there is no morbidity related to donor site. Ratcliffe *et al.*[7] and Cil *et al.*,[8] in their respective studies also, have no morbidity related to donor site.

As the thumb is major factor in hand function, any repair of the thumb defect must also restore functional integrity. In our study, four patients attained full functional range of motion of their thumb and are able to do their work while three patients had partial recovery owing to underlying bony and tendon injuries although they are able to do their work. In literature, there are no much studies evaluating functional outcomes after FDMA flap and comparing it with other options available.

CONCLUSION

We conclude that FDMA flap is a good option for thumb defect reconstruction as it provides "local and like" tissue and with no donor site morbidity. Flap is easy to harvest and is able to cover the most of the defects, whether dorsal or volar. We recommend more studies with large number of patients and longer follow-up to assess the functional integrity.

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Original Article

Outcome Analysis of Breast Cancer Patients - A Retrospective Study

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Abstract

Introduction: Breast cancer is one of the most common cancers in women and is the second leading cause of cancer-related death in women. Survival rate can be used as a yardstick for assessing the standard of any cancer therapy and this helps in developing cancer-related policies and programs.

Purpose: To find out 5-year survival of breast cancer patients treated in the year 2014 at Government Medical College, Kozhikode, and to evaluate the prognostic factors and the difference in survival based on the stage of presentation.

Methods: A retrospective audit of breast cancer managed in the year 2014 was carried out and now reporting 5-year disease-free survival (DFS), overall survival, and prognostic factors of patients treated at Government Medical College, Kozhikode.

Results: This study included 369 breast cancer patients with ages ranging from 20 to 90 years with a median age of 50 years. Two hundred and twenty patients had early breast cancer and 149 had locally advanced breast cancer (LABC). A 5-year DFS in exhaled breath condensate (EBC) was 91.5% and in LABC was 62.2%. The 5-year overall survival in the EBC group was 92.3% and in the LABC group was 65.7%. The factors adversely affecting survival were found to be tumor size, number of positive nodes, hormone receptor negativity, and lymphovascular space invasion.

Conclusion: The survival rates in the study were comparable with documented Indian studies. Tumor size, node positivity, lymphovascular space invasion, and hormone receptor negativity are important negative prognostic factors for breast cancer.

Key words: Breast cancer, Disease-free survival, Overall survival, Prognostic factors

INTRODUCTION

Breast cancer is a leading cancer and second-leading cause of cancer-related death in women. In India, the crude rate and age-adjusted risk vary from 12.7–34.8 to 13.9–41/100,000 population across several states, according to the Indian Council of Medical Research sponsored population-based cancer registry program. A report stated that cancer caused 5% of disability-adjusted life years in the Indian population in 2016. During the last decade, breast cancer has been rising steadily in India, and in 2012, it was the most common cancer among women in India, a way ahead of cervical cancer.

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Data on the clinical profile of early breast cancer in India are scant. Due to differences in genetics, environment, lifestyle, socio-demographic structure, and ethnicity, the presentation and behavior of breast cancer in India may be diverse. Early breast cancer patients usually with a painless breast mass or an abnormal screening mammogram. Advanced tumors may have skin changes, bloody nipple discharge or occasionally changing size and shape of the breast.

Several features help predict the probability of successful outcome after treatment of breast cancer. The established prognostic factors for this condition include histological subtype, tumor grade, estrogen receptor status, HER2/neu amplification, lymphovascular invasion, genetic profile, age, race obesity, and body mass index of which the most important being the size of the primary tumor and status of the regional lymph node. Survival rates can be used as a yardstick for assessing the standards of any cancer therapy. This help in developing cancer-related

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policies and estimating baseline survival rates in each patient population.

This retrospective analysis is intended to evaluate the 5-year survival rate and prognostic factors of carcinoma breast in patients who were initiated on treatment in 2014 at the Government Medical College, Kozhikode. The 2014 data give us a snapshot of trends over the last 7 years and outcomes of patients managed as per the guidance and evidence-based medicine

METHODS

Newly diagnosed breast cancer patients from stage I to IIIC are included in the study. A retrospective audit of carcinoma breast cases registered in the year 2014, using the details in the master file of the patients kept in the department was carried out. Detailed data collection including patient age, presenting symptom, menstrual status, parity, family history, the initial stage of presentation, pathological stage, hormone and Her2 status of the patient, grade, lymph-vascular space invasion (LVSI) status, treatment details and type of surgery were obtained from master file kept in the department. Patients' follow-up details for 5 years of diagnosis were collected. The details of recurrence, if any, were collected from the clinical examination details of the patient, radiological investigations, and histopathology report from the master file. Three hundred and sixty-nine patients' details were used for the final analysis. Usual workup for newly diagnosed breast cancer patients includes complete blood count, biochemistry with mammogram, and pathology confirmation. In locally advanced breast cancer (LABC), a metastatic workup including chest X-ray, ultrasonography abdomen/computed tomography thorax and abdomen are done. Early breast cancer patients are offered breast conservation if there are no known contraindications. Those who were not eligible for conservation or did not choose it proceeded with modified radical mastectomy (MRM). If the patient presents with LABC or a tumor breast ratio inadequate for conservation, then neoadjuvant chemotherapy followed by surgery is done. All patients who were operated for breast cancer underwent axillary clearance. Patients with Her2/Neu-positive breast cancer were offered neoadjuvant and adjuvant trastuzumab. Pre-menopausal women with hormone receptor-positive disease received 5 years of adjuvant tamoxifen, while post-menopausal women were given 5 years of aromatase inhibitor, letrozole. All women who underwent breast conservation surgery were given adjuvant radiation to the involved breast. In case of high-risk, patients this is followed by a boost to the tumor bed. Post-mastectomy women with T1T2N0 Stage were not offered adjuvant radiation unless they got neoadjuvant chemotherapy. All women with lymph node positivity and those who received neoadjuvant chemotherapy received adjuvant radiation to the chest wall and supraclavicular fossa. Follow-up after treatment done by careful history and physical examination done every 3 months for 3 years, followed by 6 months for 2 years and annually thereafter. The diagnostic mammogram was done every 6 months for the first 2 years, followed by yearly thereafter. Statistical analysis was done using IBM SPSS statistics software. Descriptive and inferential statistical analysis have been carried out in the present study. Frequencies and percentages have been used for variables. The Kaplan–Meier estimator was used to estimate the survival function. Log-rank test was used to assess the statistical significance of univariate analysis. The Cox hazard regression model was used for multivariate analysis to assess the impact of individual prognostic factors on survival.

RESULTS

The complete data set consists $n = 369$ observations who were diagnosed with carcinoma breast in the year 2014 and treated with a radical indent (stage I, II, and III). The time scale used in the study is "month since diagnosis to 60 months."

Descriptive Data

A total of 369 patients were studied, of which 59.6% (220) had early breast cancer and 40.4% (149) had LABC.

Patients above the age of 20 years were included in the study. The median age of the study population was 50. In exhaled breath condensate (EBC) group 164 (75.56%) out of 220 patients presented within 3 months of onset symptoms, 28 (12.21%) patients between 3 and 6 months, and 28 (12.21%) after 6 months of onset of symptoms. Among LABC patients 79 (52.02%) out of 145 presented within 3 months of the onset of symptoms, 36 (25%) patients between 3 and 6 months, and 34 (22.9%) after 6 months of the onset of symptoms. Of 369 patients studied, 164 (44.2%) were in the reproductive age group and 205 (55.8%) were post-menopausal. In both groups, most of the patients were post-menopausal females and 11% (41) were nulliparous. A positive family history of breast-ovarian malignancies was found in 7.9% of studied patients. The commonest histological type of breast cancer was infiltrating ductal carcinoma in the population studied. Most of the patients in EBC were Grade 2. In LABC Grade 1 tumor. About 48.5% of patients were node negative on pathological examination. This include patients who received neoadjuvant chemotherapy and

patients who were taken up for upfront surgery. About 23.6% of patients had lymph vascular space emboli. Among EBC patients 17.72% had LVSI and among LABC patients 32.21% had LVSI. About 59.1% of the patients were ER-positive this include 141 patients in the EBC group and 77 patients in the LABC group. The majority of ER-positive tumors were in the EBC group. Her2/Neu amplification was seen in 95 (25.7%) patients. About 45% of Her2/Neu-positive patients were in the EBC group and 54.7% in the LABC group. Among early breast cancer patients, 91.4% (202) underwent MRM surgery and 8.5% (19) underwent breast conservation surgery. In the LABC group, 96.62% of patients (144) underwent MRM and 3.4% (5) had BCS. Post-surgery margin positivity was seen in 6 (2.7%) of early breast cancer patients and 3 (6%) of LABC patients. About 23.3% of patients received electron beam RT and 47.2% received photon beam RT. Of the total 95 Her2/Neu-positive patients, 79 completed anti-Her2/Neu targeted therapy. About 29.5% of patients took endocrine therapy with tamoxifen and 30.1% of patients took letrozole therapy. Recurrence in the form of local recurrence or distant failure was studied in both groups separately. Among the early breast cancer group, 18 patients out of 220 had disease recurrence within 5 years of follow-up (8.1%). In LABC group, 54 patients had disease recurrence (36.24%). Two patients in the EBC group developed locoregional recurrence. In the LABC group, 9 patients out of 149 had a locoregional recurrence in the form of chest wall, axillary, or supraclavicular lymph node recurrence. The most frequent sites of metastasis in EBC patients were bone and lung. About 5 patients had bone and lung secondaries in 5 years. In LABC patients bone secondaries were the most common form of metastasis followed by brain metastasis.

Survival Analysis

Kaplan–Meier is used for estimating the overall survival and the Cox regression model to analyze how covariates affect survival disease-free survival (DFS) was assessed separately in EBC and LABC. Patients in EBC had significantly better disease-free survival than LABC, as expected. From the Kaplan–Meier estimator, 5-year DFS for EBC was 91.5 (95% CI 87.776–95.224), and 5-year DFS for LABC was 62.2 (95% CI 53.968–70.432) [Figure 1]. A total of 70 deaths occurred during the study period –18 deaths in the EBC group and 52 deaths in the LABC group. Twelve deaths were due to breast cancer-unrelated causes. The 5-year overall survival in the EBC group was 92.3% (95% CI 88.77–95.828) [Figure 2]. The 5-year overall survival in the LABC group was 65.7% (95% CI 60.35–74.746). Cerebrovascular and cardiovascular were the leading causes of cancer-unrelated deaths.

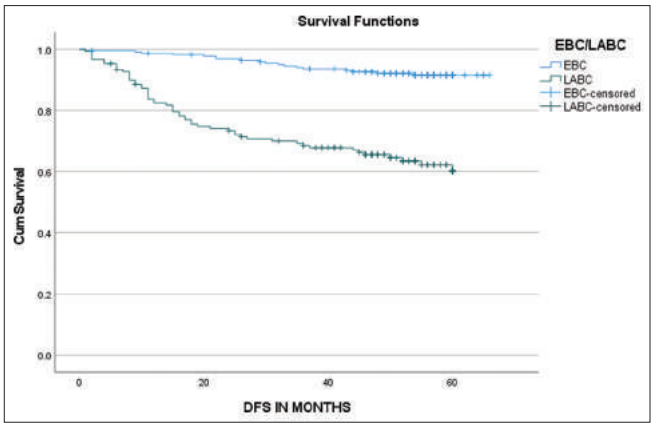

Figure 1: Disease-free survival of the study population

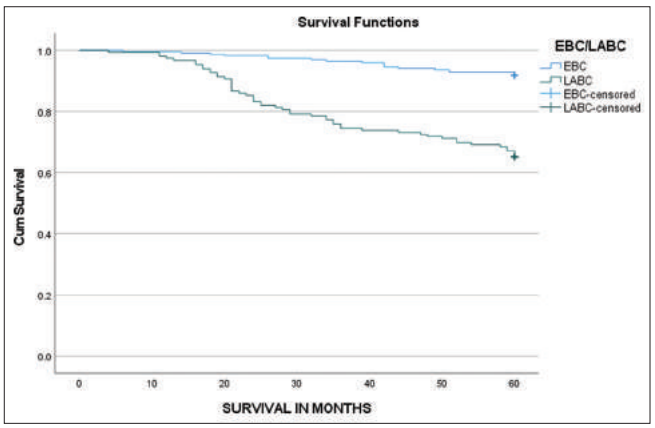

Figure 2: Overall survival of the study population

Univariate analysis of the whole study population showed that the association of tumor size, number of nodes, grade, ER status, and LVI with survival was statistically significant. Menstrual status, HER 2-amplification status, and adjuvant radiation did not show a statistically significant association with survival [Table 1]. Univariate analysis in EBC patients showed that LVSI and ER status were significantly associated with survival. However, menstrual status, HER 2-amplification status, and grade of tumor were not significantly associated with survival [Table 2]. Univariate analysis in LABC patients showed that LVSI and ER status were significantly associated with survival. However, menstrual status, HER 2-amplification status, and grade of tumor were not significantly associated with survival [Table 3].

In multivariate Cox regression analysis, tumor size (heart rate [HR] 2.714, 95% CI 1.947–7.776, $P < 0.001$), nodal status (HR 2.668, 95% CI 1.288–5.530, $P = 0.008$), and LVSI (HR 3.306.95% CI 1.757–5.247, $P < 0.001$) emerged as factors associated with poor prognosis independent of others. ER-positive status (HR 0.591, 95% CI 0.359–0.973, $P = 0.039$) was found to be protective [Table 4].

Table 1: Summary of univariate analysis of all the patients

Variable	Subgroup	Number	Overall survival %	*P*-value
Tumor size	≤2 cm	48	89.6	<0.001
	2–5 cm	189	86.2	
	>5 cm	73	83.6	
	Local infiltration	59	54.2	
Number of positive nodes	0	179	91.6	<0.001
	1–3	107	80.4	
	3–9	57	64.9	
	>9	26	46.2	
ER	Positive	218	87.2	<0.001
	Negative	151	72.2	
HER2	Positive	95	76.8	0.233
	Negative	274	82.5	
Grade	G1	90	90.0	0.047
	G2	191	77.5	
	G3	88	79.5	
LVSI	Present	87	62.1	<0.001
	Absent	282	86.9	
Menstrual status	Menstruating	164	82.3	0.604
	Post-menopausal	205	80.0	
Adjuvant radiation	None	109	88.1	0.079
	Electron	86	79.1	
	Photon	174	77.6	

LVSI: Lymph-vascular space invasion

Table 2: Summary of univariate analysis in EBC

Variable	Subgroup	Number	Overall survival %	*P*-value
ER	Positive	141	95.0	0.017
	Negative	79	86.1	
HER2	Positive	43	91.5	0.756
	Negative	177	93.0	
Grade	G1	79	91.1	0.398
	G2	103	90.3	
	G3	38	97.4	
LVSI	Present	39	76.9	<0.001
	Absent	181	95.0	
Menstrual status	Menstruating	101	94.1	0.275
	Post-menopausal	119	89.9	

EBC: Exhaled breath condensate, LVSI: Lymph-vascular space invasion

Table 3: Summary of univariate analysis in LABC

Variable	Subgroup	Number	Overall survival %	*P*-value
ER	Positive	77	72.7	0.023
	Negative	72	56.9	
HER2	Positive	52	63.5	0.842
	Negative	97	66.0	
Grade	G1	11	81.8	0.469
	G2	88	62.5	
	G3	50	66.0	
LVSI	Present	48	50.0	0.007
	Absent	101	72.3	
Menstrual status	Menstruating	63	63.5	0.698
	Post-menopausal	86	66.3	

LABC: Locally advanced breast cancer, LVSI: Lymph-vascular space invasion

DISCUSSION

Survival analysis is a branch of statistics for analyzing the expected duration of the time for one event to occur. In this study, the following methods are used for calculating the probability of survival of breast cancer patients after 5 years of diagnosis.

1. Kaplan–Meier curve - plot to visualize the survival curve
2. Log-rank test to compare survival curves between two groups
3. Cox proportional hazard regression to describe the effect of variables on survival.

The statistical significance level is taken as $P < 0.05$. The results are described by hazard ratio, confidence interval from the summary of the Cox model, and *P*-value.

Table 4: Multivariate analysis using Cox proportional-hazards model

Variable	Hazard ratio	95% confidence interval	*P*-value
Tumor size (T1, T3)	2.714	1.947–7.776	<0.001
Nodal status (N0, N3)	2.668	1.288–5.530	0.008
Grade (G1, G3)	1.286	0.880–1.878	0.193
LVSI (Present, Absent)	3.306	1.757–5.247	<0.001
ER Status (Positive, Negative)	0.591	0.359–0.973	0.039
HER2 NEU (Positive, Negative)	0.659	0.372–1.141	0.134
Margin Status (Positive, Negative)	1.666	0.789–3.514	0.180
Post-op RT (None, Photon)	0.440	0.174–1.114	0.083

The table model was significant at a *P*<0.001

A hazard ratio >1 indicates that there is an incremental change in hazard in that category in relation to the reference category. In our study, 59.6% of the total study population

were early breast cancer and 40.4% were LABC. Most patients in India are diagnosed at an advanced stage as per the cancer statistics 2020 report on national cancer registry programs.[1] Our data show slight EBC predominance because we excluded all metastatic cases at presentation and patients who are unfit for treatment with a radical indent from the study. Cancer awareness programs and health education measures also have led to increased awareness among women in Kerala and the stage at which they present to health-care facilities improved compared to the past.

The maximum number of patients were in the 40–50 years age group in our study. Epidemiological studies at global and regional levels suggest breast cancer occurs at younger premenopausal ages in Indian and Asian women. Indian women having breast cancer are found to be a decade younger than Western women.[1] Cancers in young tend to be more aggressive. India may face a potential breast cancer epidemic over the next decade as our population adopts major lifestyle changes in diet, exercise, late marriage, bearing children at a later age, and decreasing parity and breastfeeding. This warrants a screening program for Indian women which should be started earlier than the Western population standard considering this age shift.

About 44% of patients in our study population were premenopausal. In EBC and LABC groups, most patients were post-menopausal. Recent studies show a significant increase in breast cancer rates among premenopausal subjects. In a study, the risk of developing breast cancer increased in both pre- and post-menopausal patients who had early onset of menarche and late menopause possibly due to the increase in the duration of hormonal exposure.[2]

In the general population, about 5–10% of breast cancer cases are due to inheritance of highly penetrant cancer susceptibility genes BRCA1 and BRCA2.[3] Our study also shows that positive family history of breast-ovarian malignancy was present in 7.9% of the study population. Inherited breast and ovarian cancer tend to occur at younger ages.

Special types of invasive carcinomas were rare in our study population. About 96% of all patients had infiltrative ductal carcinoma. Asian and Indian women had more invasive ductal carcinoma and less invasive lobular carcinoma than the Caucasian population, according to SEER data 2010. This may be due to a lower use of post-menopausal hormone treatment in these patients. A study from India done by Goel *et al.* also shows infiltrating ductal carcinoma in >90% of patients.[4]

On analyzing tumor size in our study population, a maximum number of patients had tumor sizes 2–5 cm. Studies show a combination of clinical examination with mammography and breast ultrasound for better estimation of tumor size for staging purpose.[5] In a study reported from India by Nair *et al.* maximum patients had tumors of size between 2 and 5 cm.[6]

Most of the patients in the study population had grade II tumors. 46.8% of patients with EBC and 59.06% of patients with LABC had grade II tumors.

Most of our patients (48.5%) had pathological negative axillary lymph node status as neoadjuvant chemotherapy might have down-staged axilla before surgery. Studies show an approximately 23% chance of lymph node metastasis even in T1 patients. Multivariate analysis in a study done by Andreas Barth *et al.* showed LVSI nuclear grade and tumor size are independent predictors of axillary lymph node metastasis.[7]

In our study population, 23.6% of patients had LVSI. A study done by Ryu *et al.* showed that LVI was present in 34.8% of breast cancer patients.[8] Zhao *et al.* conducted a study on the prognostic role of LVSI and found LVSI in 40% of the study population.[9]

In our study population, 64% of patients in EBC and 51% in LABC were ER-positive. A study done by Nair *et al.* showed similar results-hormone receptor positivity was seen in 64% of EBC and 51% of LABC.[6] A multi-institutional study from India in 2020 showed that ER-positive tumors constitute 64.1% in the Indian population.[10]

HER2/NEU amplification was seen in 19% of EBC and 34% of LABC patients. It was 17% of EBC and 36% of LABC in the study conducted by Nair *et al.*[6] There is lot of heterogeneity in HER2 receptor positivity among Indian population which ranges from 16% to 36%.[11]

In our study, 8.5% of EBC patients and 3.4% of LABC patients underwent breast conservation therapy. Very low rates of BCS have been reported in India from most centers mainly because of the unacceptability of the safety of conservative surgery by patients and reluctance to undergo post-operative RT. However, Nair *et al.* had shown a BCS rate of 63% among EBC patients.[6]

Post-operative margin positivity was seen in 2.7% of patients in EBC and 6% of patients in LABC. Microscopic involvement of resected margin was associated with an increased risk of local recurrence following breast conservation surgery and hence every effort should be made to achieve negative margins intraoperatively.[12]

In our study, 29.5% of patients did not have indications for adjuvant RT. About 23.3% and 47.2% received electron beam RT and photon beam RT, respectively. Allocation to these various groups was based on department protocol.

Of the 95 HER2/NEU-positive patients, 79 completed HER2/NEU-targeted therapy with Trastuzumab. Cardiac comorbidity and financial constraints were the reasons for incomplete therapy.

About 29% of the patients took endocrine therapy with Tamoxifen and 30% received Letrozole based on menstrual status. Major switching trials showed greater recurrence reduction in patients taking an AI during any point in the trial, even with varied treatment regimens. Overall, AI's reduced recurrence rates by nearly 30% compared to tamoxifen in all studies.[13]

In a study done by Bartelink *et al.*, the recurrence rate in EBC was 7.3%.[14] Klein *et al.* showed a recurrence rate of 31% in LABC.[15] Our study showed a recurrence rate of 8.1% and 36.24% in EBC and LABC, respectively.

About 18 patients out of 220 EBC patients and 54 out of 149 LABC patients developed recurrence within 5 years of diagnosis. Bone metastasis was the most frequent site of metastasis in the both EBC and LABC. Metastasis of breast cancer cells to bone consists multiple sequential steps. Once breast cancer cells arrest in bone, bone is a storehouse of a variety of cytokines and growth factors, and thus provides an extremely fertile environment for the cells to grow.[16]

Survival analysis included 369 patients, of which 220 had EBC and 149 had LABC. DFS of the study population was assessed separately in EBC and LABC. DFS of patients with EBC was significantly better than LABC patients as expected. About 5-year DFS in EBC was 91.5% and in LABC was 62.2%. In a study done by Nair *et al.*, 5-year DFS in EBC was 85.5% and in LABC was 67.7%.[6]

During the study period, 70 patients died in the study population. Eighteen deaths were in the EBC group and 52 in the LABC group. Tweleve deaths were due to breast cancer-unrelated causes. Cerebrovascular accidents and cardiovascular diseases were the leading causes of cancer-unrelated deaths.

In univariate analysis of our study, factors adversely affecting overall survival were found to be tumor size, number of positive nodes, ER-negative status, high grade of tumor, and LVSI. On sub-group analysis, it was found that tumor grade did not affect survival in both EBC and LABC groups. Other than tumor grade, all the above-mentioned factors were significantly associated with survival in both groups.

The multivariate analysis using Cox proportional hazards model was done to assess the impact of individual factors on survival in the study population. The analysis showed that tumor size, node status, ER status, and LVSI had a significant impact on survival independent of other factors tested. The study showed patients who had T3 tumors at presentation is having a 2.7 times probability of death compared to patients with T1 tumors. Similarly, the N3 node at presentation is having 2.6 times the probability of death compared to node-negative patients. The hazard ratio for LVSI was 3.3 in the study population.

Nodal status was found to be the primary prognostic discriminant of breast cancer survival by Fisher *et al.*, in 1983.[17] Carter *et al.* reported two of the most important prognostic indicators for breast cancer to be tumor size and extent of axillary lymph node involvement.[18] Elston and Ellis showed from their study that histological grade forms part of the Nottingham prognostic index, together with tumor size and lymph node stage can be used to stratify individual patients for appropriate therapy.[19] Elston *et al.* studied the effect of vascular invasion on recurrence and survival and concluded that histological assessment of vascular invasion provides independent prognostic information.[20]

ER positivity was found to be protective with a hazard ratio of 0.59 among the patients studied. In a study from Kerala done by Vettuparambil *et al.*, hormone-receptor status showed a statistically significant association with overall survival and the highest mortality was found among ER/PR-negative patients.[21]

Margin positivity, HER2/NEU status, and post-operative RT failed to show any effect on survival in the Cox regression model. EBCTCG metanalysis 2011 showed an absolute reduction in breast cancer mortality by 3.8% with adjuvant RT at 15 years.[22] Hence, a long-term follow-up of these patients may be needed to confirm the survival benefit of adjuvant RT.

CONCLUSION

The 5-year overall survival of breast cancer patients treated with a radical indent at Tertiary cancer care center Kozhikode in the year 2014 was 92.3% in the early breast cancer group and 65.7% in the LABC group. The DFS in early breast cancer patients was 91.5%, while LABC patients were 62.2%.

In this study, the tumor size, node status, ER status, and LVSI showed a significant impact on survival. These results were comparable with documented Indian studies.

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Original Article

Analysis of P53 Protein Expression in Odontogenic Cyst – An Immunohistochemical Study

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Abstract

Introduction: p53 is a tumor suppressor gene which arrests the cell cycle at G1 phase. At this phase, it allows the repair of possible DNA damage and prevents the cell cycle progression to S phase. In normal cells, it is found at low level whereas its expression is elevated in many tumor. Hence, p53 is used as a marker of neoplasia, malignancy, and tumor progression.

Purpose: The aim of the study was to evaluate the expression of P53 protein in biopsy specimen of Odontogenic Keratocyst (OKCs), Dentigerous cyst (DCs), and Radicular cyst (RCs) by immunohistochemistry (IHC) to know the biological behavior of these cases.

Materials and Methods: This study is carried out in histopathologically diagnosed 15 cases of OKCs, 10 cases of DCs and 10 cases of RCs that were formalin fixed, processed, and paraffin embedded. Sections of 4-micron thickness were cut from paraffin embedded tissue blocks and stained with IHC marker p53 following standardized protocol. The presence of brown colored nuclear reaction at the site of target antigen was considered immune positive for p53.

Results: In our study, we found in OKCs, the intensity of p53 expression was more for supra basal layers (46% in the supra basal layers showed intense positivity) than basal and superficial layers. In DCs and RCs, the more intensity of p53 expression in basal layer than supra basal and superficial layers was found.

Conclusions: p53 was over expressed in OKCs compared with other lesions. Mutations in the p53 gene yield a p53 protein which has an increased half-life, thus allowing this mutated protein to be detected immunohistochemically. p53 protein is related to cell proliferation activities in OKCs.

Key words: Dentigerous cyst, Immunohistochemistry, Odontogenic cysts, Odontogenic Keratocyst, p53 protein, Radicular cyst

INTRODUCTION

Odontogenic cysts are the cysts which arise from the enamel organ or their remnants.

Odontogenic cysts are because of second most common lesions in the oral and maxillofacial specimens, it has an important role in oral and maxillofacial pathology.[1] The three common odontogenic cysts include odontogenic keratocysts (OKCs), dentigerous cysts (DCs), and radicular cysts (RCs).[2] OKCs and DCs are developmental origin whereas RCs are the result of inflammation.[3]

The p53 protein is a nuclear protein with a molecular weight of 53 kilodalton, which is coded by the p53 gene located on chromosome 17. This tumor suppressor gene has a valuable role in apoptosis, cell cycle, regulation of cell proliferation, and genetic stability.[4-6] The p53 protein is a regulative factor of many processes necessary for the proper functioning of cells, and it corresponds to a number of processes associated with its life and death. The p53 protein regulates the repair of cellular DNA and induces apoptosis when the damage of the gene is too serious and it is impossible to repair. This protein is also

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responsible for the regulation of the senescence of cells and the cell entering and leaving the subsequent stages of the cellular cycle.

Under normal conditions, p53 protein is continuously formed. It binds to the MDM2 protein and forms MDM2/p53 complexes in the nucleus and then this complex exported to the cytoplasm followed by degradation by proteosomes. The cell concentration of p53 maintained low through this process. Thus, the increase in p53 protein concentration does not depend on gene activation, transcription, and translation, but rather on inhibition of its degradation. Under stress, certain types of protein are released from the nucleus to the nucleoplasm, where it binds to MDM2 or to the MDM/p53 complex, blocking p53 export to the cytoplasm and later preventing its degradation, which results in the accumulation of the p53 protein in the nucleus.[7]

Mutations in the p53 gene yield a p53 protein which has an increased half-life, thus allowing this mutated protein to be detected immunohistochemically.[8,9]

Over expression of p53 protein in the lining epithelium of OKCs compared to DCs and RCs has been documented in a few articles.[10-13]

In this study, p53 protein expression will be noted in OKCs, DCs, and RCs to know the different behavior of OKCs than other cysts of oral cavity.

MATERIALS AND METHODS

An immunohistochemical study was done on total 35 histopathologically diagnosed cases (15 cases of OKC, 10 cases of DC, and 10 cases of RC) that were formalin fixed (10% formalin for 24–48 h), processed and paraffin embedded. These cases were retrieved from the Department of Oral Pathology and Microbiology by random sampling. Ethical clearance was taken from ethical committee.

Inclusion Criteria

The following criteria were included in the study:

1. Non-inflammatory OKCs and DCs cases
2. Only primary cases are included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Recurrent cases and syndromic cases
2. Patients with multiple OKCs
3. OKCs and DCs with neoplastic changes are excluded from the study
4. Cases of orthokeratinized odontogenic cyst were also excluded from the study.

Immunohistochemical Staining with p53 Protein Using Universal Immunohistochemistry Staining Kit (Biogenex)

Sections of 4 μm thickness were taken on Poly-L-Lysine adhesive coated glass slides and kept in universal hot air oven at 60°C for 60 min for proper attachment of tissue to the slides. Sections were treated with three changes of xylene 5 min each, rehydrated with descending grades of alcohol (100%, 80%, and 50%) 3–5 min each, washed twice with Tris-buffer solution 2 min, kept in 0.3% peroxidase solution for 7–10 min to block the endogenous peroxidase activity, washed again with Tris-buffer solution for 2–3 min.

Antigen retrival (using EZ Antigen Retrival Solution 2) was done in pressure cooker at 95°C temperature for 60 min. Slides were arranged on racks of immunostain humidity chamber, washed with Tris-buffer 2 times, and rounded the pap pen in surrounding tissue.

Protein block (Background sniper) was applied for 5 min to minimize the nonspecific binding of antibodies (blot only step, no washing), primary antibody p53 protein applied and incubated for 1 h and 30 min in immunostain humidity chamber. The slides were washed with Tris-buffer twice, power block mouse probe was applied for 15 min and washed again with Tris-buffer twice. SS Label Universal HRP Polymer was applied for 30 min, washed with Tris-buffer twice and diaminobenzidine tetrahydro chloride chromogen working solution was applied for 1–2 min at room temperature. Slides were washed with deionized water, counterstained with Harris hematoxylin for 1 min (5–7 dips), dehydrated by passing them through ascending grades of alcohol (50%, 80%, 100%), cleared in three changes of xylene 2 min each, and mounted in DPX using coverslips.

The intensity, pattern of distribution, and localization of the immune reactive cells were determined using trinocular light microscope with digital camera (Motic). Images were captured by digital camera attached with light microscope and analyzed using image analysis software (ij152-win-java8 imageJ). Examination was carried on trinocular light microscope (Motic) with provision for photomicrograph with SC 600, 6MP digital microscope camera. Five different areas of the epithelium were selected under low power magnification (×10) of light microscope. These representative areas should have sufficient number of cells. Positively stained cells were assessed per high power field (×40) of light microscope qualitatively by grading the immune reactivity in four grades scoring system. The intensity of p53 expression was scored varying from 0, 1, 2, 3. Here, 0 was being defined by negative and 1, 2, and 3 as being weak, moderate, and intense, respectively.

RESULTS

Table 1 represents mean age of the subjects. For OKC, the minimum age was 15 years and maximum was 47 years, for DC, the minimum age was 12 years and maximum was 45 years and for RC, the minimum age was 8 years and maximum was 45 years. The result was statistically non-significant for the values between the groups ($P > 0.05$).

Table 2 denotes distribution of different groups according to gender. In OKC, DC, and RC 66.7%, 90%, and 40% were male, respectively, whereas 33.3%, 10%, and 60% cases were female for OKC, DC, and RC, respectively.

Table 3 shows that in OKC maximum cases involved posterior mandible and DC, the most common site involved was anterior maxilla and posterior mandible. Most of the RC cases were found in the posterior mandible. There was a statistically non-significant difference seen for the frequencies between the groups ($P > 0.05$).

Table 4 shows comparison of qualitative analysis of p53 expression in basal layer of OKC, DC, and RC. Intensity of p53 expression in basal layer was weak in 11 cases of OKC, moderate expression in four cases of DC and weak to moderate expression in RC. There was a statistically non-significant difference seen for the values between the groups ($P > 0.05$).

Table 5 shows comparison of qualitative analysis of p53 expression in supra basal layer of OKC, DC and RC. The intensity of p53 expression in supra basal layer was intense in seven cases and moderate expression in five cases of OKC. In DC, the intensity was weak in five cases and weak to negative expression in RC. There was a statistically significant difference seen for the values between the groups ($P < 0.05$).

Table 6 shows comparison of qualitative analysis of p53 expression in superficial layer of OKC, DC, and RC. The intensity of p53 expression in superficial layer was weak to negative in OKC. In DC and RC, the intensity was negative. There was a statistically non-significant difference seen for the values between the groups ($P > 0.05$).

Table 7 shows qualitative analysis of p53 expression in different layers of OKC, DC, & RC. In OKC, the intensity was more for supra basal layers than basal and superficial layers [Figure 1]. In DC, the more intensity in basal layer than supra basal and superficial layers [Figure 2]. In RC, the more intensity in basal layer than supra basal and superficial layers [Figure 3]. The result was statistically highly significant for the values in each the groups ($P > 0.05$).

DISCUSSION

Odontogenic cyst is a cyst of jaws originated from odontogenic apparatus or its remnants. Being the second most common lesions in the oral and maxillofacial specimens, it has an important role in oral and maxillofacial pathology. There are three common odontogenic cysts including OKCs, DCs, and RCs.[1]

The p53 is one of the most common tumor suppressor genes located on the short arm of chromosome 17.[14,15] The disturbed function of p53 results in uncontrolled proliferation of the cell. Mutations of p53 are present in more than 50% of malignant tumors and are commonly related to the decreased differentiation of cells and early recurrence.[16]

In this study, comparison of p53 expression between OKC, DC, and RC was done to assess the aggressiveness of cysts.

It was found that in this study, the highest mean age in OKC 27 ± 9 years and lowest in RC 25.1 ± 14.8 years and in DC was 25.4 ± 10.3 years where as in Gaballah and Tawfik[17] study, the mean age was 37 ± 16.1 years, 31 ± 20.2 years, and 33 ± 15.8 years in OKC, DC, and RC cases, respectively. In this study, we take this age group because most common age of occurrence for cysts is this age.

The predominance of males in cases of the present study was reported in OKC and DC cases and female predominance was reported in RC cases where as the predominance of males in all the odontogenic cyst cases was reported in Ochsenius *et al.*,[18] Tortorici *et al.*[19] studies.

We saw that the most common site for OKC was posterior mandible, for DC anterior maxilla and posterior mandible

Table 1: Intergroup comparison of mean age

	n	Mean	SD	SE	95% CI for mean		Minimum	Maximum	*F*	*P*
					Lower bound	Upper bound				
OKC	15	27.73	9.043	2.335	22.73	32.74	15	47		
DC	10	25.40	10.352	3.273	17.99	32.81	12	45	0.208	0.813#
RC	10	25.10	14.881	4.706	14.46	35.74	8	45		

CI: Confidence interval, SD: Standard deviation, SE: Standard error, OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

Table 2: Intergroup percentage distribution and comparison according to gender (male and female)

	Group			Total
	OKC	DC	RC	
Sex				
Female				
Count	5	1	6	12
Percentage within sex	41.7	8.3	50.0	100.0
Percentage within group	33.3	10.0	60.0	34.3
Male				
Count	10	9	4	23
Percentage within sex	43.5	39.1	17.4	100.0
Percentage within group	66.7	90.0	40.0	65.7
Total				
Count	15	10	10	35
Percentage within sex	42.9	28.6	28.6	100.0
Percentage within group	100.0	100.0	100.0	100.0

OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

Table 3: Distribution of different groups according to clinical site involved

Site	Group			Total
	OKC	DC	RC	
Ant. maxilla	2	4	3	9
Ant. mandible	1	1	0	2
Ant. and post-maxilla	2	1	1	4
Post-mandible	9	4	5	18
Post-maxilla	1	0	1	2
Total	15	10	10	35

Chi-square tests	Value	df	*P*
Pearson Chi-square	4.148[a]	8	0.844

OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

Table 4: Comparison of qualitative analysis of p53 expression in basal layer of OKC, DC, and RC

Intensity of p53 expression	Group			Total
	OKC	DC	RC	
0	2	1	0	3
1	11	3	5	19
2	2	4	5	11
3	0	2	0	2
Total	15	10	10	35

Chi-square tests	Value	df	*P*
Pearson Chi-square	11.295[a]	6	0.080

OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

and for RC was posterior mandible. Similar finding was seen by Carvalhais *et al.*[20] in OKC and RC cases.

In the OKCs, the p53-positive ratios of cells in the lining epithelium revealed remarkably high values; about 77.33% in the basal layer showed weak positivity, 46% in the supra basal layers showed intense positivity, 53% in the superficial layers showed weak positivity. Although these results cannot be compared directly with previously reported

Table 5: Comparison of qualitative analysis of p53 expression in supra basal layer of OKC, DC, and RC

Intensity of p53 expression	Group			Total
	OKC	DC	RC	
0	1	3	2	6
1	2	5	8	15
2	5	1	0	6
3	7	1	0	8
Total	15	10	10	35

Chi-square tests	Value	df	*P*
Pearson Chi-square	19.396[a]	6	0.004

OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

Table 6: Comparison of qualitative analysis of p53 expression in superficial layer of OKC, DC, and RC

Intensity of p53 expression	Group			Total
	OKC	DC	RC	
0	8	9	8	25
1	7	1	2	10
Total	15	10	10	35

Chi-square tests	Value	df	*P*
Pearson Chi-square	4.457[a]	2	0.108

OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

Table 7: Qualitative analysis of p53 expression in different layers of OKC, DC, and RC

Layers	*n*	Mean	SD	SE	*F*	*P*
OKC						
Basal layer	15	1.00	0.535	0.138	24.662	0.000**
Suprabasal layer	15	2.20	0.941	0.243		
Superficial layer	15	0.47	0.516	0.133		
DC						
Basal layer	10	1.70	0.949	0.300	10.218	0.000**
Suprabasal layer	10	1.00	0.943	0.298		
Superficial layer	10	0.10	0.316	0.100		
RC						
Basal layer	10	1.50	0.527	0.167	20.053	0.000**
Suprabasal layer	10	0.80	0.422	0.133		
Superficial layer	10	0.20	0.422	0.133		

OKC: Odontogenic keratocyst, DC: Dentigerous cyst, RC: Radicular cyst

data because the methods used were different as used by Ogden *et al.*,[11] Muzio *et al.*[21] and Kimi *et al.*,[22] they revealed that in OKCs, the p53-positive ratios of cells in the lining epithelium revealed remarkably high values; about 66% in the basal, 72% in the intermediate, and 45% in the surface. We found that the highest p53 positive ratio was seen in the supra basal layer was in accord with previous reports by Ogden *et al.*[11] and Kimi *et al.*[22] This was seen because the cells constituting the intermediate or supra basal layers possess the highest proliferative activity in the OKCs. Low p53 expression in surface layers is because of apoptosis in surface layers.

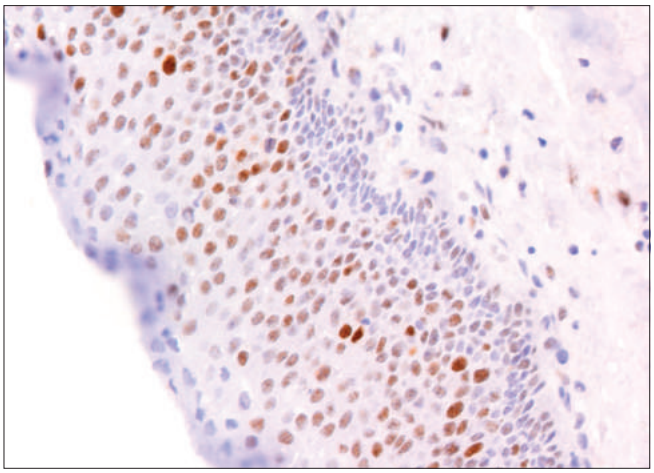

Figure 1: p53 protein stained section of odontogenic keratocyst (×40)

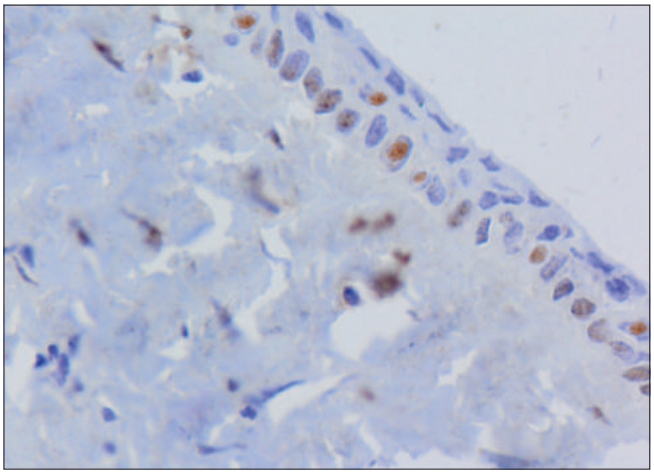

Figure 2: p53protein stained section of dentigerous cyst (×40)

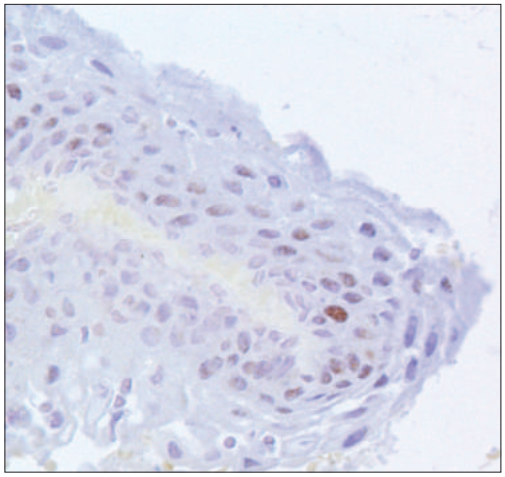

Figure 3: p53protein stained section of radicular cyst (×40)

In the DCs, the p53-positive ratios of cells in the lining epithelium revealed remarkably high values; about 40% in the basal layer showed moderate positivity, 50% in the supra basal layers showed weak positivity, 20% in the superficial layers showed weak positivity. The results found out by Kichi *et al.*[23] (2005), Piattelli *et al.*[13] (2001), and Li *et al.*[12] (1996) were in accordance with our result. It was seen because of high mitotic activity in basal layer.

In the RCs, the p53-positive ratios of cells in the lining epithelium revealed remarkably high values; about 50% in the basal layer showed moderate positivity, 80% in the supra basal layers showed weak positivity, 20% in the superficial layers showed weak positivity. The results found out by Kichi *et al.*[23] (2005), Piattelli *et al.*[13] (2001), and Li *et al.*[12] (1996) were in accordance with our result. It was seen because of high mitotic activity in basal layer.

There was a statistically significant difference between in each layer of three types of cyst ($P < 0.001$) [Table 7].

In our study, we found high expression of p53 in OKC compared to DC and RC because the greater proliferation activities of the epithelial lining in OKC. A p53 gene mutation may be one of the causes of cell proliferation.

CONCLUSION

Our results show a statistically higher occurrence of p53 in OKCs, compared with DCs and RCs. Thus, it can be stipulated that p53 protein expression can be used as a prognostic marker in odontogenic cyst suggest that p53 overexpression may be involved in the pathogenesis of some odontogenic cysts and tumors.

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Original Article

Efficacy of Ultrasound-Guided Interventions in Musculoskeletal Pathologies

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Abstract

Ultrasound (USG) is being increasingly used for the detection of MSK pathologies. Moreover, USG is further utilized for guided interventions such as therapeutic injections, tenotomies, releases, and hydrodissections. Our study is aiming to determine the usefulness of such ultrasound-guided injection (UGI) techniques and comparison of UGI with landmark-guided intervention techniques.

Key words: Arthritis, Injection, Landmark, Musculoskeletal, Tendinopathy, Tendinosis, Tenosynovitis, Ultrasound

INTRODUCTION

Although, USG is operator-dependent and has limited FOV, ultrasound (USG) is extensively utilized to diagnose disorders of bone, joints, tendons, muscles, ligaments, blood vessels, and nerves as well as to guide interventions such as aspirations, diagnostic or therapeutic injections, tenotomies, releases, hydrodissections, and biopsies [Figure 1]. This is because it gives better visualization of soft tissues, no radiation or contrast exposure, ease of performance, repetition, less expense, portability, and better patient cooperation.[1-4]

MATERIALS AND METHODS

We performed our study in a multispeciality 200 bedded hospital on 100 patients on OPD basis [Figure 2].[5] We have a decent emergency and orthopedic workload. The patient who had joint pains, bursitis, inflammatory arthritis, tenosynovitis, chronic tendinopathy, carpal/tarsal tunnel syndrome, and osteoarthritis were selected.

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Two equal groups were made: first once was the ultrasound-guided injection (UGI) group and second was the landmark-guided injections (LGI) group in which the injections were made after recognizing the surface anatomic landmark by palpation method. In the UGI group, screening by high-resolution USG machine, anatomical planes were observed and accurate placement of the needle was done. The USG machine used was Toshiba Aplio with a high-frequency (9–14 MHz) linear transducer. THI and electronic steering functions were routinely used. Doppler was used occasionally for localized cystic lesions to rule out vascular pathology. USGs were always performed by the same sonologist while the same experienced radiologist did the UGIS, which were injections (Steroid/local anesthetic agents in the joint, in peritendinous region, and in bursal collections), needle aspiration, needle lavage – barbotage, and hydrodissection. Common injection sites apart from joints were the subacromial bursa, long head of biceps tendon, tendoachilles, 1st compartment extensor tendons of the wrist, pes anserinus tendon, Hamstring tendon, medial and lateral epicondyles, and plantar fascia [Figure 1].

For injections, the mixture of bupivacaine-methylprednisolone was made by a 25G needle after ruling out drug allergies. Dynamic viewing of the needle into the joint space or peritendinous area was monitored for the accurate positioning of the needle tip [Figure 1]. Caution was made to avoid neurovascular bundle or tendon injury. Patients were assessed at the time of the procedure, 1 month and 3rd for pain, range of movement, tenderness,

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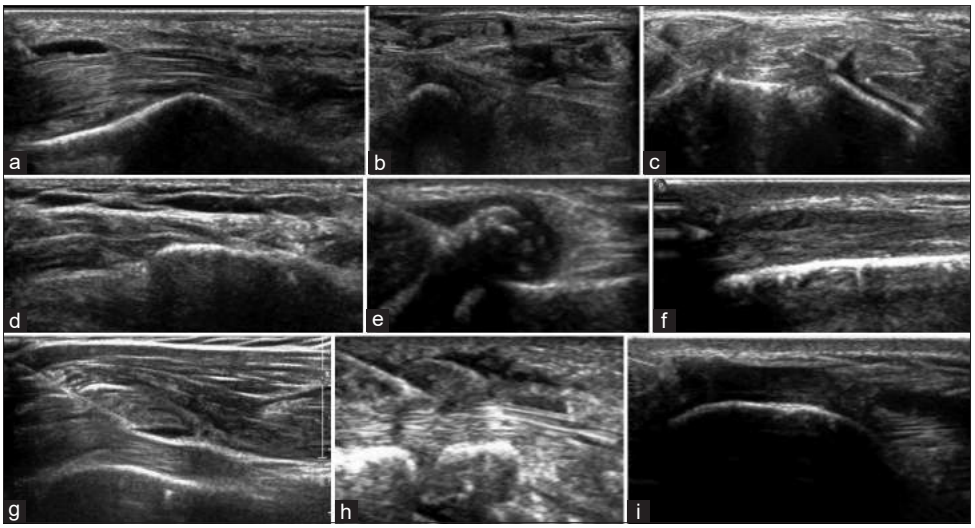

Figure 1: Ultrasound-guided injection; (a) PTT peritendinous, (b) peroneal peritendinous, (c) MTP joint, (d) subacromial, (e) – barbotage, (f) intersecting peritendinous, (g) LHB peritendinous, (h) tibialis anterior peritendinous, (i) rotator cuff peritendinous

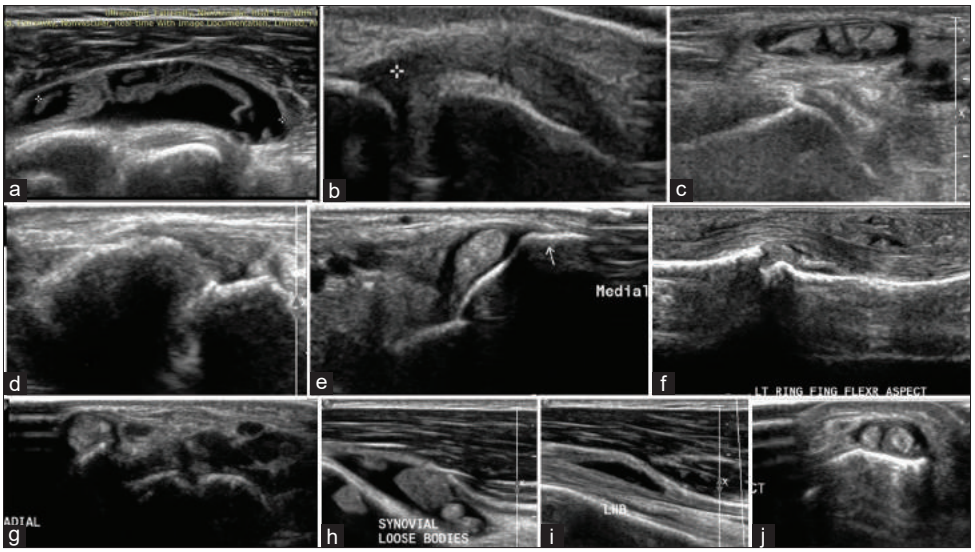

Figure 2: Depicting various MSK pathologies; (a): bursitis, (b): MTP arthritis, (c and d): ACJ arthritis, (e) PTT peritendinitis, (f) trigger finger, (g) tenosynovitis, (h) synovitis, (i) LHB tendinitis, and (j) Quervain's tenosynovitis

improvement in routine functioning, and work activities. The parameters were noted in patients' file. Furthermore, LGIs were performed for ACJ and SIJ, the results were compared to UGIS.

RESULTS

In our study, the most common procedure was peritendinous infiltration followed by joint injections and thereafter hydrodissection.[6] The most common joint was shoulder to target. Joint injections were usually single in ankle, MTP, ACJ, SIJ, and wrist joints. Very few multiple joint injections are made in ankle and subtalar or TMT and MTP joints. The accuracy of UGI group was more precise due to high-resolution soft-tissue differentiation [Figure 1]. Furthermore, the performing radiologist was single, experienced, and skilled. The procedure time of UGI was shorter and periprocedural pain was far less than UGI.[7] UGI was better than LGI only in passive abduction ROM but not in active abduction ROM, pain VAS, and shoulder disability. Efficacy UGI was better than LGI in most of the procedures, except for a few joint injections like SIJ and ACJ.[8,9] Overall, cost-effectiveness of UGI was less. LGI needed more OPD visits and sittings.[10,11]

DISCUSSION

In the last one decade, MSK US studies increased by 3 times and USG-guided procedures by 7 times.

Parameters	UGI	LGI
Procedure time	8–10 min	15–20 min
Peri-procedural pain	Mean score of three out of 10-point scale	Mean score of 6/7 out of 10-point scale
Accuracy	90–95%	60–80%
Post-procedure immediate pain relief	*90%	70%
ROM	*85% (>160°)	65% (<120°)
Efficacy	More than 80%	Around 65%
Safety	More than 97%	Around 60%

*Wrist, SIJ, and ACJ were the exceptions in which the results were almost equal, LGIs: Landmark-guided injections, UGI: Ultrasound-guided injection

UGI was associated with significantly greater improvement in pain, function, and ROM outcomes. UGI was associated with significantly greater improvement in pain, function and ROM outcomes; thereby reducing the need for repeated steroid injections, mainly in tendinous and peritendinous pathology.[7] UGI was safer than blind injections by avoiding neurovascular structures, tendon, less needle trauma, and ability to dilate/hydrodissect with local before injection. UGI was also proved to be more efficacious than LGI in shoulder impingement syndrome outcomes. UGI had higher accuracy for most of the interventions, especially in fluid aspiration and total volume of aspirated fluid. UGI group at the 3-month follow-up revealed less architectural distortion of the anatomical planes in the UGI group. UGI was more accurate than LGI (100% vs. 75.8%) in and around the wrist and ankle joint. UGI significantly reduced procedural pain by half due to higher accuracy of the tissue infiltrated and lesser needle punctures. UGI reduced the cost of patient in OPD setup per year due to fewer hospital OPD visits and high response rates.

Around the wrist, the UGI group had immediate pain relief (within 1st week); however, the ROM and function remained the same in the two groups. No significant differences between the 2 groups in injecting symptomatic SIJ and ACJs were noted since the joints were more superficial and accessible.

CONCLUSION

As compared to LGI, UGI has higher accuracy, safety, reduced procedural time, reduced discomfort, higher short-term clinical outcome in terms of pain reduction, improved function as well as ROM in tendinopathy, bursitis, carpal tunnel area, and large joint osteoarthritis.

Becoming the preferred modality for MSK interventions especially in sports medicine Moreover, US-guided interventions will evolve to perform advanced procedures and USG surgical techniques in the future.

Limitations

Long-term outcomes could not be evaluated due to poor patient follow-up, heterogeneity of joint pathology, and variable treatment modes. The need for large blinded clinical trials in the future is warranted.

DISCLOSURES

None.

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Original Article

Two Stage Superiorly Based or Inferiorly Based Retroauricular Flaps in Partial Ear Defects

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Abstract

Background: Partial ear defects present a unique challenge in reconstructive surgery due to their complex anatomical characteristics and aesthetic importance. Various surgical techniques have been developed to restore the helical rim contour and provide optimal outcomes. One such technique involves the utilization of retro-auricular flaps either superiorly or inferiorly based, which offer several advantages, including a reliable blood supply, inconspicuous donor site, and versatility in flap design. This study provides a comprehensive review of retro-auricular flaps in partial ear defects, outlining their indications, surgical techniques, and outcomes.

Key words: Inferiorly based, Partial ear defect, Retro-auricular flaps, Superiorly based

INTRODUCTION

Partial ear defects can arise from various causes and pose challenges in reconstructive surgery due to their intricate anatomy and aesthetic significance. The absence of certain parts of the auricular region is a significant esthetic problem. Cartilage reconstruction procedures are performed on over one million patients in the developed world each year.[1] Several approaches have been proposed to restore the helical rim contour and achieve favorable functional and cosmetic outcomes. Reconstructive plastic surgery techniques, including primary repair, local flaps, regional flaps, and skin grafts, can be used to manage the defect. Extensive injuries often require multistage procedures for optimal repair.[2]

Two-stage superiorly and inferiorly based retro-auricular flaps have become popular due to their availability and ability to address various defects along the helical rim, scapha, and antihelix. The donor site for these flaps includes the superior ear, posterior ear, and mastoid area.[3]

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The advantages of this flap include the availability of similar tissue, robust vascularity, and no need for cartilage, resulting in inconspicuous scarring.[4,5] However, the main disadvantage lies in the two-stage procedure and the inclusion of hair-bearing skin in the flap.[6,7]

These flaps are particularly useful in cases with limited tissue laxity or compromised blood supply. They can be used for both acute and delayed reconstructions, allowing flexibility in timing surgical intervention.[4]

MATERIALS AND METHODS

This study enrolled 21 patients (9 females and 12 males) with partial ear defects treated between March 2022 and February 2023 at our institution. Informed consent was obtained before surgery, and patients were categorized based on age, gender, etiology, location of the flap, and area of the defect. Wounds caused by human bites and traumatic injuries were considered dirty wounds with a high risk of infection, so wound rinsing and cleaning were mandatory. Devitalized wound edges were carefully excised. Prophylactic measures, including anti-tetanus vaccination in acute settings and antibiotic administration 1 h before surgery, were implemented. Postoperative follow-up was conducted at 4 and 8 weeks.

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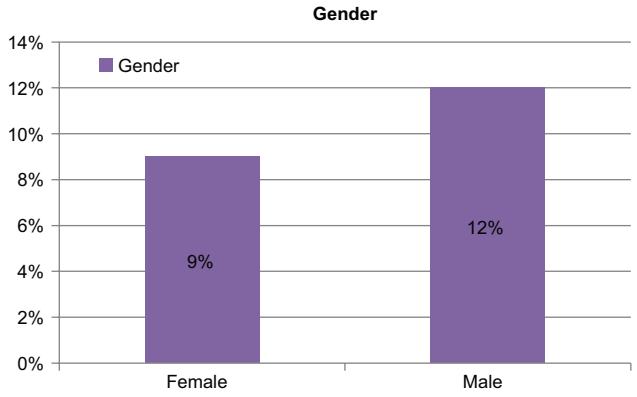
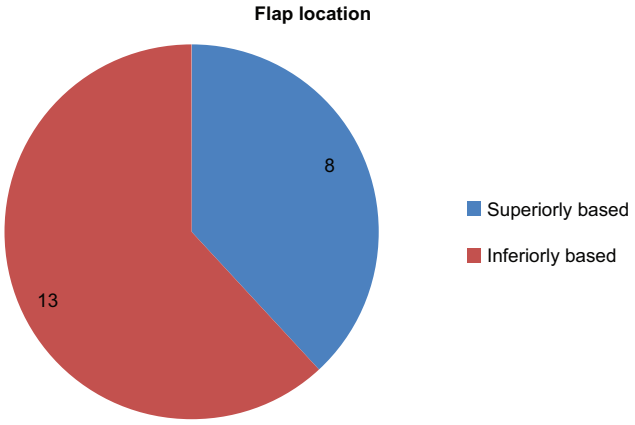




Surgical Technique

All patients underwent reconstructive surgery for ear defects using either general anesthesia or local anesthesia following thorough preoperative planning. The scar margin of the helical rim defect was exposed, and with the help of proper marking and a predetermined pattern, a flap was raised either superiorly or inferiorly based on the desired outcome. The flap was raised above the fascia to ensure a rich blood supply and adjusted to an appropriate length based on the mobility required.

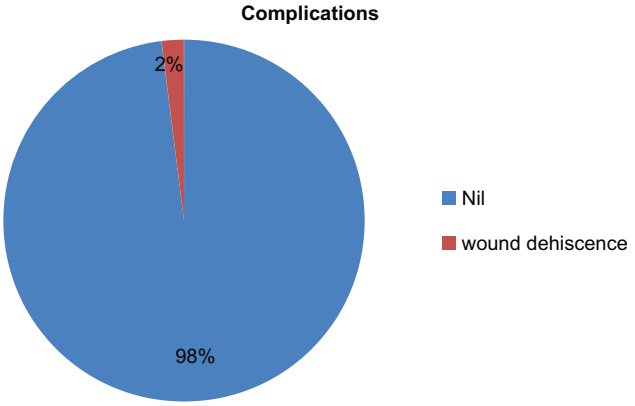
Subsequently, the anterior margin of the flap was approximated to the anterior edge and the posterior margin to the posterior edge of the denuded helical defect using multiple interrupted sutures (5–0 ethilon). The second stage of the procedure was performed 3 weeks after the initial surgery. During this stage, the flap was detached with caution, ensuring complete coverage of the entire defect, and then repositioned using fine non-absorbable sutures. In this technique, cartilage was not utilized, and the majority of the defects involved the upper helical rim. The post-auricular region was chosen as the ideal donor site due to its proximity and color match with the helical rim.

The donor site defect of the flap was primarily closed when the defect was small, whereas a skin graft was used to cover larger defects. A non-adhesive firm dressing was applied, and sutures were removed on the 7th post-operative day. Detailed patient information, including demographic characteristics and the techniques employed, is found in Table 1. In addition, the illustrations [Figures 1-3] provided depict the surgical procedure.

RESULTS

The study reported positive outcomes from the two-stage retroauricular flap reconstruction technique used to address partial ear defects. Among the 21 cases of partial ear defects, 8 superiorly based and 13 inferiorly based retroauricular flaps were designed, resulting in excellent survival rates and achieving a good texture and color match. Aesthetic outcomes were considered satisfactory in 19 patients, with only 2 patients experiencing wound dehiscence during follow-up, which healed through secondary intention.

The survival of the flaps can be attributed to their robust vascular supply, which enables reliable restoration of the anatomical contour and a natural appearance. As a result, there is an improvement in symmetry and aesthetics, leading to high patient satisfaction rates. However, in cases where superiorly based flaps were used and the hair-bearing area cranial to the auricle was incorporated into the flap, the presence of hair over the ear was deemed unsatisfactory, particularly for female patients. This issue was later addressed by employing laser epilation as the preferred method to minimize hair growth on the flap while maintaining its aesthetic qualities.



Outcome of Two stage Retroauricular Flaps

Outcome	No. of patients (%)
Uneventful healing	19 (90.4)
Wound dehiscence	2 (9.6)
Total	21 (100)

AESTHETIC OUTCOME	Male[9]	Female[12]	TOTAL[21]
1. Hair bearing flaps	3[42.8%]	4[57.1%]	7[100%]
2.Notcing	2[50%]	2[50%]	4[100%]
3.Bulky flap	4[57.1%]	3[42.8%]	7[100%]
4.Scarring of donor region	1[33.3%]	2[66.6%]	3[100%]
5.Satisfaction rate	7[43.8%]	9[56.2%]	16[100%]

Table 1: Details of the patients and techniques used

S. No.	Age	Gender	Etiology	Site	Flap location	Donar site closure	Complication	Area treated
1	23	Female	Trauma	Middle 1/3rd	Superiorly based	Primary closure	Nil	Helix
2	44	Female	Trauma	Upper	Superiorly based	Primary closure	Nil	Helix
3	17	Male	Trauma	Upper+middle	Inferiorly based	Skin graft	Nil	Helix+superior crus of anti helix
4	32	Female	Trauma	Middle	Inferiorly based	Primary closure	Nil	Helix
5	25	Male	Trauma	Middle	Inferiorly based	Skin graft	Nil	Helix+scapha
6	41	Female	Trauma	Upper	Superiorly based	Primary closure	Nil	Helix
7	22	Male	Trauma	Upper	Inferiorly based	Primary closure	Nil	Helix
8	42	Male	Human Bite	Upper	Superiorly based	Primary closure	Nil	Helix
9	26	Female	Trauma	Middle	Superiorly based	Primary closure	Wound Dehiscence	Helix
10	45	Female	Trauma	Middle	Inferiorly based	Primary closure	Nil	Helix
11	53	Male	Trauma	Upper+Middle	Inferiorly based	Skin graft	Nil	Helix+superior crus of anti helix
12	19	Male	Trauma	Upper	Inferiorly based	Primary closure	Nil	Helix
13	35	Male	Human bite	Middle	Inferiorly based	Primary closure	Nil	Helix
14	16	Male	Trauma	Middle	Superiorly based	Primary closure	Nil	Helix+scapha
15	29	Male	Trauma	Middle	Superiorly based	Primary Closure	Nil	Helix
16	44	Female	Trauma	Upper	Inferiorly based	Skin graft	Nil	Helix
17	26	Male	Trauma	Upper	Superiorly based	Primary closure	Nil	Helix
18	39	Female	Trauma	Upper+middle	Inferiorly based	skin Graft	Wound Dehiscence	Helix
19	20	Male	Trauma	Upper+middle	Inferiorly based	Skin graft	Nil	Helix+superior crus of anti helix
20	37	Male	Trauma	Middle	Inferiorly based	Primary closure	Nil	Helix
21	51	Female	Human bite	Upper	Inferiorly based	Skin graft	Nil	Helix

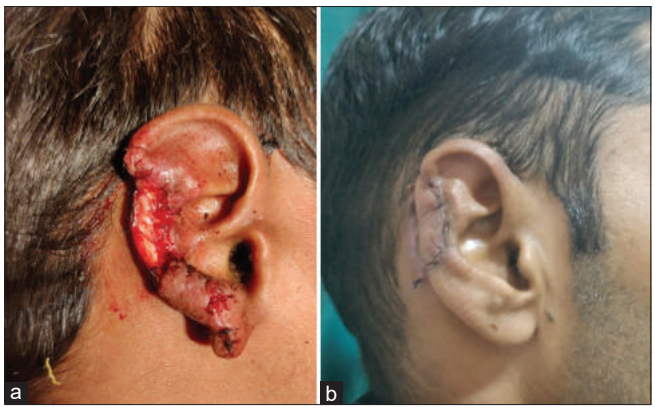


Figure 1: (a) Intraoperative image showing exposed cartilage of the left ear following trauma. (b) Post-operative image of well-settled flap

DISCUSSION

Auricular reconstruction is a complex procedure due to the intricate structure of the ear. Distortions in the ear architecture can have a significant impact on facial aesthetics. There are various reconstructive options available, and the choice should be individualized based on each case and the surgeon's preference.[8] In addition to flap reconstruction, there are alternative methods such as spontaneous healing, skin grafts, and wedge excisions, which can be used to reduce auricular height. Flap reconstruction is primarily effective for one-third auricular defects. In cases where there is a wide defect (>2.5 cm) that cannot be repaired through resection and primary closure (<1.5 cm), flap techniques involving multi-stage reconstruction operations are chosen.[9]

In 1946, Brown and Cannon introduced the postauricular or auriculomastoid area as a donor site for free skin and composite grafts. Subsequently, postauricular flaps were used in staged partial and total reconstruction of the ear. These flaps are random pattern flaps with a robust vascular supply based on branches of the posterior auricular, superficial temporal, and occipital arteries. The use of a wide-based pedicle maximizes the availability of blood supply from the rich vascular retroauricular skin, thereby increasing the success rate of the reconstruction procedure. However, the main disadvantage of this flap is the need for a two-stage procedure.[10] The superior ear, posterior ear, and mastoid area provide a good match in terms of skin color and texture, resulting in excellent aesthetic results.[11]

In most cases, loss of cartilage can be tolerated for ear defects, and if the defect involves the loss of a portion of the helical defect, the flap can be folded onto itself to provide adequate thickness and support without requiring a cartilage graft.[12] Both superiorly based and inferiorly based two-stage retroauricular flaps are considered effective methods for repairing partial ear defects, offering high aesthetic and functional results with the restoration of ear architecture.[1]

However, the study suggests that inferiorly based retro-auricular flaps are superior to superiorly based retro-auricular flaps in terms of transferring tissue devoid of hairs.[13]

Before proceeding with reconstruction, it is important to identify and address patient-specific factors. The

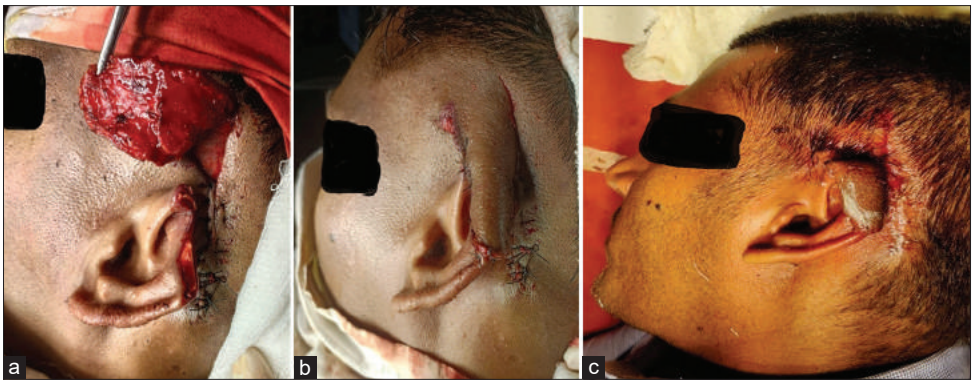


Figure 2: (a) Intraoperative image showing superiorly based retroauricular flap (b) Immediate post-operative image (c) Immediate post-operative image after division and insetting in a second-stage procedure

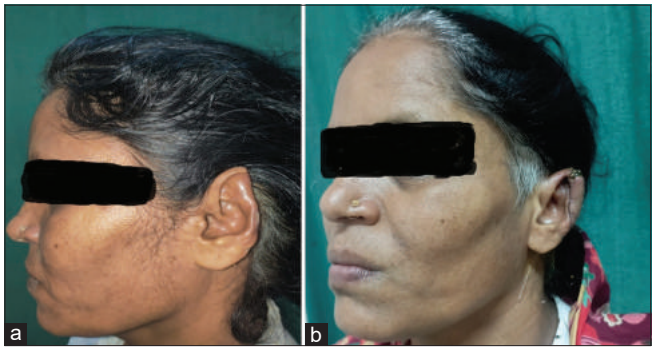


Figure 3: (a) Pre-operative image of left auricle defect post-human bite (b) Post-operative image after a well-settled flap

surgeon should discuss the patient's expectations and any comorbidities that may affect the feasibility of lengthy or multi-staged operations. Conservative treatment may be the best option for some patients, especially the elderly or critically ill, either due to necessity or patient preference. Secondary intention healing of full-thickness auricular defects has been evaluated, and it was found that all wounds healed within 10 weeks.[14] Exposed cartilage was not found to be a contraindication for secondary intention healing. Agrawal *et al.* have advocated primary reconstruction in all human bite, provided the wound is not infected clinically.[15]

CONCLUSION

The two-stage retroauricular flap is a versatile option for reconstruction of partial ear defects and is considered a viable solution in the management of auricular defects as a "flap bank" for ear reconstruction. While the use of two-stage retroauricular flaps shows promising outcomes in partial ear defect reconstruction, there are limitations to consider. Achieving flap thickness and contour match, particularly in patients with thin helical rims, can be challenging.

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Original Article

Outcome Analysis of Closed Displaced Intraarticular Fracture of Calcaneum Treated with Calcaneum Locking Plate

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Abstract

Introduction: Around 75% of calcaneal fractures are intra-articular and have previously been linked with poor functional outcomes. The operative treatment has become more popular, as fracture care has improved. However reviews on this subject, have failed to demonstrate indisputable superior results of a single line of treatment for displaced intra-articular calcaneal fractures. The comparison of studies is difficult because of different outcome variables used for evaluation.

Aims and Objective: To evaluate the functional outcome of patients treated with open reduction and internal fixation with plate/screw fixation for intra-articular fracture calcaneum of Sander's CT Type II, III, IV using Maryland Foot Score (MFS).

Methods: A prospective study, including 16 patients with an intra-articular calcaneal fracture who met the inclusion criteria, was conducted in tertiary care hospital of central India between March 2021 to October 2022. The patients were managed surgically with open reduction and internal fixation. Radiological outcome and functional outcome using Maryland Foot Score was evaluated at 6 months.

Results: Mean age of the patients was 35.5 years. The mean duration from the time of injury to the time for surgery was 6.8 days. Out of 16 patients, functional outcome among 62.5% cases was good (75-89) and 31.25% cases was moderate (54-74) while 6.25% had poor score. The mean score (MFS) among the study participants was found to be 76.81 ± 8.109.

Conclusion: We conclude that with good pre-operative planning, surgery timing, intra-operative expertise of the surgeon, and post-operative care, surgical treatment of intra-articular fracture utilizing a locking plate results in a better outcome with few complications.

Key words: Calcaneal fractures, Intra-articular, High energy fractures, Soft tissue, Operative technique

INTRODUCTION

Calcaneal fracture is comparatively the most common fracture of tarsal bone representing 60% of all tarsal fractures in adults, with a reported occurrence of 2% of all fractures. 75% of calcaneal fractures are intra-articular. These fractures occur mostly among young age male patients due to vertical fall from height when lateral process of talus hits like a hammer on the Gissane's angle and then breaks through the posterior articular facet.[1,2] The annual incidence of calcaneal fractures is 11.5 per 100,000 people, with a male to female ratio of 2.4:1, according to a retrospective study of 752 cases during a 10-year period. Falls are the cause of 72% of these fractures. About 10% cases are associated with spine fractures and 26% associated with other trauma.[3]

In 5–10% of cases of fracture calcaneum, both heels are injured at the same time. Although crush injuries recover biologically, they are likely to result in long-term disability.

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A perception formed at the start of the 20th century, at least from the perspective of industry, was that "the man who breaks his heel-bone is finished." Following this, efforts were made to alter the outcome by open reduction and internal fixation of these fractures over the latter half of that century.[4]

Controversy remains with respect to whether displaced intra-articular calcaneal fracture be treated operatively or non-operatively.[2] Historically, displaced intra-articular calcaneal fractures were treated conservatively, as predictable outcome of operative reduction and fixation was not achieved. Operative treatment became more popular, as fracture care improved. Reviews on this subject, however, have failed to demonstrate indisputable superior results of a single line of treatment for displaced intra-articular calcaneal fracture.

Aim and objective

1. To evaluate the functional outcome of patients treated with open reduction and internal fixation with plate/screw fixation for intra-articular fracture of calcaneum for Sander's CT Type II, III, IV calcaneal fractures.
2. To assess the incidence of infection and complications following open reduction and internal fixation of calcaneal fractures.

MATERIALS AND METHODS

Study Design: The prospective study was conducted at Pt. JNM medical college and associated Dr Bhimrao Ambedkar Memorial Hospital, Raipur (C.G) in central India between March 2021 to October 2022.

Sample Size: A total of 16 patients with intra articular fracture of calcaneum meeting the inclusion and exclusion criteria were included in the study.

Inclusion Criteria

1. Patients with closed intra articular, displaced calcaneal fractures
2. Patients aged between 18 to 60 years.

Exclusion Criteria

1. Local site infections
2. Coexisting spinal injury with paraplegia
3. Significant coexisting diseases (bleeding disorder etc.) comorbidities with contradiction to any anesthesia.
4. Patients with extra articular fracture, open fracture or Sander's CT type 1 fracture.

Methodology and procedure

The patients with displaced intra articular fractures of calcaneum were selected by CT Sander's grading (grade II, III and IV) and treated with open reduction and internal fixation with locking compression Plate/CC screw. The patients satisfying the inclusion and exclusion criteria were included in the study after taking the informed consent. The patients' details were collected, and preoperative radiological imaging was performed and pre-operative planning was done.

All the patients being taken for open reduction and internal fixation were primarily treated by limb elevation, ice application and crepe bandage to reduce the edema. Pre-operative x-rays-lateral and axial view of the calcaneum and CT scan of calcaneum were obtained and pre-operative planning was done. Pre-Operative Bohler's and Gissane's angles were measured using radiographs and fractures were classified using Sander's classification with the help of a CT-scan. After obtaining informed consent from the patients and ethical committee clearance, the patients were taken up for surgery once the swelling was reduced and the wrinkle sign was positive. Patients subjected to surgery for calcaneum fracture were followed up at regular intervals with clinical and radiological evaluation. The surgery was performed to restore the height and length of the calcaneum, realign posterior facet of the subtalar joint, and restore mechanical axis of the hindfoot.After the appearance of wrinkle sign surgery was done by standard lateral approach. (Benirschke and Sangeorzan).[5]

The patient was made to lie in lateral position on a radiolucent table after the patient was anaesthetized. The lateral skin incision (L shape EXTENDED LATERAL APPROCH) extending from the calcaneal tuberosity to the calcaneo-cuboid joint was made extending upwards between posterior border of distal fibula and the lateral aspect of the Achilles tendon. It is preferable to raise a thick skin flap to avoid skin necrosis and in all cases k-wires were placed at the proximal end of the wound, bent at an angle of 90 degrees to avoid repeated handling of the skin flap. Care was to taken to preserve the neuro vascular structures (Sural nerve and the short saphenous vein).

Fracture visualization was achieved by using k wires (Three K Wires- one in fibula, one in cuboid, one in neck of talus) and the depressed articular facet fragments were elevated as needed after hinging down the lateral wall subperiosteally for access. Appropriate size plate was fixed over fracture fragment which was reduced and proper size and length of screws used. Complete procedure was done under c-arm(image intensifier) guidance. When there was any deficit then it was filled with cancellous bone graft (autograft).

This plate in all of the procedures was kept under peronei tendons to avoid future impingement. After this procedure

we sutured the back the flap which was kept elevated by k wires and moistened intermittently and skin suturing was done without tension, using Allgower stitch (atraumatic skin closure technique), and suture removal after 3 weeks was recommended. Surgical site was now dressed with sterile gauze and dressing material and the patient given below knee POP slab for immobilization of affected limb.

First sterile dressing was done on the third post-operative day and non-weight bearing mobilization and ankle pumps advised. Then reapplication of below knee POP slab was done for at least 03 - 04 weeks. The surgical site was examined properly for any wound dehiscence in all subsequent dressings. Complete weight bearing was recommended only after ensuring fracture union on x-ray.

During the follow up period the patient operated was assessed radiologically for Bohler's angle and Gissane's angle and height and width of calcaneum immediately after surgery and at 6 weeks of surgery and Maryland food score was taken and evaluated at 6 weeks,3 months and 6 months post operatively. The patient was also assessed for fracture healing at each visit.

STATISTICAL ANALYSIS

The data was collected and entered into a Microsoft Excel spreadsheet and analyzed using SPSS version 21. The results were averaged (mean + standard deviation) for each parameter for continuous data and numbers and percentages for categorical data presented in Tables and Figures.

RESULTS

The study included 16 patients. The variables like age, gender, mode of injury, type of fractures, comorbidity, duration of fractures and day of injury to the operative day, complications related to fracture and wound healing, functional outcome at 06 months were analyzed.

In our study, patients were between the age group 20 to 53 years with a mean age of 35.5 ± 8.556 years and majority (62.5%) belonged to the age between 20-40 years of age. The majority of the patients in the study were males, with 87.5 % of the study population being males.

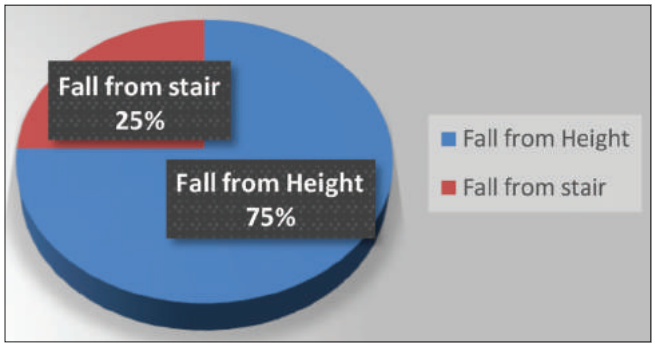


Figure 1: Mode of injury among study subjects

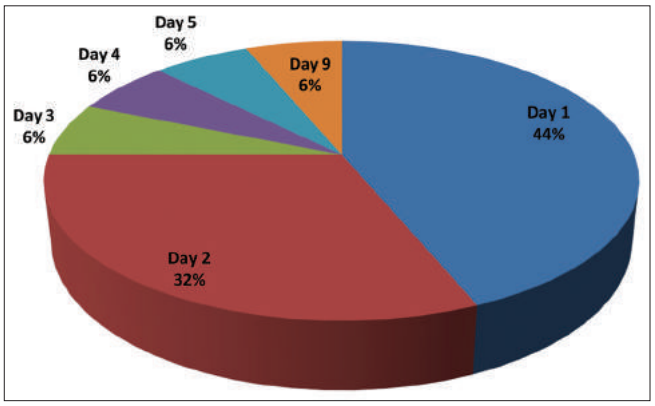


Figure 2: Presenting day among study subjects

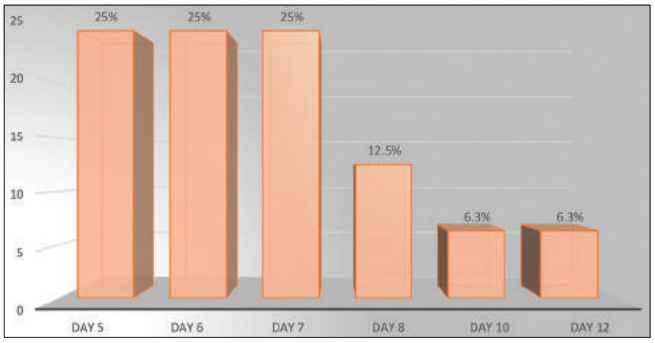


Figure 3: Operated day among study subjects

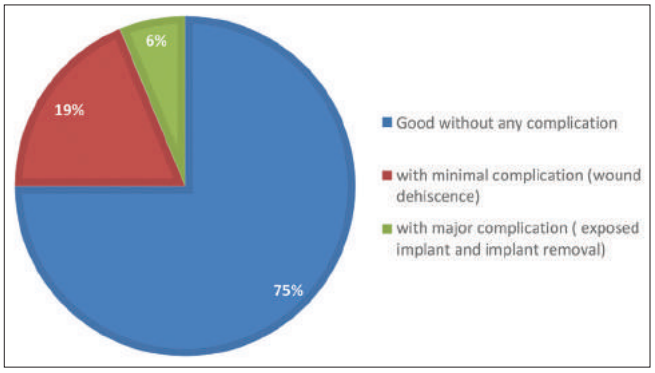


Figure 4: wound healing at 6 week among study Subejcts

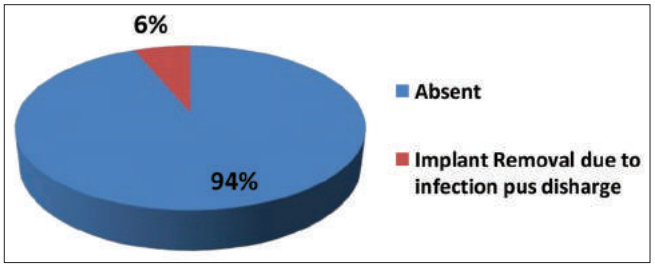


Figure 5: Major complication needing removal of plate among study subjects

Table 1: Age and gender distribution among study participants

Variables	Frequency (n=16)	Percent (%)
Age		
20-40 years	10	62.5
41-60 years	6	37.5
Mean±SD	35.5±8.556	
Gender		
Female	2	12.5
Male	14	87.5

Table 2: Sander's type among study subjects

Sander's type	Freq.	Percent
Type II	4	25
Type III	9	56.25
Type IV	3	18.75
Total	16	100

Table 3: Wound healing at six week among study subjects

Wound healing at 6 week	Frequency	Percent
Good without any complication	12	75.0
With minimal complications (wound dehiscence)	3	18.5
With major complication (exposed implant and implant removal)	1	6.5
Total	16	100.0

Table 4: Maryland foot score among study subjects

Maryland foot score	Frequency	Percent
Good (75-89)	10	62.5
Moderate (54-74)	5	31.25
Poor (<54)	1	6.25
Mean±SD	76.81±8.109	

The mode of injury among study subjects shows that 75% had injury due to fall from height and 25% had injury due to fall from stairs.

The distribution of Sander's type among study subjects shows that among 16 cases 4 (25%) had Sander's type II, 9 cases (56.25%) had Sander's type III and 3 cases (18.8%) had Sander's type-IV calcaneal fractures.

Presenting day among study subjects shows that majority 7 (43.8%) cases presented at day-1 and 5 cases (31.3%) presented on day 2 rest one case each presented on day-3,4,5 and 9.

Operated day among study subjects shows that 4 patients each (25%) were operated on day-5, 6 and 7, 2 (12.5%) operated on day 8 and 6.3% each operated on day 10 and

Table 5: Wound Dehiscence among study subjects

Minor complication	Frequency	Percent
Absent	12	75.0
Wound Dehiscence	4	25.0
Total	16	100.0

Table 6: Major complication needing removal of plate among study subjects

Major complication	Frequency	Percent
Absent	15	93.8
Implant Removal due to infection pus discharge	1	6.3
Total	16	100.0

day 12. The mean duration of time for the surgery to be done was 6.8 days.

Wound healing at 6 weeks in study subjects shows that in 75% patients it was without any complications, in 18.5 % cases there were minimal complications and in 1 case (6.5%) there was a major complication needing implant removal.

Maryland foot score among study subjects shows that among 62.5% cases it was good (75-89) and in 31.25% cases it was moderate (54-74) and 6.25% had poor score. The mean score among the study participants was found to be 76.81 ± 8.109.

Among 75% cases wound dehiscence was absent while it was seen in 25% cases.

Major complication needing removal of plate among study subjects shows that it was absent in 93.8% cases and in one case only Implant Removal was done due to infection and pus discharge [Figures 1-5 and Tables 1-6].

DISCUSSION

The hospital based prospective analytical study was conducted at Department of Orthopedics at a tertiary care hospital in India to assess the outcome of patients treated with ORIF and plating for intra-articular fracture calcaneum for Sander's grade 2,3,4 calcaneal fractures. The study included 16 patients of intra-articular fracture of calcaneum who were evaluated with X-ray of the calcaneum —axial, lateral and AP views and CT scan for classification of fracture calcaneum. All of them underwent open reduction and internal fixation and functional outcome was accessed using Maryland Foot Score at 6 weeks, 3 months and finally at 6 months.

In the present study majority (62.5%) of patients belonged to the age group of 20 to 40 years and 37.5% between 41 to

60 years and males comprised of 87.5% of study participants while only 12.5% were females. It was comparable to previous studies by Mitchell MJ *et al.,* and O'Farrell DA *et al.*, that revealed that fractures were more prevalent in younger age groups and that the majority of patients were male.[3,6]

In our study, the mode of injury among most of the study participants was fall from height (75%) while 25% had injury due to fall from stairs which was similar to the study conducted by Mitchell MJ *et al.,* (fall from height 71.5%) and Chandrashekhar HS *et al.,* (fall from height 80%).[3,7]

In our study 11 patients had fracture in left calcaneum while 5 had fracture in right calcaneum. The majority of patients had Sander's type 3 fracture (9patients, 56.25%), while 4 patients (25%) had Sander's type 2 fracture and 3 patients (18.75%) had Sander's type 4 fracture in either left or right calcaneum.

In order to reduce wound complications, our study delayed surgical intervention until the wrinkle sign was positive. The surgery was performed within the first two weeks of injury, as open reduction and internal fixation is not recommended with more than three weeks of delay.[8] The mean duration between time of surgery and injury in our study was 6.8 days.

Pendse *et al.*, concluded that in intra-articular calcaneus fractures open reduction and internal fixation with a plate for restoring the anatomical articular congruency, early mobilization, and the primary option for subtalar arthrodesis if necessary are the most effective treatments. [9] Schepers *et al.*, also reported that ORIF is the mainstay among all the treatment modality.[10]

Although calcaneal fracture surgery can be performed using medial, lateral, or mixed approach.[11-14] In our study, the lateral extensile exposure popularized by Benirschke and Sangeorzan was used.[5]

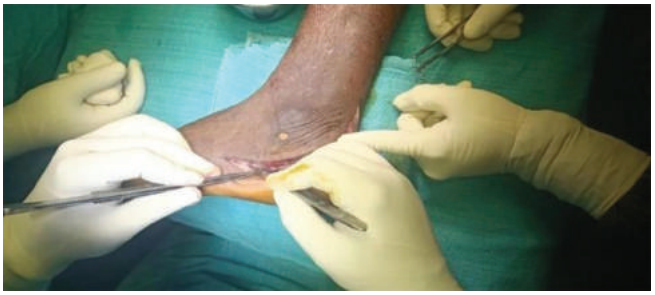
In our study, the wound healing at six weeks showed that 75% of patients had wound healing without any complications, 18.75% (3) cases had minimal complications and 6.25% had major complication. Minor complications among study subjects shows that in 75% cases it was absent and Wound Dehiscence was seen in 25% cases. Major complications needing removal of plate was absent in 93.8% cases and in one case only Implant Removal was done due to infection pus discharge. This is similar to the study conducted by Chandrashekhar HS *et al.,*[7] where out of 25 patients, 24 % had minor complications which included 2 with ankle and foot stiffness, 2 with implant prominence and 2 with superficial wound infection. The major complication of deep wound infection was reported in one patient in the study which is similar to our current study. In the study by Biz C *et al.,* the wound dehiscence was observed in 5 cases out of 19 (26.31 %) cases in which open reduction and internal fixation was used for calcaneal fracture management.[15]

Maryland foot score among study subjects showed that 62.5% of patients had good (75-89) score and 31.25% had moderate score (54-74) and 6.25% had poor score (<54). In our study Maryland foot score ranged from 53 to 88 among the patients with mean score of 76.81 with the standard deviation of 8.109. However in the study conducted by Dhillon *et al.,* the group receiving open reduction and internal fixation of calcaneal fracture had a MFS of 84.4 and an AOFAS score of 86.1 at one year which was comparatively higher than the current study.[16] Similarly in the study conducted by Biz C *et al.*, among the 19 patients who underwent open reduction and internal fixation for calcaneal fracture authors reported MFS in the range of 76 to 99 with the mean of 87 and AOFAS score of 82 with the range of 66 to 97.[15]

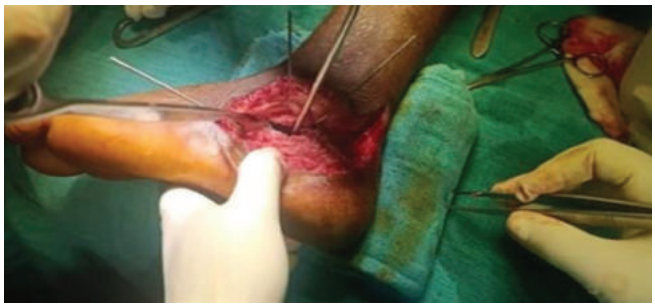
Many studies used AOFAS score to assess the functional outcome after the treatment. Biz *et al.,* examined the functional outcomes with the AOFAS score, and they reported excellent results in 11 (12.6%) patients, good results in 46 (52.9%) patients, fair results in 26 (29.9%) patients, while 4 (4.6%) patients were graded as failures.[15] Similarly Voclav *et al.,* reported outstanding results in 24 (32%) patients, good results in 28 (37%) patients, acceptable results in 14 (18%) patients, and bad results in 10 (13%) patients.[17]

The present study has few limitations. Due to short duration of study and limited number of study subjects only limited data was collected. However, it derives few important findings, the fracture is more common in age group of 20-40 years compared to 41 to 60 years and most of the cases result from fall from height.

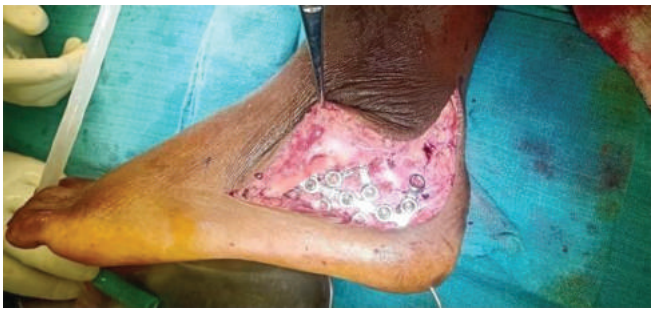
Younger age group had less comminuted fracture (Sanders type II and III) while 41-60 years had more comminuted fractures (Sanders type III and IV). The Maryland foot score of patients improved for all study participants with the mean of 76.81 ± 8.11.



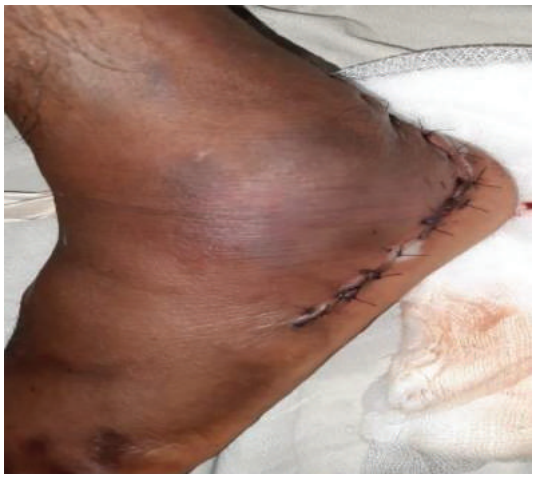
Surgical incision (Extended Lateral Approach).



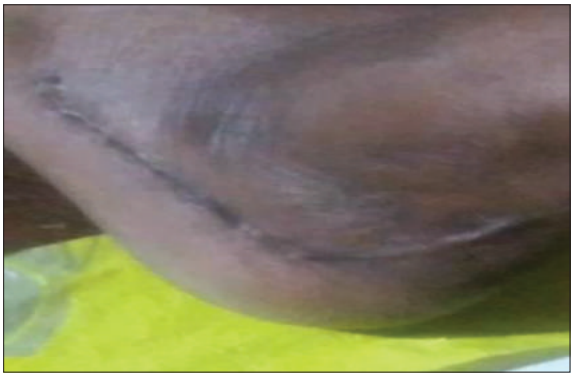
Skin flap raised by 3 k' wires



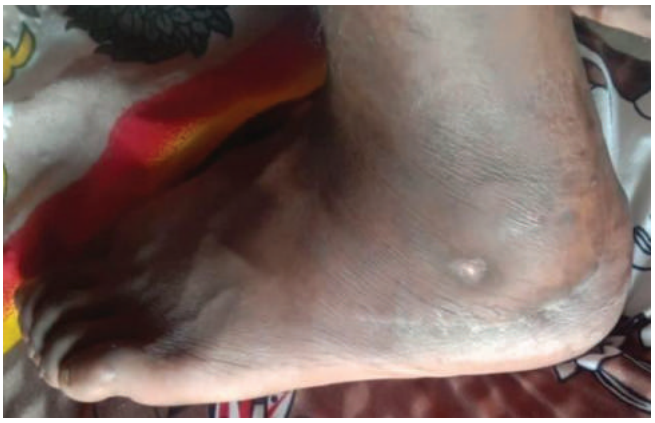
Reduction & lateral locking plate fixation



1st post op dressing

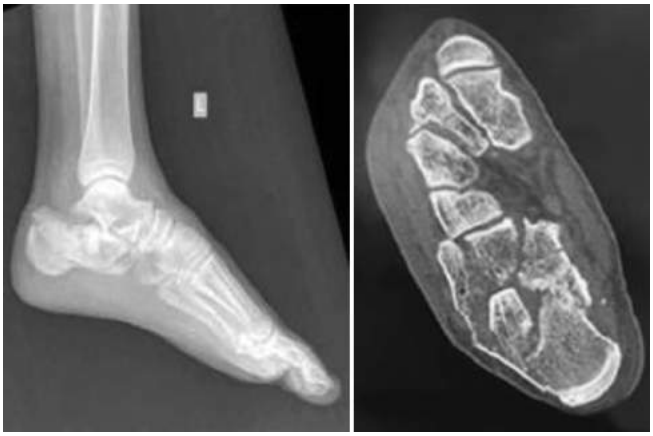


Follow up at 6 weeks
(wound completely healed)

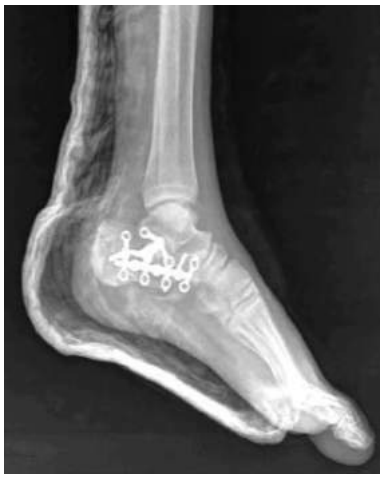


Another patient at 3 months follow up

Case 1

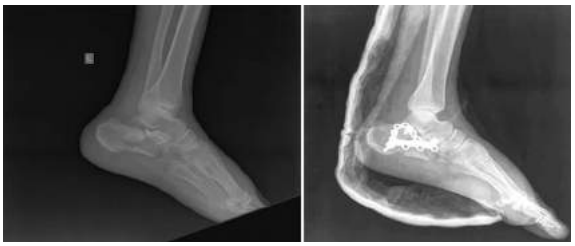


Pre-operative X rays and CT scan showing comminuted calcaneal fracture



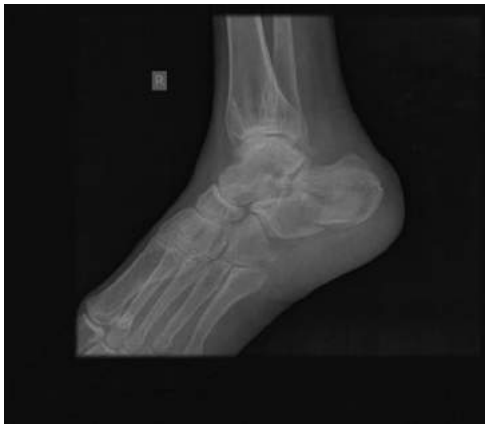
Post-Operative X rays
with restoration of anatomy

Case 2

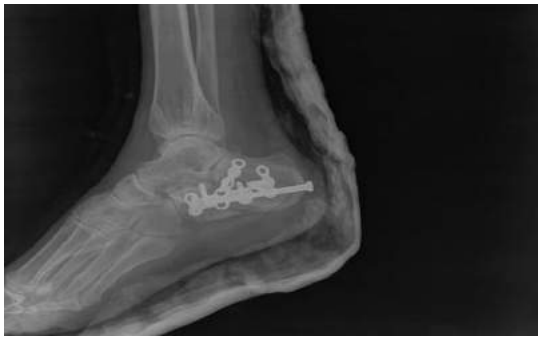


Pre op and Post op X rays of another comminuted calcaneal fracture operated with calcaneal plating

Case 3

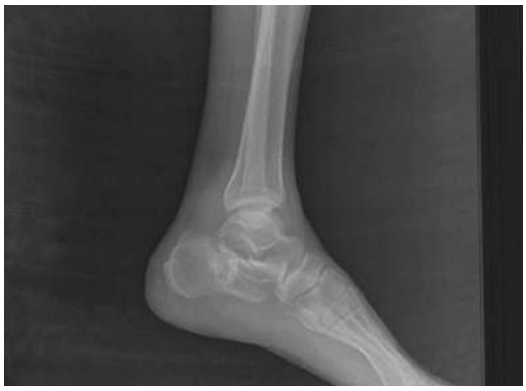


Pre-operative picture of another calcaneal fracture

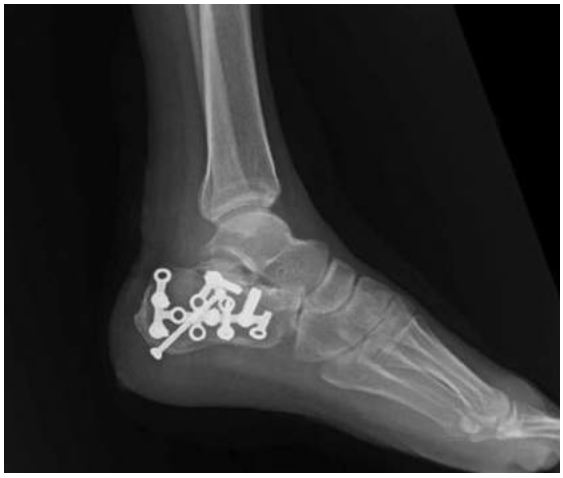


Post-operative picture of the same patient

Case 4



Severely comminuted calcaneum fracture



Post-operative x rays of the patient with good restoration of anatomy

CONCLUSION

Open reduction internal fixation of fracture calcaneum is a good tool for achieving good results in displaced intra-articular calcaneum fracture. Precise timing of surgery, operative expertise of the surgeon, good post-operative care, and surgical treatment of intra-articular fracture utilizing a locking plate results in a better outcome with few complications.

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Original Article

Comparison of the Pediatric Risk of Mortality Score III, Risk Adjustment for Congenital Heart Surgery 1 and Pediatric Index of Cardiac Surgical Intensive Care Mortality Score in Post-Operative Pediatric Cardiac Surgical Patients: A Single-Center Validation Study in South India

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Abstract

Background: Outcome predictions of mortality using scoring systems have now become an integral part of the intensive care units (ICUs). The present study compared and validated the pediatric risk of mortality III (PRISM-III), risk adjustment for congenital heart surgery 1 **(**RACHS-1) and pediatric index of cardiac surgical intensive care mortality (PICSIM) score for predicting mortality and ICU length of stay (ICU-LOS) in post-operative pediatric cardiac surgical patients in an Indian cohort.

Methods: The study conducted at Amrita Institute of Medical Sciences and Research Center during the period January 2020–December 2020. Total 269 patients <18 years of age undergoing congenital heart surgery and admitted into the pediatric cardiac ICU (PCICU) were included in the study. Physiologic variables collected within 1 h and 12 h of admission to PCICU after cardiac surgery were used to calculate PRISM-III and PICSIM. RACHS-1 category was assigned based on the surgical procedure performed. Correlation and regression analysis was applied to quantify and confirm the association between each categorical independent and dependent variable.

Results: There was a significant ($P < 0.001$) positive correlation between the ICU-LOS of patients and RACHS-1 score (r = 0.553), PRISM-III (r = 0.418) and PICSIM score (r = 0.582), PICSIM seemed to have a better correlation with ICU-LOS. The area under the curve for PRISM-III score (0.920) was slightly higher compared with PICSIM (0.813) and RACHS-1 (0.708). This result indicates that PRISM-III score showed better prediction of mortality as compared to PICSIM and RACHS-1 system.

Conclusion: The study concluded that PICSIM score demonstrated better performance in predicting ICU-LOS and next to PRISM-III in predicting mortality in an Indian cohort. All the 3 risk stratification models had significant correlation with ICU-LOS. Therefore, identifying cohorts with worsen outcomes will enable PCICUs to deliver better quality of care to vulnerable patients.

Key words: Mortality prediction, Pediatric cardiac intensive care unit, Pediatric index of mortality 3, Pediatric risk of mortality

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INTRODUCTION

In recent years due to advancements in intensive care, prenatal diagnosis, neonatal surgery, cardiac catheterization and anesthesia, and cardiopulmonary bypass techniques, there was significant improvement observed in the treatment and diagnosis of congenital heart disease

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(CHD).[1] As a result of medical advancement, the in-hospital mortality rates after pediatric heart surgery reduced appreciably from 4.3% to 2.2%.[2,3] A suitable mortality risk scoring system can accurately predict mortality while adjusting the severity of disease, and capture possible data in clinical practice.[4-6] Usual pediatric intensive care scores determine intensive care unit (ICU) admission, and the prediction data are typically obtained both before and after ICU admission. Most commonly used mortality prediction models in pediatric intensive care units are pediatric index of mortality 3 (PIM-3), and pediatric risk of mortality (PRISM-III). Pollack *et al.* in 1996 developed PRISM-III, a third generation mortality scoring system based on pediatric physiology for mortality risk assessment of infant.[7] PRISM scoring model is a physiology-based severity of illness assessment tool utilized in adult and pediatric intensive care population. This scoring system gives values reflective of mortality risk based on derangements in physiological variables. PRISM scoring model has been shown to be effective in patients undergoing congenital heart surgery. The PRISM scoring algorithm simultaneously estimates fresh functional morbidity and mortality from hospital discharge.[8-10] Prior study also compared and validated different prediction models and demonstrated advantages of one score over the other scores in terms of being fewer affected by the retrieval process and easier to assemble.[11] Recently, data from a large multicenter study has revealed that the performance of PRISM-III was suboptimal when applied to assess mortality risk specifically in pediatric cardiac surgical patients and cardiac medical populations.[10]

The risk adjustment for congenital heart surgery 1 **(**RACHS-1) score is capable of categorizing patients into six groups based on the type of surgical procedure to predict hospital mortality.[12-14] RACHS-1 score is extensively applied to evaluate mortality and to compare the performance of cardiac surgical units. The RACHS-1, however, does not consider the individual and structural components of services that directly influence operational outcome. However, successful integration of pediatric index of cardiac surgical intensive care mortality (PICSIM) in assessing and correcting ICU care of children undergoing heart surgery can address these challenges.[5,15] PICSIM score overlies with the PIM which does not execute well in heart surgery patients. As the majority of PICSIM's prediction capacity comes from the operational complication score, thus PICSIM score to evaluate intensive patient care quality is restricted.[16,17] Jeffries *et al.* developed a mortality risk-assessment tool exclusively for the pediatric cardiac surgical intensive care patients named as the PICSIM score which is based on common and targeted categorical variables, and a partial set of physiological and therapeutic variables. PICSIM score aimed at assessing the relationship of the ICU components to cardiac surgical care and mortality in infants undergoing congenital heart surgery.[18,19] Since the majority of PICSIM's prognostic command comes from the surgery or operational complexity score, use of PICSIM to evaluate intensive care is partial.[16,20] The prevalence of CHD is not uniform in India varying from 1.3 to 50.89/1000 live births.[21] In India, 10% of the present newborn child mortality might be accounted to CHD. Prolonged ICU stay after pediatric cardiac surgery often indicates a greater severity of illness and has been associated with poor outcomes.[22] In addition, prolongation of intensive care demands tremendous resource utilization and present substantial challenges to the viability of pediatric heart programs. Validating scoring systems which has the potential to predict ICU-length of stay (ICU-LOS) thus becomes relevant in limited-resource settings. There is a paucity of data pertaining to validation of risk prediction models in pediatric cardiac surgical patients from developing countries. At our center, we have been traditionally using the RACHS-1 scoring system for categorizing pediatric cardiac surgical patients in terms of surgical complexity and severity of illness. However, with the emergence of newer tools like PICSIM which has been acclaimed for better performance in pediatric cardiac surgical patients and a decline in mortality rates at our center to <2.5%, we sought to compare and validate the PICSIM score, PRISM-III score, and RACHS-1 score for predicting mortality and ICU-LOS in post-operative cardiac surgical patients in an Indian population. Therefore, the main objective of the present study was to compare and validate the PICSIM score, PRISM-III score, and RACHS-1 score for predicting mortality and length of ICU-LOS in post-operative pediatric cardiac surgical patients in an Indian cohort.

METHODS

Selection and Description of Participants

This is a prospective validation study conducted at Amrita Institute of Medical Sciences which is a tertiary care multispecialty hospital in South India. The study was conducted during the period January 2020–December 2020. The study was approved by the institutional review board and a written informed consent was obtained from the parents of all participants before recruitment into the study [Appendix 1: Informed consent]. Consecutive patients <18 years of age undergoing congenital heart surgery and admitted into the pediatric cardiac ICU (PCICU) for perioperative care were recruited into the study.

Since we did not come across a previous study in literature which validated the risk scoring tools in paediatric cardiac patients in an Indian cohort for sample size prediction, a pilot study was conducted with 10 patients. Based on

correlation coefficient of ICU-LOS obtained with scoring systems, namely RACHS-1, PRISM-III, and PICSIM in the pilot study and with 95% confidence interval and 80% power, minimum sample size was estimated to be 198.

Technical Information

The primary objective of the study is to compare and validate the three risk stratification models, namely PRISM-III, RACHS, and PICSIM score as a predictors of ICU-LOS in post-operative pediatric cardiac intensive care patients in the Indian population.

The secondary objective is to assess mortality.

Inclusion criteria

All consecutive patients <18 years of age undergoing congenital heart surgery and admitted into the PCICU for perioperative care were included in the study.

Exclusion criteria

1. Patients above the age of 18 years undergoing congenital heart surgery
2. Patients who underwent cardiac surgery and transferred directly to neonatal ICU or intermediate care unit from the operating room were also excluded.

All patients in the study cohort were admitted into a dedicated PCICU after congenital heart surgery. Patients who were critically ill before surgery sometimes needed admission to the PCICU before surgery for preoperative optimisation and hence the time of admission to the PCICU with respect to cardiac surgery (i.e. before or after cardiac surgery) was also included among the variables. Preoperative variables, including demographic data, anthropometric measurements, and cardiac diagnosis, were collected at the time of pre-operative anesthesia evaluation. Physiological variables that were collected prospectively within 1 h and 12 h of admission to PCICU after cardiac surgery were used to calculate PRISM-III and PICSIM. RACHS-1 category and STAT scores were assigned based on the surgical procedure performed. The preoperative, intra-operative, and postoperative variables required for calculating the three risk scores are elaborated in the study pro forma which was used for the data collection [Appendix 2: The study pro forma]. The outcome variables included 30-day mortality and ICU-LOS. ICU-LOS was defined as the time interval in hours from admission to PCICU after surgery to discharge from the PCICU.

Statistics

Statistical analysis was done using IBM SPSS Statistics for Windows, version 23.0 (Armonk, NY: IBM Corp.). The categorical variables were expressed as frequencies and percentage. The continuous variables were expressed as mean ± standard deviation or median and range as appropriate. The correlation between ICU-LOS (hours) and RACHS-1, PRISM-III, and PICSIM score was analyzed using the Spearman correlation test. Linear regression was employed to find out the effect of one variable on others. The association between mortality and RACHS-1, PRISM-III and PICSIM score was calculated using regression analysis. Validation of three risk stratification models to predict mortality was performed by analysis of receiver operating characteristic (ROC) curve and area under the curve (AUC) obtained for each model. $P < 0.05$ was statistically considered to be significant.

RESULTS

269 patients were recruited in to the study, of these 153 (56.9%) were male and 116 (43.1 %) were female. The height and weight of the patients was 7.63 ± 8.49 kg and the mean height was 68.36 ± 24.71 cm. The distribution of patients according to surgical procedure shown in the [Figure 1] BAR diagram and the most frequent being ventricular septal defect (VSD) repair (22.7%), repair of tetralogy of Fallot (17.8%), and arterial switch operation with/without VSD closure (12.6%).

In this study, we observed that the minimum ICU-LOS was 20 h and maximum ICU-LOS was 1152 h. Moreover, the mortality in the entire study cohort was 1.9%.

On correlating ICU-LOS with PRISM-III, we get a positive moderate correlation coefficient (r = 0.418) which was found to be statistically significant with $P < 0.001$. This represents that, when the PRISM-III increases, the ICU-LOS will also increase. Positive changes in PRISM-III will reflect as positive changes in ICU-LOS and this holds true vice versa as well [Table 1 and Figure 2].

Regression equation with PRISM-III and ICU-LOS = 9.606 (PRISM-III) + 71.002

On correlating ICU-LOS with RACHS-1, we get a positive moderate correlation coefficient (r = 0.553) which was found to be statistically significant with $P < 0.001$. This represents that, when the RACHS-1 score increases, the ICU-LOS will also increase. Positive changes in RACHS-1 will reflect as positive changes in ICU-LOS and this holds true vice versa as well [Table 2 and Appendix 1].

Regression equation with RACHS-1 and ICU-LOS = 41.68 (RACHS-1) + 19.485

On correlating ICU-LOS with PICSIM, we get a positive moderate correlation coefficient (r = 0.582) which was found

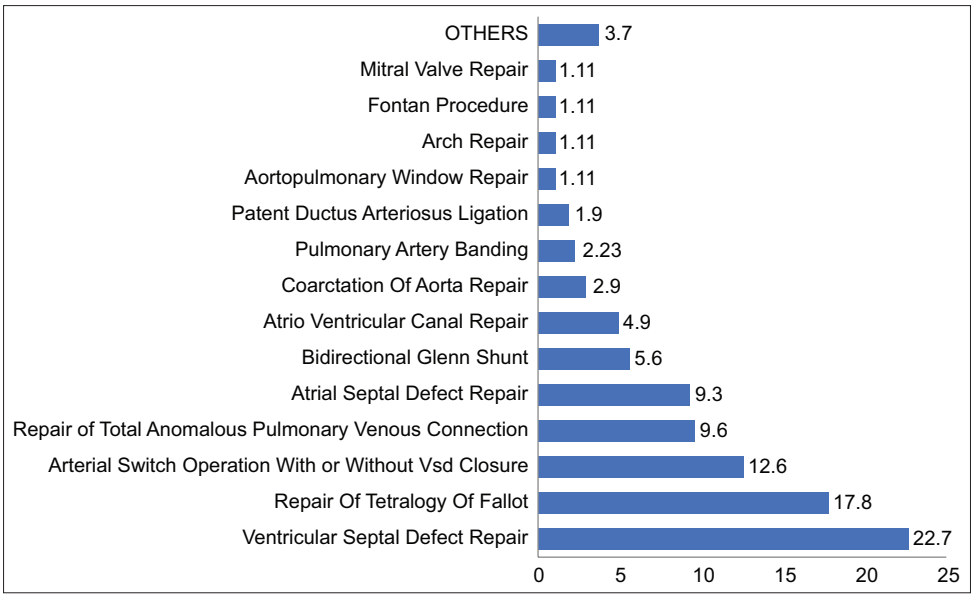

Figure 1: Bar diagram for distribution of cardiac surgical procedures

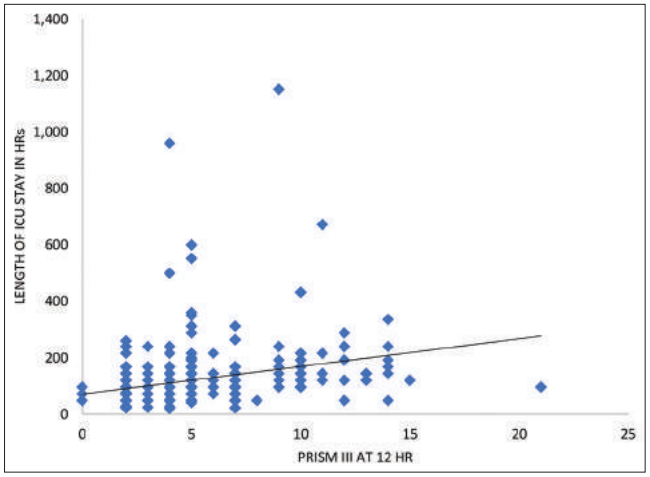

Figure 2: Scatter diagram for length of intensive care unit stay versus pediatric risk of mortality-III

Table 1: Correlation between length of ICUs stay and PRISM-III

Correlation between length of ICU stay and PRISM-III score	
Spearman's coefficient of correlation (r)	0.418
P	<0.001
n	269

ICU: Intensive care units, PRISM-III: Pediatric risk of mortality score III

to be statistically significant with $P < 0.001$. This represents that, when the PICSIM score increases, the ICU-LOS will also increase. Positive changes in PICSIM will reflect as positive changes in ICU-LOS and this holds true vice versa as well [Table 3 and Appendix 2].

Regression equation with PICSIM score and ICU-LOS= 4.965(PICSIM) + 73.401

Table 2: Correlation between length of ICUs stay and RACHS-1

Correlation between length of ICU stay and RACHS-1	
Spearman's coefficient of correlation (r)	0.553
P	<0.001
n	269

ICU: Intensive care units, RACHS-1: Risk adjustment for congenital heart surgery 1

Table 3: Correlations between length of ICUs stay and PICSIM score

Correlation between length of ICU stay and PICSIM	
Spearman's coefficient of correlation (r)	0.582
P	<0.001
n	269

ICU: Intensive care units, PICSIM: Pediatric index of cardiac surgical intensive care mortality score

Appendix 3 depicts ROC curve for RACHS-1, PRISM-III, and PICSIM score. In ROC curve, higher X-axis value indicates a higher number of false positives whereas, higher Y-axis value indicates a higher number of true positives rate. Here, PICSIM showed better true positive rate as compared to RACHS-1 and PRISM-III. Therefore, PICSIM has better discriminative power for predicting mortality as compared to RACHS-1 and PRISM-III.

The discrimination based on the AUC for PRISM-III at 12 h score (0.920) was observed to be higher compared to PICSIM (0.813) or RACHS-1 (0.708). This indicates that PRISM-III score showed slightly better prediction of mortality as compared to PICSIM and RACHS-1 system and was found to be statistically significant with $P < 0.001$ [Table 4 and Appendix 3].

DISCUSSION

The various risk stratification tools in pediatric cardiac surgical patients allow prediction of adverse outcomes and benchmarking of performance between various pediatric cardiac units. Previous studies have demonstrated that severity of illness scores such as mortality score would execute better in homogenous populations. Prediction scores developed for general paediatric critical care may not work appropriately in specific population subsets such as cardiac surgical patients.[7,8] Thus, it is important to develop and validate severity of illness scores for individual disease condition and population. Severity of illness scores has tremendous applications in low-middle income countries for triaging critically patients as well as facilitating optimal utilization of available resources. Although RACHS-1, PRISM-III, and the newly developed PICSIM scores are being currently applied to pediatric cardiac surgical patients in most of the developed nations, there is a paucity of data pertaining to the validation of these risk scoring tools in an Indian cohort. Our study has been an attempt to compare and validate the three risk stratification models namely PICSIM, RACHS-1 and PRISM-III to predict mortality and ICU-LOS in an Indian population.

The present study revealed that PRISM-III scoring system showed better prediction of mortality as compared to PICSIM and RACHS-1. The 30-day mortality rate of 1.9% observed in our study is comparable to the outcomes from the developed world.[1,3] We evaluated AUC from ROC curve to compare and validate mortality prediction systems. The discrimination based on the AUC for PRISM-III at 12 h score (0.920) was higher compared with PICSIM (0.813) and RACHS-1 (0.708). Although all risk models showed significant positive correlation with ICU-LOS, PICSIM (0.582) showed marginally better correlation compared to RACHS -1 (0.553) and PRISM–3 (0.418). The results of regression analysis also conclude that all three risk scoring models have utility in predicting the ICU-LOS.

Table 4: Area under the receiver operating curve for RACHS-1, PRISM-III and PICSIM

Variable	Area under the curve	*P*	Asymptotic 95% CI	
			Lower bound	Upper bound
RACHS-1 category score	0.708	0.244	0.358	1.058
PRISM-III at 12 h	0.920	<0.001	0.787	1.053
PICSIM score	0.813	0.003	0.609	1.018

CI: Confidence interval, PICSIM: Pediatric index of cardiac surgical intensive care mortality score, PRISM-III: Pediatric risk of mortality score III, RACHS-1: Risk adjustment for congenital heart surgery 1

Since most risk scoring systems rely on mortality and surgical complexity, the impact of ICU elements on clinical outcomes may not be accurately projected while using these models in paediatric cardiac population subsets. This often limits the applicability of mortality-based scoring systems for quality improvement in therapeutic approaches in pediatric cardiac intensive care. PICSIM score, in addition to physiological variables and STAT score also factors in supplementary data like timing of admission to ICU with respect to cardiac surgery and employment of extracorporeal life support within 12 h of post-operative ICU admission. Tibby SM *et al.* in his elegant study showed that the PICSIM had better capability to discriminate risk of mortality as compared to PRISM-III, PIM-2, and the complexity-based scores (STAT categories and RACHS-1 score) for children undergoing heart surgery.[11] The capability to discriminate risk of mortality was found excellent, both for low and high-risk cardiac surgery patients. Our results demonstrating improved performance of PICSIM in predicting ICU-LOS but PRISM-III had slight edge over PICSIM in predicting mortality according to our study as AUC of PRISM-III at 12 h (0.920). We speculate that the enhanced performance of PICSIM in predicting ICU-LOS in paediatric cardiac patients might be attributed to the addition of ICU-related variables which are not included in either RACHS-1 or in PRISM-III. In addition, PICSIM was validated exclusively in the unique subset of patients undergoing congenital heart surgery. Overall, these results indicate that the PICSIM score is more appropriate for predicting ICU-LOS and severity of illness in pediatric cardiac surgical population. Moreover, pairwise comparison of RACHS, PRISM-III at 12 h, and PICSIM was not found to be statistically significant.

We would like to highlight the fact that the present study is particularly relevant in the context of resource-limited environments for identifying those patients who are likely to have adverse outcomes and an extended stay in the post-operative period. Prolonged ICU stay can often exhaust ICU resources and challenge the economic viability of many paediatrics heart programs in the developing world. Identifying patients who are likely to overstay early in the disease trajectory can enable the caretakers to target high quality perioperative care to the vulnerable patients with the goal of improving overall survival and post-operative morbidity.

There are some limitations to this study. First, the physiological variables included in the PICSIM score offer only a marginal enhancement in the ability to discriminate ICU-LOS and slightly lesser prediction in mortality than PRISM-III as indicated by AUC (PICSIM 0.813, PRISM-III 0.92, RACHS-0.708). Therefore, capability

of PICSIM to discriminate ICU-LOS and mortality is mostly influenced by surgical complexity, hence restraining its capacity to facilitate quality improvement. Second, we acknowledge the fact that the present study was conducted on a small sample size of 269 patients, and thus need further validation in larger patient populations. Third, PICSIM has not been comprehensively evaluated in cohorts of pediatric cardiac patients admitted to ICU for cardiac intensive care and not undergoing surgery in the subsequent period.

CONCLUSION

Based on the results of our study, we conclude that PICSIM score demonstrated better discriminative power in predicting ICU-LOS after congenital heart surgery compared to PRISM-III and RACHS-1 and next to PRISM-III in predicting mortality in an Indian cohort. There was significant positive correlation between all the 3 risk stratification models (PICSIM, RACHS-1 and PRISM-III) with ICU-LOS after congenital heart surgery and pairwise comparison wasn't statistically significant. Even though by a low margin, PICSIM seemed to have a better correlation with ICU-LOS in post-operative paediatric cardiac patients compared to PRISM-III and RACHS-1. Identifying cohorts who are likely to have worser outcomes will enable PCICUs to target high quality care to vulnerable patients.

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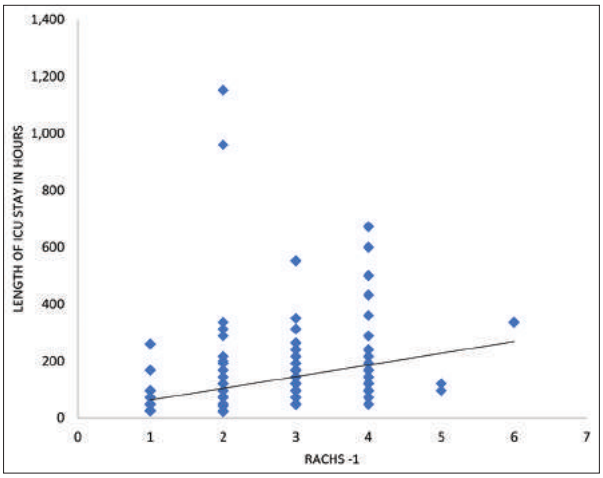
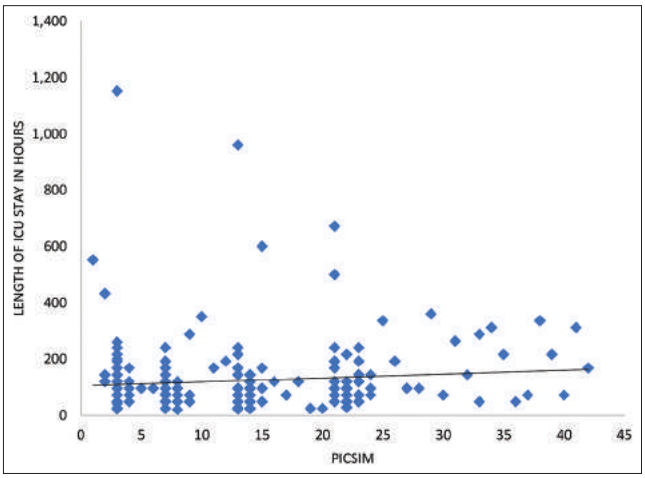
Source of Support: Nil, **Conflicts of Interest:** None declared.

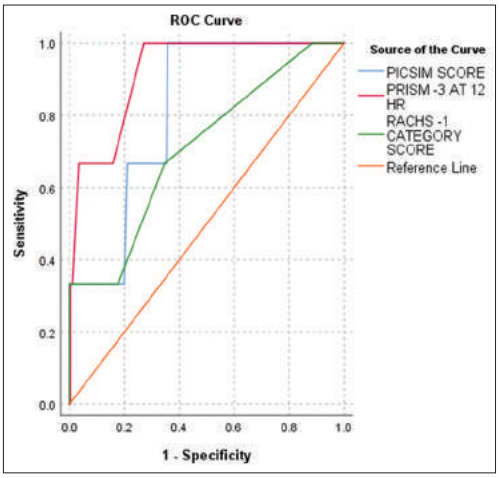
APPENDIX



Appendix 1: Scatter diagram for intensive care unit stay versus risk adjustment for congenital heart surgery-1



Appendix 2: Scatter diagram for length of intensive care unit stay and pediatric index of cardiac surgical intensive care mortality



Appendix 3: Receiver operating characteristic (ROC) curve for risk adjustment for congenital heart surgery-1, pediatric risk of mortality-III and pediatric index of cardiac surgical intensive care mortality

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Original Article

A Prospective Study of Reconstructive Modalities of Soft-Tissue Defect around the Knee Joint

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Abstract

Introduction: Defects of soft tissue of the knee represent a challenge in reconstruction. These may occur due to multi-factorial causes such as traffic accidents, shotguns, post-burn contracture release, and post-tumor excision.

Materials and methods: The study was conducted in the Department of Burns and Plastic Surgery B. J. Medical College and Civil Hospital Ahmedabad for from May 2021 to May 2023. Twenty cases of flap coverage for soft-tissue defects around the knee joint have been included in the study. The pro forma for the collection of data is made.

Results: From May 2021 to May 2023, 20 patients were treated with different types of flap coverage. Out of 20 patients, 16 were male and 4 were female patients. The mean age was 40 years (Range: 20–60 years).

Conclusion: From the study of 20 patients with soft-tissue defects in the age range of 20–60 years it is concluded that the following are the modalities for reconstruction. The proximally based medial sural artery fasciocutanous flaps provides tissues similar in skin texture and thickness to the lost ones and is thin and pliable. Rotation advancement flaps and transposition flaps are the best options when there are small-to-moderate anterior knee defects and external fixators in situ. P.

Key words: Knee Joint, Reconstructive, Soft-Tissue Defect

INTRODUCTION

Defects of soft tissue of the knee represent a challenge in reconstruction. These may occur due to multi-factorial causes such as traffic accidents, shotguns, post-burn contracture release, and post-tumor excision. A vivid number of reconstructive options for covering soft-tissue defects around the knee, including several muscle flaps, fasciocutaneous flaps, and free flaps, each with its inherent advantages and disadvantages, have been documented.

Management of soft-tissue defects of the knee remains a challenge for both modalities of specialists of the Plastic Surgeon and Orthopedician. Soft tissue management in knee surgery forms an integral factor in determining the success or failure of the entire procedure. Historically, soft-tissue coverage procedures were most commonly used during knee surgery when problems with wound closure were encountered or in salvage circumstances when primary wound healing problems occurred in the post-operative period, often in association with infection and exposed prosthesis.

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Aims and Objectives

The aim of this study was to successfully use different types of flaps for soft-tissue reconstruction around the knee while preserving its function and cosmetic characteristics.

To provide a reconstructive algorithm for different sizes and locations of soft-tissue defects around the knee joint using pedicled flaps and free flaps.[2-4]

MATERIALS AND METHODS

The study was conducted in the Department of Burns and Plastic Surgery B. J. Medical College and Civil Hospital

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Ahmedabad for from May 2021 to May 2023. Twenty cases of flap coverage for soft-tissue defects around the knee joint have been included in the study. The pro forma for the collection of data is made. All the relevant details of the patient during pre-operative, surgical, and post-operative and follow-up periods will be collected and analyzed.

Inclusion Criteria

In the following study, small, medium, and large-size defects around the knee joint in patients with acute trauma, with post-surgical defect with implant exposure, post-traumatic contracture release defects of posterior knee joints, post-burn contracture release defects of posterior knee joints, post-electric burn defects were included in the study.

Exclusion Criteria

Patients with age >60, chronic smokers with peripheral vascular disease, uncontrolled diabetic patients, infected wounds, patients with peripheral vascular diseases, debilitated patients, raw area over knee joints covered with only STSG, irradiated patients were all excluded from the study.

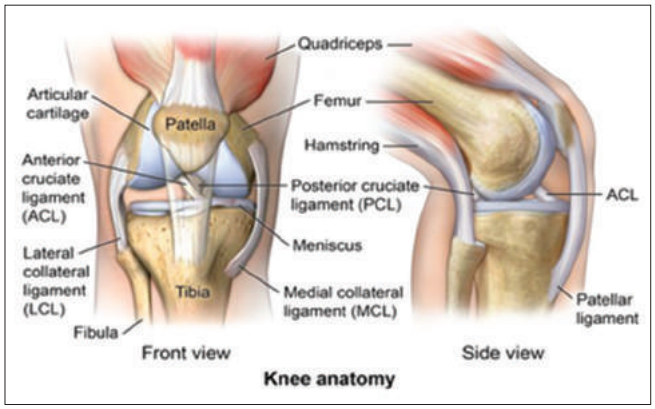


Figure 1: Knee Anatomy

Regional Anatomy

Knee joint anatomy and blood supply [Figures 1 and 2]

The structure of the knee joint is determined by its adaptations for weight bearing, locomotion, and the maintenance of equilibrium. Functional requirements of a reconstructed knee joint are a stable post with adequate soft-tissue coverage and protective sensation. The anatomical features relevant in the context of soft-tissue reconstruction of knee joint are discussed below.

The knee joint is a hinge-type synovial joint which permits flexion and extension about transverse axis, and a small medial and lateral rotation about the axis of the lower leg in the flexed position. The minimal range of knee motion that is associated with everyday activities is a near-full extension to approximately 120° of flexion. Walking on a flat surface requires 70° of flexion, descending stairs 90° of knee flexion, and normal sitting 100° of flexion. Consequently, the near-normal motion of the knee joint is essential for comfortable function hence a pre-requisite for complex reconstructions of the lower leg.

The blood supply around the knee comes mainly from the femoral and the popliteal vessels. The branches and perforators which arise from these vessels form an anastomosis around the knee which forms the basis for distally based flaps. On the medial side, there are perforators from the descending genicular artery and the recurrent artery from the anterior tibial artery. On the lateral side, superior and inferior lateral genicular arteries arising

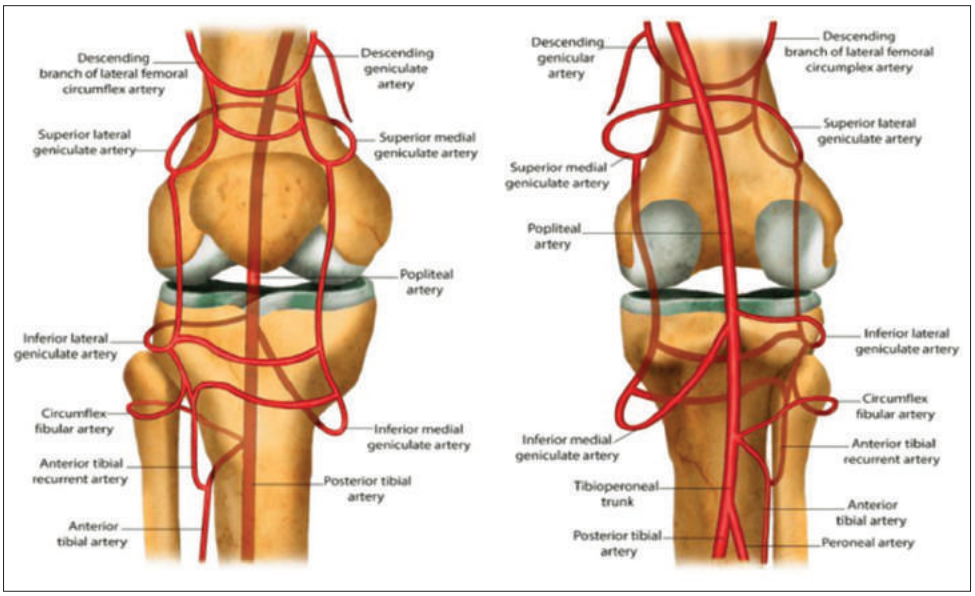


Figure 2: Knee Joint

from the popliteal artery contribute to anastomosis. The flaps can be raised based just on the perforators or along with the underlying muscles and their feeding vessels. In the leg, they can be based on the perforators from the anterior tibial, posterior tibial, or peroneal arteries or along with the muscle and their feeding vessels.

Different Modalities of Coverage

The defect can be covered based on the size of the defect and exposure of the tendon or both. There are different modalities of treatment for anterior knee defects such as a skin graft, fasciocutaneous flaps such as transposition flap, rotation flap, pedicles muscle-only flaps and musculocutaneous flaps, and free flaps. If the defect size is, <4 cm it is covered with STG if the defect is 4–8 cm and exposing only tendons then fasciocutaneous flaps such as transposition flap and rotation flap, could be used to cover the defect. If the defect exposed bone, pedicled muscle flaps would be a good option for coverage and those that are in depth wounds are covered with musculocutaneous flaps. If the defect is very large, then it is covered with free flaps.

Here the defect coverage is described under fasciocutaneous flaps, muscle-only flaps, musculocutaneous flaps, and free flaps.

Fasciocutaneous Flaps

Rotation flap [Figures 3 and 4]

The medial thigh-based rotation advancement flap and wound debridement was done for the soft-tissue defect in the anterior knee region. An incision was extended to the thigh laterally with the base of the flap on the medial side. The vascular basis of this flap was based on the perforators from the medial genicular arteries and the musculocutaneous perforators. Depending on the wound size, a rotation flap was constructed and a flap inset was given with skin graft.

Transposition sliding flap [Figures 5 and 6]

A sliding transposition flap adjacent to the defect was used in a patient with a suprapatellar defect of size 5 and 3 cm defect with a heavy external fixator for fracture reduction. Here, the medial base is taken to the defect. From the lower end of the defect, an oblique line is drawn, this being the distal edge of the flap. Its length should be equal to the contralateral side of the defect. From the end of this line, the lateral edge of the flap is drawn proximally toward its base. The width of the flap is adequate to sustain the circulation of the flap. The length-to-width ratio was taken as 3:2. After marking the flap, the recipient site is prepared and the fasciocutaneous flap was raised and the flap is transposed by sliding toward the recipient site. The inset of the flap was done so that its long lateral edge is sutured to the contralateral side of the defect. The donor site is covered with STSG. Due to the degree of excursion, there was a dog-ear, but Kater regressed with time Figures 3-7.

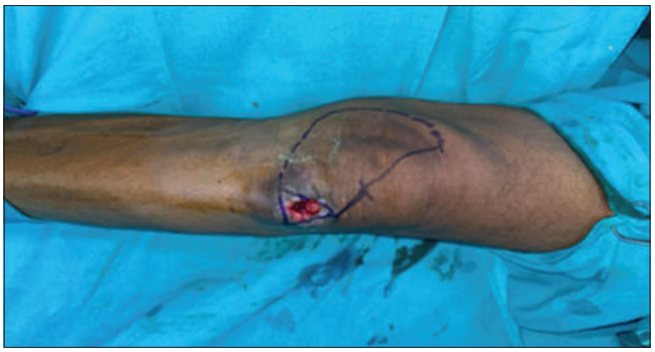


Figure 3: Pre-operative

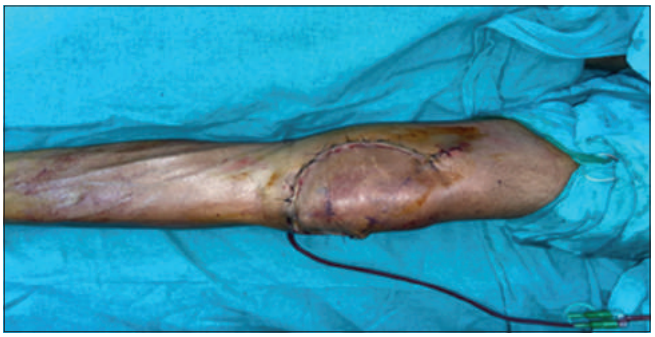


Figure 4: Post-operative

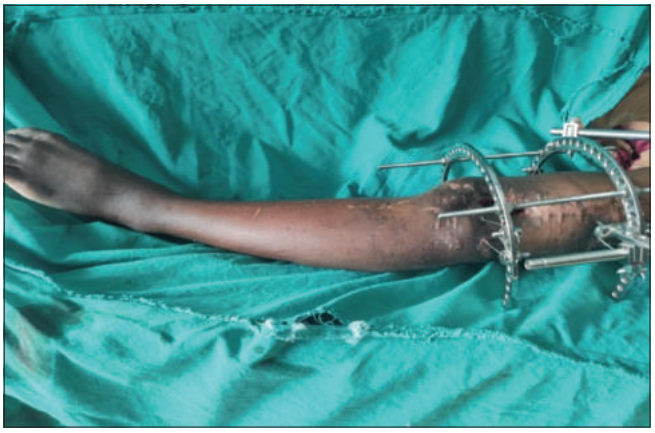


Figure 5: Pre-operative

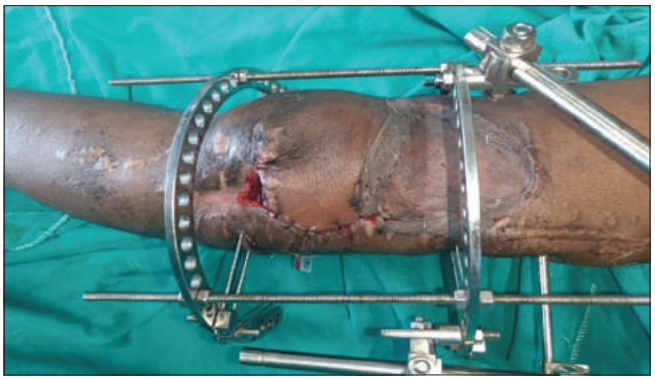


Figure 6: Post-operative

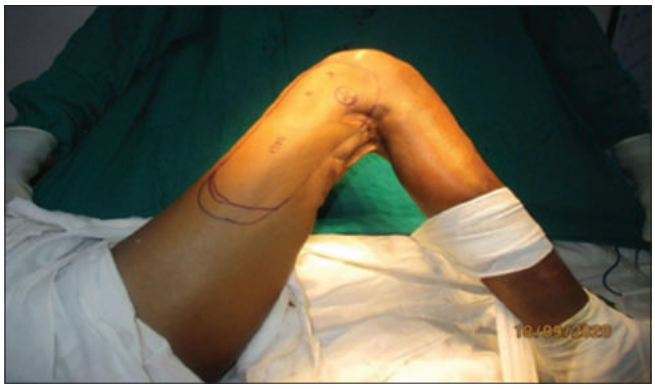


Figure 7: Pre-operative

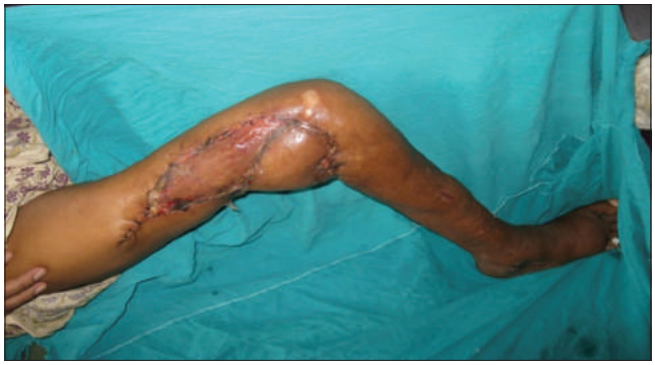


Figure 8: Post-operative

Propeller flap [Figures 7 and 8]

Once the wound has been adequately prepared, the cutaneous skin paddle was designed within the area of the proposed perforating vessel. These can be identified using a hand-held Doppler at the time of surgery, or in more complex cases, these vessels may be mapped preoperatively using duplex ultrasound. This can potentially avoid problems related to variability in local anatomy. After designing a flap that fully incorporates the perforating vessel, microsurgical dissection of the perforator is performed. The entire cutaneous flap may be reliably raised on this single skeletonized vessel and can then be fully rotated as a propeller flap up to 180° around this pedicle. The pedicle should be carefully dissected in all directions to allow adequate mobility of the perforator in the direction of its transfer. The flap was transferred directly into the defect as it is designed adjacent to the wound. It is recommended that this bridge be at least 5 cm in width to avoid any compromise of its vascularity. It is recommended to connect the 2 areas in these cases, therefore avoiding any additional compromise of the flap through compression or kinking of the pedicle from the overlying skin bridge. The donor site is the primary closure and split-thickness skin graft.

Proximally based median sural flap

Preoperatively, the superficial sural artery is first detected with a Doppler flow meter. The operation can be performed with the patient in any position but the prone position is usually best. The flap territory extends from the superior flexion crease of the calf at the popliteal fossa to the junction of the middle and inferior thirds of the posterior calf. The flap is designed in the calf and includes a line representing the course of the superficial sural artery, either in the center or in the lateral part of the calf. Medially and laterally, the midaxial lines serve as the anterior limits. After marking the flap boundaries according to the above guidelines, elevate the flap distally with an incision through the skin, subcutaneous tissues, and deep fascia.

The flap is elevated subfascial to avoid damaging the vessels. When incising both sides and exposing the pedicle, take care to prevent injury to the common peroneal nerve and the pedicle of the flap, preserving both medial and lateral superficial sural arteries until both are observed. Furthermore, both fasciocutaneous vessels may unite before their junction with the popliteal artery and vein. Once clearly defined, the larger vessel is included in the mid-axis of the flap. Proximal superficial draining veins are also preserved to enhance venous drainage in standard flap transposition or for use in micro vascular composite tissue transplantation.

Deep to the fascia, the distal lesser saphenous vein is identified, divided, and included with the flap. The sural nerve, which runs close to the arterial supply, is also transected distally and included. Dissection of the sural nerve from the vascular pedicle places the artery and its venae comitantes at undue risk of injury.

As the dissection proceeds superiorly, gastrocnemius perforators must be divided. In elevating the flap, musculocutaneous perforators that anastomose with the sural cutaneous artery may be encountered. Ligation of these can result in poor perfusion to the flap, and sequentially ligating or performing a trial occlusion may be safer. Small sural cutaneous arteries are often found concurrently with large perforators, and the sacrifice of these perforators may compromise the flap. Only after the vascular pedicle has been identified on the deep surface of the flap may the superior skin margin be incised safely. If the venous congestion which is uniformly noted after initial flap elevation, is irreversible or the venae comitantes prove to be exceedingly small, then a subcutaneous vein should be included with the flap proximally to serve as an additional source of venous outflow.

After cleaning the recipient site, the flap is transferred to the skin defect. It can be transposed as a peninsular fasciocutaneous flap or isolated on its vascular pedicle alone for transposition as an island flap. The rotation point of the pedicle is usually located at the popliteal fossa. Tension

and kinking or twisting of the pedicle must be avoided. Drains are placed under the flap. Primary closure of the donor site is possible with a flap having a width of 6 cm or less, but larger flaps require a skin graft of the donor site. Inevitably, the sural nerve is divided; consequently, the outer aspect of the foot is rendered numb. The transection of this nerve also carries the risk of neuroma formation in the transferred flap.

Median genicular artery perforator based flap [Figures 9 and 10]

The avulsion wound involved the popliteal fossa extending to the posterior border of the proposed flap making it a favorable option. His hemogram and serum electrolytes were within normal limits. The patient had debridement and was planned for popliteal fossa resurfacing with medial genicular artery flap about 8 days after injury. Flap was raised under spinal anesthesia and a tourniquet. Flap was planned in reverse and about 16 × 10 cm flap was raised as fasciocutaneous tissue designed about the midpoint of an imaginary line joining the midpoint of the inguinal ligament to the medial femoral condyle as the axis. Flap was inset on the defect with nylon sutures over a corrugated drain. The secondary defect was resurfaced with split-thickness skin grafting. Nearly 100% flap survival was achieved except for slight marginal tip necrosis that healed with dressing. Knee function was satisfactory and the patient was discharged to continue follow-up on an out-patient basis.

Lateral genicular artery perforator flap [Figures 11 and 12]

Pre-operative marking was done by identification of superior lateral genicular artery perforators by an 8 MHz hand-held Doppler at the septum between the vastus lateralis and short head of biceps femoris, from the knee level proximally. The flap was marked from knee level up to midpoint between the femoral condyle and greater trochanter, with flap axis laying over that intermuscular septum, Figure 1a. The procedures were done under spinal anesthesia with tourniquet control without exsanguination to easily detect the LGA perforators. The anterior margin of the flap was incised down to deep fascia with subfascial dissection toward the intermuscular septum to identify the LGA perforators. We did not skeletonize the perforators, only dissect them to allow tension-free flap inset without perforator kinking or spasm. After dissection and isolation of the LGA perforators, dissection continued in the subfascial plane toward the flap posterior margin, which was incised to completely island the flap, to be only hinged by the perforators. The tourniquet was deflated, flap viability was checked, and the minor perforator was clamped, preserving only the dominant perforator. The perforator flap could be rotated 90° clockwise to cover the anterior surface of the knee or popliteal fossa, respectively,

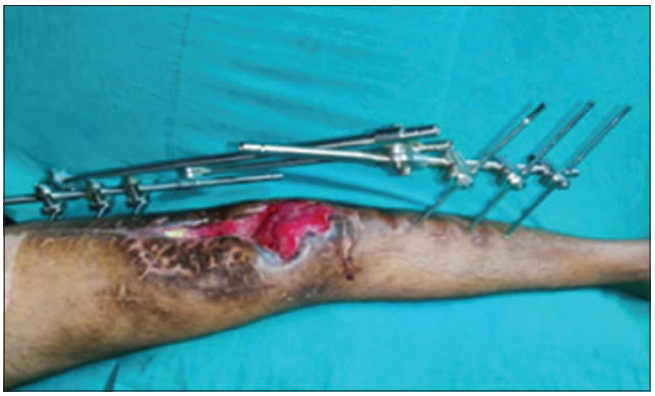


Figure 9: Pre-operative

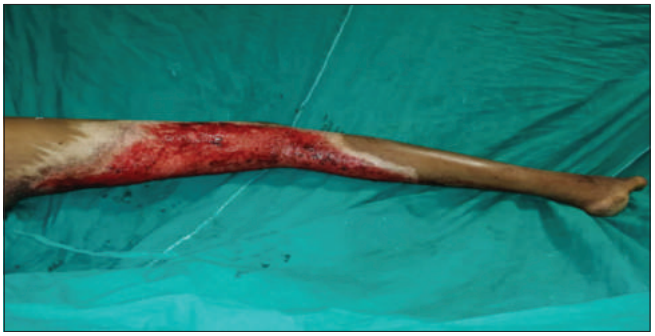


Figure 10: Post-operative

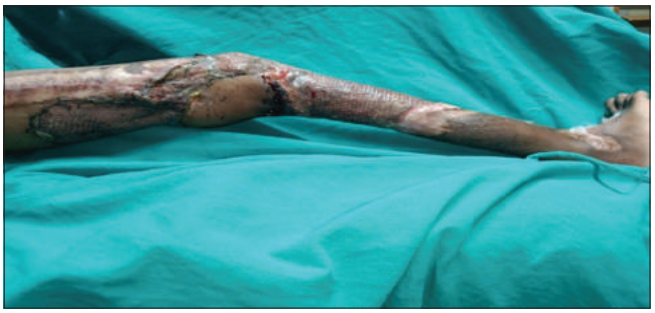


Figure 11: Pre-operative

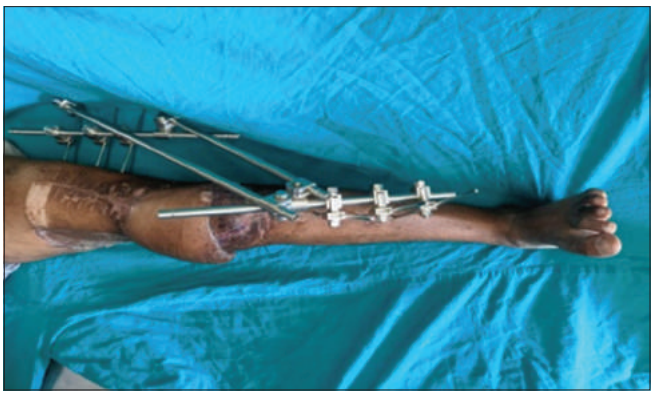


Figure 12: Post-operative

or even rotated 180° in a propeller fashion to cover the proximal one-third of the leg. The LGA perforator flap was transferred into the defect, with excision of any intervening skin bridge, with a suction drain inserted on need. The flap

was inset tension-free to avoid spasms or kinking of the pedicle and the flap donor site was either closed primarily or split-skin grafted.

Muscle Flap

Gastrocnemius muscle flap

This is the first choice in case of knee and upper third leg defects. Either the medial or the lateral belly or both can be used for coverage. They get their blood supply from the femoral artery with the branches that originate above the knee joint. As the origin of these vessels is deep inside the popliteal fossa, the pedicles are usually protected in case of trauma and are available for use. The flap is raised proximally up to its origin. The reach of the flap can be increased by dividing the tendinous fibers at the origin on the superficial surface or scoring the aponeurotic layer in the undersurface of the muscle or totally islanding the flap based on its vascular pedicle. In the case of the gastrocnemius muscle flap, the incision was extended from the defect downward the leg vertically either in the posterior midline or medially 2 cm from the medial border of the tibia depending on the defect. The skin flap was undermined and the gastrocnemius muscle was dissected and elevated along with 1 cm of the tendinous portion of Achilles tendon and the muscle flap is tunneled subcutaneously into the defect and inset given. The raw area is covered with STSG and the donor area is closed with primary suturing.

Musculocutaneous Flaps

When the reach of the muscle alone is not good or when we need a cutaneous component to provide a better cover that can be opened later for secondary procedures, a musculocutaneous flap is planned. The following are the musculocutaneous flaps that are commonly used.

Gastrocnemius musculocutaneous flap [Figures 13 and 14]

This skin overlying the muscle is elevated along with it as a flap. This can extend distally onto a point 5 cm proximal to the ankle. This skin component of the flap is supplied by a perforator arising from the muscle belly and the fascial network of vessels. This provides a longer flap with more skin when only the gastrocnemius muscle flap will not be sufficient to cover the defect. In the traditional design, both the muscle and the skin flap move together in the same direction. Some modifications are described which can facilitate the differential movement of the muscle and the skin component which can better cover the defects as per the needs. This modification describes the skin component as islanded on the perforator, which comes out of the muscle belly and supplies the overlying skin, especially the lateral row of the perforator. Soft-tissue defects were thoroughly debrided surgically. In the case of the medial gastrocnemius myocutaneous flap, the incision

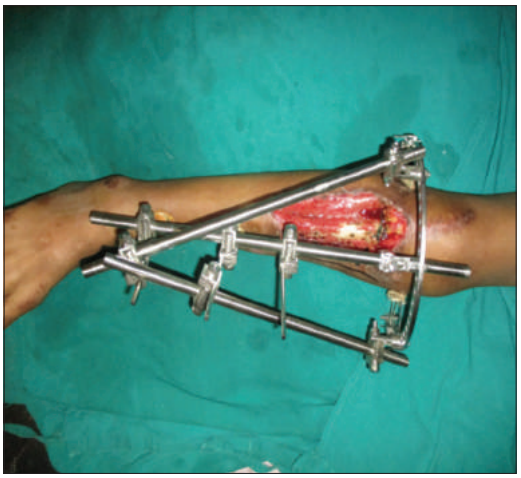


Figure 13: Post-operative

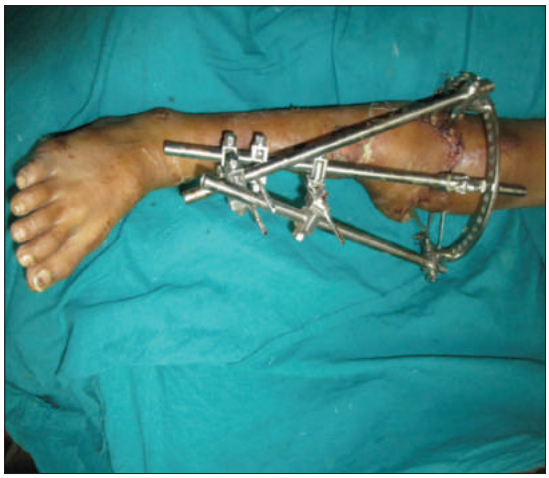


Figure 14: Post-operative

was extended downward vertically from the wound in the anterior knee, 2 cm from the medial border of the tibia bone, and a posterior incision in the posterior midline was made to include the cutaneous flap. These two incisions were connected to raise the flap about 10 cm above the medial malleolus. The medial gastrocnemius muscle was dissected. The musculotendinous junction at the tendon Achilles was identified and divided with one cm of tendon Achilles extension with the muscle. The muscle flap was tagged to the cutaneous paddle with 3–0 vicryl suture. The myocutaneous flap was elevated and rotated to the anterior knee defect. The flap inset was given to the knee defect with 3–0 ethanol. The muscle and donor site were covered with a skin graft taken from the thigh.

Reverse flow anterolateral thigh (ALT) flap [Figures 15 and 16]

ALT flap can be used as a distally based pedicled musculocutaneous flap to cover the defects over the knee. The descending branch of the lateral circumflex femoral artery has rich communications distally with perforators of

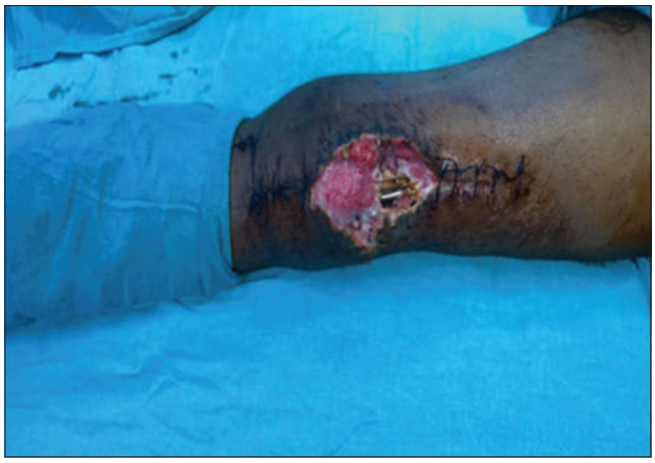


Figure 15: Post-operative

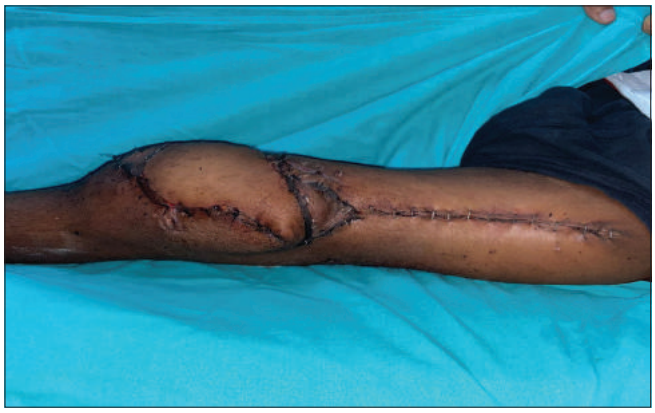


Figure 16: Post-operative

the lateral genicular artery and anastomosis around the knee joint. This flap has a large size and can reach up to 14 cm below the knee joint. The fascia lata can be utilized for reconstructing the quadriceps tendon if required. Reverse ALT flap is based on the perforators from reverse flow from the lateral genicular artery which will be about 8–10 cm from the superolateral border of the patella, which forms the pivot point of the flap and the skin paddle is on the anterolateral region of the thigh. The flap design was done according to the defect size. The skin flap was raised along with the perforators arising from the descending branch of the lateral circumflex femoral artery, which has communication to the lateral genicular artery and also included a part of the vastus lateralis muscle for the venous drainage. The flap was dissected up to the pivot point. Skin incision was made connecting the flap and defect and the flap was transposed to the defect along with the vascular pedicle dissected. Flap inset was given with 3–0 nylon. The donor site was covered with a skin graft taken from the thigh.

Free flaps

When the defects are large and when the local flap options are either not available or used up, free flaps are chosen. The commonly used free flaps are the ALT flap. The recipient vessels have to be chosen according to availability. The major vessels such as superficial femoral vessels and popliteal vessels can be used and the anastomosis to these can be performed in end to side fashion. The tibial vessels lie deep and can be exposed using a posterior incision and splitting the gastrocnemius and soleus muscles in the prone position and used as recipient vessels. Descending branch of the lateral circumflex femoral artery too has been used. The other vessels nearby are the medial sural artery which supplies the medial belly of gastrocnemius which can be detached and used. Descending genicular branch of the femoral artery which runs in the adductor canal can be used to attach the free flap. These obviate the need for changing the position of the patient during surgery as they can be exposed in the supine position. In case there is no ideal vessel nearby, procedures such as vessel loops and vein grafts have been described, but the failure rate is more with

OBSERVATION AND RESULTS

From May 2021 to May 2023, 20 patients were treated with different types of flap coverage. Out of 20 patients, 16 were male and 4 were female patients. The mean age was 40 years (Range: 20–60 years).

Etiology Distribution

In the present study, the etiology of defects is distributed as post-traumatic which are further divided into low-velocity trauma, moderate velocity, and high-velocity trauma which include major cause a total of 17 cases are due to post-traumatic causes which comprises 85% and the rest are due to post-electric burn defect and post-traumatic contracture release and post-burn contracture release.

Location of the Defect

Out of 20, 13 patients which is more than 50% had defect over the anterior region, 3 were on the posterior aspect, 2 cases were on the medial aspect and 2 were on the lateral aspect of the knee joint.

Sizes of the Defect

In the following study, the defects are categorized into different sizes as small (<4 cm), moderate (4 –8 cm), and large defects (>8 cm) based on the size of the defect.

Types of Defects

There are different types of defects in this study exposing tendon, defect opening into the joint, or exposed orthopedic implants. There were a total of 8 patients with tendon defects, 10 patients with joint exposure, and 2 patients with orthopedic plate exposure.

Phases of Coverage

Out of 20 patients operated, 1 patient was operated in the acute phase which is within 72 h of injury and 17 patients were operated in the subacute phase which is from 72 h to 6 weeks, and 2 patients were operated in the chronic phase which is >6 weeks.

Types of Modalities used for Coverage

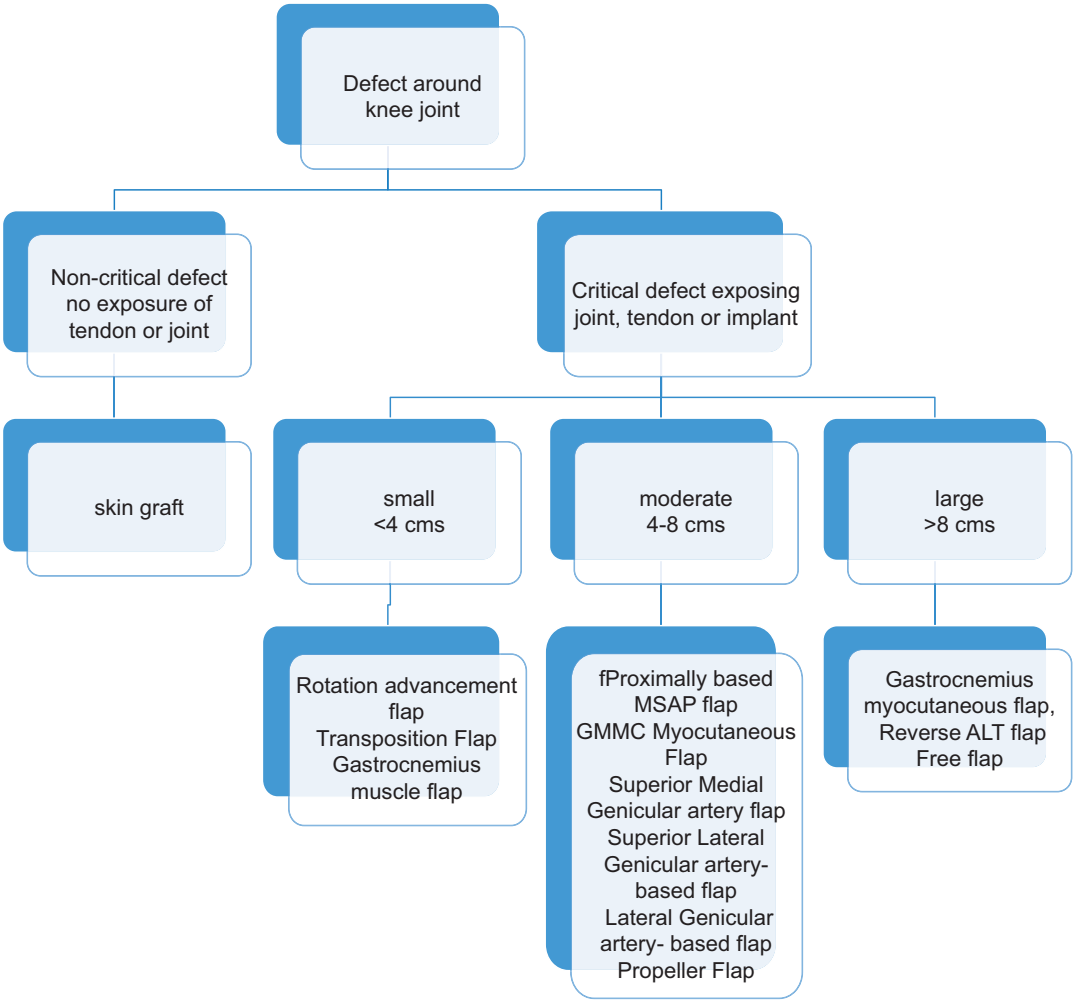
Among 20 patients operated for different locations of defects, different modalities were used. Four out of 20 patients were operated with different types of fasciocutaneous flaps, one patient was operated with a gastrocnemius muscle flap and covered with STG, 10 patients were operated with myocutaneous flaps such as medial gastrocnemius, lateral gastrocnemius and reverse ALT flaps, 4 were operated with perforator based flaps such as medial genicular perforator based flaps and lateral genicular artery perforator based flaps and one patient is operated with free ALT flap.

Different Flaps Used for coverage

Out of the total of 20 patients operated, different types of flaps were used as described above and out of the different modalities used for coverage the following are the flap surgeries done in the patients. Out of 4 fasciocutaneous flaps used for coverage, one is medial thigh-based rotation advancement thigh flap coverage for anterior suprapatellar defect, one is random pattern transposition flap, one is propeller flap based on medial genicular artery perforator, one is proximally based median sural artery flap. One patient was operated with a medial gastrocnemius muscle-only flap and coverage was done with STG. Among 10 myocutaneous flaps operated all the flaps were done for anterior knee defects of which 5 flaps were medial gastrocnemius myocutaneous flaps based on the medial sural artery, 4 flaps were lateral gastrocnemius myocutaneous flaps based on the lateral sural artery and 1 flap is reverse ALT flap included a part of vastus lateralis muscle. Out of 4 perforator-based flaps 2 were superior medial genicular perforator-based flaps and 2 were superior lateral genicular perforator-based flaps. One patient has been operated with a free ALT flap with vascular anastomosis of vessels.

Complications

Out of the 20 patients operated for reconstruction, 5 patients had suffered complications of which 2 had wound infection, 1 had wound gaping, 1 had marginal



flap necrosis, and 1 had donor site soft-tissue defect which were all managed conservatively. Overall all the flaps could provide good coverage and there was no flap loss.

Reconstructive Algorithm

DISCUSSION

The knees are the biggest and most important joints that tolerate all kinds of loads and absorb the shock.[1]

The present study included 20 patients with only soft-tissue defects around the knee joint that has tendon exposure, joint exposure, and neurovascular bundle exposure defects and implant exposure.

In this study rotation advancement flap and transposition flap coverage were used in 2 patients with small anterior knee defects and are good options for coverage when there is an external fixator *in situ* and local pedicled flaps are difficult or unavailable. The rotation flap provided good coverage whereas the transposition flap coverage had a complication of wound gap which was managed with secondary suturing

Propeller flap was used to cover the posterior knee soft-tissue defect caused due to post-traumatic contracture release. The flap was based on the superior lateral genicular artery perforator. Rao *et al.*,[9] Wagner *et al.*,[10] and Amin *et al.* articles described various reconstructive options following total knee arthroplasty. However, the etiologies included in our present study were not only the knee defect following total knee arthroplasty but also included other etiologies such as knee defects caused due to post-traumatic contracture release, post-burn contracture release, and post-traumatic defects. Gastrocnemius muscle flap is used in 1 patient having a smaller anterior knee defect and needs a short time and is esthetically good in small defects and useful when the defect depth is less and smaller. In the present study its usage has been limited in cases of knee defects as the major defects were in joint space having large internal deficit and STG for a knee defect later on could cause contracture and limit the movement of knee joint excursion would rather be the best option for upper and middle third leg defects or exposed implants. Most of the knee defects were presented with an external fixator is also one of the reasons to avoid gastrocnemius muscle-only flap with the fixator being in the way of muscle rotation.

Gastrocnemius myocutaneous flap needs a short surgery time and is rather easy to handle or inset the flap and thus is the most widely used as a workhorse for the knee defects until now. These flaps are almost always available and provide good vascular supply to the recipient area for good wound healing, even in high-velocity traumatic defects. These flaps provide the best coverage for large medial and lateral defects even in the acute phase of injury operated in <72 h of trauma. A total of 9 patients were operated with gastrocnemius myocutaneous flaps of which 5 were on a median sural artery and 4 were on lateral sural artery-based flaps and none had the complications of the flap and all provided good coverage. Only 1 patient had donor site tendon exposure defect, which was healed by secondarily on dressing and two patients had infection and discharge from the wound site, which was managed by systemic antibiotic coverage after culture sensitivity. However, there is a risk of donor site morbidity resulting from the sacrifice of muscle; defect size is likely to be large, or the site is more proximal than the patella; and the use of the surgery is limited in case of quadriceps tendons.[12-14]

In this study, perforator-based flap was done in 4 cases, of which 2 were based on superior medial genicular artery perforator flap and 2 were superior lateral genicular artery-based flaps, of which all the flaps provided good flap coverage with limited donor site morbidity. In post-burn contracture release defect covered with superior medial genicular artery flap suffered marginal flap necrosis, which was debrided STSG coverage was given.

Reverse ALT flap is performed in one patient with knee implant exposure on the anterior aspect using the descending branch of lateral circumflex femoral artery, has a number of advantages as compared with the study by Chen *et al.* This flap is able to cover the front knees, the defect of the lateral side, and especially the defect of the lower third in the thigh.

Proximally based medial sural artery perforator flap was performed in one patient and is ideal when the defect is below or inside the patella. As per the study by Lee *et al.* it is proved that the anatomy of the perforator is very consistent and this is, in fact, the most widely used. The perforator is able to be observed on the imaginary line between the popliteal crease and the midpoint of the medial malleolus. The first perforator is located in a circle of 2 cm radius about 8 cm away from the proximal of the imaginary line. Very thin and pliable flap can be obtained; flap elevation is easy; and there is a low likelihood of donor site morbidity.

Free flap was performed in one patient with a large anterior defect exposing the almost entire knee joint. A free flap is useful and provides good result yet it requires a lot of time to perform the surgery and a lot of surgical skill expertise for dissection and anastomosis to the deeper recipient vessels as comparable to the description in Lee *et al.* article.

Thus, there is a wide range of choices for flaps for defect coverage depending on the defect site, size, location of scar, and the condition of surrounding soft tissues. At the location of the defect mainly, the flap can be selected as one of the five modalities described earlier.

A simple reconstructive algorithm has been provided based on this present study for defects around the knee joint.[5-8]

CONCLUSION

From the study of 20 patients with soft-tissue defects in the age range of 20–60 years it is concluded that the following are the modalities for reconstruction. The proximally based medial sural artery fasciocutanous flaps provides tissues similar in skin texture and thickness to the lost ones and is thin and pliable. Rotation advancement flaps and transposition flaps are the best options when there are small-to-moderate anterior knee defects and external fixators *in situ*. Propeller flaps allow the surgeon the freedom to select, tailor or compose the flap independent of the limited indications of conventional flaps. Pedicle perforator flaps such as superior medial and superior lateral genicular flaps of the refined design can be used effectively in various reconstructions of medial, posterior, and lateral defects of the knee joint, especially when gastrocnemius is not available. Reverse ALT flaps provide good coverage in implant exposure and large defect coverage and have consistent and reliable anatomy-free flaps that provide the best coverage in large knee defects but need longer surgical duration.

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Original Article

Prognostic Significance of Intraoperative KOH Wet Mount in COVID-19-Associated Rhinomaxillary Mucormycosis

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Abstract

Background: Fungal skin infections have been diagnosed with the help of the potassium hydroxide (KOH) wet mount technique for decades. Scrapings on a slide mixed with a drop of KOH are heated to dissolve cells other than fungi to visualize the fungal contents. Our study applied this principle with a modification as an intraoperative debridement guide in maxillary mucormycosis cases.

Materials and Methods: From our institute, 20 osteomyelitis cases admitted for surgical debridement with COVID-19 history were taken for study. Intraoperatively, fresh tissues from the borders of the debrided maxillectomy site were collected in test tubes with 20% KOH. The tissues were dissolved by boiling until turbidity cleared and left undisturbed. The sublimate was visualized and scanned under the light microscope with and without staining for fungus. For each site, the presence of fungal hyphae was noted as positive. Then, the number of positive borders, histopathological diagnosis, and recurrence after surgery are compared.

Results: Eight of 20 cases were negative in KOH, among which two cases had no demonstrable fungi in histopathology. Two of 20 cases had one positive border, four of 20 cases had two positive borders, and four of 20 cases had three positive borders. Two of the 20 cases were positive in all borders, of which one had a recurrence.

Conclusion: Applying this technique as an intraoperative guide can guide the surgeons to selectively debride the area of fungal invasion, make fungi-negative surgical margins for better prognosis, and conserve the remaining tissue.

Key words: COVID-19, Fungal osteomyelitis, Margins of excision, Mucormycosis, Prognosis

INTRODUCTION

During the COVID-19 pandemic, several opportunistic infections started resurfacing due to alterations in the immune system. According to a meta-analysis, the pooled prevalence of co-infections was 19%, and the pooled prevalence of superinfections was 24% in SARS-CoV-2 patients, among which 4% were fungal coinfections and 8% were fungal superinfections.[1] In a study comparing bacterial and fungal osteomyelitis of the skull base, the fungal osteomyelitis was the one that had an earlier presentation, faster spread, and higher morbidity and mortality.[2] We know that fungal and bacterial osteomyelitis can masquerade as each other;[3] this can be a reason for higher mortality by the delay of appropriate treatment.

Decades before, the diagnosis and treatment of osteomyelitis focused primarily on bacterial etiology during the empirical treatment phase. The fungal etiology was considered only after non-responsive antibacterial therapy. This delay is a disadvantage in this pandemic situation as the fungal osteomyelitis cases, especially in mucormycosis (zygomycosis). Mucormycosis has an overall case fatality of 50%.[4] Hence, the diagnosis at the earliest possible time is essential for a good prognosis. Fungal infections, including oral mucormycosis (8.6%), aspergillosis, and invasive candidiasis (64%), have been reported in patients with severe COVID-19 or those

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recovering from the disease. Patients with diabetes got infected predominantly.[5] According to the World Health Organization, mucormycosis has an incidence range of 0.005–1.7/million population. In India, the prevalence of mucormycosis is estimated at 140/million, about 80 times higher than that in Western countries.[4] During the COVID-19 pandemic period, diabetes, along with the usage of steroids, these rare fungal infections, showed up their increasing chances and caused a sudden surge in the incidence rate; India contributed 45% of the world's new mucormycosis cases and 34% of deaths due to mucormycosis in 2021.[6] More than 47,000 new cases have been reported in India in 3 months, around May 2021.[7]

Due to its angioinvasive potential, the pathogenic invasion seems much wider than the visible necrotic bone area in an intraoperative situation. A recent case report article states the author's onerous problem of getting the mucormycosis in maxillae controlled only after two or more surgical interventions.[8] It is still a dilemma whether the unresolved infection is a recurrent or residual one.[9] However, studies show that debridement plays an important role. A study shows that 100% of rhinomaxillary mucormycosis cases needed surgical debridement to control the disease.[2] Thus, the quality of surgical debridement seems to be an essential factor in disease recurrence, especially bone involvement.

Universally surgical debridement of osteomyelitis is concluded when fresh bleeding tissue is noted. However, mucormycosis being angioinvasive can spread more expansive in the tissue dissecting in and around the blood vessels [Figure 3], and initial invasion shows minimal to no signs. This phenomenon makes the complete removal of the pathogen difficult by judging the tissue with the help of bleeding spots. In literature, we have seen that many recurrent cases needed a complete resection of the involved bone after unsuccessful debridement efforts to control the disease. This shows a need for an intraoperative guide for enhancing surgical debridement. Necessity is the mother, and thus, a baby-like procedure that still needs experimentation, adaptation, and application came into existence in our institute.

For several years in dermatology, potassium hydroxide (KOH) wet mounts have been used to diagnose superficial fungal infections successfully and reliably. In the COVID-19 pandemic, most case reports show the usage of KOH wet mount from the nasal swabs of suspected mucormycosis cases preoperatively. This study proposes a new variation of the KOH wet mount technique to use intraoperatively as a guide for the debridement of the orofacial mycoses, which could enhance the debridement and near-complete removal of the pathogen from the affected as well as infected areas.

MATERIALS AND METHODS

From RUHS College of Dental Sciences, Jaipur, 20 newly diagnosed osteomyelitis cases admitted for surgical debridement with COVID-19 history were taken for study. Intraoperatively, fresh tissues from the debrided borders of the maxillectomy site were collected with a clean and sterile bone file (from hard tissue) or a scalpel/scissor (from soft tissue) in separate labeled test tubes with 20% KOH [Figure 1]. Before adding them to KOH, soft tissues were minced on a sterile glass slide. The tissues were dissolved by boiling until the solution cleared and left undisturbed. The sublimate from each test tube was taken in three wet mounts, one without any stain and one with saffranine O and one with India ink to visualize fungus, and was scanned by a pathologist thoroughly in a pattern similar to that used in WBC counting on a peripheral blood smear. On finding fungal hyphae [Figure 2], the border is considered positive, and the absence of hyphae is considered negative. The number of positive borders was noted for each case. Histopathological diagnosis is made with regular hematoxylin and eosin staining and periodic acid Schiff staining. A minimum follow-up data of 6 months were collected from the surgeons and surgical residents for each case. It was cross-checked that there was no variation in the pharmacological treatment protocols among the cases included in the study. The histopathological diagnosis, number of positive borders in KOH, and recurrence were tabulated and analyzed [Table 1].

RESULTS

In our study, only two patients showed positive KOH mounts from all the sites sampled, and among them, one patient had a recurrence and needed surgical reintervention. The rest of the cases had a variable number of positive sites, as shown in table. The most necrotic area from the debrided tissue was used for diagnostic purposes, and even among those, 50% showed no fungal hyphae in KOH mount. 5/10 cases that were negative for fungi in KOH had a histopathologically demonstrable fungal infection. About 60% of cases have demonstrated fungi in histopathology, among which two cases were not positive for fungi in KOH. Standardization of the collection site and centrifugation of the dissolved liquid can improve the results of KOH.

DISCUSSION

Our study evolved from the regular KOH wet mount when we started in the initial days of resurfacing mucormycosis. Most of the KOH mounts taken from the nasal swabs were negative; however, the histopathology had demonstrable

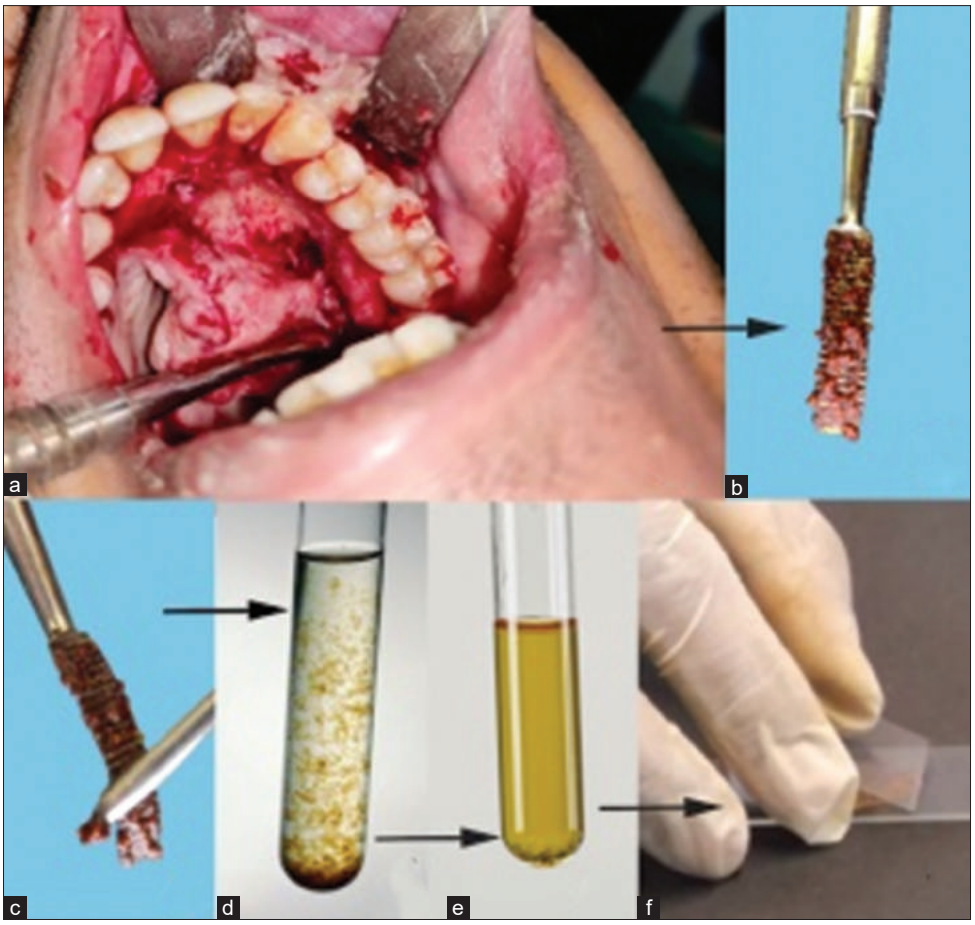

Figure 1: (a) Collection of bone fragments from the surgical site with a bone file, (b) bone file with the osseous coagulum, (c) collecting the sample with a periosteal elevator, (d) sample in potassium hydroxide solution, (e) after heating, dissolving and settling down, (f) and the sublimate on the wet mount

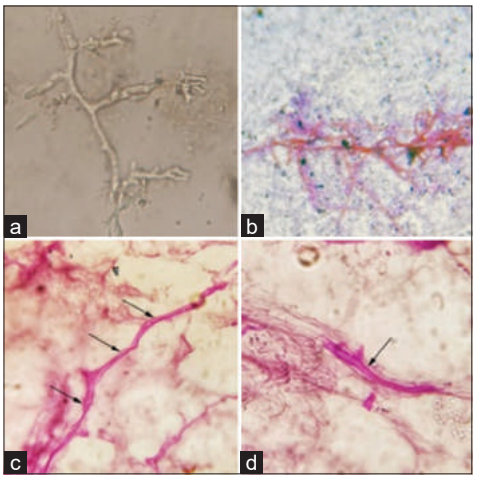

Figure 2: (a) Unstained potassium hydroxide (KOH) wet mount showing fungal hyphae with characteristics of mucor, (b) KOH + safranin O stain showing fungal hyphae, and (c and d) decalcified, paraffin-embedded, periodic acid Schiff-stained sections of the same patient's debrided hard tissue

fungi. Since mucor spreads deeply in osteomyelitis and does not show up in superficial tissues, we could not get fungal hyphae in superficial swabs and scrapings with a considerable consistency compared to histopathology, which made us request the surgeons to send unfixed tissue in saline immediately after completion of the procedure. Those unfixed tissues yielded good diagnostic data despite being cumbersome to process on the slide. Subsequently, we started collecting and dissolving the tissues in 5 mL test tubes. Increasing the concentration to 20% KOH improved the clearance rate. This expedited diagnosis and evolved into collecting tissue from the debrided debris and the surgical borders after complete irrigation of the debrided area for better diagnostic purposes intraoperatively. During this evolution, we have undergone several changes in visualization also. Unstained wet mounts were challenging to scan and much more challenging to appreciate the fungal hyphae. Same time due to the situation, the demand for stains raised, fortunately, or unfortunately, which led us to use Safranine O and India ink for our KOH mounts. Even smearing and PAP staining of the sublimate of KOH solution with sample have been tried. After all these experimentations and the regular histopathological analysis, we standardized the KOH with India ink, KOH with Safranine O, and KOH plain for analysis. Safranin O produced a background precipitate;

Table 1: Comparison of intraoperative KOH preparations and recurrence

Serial number	Age	Gender	Intraoperative positive KOH wet mount preparations from different sites					Total	Demonstrable in H and E/PAS	Recurrence
			Lateral	Medial	Posterior	Superior	Visually most necrotic*			
1	50	Male	−	−	−	+	+	1	No	−
2	35	Female	−	−	−	−	−	0	No	−
3	24	Male	+	+	+	+	+	4	Yes	Yes
4	45	Female	+	+	−	−	+	2	Yes	−
5	32	Male	−	−	−	−	−	0	No	−
6	40	Female	+	+	−	+	+	3	Yes	−
7	30	Female	−	−	−	−	−	0	No	−
8	40	Male	−	−	−	−	−	0	No	−
9	29	Male	−	+	−	+	+	2	No	−
10	52	Female	+	+	+	+	+	4	Yes	−
11	60	Female	−	−	−	−	−	0	No	−
12	50	Male	+	−	−	−	+	1	Yes	−
13	50	Male	+	−	−	−	+	1	Yes	−
14	66	Male	−	+	−	+	+	2	Yes	−
15	45	Male	−	−	−	−	−	0	Yes	−
16	48	Female	−	−	−	+	−	1	Yes	−
17	51	Male	−	−	−	+	+	1	Yes	−
18	45	Male	−	−	−	−	−	0	No	−
19	35	Female	+	−	+	−	−	2	Yes	−
20	33	Male	−	−	−	−	−	0	Yes	−

*Not counted in the total positive sites, taken for diagnostic purposes only from most necrotic areas in the gross specimen. In KOH columns, "−": Negative for fungal hyphae, "+": Positive for fungal hyphae, No: Fungi nondemonstrable, Yes: Histopathologically demonstrable fungi in tissue. H and E: Haematoxylin and eosin, PAS: Periodic acid Schiff, KOH: Potassium hydroxide

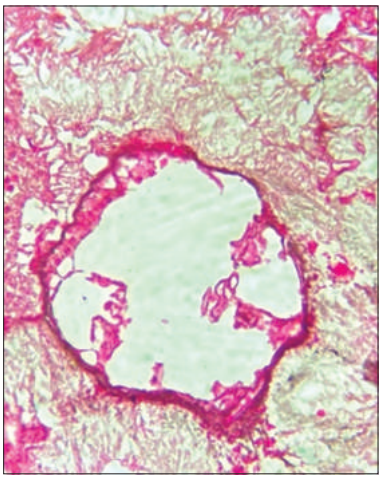

Figure 3: Vascular invasion and growth of fungal hyphae in blood vessel demonstrated by periodic acid Schiff staining

however, it stained the fungi strongly so that it was easy to detect by inexperienced residents.

We know positive surgical margins are associated with worst outcomes in the oncosurgeries.[10] Even after tremendous advances in molecular-level diagnosis and pharmacology, mucormycosis involving bone is not treated solely with pharmacotherapy; surgical removal is needed in 100% of cases to date, which reveals the need for complete removal of the pathogen in its vegetative state from the bone tissue. The distribution rates of antifungal drugs in soft tissue show probabilities of non-surgical therapy of isolated soft-tissue mucormycosis only. The literature shows a non-surgical cure in an isolated soft-tissue mucormycosis case in the cerebrum without bone involvement,[11] lung,[12] and gastric tissue.[13] To the best of our knowledge, we could not find a case report of mucormycosis with bone involvement cured without surgical intervention.

Possible Future Direction of this Study

We know that theories and practices bloom and fade in time according to the necessity and phase of development. At some stages, very primitive ways may be helpful in treatment. If continued at a multi-center level, this study can give knowledge on recurrent mucormycosis, whether it is recurrent or residual. Further, improvements in the processing, as follows, may be applied.

i. Standardization of sampling areas
ii. Centrifugation of the dissolved solution for a better yield of diagnostic material on a wet mount
iii. Developing a "number of samplings to the number of positive" ratio and analyzing its relations to the
iv. Disease progress and treatment outcome.

CONCLUSION

Technology and research are speeding at a high rate to find a better combination of antifungal mucormycosis cases to find a better combination of antifungal drug therapy for mucormycosis cases; still, this study can reveal answers to the aforementioned unanswered questions in the effect

of treatment on bony involvement in mucormycosis cases, especially in the maxillofacial region. Our KOH wet mount intraoperative guidance for maxillofacial bony fungal infections could be an easy intraoperative surgical margin cross-check procedure, which anyone could do with minimal expertise and bring about a major change in the prognosis of the patient. Further, exploration of possible application of this hypothesis and standardization could be done on a multi-center basis to get more samples and statistically arguable data.

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Original Article

Neurocognitive Assessment of the Mild Traumatic Brain Injury Patients using Montreal Cognitive Assessment Score: Six Months' Follow-up Study

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Abstract

Objective: To explore the cognitive patterns in mild traumatic brain injury (mTBI) patients using Montreal Cognitive Assessment (MoCA) score over a period of 6 months and association with different brain lesions.

Material and Methods: This study is a hospital-based, observational, prospective longitudinal study undertaken at tertiary trauma center, SMS Medical College and Hospitals, Jaipur, Rajasthan, India from January 2019 to June 2020, on mild TBI patient total 169 mTBI patients aged between 15 and 65 were included in this study. All the patients evaluated were awake, comfortable and co-operative accompanied with one family member. MoCA (Hindi version 7.01) scale was used and same version was also used during their follow-up visits at 6 months, in the outpatient department clinic. A cutoff score of <26 on the MoCA indicated cognitive impairment (an additional score of 1 was added to the total score for patients with <12 years of education), as recommended in the literature. Computer software (SPSS trial version 23 and primer) was used for the statistical analysis. First, demographic characteristics of the mTBI patients were analyzed. Then, cognition with respect to TBI severity and lesion sites was measured. Finally, a multiple linear regression model was constructed based on the least square method. This model was used to analyze the significance of demographic variables, lesion site, and TBI severity (measured by the Glasgow Coma Scale [GCS] score) in predicting cognitive outcome in mTBI patients, specifically, with age, years of education, GCS score as a continuous variables and the gender and lesion site as nominal variables.

Results: Results show mean MoCA score of 20.82 ± 5.265 during their admission period and mean score of 25.14 ± 3.11 at 6 months with significance improvement in cognitive score. This improvement was significant in all subsets of MoCA on follow-up ($P < 0.001$). Sex, education status, and GCS were significant; age and brain lesions were non-significant factors to determine cognitive functions. Comparison of MoCA scores with brain lesions shows occipital injury with highest MoCA score (24.0 ± 4.1) and mixed injury group with lowest score (19.19 ± 5.46). At 6 months' follow-up, 51.66% of patient continues to show cognitive impairment (MoCA score <26/30).

Conclusions: MoCA scale reliably detects cognitive impairment in mild TBI patients. Compare to 6 months score, there are significant improvement in function of executive/visuospatial functions, memory, abstract thinking, attention, language, and orientation. As there are still residual deficit, these patient may require detailed neuropsychological and neurocognitive evaluation, so that rehabilitation can be planned to improve their cognitive ability, and thus improve the quality of life.

Key words: Cognitive impairment, Cognitive rehabilitation, Follow-up study, Mild traumatic brain injury, Montreal Cognitive Assessment

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INTRODUCTION

According to the World Health Organization (WHO), traumatic brain injury (TBI) is a public health issue, resulting in high rates of morbidity and mortality.[1] Traumatic brain injuries are the seventh leading cause of mortality in India and 78% of these deaths are due to

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road traffic accident (RTA) alone.[1] Even after survival, the morbidity leads to a significant burden on health system worldwide.[1] Patients suffer from loss of physical and cognitive functions in varying degrees which causes significant deterioration in not only functional ability, social skills, and economic productivity but overall quality of life. With the advancement in modern medicine and availability of newer technique of treatment, survival rate of TBI patient has increased and so as people living with cognitive impairment.[2-5]

Recovery after mild TBI (mTBI) may have different patterns as shown by study where most cognitive deficits post-trauma usually disappear beyond 1 month.[6] Other reviews show that the recovery of cognitive functions does not occur in a steady manner. It is usually faster in first 90 days and then it tends to slow down. Frencham *et al.* have suggested that almost all the cognitive domains follow similar recovery pattern after mild TBI except for working memory, which may see significant impairment for up to 93 days.[7] According to one meta-analysis, cognitive functions which are affected most between 48 h and 1 month after mild TBI are verbal learning, concentration, and information processing.[8] Other studies have shown that in about 5–10% of patients some atypical cognitive impairment may persist up to 1 year.[9]

Since a significant percentage of patients of mild TBI have a risk of developing debilitating and persistent cognitive deficits for longer periods of time, it becomes extremely important to assess the cognitive functions in every patient of mild TBI and recognize the impairments associated with mTBI early.[10] It is essential that with the help of an assessment tool, screening of all patients for cognitive deficit and a prediction of the possible late outcome be made so that a quick and efficient planning of rehabilitation can be done for these patients after the initial management. Moreover, the nature of TBI is such that the effects on cognition are of varying degrees and duration which makes it difficult to assess their prognosis.[10] Therefore, various factors must be taken into account including impairment in cognition in the acute phase of injury.[11]

In recent update of ontario neurotrauma foundation 3rd Edition have suggested use of various screening tools to assess the cognitive functions in TBI patients.[12] MoCA is one such tool, which can be used to evaluate the cognitive impairment in TBI population. Montreal cognitive assessment (MoCA) is a brief standardized tool, use to assess mild cognitive impairment[13] and has been used widely in various population group including TBI patient.[14,15]

In general, 80–85% of mTBI patients with normal computed tomography (CT) findings show complete cognitive recovery but there is always some percentage of patients, who continue to show persistent cognitive deficit and data analysing their etiology and further prognosis of the patient remains insufficient.[16] Furthermore, there is no sufficient data to show various demographical and accident-related factor effect the cognitive performance on the MoCA scale in our geographical setup, Western part of India. Therefore, the first aim of our study was to assess the cognitive pattern in mild TBI patients over a period of time using MoCA as a cognitive assessment tool. The second objective was to explore the effect of various demographic variable, TBI severity and different lesion site have over the cognitive profile of TBI patient. Finally, how different lesion site of brain affect the various substrate of global cognitive function over the period of time. We hypothesized that generalized improvement in global cognitive functions (improve MoCA score) over a time period in most of mild TBI patients. We expect that different demographic and others factors such as age, education, and TBI severity has effect on cognitive functions. We also expect improvement in different cognitive function (different MoCA subscales) associated with different brain lesions site.

MATERIALS AND METHODS

Study Design

This study is a hospital-based, observational, prospective longitudinal study undertaken at tertiary trauma center, SMS Medical College and Hospitals, Jaipur, Rajasthan, India from January 2019 to June 2020, on mild TBI patient. Ethical committee clearance was taken from our institute before commencement of this study. Hindi edition of MoCA version 7.01 was used for assessment.

Participants

Patient admitted between ages of 15–65 years in a trauma center of Department of neurosurgery for TBI, were enrolled for the study. Informed consent was taken from the patient or a close relative about the study. The patients were later followed up after discharge from ward, in outpatient clinic of our neurosurgery department after a period of 6 months. Criteria for mTBI were selected according to Glasgow Coma Scale score of 13–15.[17] Other than above classification, definition of mild TBI given by Brain Injury Committee on head injury was used.[18] mTBI is defined as "a person who has had a traumatically induced physiological disruption of brain function, as manifested by one or more of the following:

1. Loss of consciousness for 30 min or less.
2. Memory loss for events before or after the accident up to 24 h.

3. Change in mental state like confusion, disorientation after the time of the accident.
4. Transient or non-transient focal neurological deficits.

Following patients was excluded from our study: previous history of head injury or neurological deficit, substance abuse, known patient of mental retardation or Alzheimer disease, or Parkinson disease or any other degenerative brain disease. Patients who could not complete the cognition test were also excluded.

Baseline data, including demographic information, educational qualification, mode of injury, GCS score, and intracranial finding of CT scan as reported by radiologist blinded from study were also taken into account. All these details were recorded in a self-designed pro forma. All the patients admitted in neurosurgery ward, initially underwent stabilization of their vitals, complete history taking, general and neurological examination was done. Management for head injury was given according to the treatment protocol followed at our institute and no cognitive intervention was done during their hospital stay.

Evaluation Methods

All the patients evaluated were awake, comfortable and co-operative accompanied with one family member. MoCA (Hindi version 7.01) Scale was used and same version was also used during their follow-up visits at 6 months, in the outpatient department clinic. A cutoff score of < 26 on the MoCA indicated cognitive impairment (an additional score of 1 was added to the total score for patients with <12 years of education), as recommended in literature.

MoCA

The MoCA is a cognitive assessment tool used as a screening test, initially developed to evaluate mild cognitive decline in degenerative diseases of CNS.[13] Since the invention of test multiple versions has been developed in different languages worldwide,[19-23] this scale is now freely available for use by health-care professional. Various studies in the past have found MoCA as an assessment tool to be effective in many diseases.[24] MoCA is a single-page test with a maximum score of 30 points, which can be completed in about 10 min. It has become one of the most common choices for quick cognitive assessment these days.

12 subsets of MoCA Scale assess seven cognitive functions, includes:

1. Visuospatial or executive function includes: score of 1 for trail making test, 2 for cube copying, and 3 for clock drawing. Total score is 6 for this function.
2. Attention and concentration function includes: 2 for digit span testing, 3 for serial subtraction, and 1 for tapping. Total score is 6.
3. Language function includes: 3 for naming, 2 for repetition, and 1 for fluency. Total score is 6.
4. Memory function include: 5 score for delayed short term memory recall test after approx 5 min, two learning trials of five nouns are given at the initial of testing. Total score is 5.
5. Abstraction function: 2-item verbal abstraction test. Total score is 2.
6. Orientation function: testing for orientation to time and place. Total score is 6.
7. Naming function: 3-item confrontation test. Total score is 3.

The MoCA detect 90% of mild cognitive impairment subjects with high sensitivity and specificity using a cutoff score of 26.[13,25,26] Similarly, Saleh *et al.*, 2018 observed in their study that a MoCA score of 26/30 or above is presumed normal.[27] Thus, a MoCA score of <26 indicates the participants are more likely to have cognitive impairment.[26,27]

RESULTS AND STATISTICAL METHODS

Computer software (SPSS trial version 23 and primer) was used for the statistical analysis. First, demographic characteristics of the mTBI patients were analyzed. Then, cognition with respect to TBI severity and lesion sites was measured. Finally, a multiple linear regression model was constructed based on the least square method. This model was used to analyze the significance of demographic variables, lesion site, and TBI severity (measured by the GCS score) in predicting cognitive outcome in mTBI patients, specifically, with age, years of education, GCS score as a continuous variables, and the gender and lesion site as nominal variables. On the basis of years of education, patients were categorized into three groups: Less than 6 years, 6–12 years, and more than 12 years. GCS score more than or equal to 13 was considered.

Descriptive Statistics

A total of 169 participants were included in the study. The age range in our study was 15–63 years, with majority of patients presenting in the age group <40 years - 146 patients (86.39%). Peak incidence was seen in the third decade. There was male preponderance - 109 patients (64.49%). The patients were classified into three groups based on their education in years as <6 years, 6–12 years, and more than 12 years and had 53 (31.4%), 60 (35.5%), and 56 (33.1%) patients in each category, respectively. Most of the traumas were caused by motor vehicle crashes/RTA 139 patients (82.2%), followed by assaults 16 (9.5%) and falls 14 patients (8.3%). GCS score was obtained. Out of 169 patients, 72(42.6%) had a score of 15, 55 (32.5%) had

a score of 14, and 42 (24.9%) received a score of 13. The sociodemographic profile is presented in Table 1.

Distribution of MoCA Total Scores by the Lesion Site at Admission and at 6-Month Follow-up

Patients were classified into six groups on the basis of site of lesion(s): frontal lobe injury, occipital lobe, temporal lobe, parietal lobe injury, multiple lobe injury, and others injuries as confirmed by radiological imaging. In the present study, multiple lobe injury means injuries in more than one lobe of brain, such as in frontal lobe and temporal lobe, or in occipital lobe and parietal lobe or any other 2 or more lobe combinations. In our study, bilateral injury of same or different lobes was also considered in the category of multiple lobe injury. Other injuries included lesions which cannot be defined in earlier groups like inter-hemispheric bleeds, brainstem lesions, or basal cisterns bleeds, as confirmed by radiography. The statistical details for MoCA score according to the site of lesion are shown in Table 2. The average score of MoCA was highest for occipital lobe injury category (average score of MoCA = 24) and lowest for mixed injury category (mean MoCA score = 19.19). The average total MoCA score at the time of admission was 20.816 which are much less than the cut-off of 26 for cognitive impairment as suggested in earlier studies (Nasreddine *et al.*, 2005) thus suggesting higher chances of cognitive impairment in these patients.[13] Overall, 81.66% participants showed cognitive impairment as per the MoCA (score < 26/30).

Correlation of Cognitive Status with Various Factors in mTBI Patients

Using demographic characteristics, site of lesion, and GCS score as independent variables and MoCA score as a dependent variable, a multiple linear regression model constructed on basis of least square method was applied to analyze the effect and correlation of these variables on cognition and their role in predicting long-term cognitive outcome in TBI patients as measured by the MoCA total score. According to the results, gender, severity of injury, and education were significant factors, affecting cognitive function in patients with TBI (Table 3). It was found that education had a positive correlation with better preservation of cognitive functions in these patients; that is, longer the duration for which patient received education, the better they performed on MoCA test and the cognitive functions were less affected by TBI in such patients, and vice versa. Similarly, severity of injury measured by GCS score also showed positive association with MoCA score. TBI patients with a higher GCS score scored better on MoCA test (Table 4). Age and site of lesion did not show any association with the total MoCA score.

Table 1: Sociodemographic profile of the patient

Variables	Number of cases (%)
Age	
≤20	36 (21.3)
21–30	78 (46.2)
31–40	32 (18.9)
41–50	18 (10.7)
>50	5 (3)
Gender	
Male	109 (64.49)
Female	60 (35.51)
Education	
<6	53 (31.4)
6–12	60 (35.5)
>12	56 (33.1)
Mode of injury	
Assault	16 (9.5)
Falls	14 (8.3)
RTA	139 (82.2)
GCS (on admission)	
13	42 (24.9)
14	55 (32.5)
15	72 (42.6)
Total	169 (100)

RTA: Road traffic accident, GCS: Glasgow Coma Scale

Table 2: Distribution of total MoCA score by lesion site

Lobe	Number of patients	At admission	At 6 months	*P*
Frontal	52	20.88±5.09	25.5±3.17	<0.001
Parietal	8	23.25±1.58	27.25±2.05	<0.001
Temporal	32	22.06±5.09	25.56±2.78	<0.001
Occipital	6	24.0±4.1	26.67±2.88	0.025
Mixed	57	19.19±5.46	24.14±3.01	<0.001
Others	14	21.57±5.87	25±3.68	0.001
Total	169	20.81±5.26	25.14±3.11	0.001

MoCA: Montreal Cognitive Assessment

Table 3: Multiple linear regression coefficients of the MoCA total score

Variables	Coefficient	SE	*t*	*P*
Constant	15.292	1.749	8.741	0
Age	0.017	0.039	0.425	0.671
Sex	4.746	1.509	3.145	0.002
MOI	0.137	0.588	0.234	0.816
GCS total	2.968	0.447	6.644	0
EDU level	1.144	0.427	2.68	0.008
Lesion site	−0.067	0.199	−0.335	0.738

SE: Standard error, GCS: Glasgow Coma Scale, MoCA: Montreal Cognitive Assessment

Comparison of MoCA Subsets Score at Admission Time and Follow-up

Mean MoCA score obtained in our sample were 20.82 ± 5.265 at time of admission and 25.14 ± 3.11 at 6-month follow-up. Paired sample *t*-test was used to analyze MoCA scores of different subsets between the two groups (Table 5). Mean of each subset was calculated with standard

Table 4: MoCA score in relation to GCS score

GCS at admission	Total MoCA score at admission	Total MoCA score after 6 months
13	16.33 ± 4.91	22.57 ± 3.02
14	21.24 ± 4.12	25.45 ± 2.58
15	23.11 ± 4.62	26.39 ± 2.64

MoCA: Montreal Cognitive Assessment, GCS: Glasgow Coma Scale

Table 5: Mean MoCA subsets score at admission time and follow-up

Function	Timing	Mean±SD	*P*
Visuospatial	At admission	3.73±1.126	0.000
	At 6 months	4.38±0.689	0.000
Naming	At admission	2.66±0.544	0.000
	At 6 months	2.89±0.346	0.000
Attention	At admission	4.43±1.507	0.000
	At 6 months	5.00±0.886	0.000
Language	At admission	1.95±0.844	0.000
	At 6 months	2.34±0.588	0.000
Abstraction	At admission	0.81±0.824	0.000
	At 6 months	1.39±0.536	0.000
Memory	At admission	2.53±1.155	0.000
	At 6 months	3.67±0.760	0.000
Orientation	At admission	4.34±1.295	0.000
	At 6 months	5.09±0.826	0.000
Total score	At admission	20.82±5.265	0.000
	At 6 months	25.14±3.111	0.000

SD: Standard deviation, MoCA: Montreal Cognitive Assessment

deviation, and then, these values were compared with those at 6 months. All subsets showed low mean MoCA scores at admission as compared to follow-up scores. A statistically significant difference ($P < 0.05$) was observed at follow-up period in all subset of MoCA score. Difference for total MoCA score at follow-up period was also found to be statistically significant.

Association of MoCA Subsets Score with Brain Lesions at Admission Time and Follow-up

MoCA score was between 10 and 30 at the time of admission and 21–30 at 6 months follow-up in the present study. To compare the effect of lesion site over various subset of MoCA during 6 months period, patients were divided into six categories based on the lesion site (Table 6). A total of 52 patients had frontal lobe injury, 32 patients had temporal lobe injury, and parietal and occipital lobe injury was present in eight and six patients, respectively. 57 patients belonged to "Mixed" injury group and 14 patients were classified under "Others" group. Mean MoCA score of each lobe is shown in (Table 6) at admission and at 6 months. Each lobe injury shows significant difference ($P < 0.05$) at 6 months' follow-up. Different subsets of MoCA score were also compared at 6 month' follow-up. Most of functions had significant improvement. For frontal lobe and mixed injury group, all MoCA subsets showed significant increase in value at

Table 6: Comparison of MOCA SUBSET Score with brain lesions at admission time and follow up

Lobe	Visuo-spatial			Naming			Attention			Language			Abstraction			Memory			Orientation		
	ADM	6 M	p value	ADM	6 M	p value	ADM	6 M	p value	ADM	6 M	p value	ADM	6 M	p value	ADM	6 M	p value	ADM	6 M	p value
Frontal	3.65	4.42	0.000	2.73	2.96	0.000	4.35	5.04	0.000	2.15	2.5	0.000	0.85	1.42	0.000	2.65	3.77	0.000	4.27	5.15	0.000
Parietal	3.75	3.75	*	3	3	*	5.0	5.75	0.048	2.00	2.5	0.033	0.5	1.25	0.003	3.25	4.25	0.007	5.75	5.75	*
Temporal	3.75	4.38	0.000	2.75	2.94	0.012	4.88	5.06	0.245	1.94	2.19	0.018	1.00	1.44	0.000	2.5	3.75	0.000	4.63	5.19	0.000
Occipital	4.67	4.67	*	3	3	*	6	6	*	2.00	2.67	0.025	1.00	1.67	0.025	2.67	3.67	0.041	4.67	5.00	0.175
Mixed	3.74	4.28	0.000	2.46	2.79	0.000	4.02	4.75	0.000	1.72	2.25	0.000	0.58	1.25	0.000	2.30	3.46	0.000	3.95	4.93	0.000
Others	3.57	4.29	0.003	2.71	2.86	0.165	4.43	4.86	0.054	2.14	2.29	0.165	1.29	1.71	0.008	2.57	3.71	0.003	4.57	5.00	0.054

(* denotes no change in score), ADM=at admission time and 6m denotes 6 month follow up

follow-up ($P < 0.05$). In temporal lobe group, all subsets showed significant increase except "attention" function, which show no significant increase ($P = 0.245$). In parietal lobe group, attention, language, abstract thinking, and memory function showed significant increase in score, whereas visuospatial/executive function, naming, and orientation showed no change in score. Similarly, occipital lobe group showed significant increase in language, abstract thinking, and memory function score, but score for orientation function had non-significant increase while visuospatial/executive, naming, and attention function showed no increase in value. For "Other" injury group, only abstract thinking, and memory function showed significant increase in score with other function showing improvement which was statistically not significant.

DISCUSSION

This study was planned with a objective to explore the cognitive patterns in mTBI patients using MoCA score over a period of 6 months. We performed MoCA on 169 patients with mTBI and evaluated them and followed them over a period of 6 months.

The results of our study showed that 81.66% of patients had cognitive impairment, at the time of their first assessment during their hospital stay. MoCA score <26 is taken as a set point in our study to consider for cognitive decline. Various past studies using different population group of TBI have also reported such high incidence of cognitive impairment (Nasreddine and Patel, 2016; Panwar *et al.*, 2018, Saleh *et al.*, 2018),[25-27] where cognitive deficit was present in 79.2% of patients. This high incidence could be explained by admission criteria followed at trauma center and likely that these admitted patients were more severely injured than those who did not need admission after sustaining mild TBI.

This group of patient was followed up in our outpatient clinic during their post TBI acute recovery period. At 6 months of follow-up, cognitive deficit was seen only in 51.66% of patient (MoCA score <26) with significant improvement in cognitive function in all the patients. Dikmen *et al.* studied 20 patients and noted that some cognitive impairment was present in cases of mTBI compared controls at 1-month post-injury which became insignificant one year and both the cases and controls showed similar performance on MoCA.[28] Ponsford *et al.* conducted a study on 84 patients and followed them up to 3 months.[29] They observed complete resolution of any cognitive impairment which was seen at 1 week. This improvement in function can be explained by the resolution of acute disruption of cerebral function after both direct physical and secondary neuro-pathological events in the brain. As brain physiology re-organizes and some degree of neurological stability is re-attained, cognitive function is tends to normalize.

In our study, level of education and TBI severity were statistically significant factors that affected cognitive functions. Patients who received education for more than 12 years performed significantly better compared to those who received it for <12 years ($P < 0.008$). These results are similar to many previous studies (de Guise *et al.*, 2014, Fretter *et al.*, 2012 and Rosetti *et al.*, 2011).[14,15,28] TBI severity at the time of admission also shows positive co-relation with MoCA score ($P < 0.05$). These results are similar to West *et al.*, 2011 and de Guise *et al.*, 2014.[14,30]

Gender turned out to be a statistically significant factor in our study ($P = 0.008$). This can be attributed to higher number of male participants compared to females in our study and greater exposure of males to RTA since males go out for field work more than females in India. Puvanchandra *et al.*, in his study has suggested that such gender difference is seen with TBI in the Indian Subcontinent.[5] Age was not statistically significant as majority of our study population were of age group <40 years. Leitgeb *et al.* conducted prospective study with 863 patients in 2012 found that age of the patients, GCS score and TBI severity were the main factors affecting the cognitive outcome post TBI.[31] Other authors also reached similar results in their respective studies (West *et al.*, 2011; de Guise *et al.*, 2014).[14,30] However, in a 2007 review by Mathias and Wheaton who did a meta-analysis of 41 studies, it was concluded that age and education were not significant factors causing cognitive deficits in TBI patients.[32] It is seen that age shows negative correlation with MoCA score and younger age group perform better at cognitive scales. This is explained by faster capacity of brain to recover from acute mechanical trauma and better brain plasticity.

A qualitative analysis of cognitive domains of MoCA demonstrated that all the MoCA subset had lower score at the time of admission as compared to at 6 months post injury with statistically significant difference in their score. This indicates global improvement in cognitive function over the period of time as brain recovers from acute injury. In this study, at 6 months, all subsets of MoCA still showed some deficit from their maximum score. Similar results were found in a study by Heitger *et al.* where they observed that cognitive impairment in mild group persisted up to 6 months post TBI.[33] Kemp *et al.* also reported early presentation of the cognitive deficit which persisted for longer time up to 8 months.[34]

Our last objective was to evaluate the effect of site of brain lesions on cognition over a period of 6 months. All the 6 categories of brain injury were compared with all the subset of MoCA at the time of admission and at follow up and their statistical significance was calculated. Results showed mixed injury had lowest mean MoCA score and occipital lobe injury had highest MoCA score. Mixed injuries have diffuse impairment in all the functions/subsets of cognition, due to extensive damage to neural pathway of cognitive function. Occipital lobe has less of cognitive pathway, so better performance in MoCA scale. When this above correlation was followed at 6 months period, all the cognitive subset showed increase in their mean value with most of them showing significant increments ($P < 0.05$). Several references of previous studies can be found in literature in which the relationship between lesion site and cognitive impairment in patients of TBI has been explored. Lehtonen *et al*., 2005 studied patients with TBI lesions in frontal and temporal lobe and the neuropsychological outcome of such injuries in comparison to patients having non-frontal or no lesions.[35] Patients with frontal and fronto-temporal lesions performed better in constructional ability but worse in executive functioning. However, no difference was found in neuropsychological and community reintegration parameters on follow-up at one year. Similarly, a study by Panwar *et al*. found that bilateral and diffuse lesions were more common in patients with moderate TBI, while patients in mild TBI group showed a greater number of unilateral lesions particularly in right frontal location.[26,36,37]

Limitations

There were a few limitations to our study. The study was conducted on mTBI patients at a tertiary care trauma center; hence, the data collected may be too homogenous to be generalized in other population groups. Results may differ between participants in other regions or countries with different population characteristics. Since present study only includes mild cases of TBI, excluding moderate and severe cases, therefore results cannot be generalized for overall TBI population. Furthermore, time period of follow-up was only 6 months so there may be chance that change in pattern of cognition beyond this period could not be detected and also any long-term deficit in cognition may not be known.

CONCLUSIONS

In conclusion, the present study demonstrated that cognitive assessment in every case of TBI is of utmost importance since even cases of mild TBI show impairment in cognitive functions which can last for weeks to months, causing significant morbidity and distress to the patients and their caregivers. MoCA is one such quick and easily implementable cognitive assessment tool which can identify the cognitive damage with fairly high sensitivity. All the main domains of cognition such as executive functions, memory, abstract thinking, attention, language, and orientation show significant improvement over 6 months' period. Even though patient continue to show recover to their cognitive function, they still need to be kept under follow-up and those with continued deficit should undergo further evaluation using detailed neuropsychological and neurocognitive tools. Future studies are still needed to evaluate the association between different domains of the global cognitive function and different brain lesions over course of time. This is the time, we focus on post-TBI rehabilitation programs even for patients with mild TBI who otherwise are not offered rehabilitation most of the time and are forced to endure the social, psychological and economic implications which may take months to recover.

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Original Article

Early Childhood Caries and its Association with Maternal Caries Status: A Cross-sectional Study in Mathura District

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Abstract

Background: There is a wide range of etiological and predisposing factors that contribute to the state of oral health, each of which plays a different role in causing disease. There is, however, little information available on how maternal factors affect oral health throughout childhood.

Aim: The aim of the study was to evaluate early childhood caries and its association with maternal caries status in Mathura District.

Materials and Methods: Children ages 24–72 months and their mothers visiting the department were included in the study. A total of 150 child–mother pairs participated in the study. The maternal risk factors were assessed by a pretested questionnaire. After obtaining consent, the mother and their children were clinically examined for dental caries using the DMFT index. Results were analyzed using the Statistical Package for Social Science 20.0.

Results: Significant correlation was found in the mother's caries activity, brushing frequency, the diet of the mother, and their child's caries experience.

Conclusion: Children's dental caries status was significantly related to maternal factors, according to the study. To limit and control dental caries, raising awareness among mothers is crucial.

Key words: Awareness, Bottle feeding, Dental caries, Preventive dentistry

INTRODUCTION

Many societies worldwide experience oral health problems, including dental caries, which affect people of all ages. Dental caries is a common and major public health oral disease that hampers the attainment and protection of oral health in different age groups.[1,2] The prevalence pattern and severity of dental caries vary with age, sex, race, sociodemographic characteristics, economic status, geographical location, food practice, and oral hygiene habits within the same country or region in various parts of the world.[3] It affects 60–90% of the children living in industrialized nations. According to the Centers for Disease Control and Prevention caries is perhaps the most prevalent infectious disease among children.[4]

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During the last few decades, the incidence of microbial diseases has amplified drastically. Microorganisms are the superbug agent responsible for causing dental caries. Many facultatively and obligately anaerobic bacteria dominate the microbial community of dental caries.[2] However, the most important etiological agent of dental caries is *Streptococcus mutans*.[3] Tooth decay takes place when a vulnerable tooth surface is colonized with cariogenic microbes and dietary sources of sucrose or refined sugar. Fermentation of carbohydrates leads to the production of lactic acid by the action of bacteria which melts the hydroxyapatite crystal structure of the tooth, which grounds caries.[5,6]

The etiology of early childhood caries (ECC) is multifactorial and heterogeneous and is heavily influenced

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by excessive bottle feeding with sugar-contained liquids; breastfeeding on demand, nursing beyond the mandatory age for weaning, increased intake of sugar-rich food, and an unbalanced diet. Other factors associated with ECC include genetic predisposition, parental education, nutritional, environmental, socioeconomic, and parental style factors. Those affected often suffer from a reduced oral health-related quality of life compared to their caries-free peers.[7]

ECC is a public health issue that affects very young children, and although it is not life-threatening, if left untreated, it can cause pain, bacteremia, weakened chewing ability, and the toxic overdose of analgesics (acetaminophen) in the early stages of their development, tooth malocclusion in their permanent dentition, phonetic issues, lower self-esteem, and a failure to thrive. In addition, it has been demonstrated that dental caries can slow down a child's ability to gain weight, which may be reversed after rehabilitating the teeth.[8] A correlation between the oral hygiene of the mother and child should be evaluated to evaluate these various aspects.

Thus, the aim of the study was to evaluate ECC and its association with maternal caries status in Mathura District.

MATERIALS AND METHODS

Ethical Considerations

This study was approved by the Committee of Ethics in Research of K.D. dental college and Hospital Mathura. Detailed information about the study was given to mothers. They were explained the procedure to be carried out on them and the children regarding the study. A written informed consent form was signed by the children's mother.

Source of Data/Sampling Method

A selection of 150 children from 24 to 72 months of age and their mothers was done from the set of patients visiting the Department of Pediatric and Preventive Dentistry of K.D. Dental College and Hospital Mathura.

Inclusion Criteria

- Children from 24 to 72 months of age, along with their mother.
- Children suffering from ECC.

Exclusion Criteria

- Children with special health care needs.
- Children with any systemic disease.
- Children with any skeletal and dental developmental disorders.

Procedural Steps

This procedure involved two rounds. In the first round, the mother and child were made to sit comfortably on a chair in a counseling room and a questionnaire was given to the mother regarding her and the child's oral hygiene status. In the second round, the child and mother were made to sit on a dental chair and an oral health examination was done.

Questionnaire

The questionnaire was presented and filled out by a trained pediatric dentist. All the required information needed to commence the study was collected. The proforma included two parts.

In the first part, a set of questions were asked from the mother regarding the child, and they were as follows:

- Type and frequency of dental visits
- His/her oral hygiene practice
- daily sugar consumption
- Feeding habit, i.e., if the child is on breastfeeding or bottle-feeding and its duration and frequency
- Any other oral habits, i.e., thumb sucking\nail biting\ tongue thrusting.

In the second part of the questionnaire, questions were asked of the mother regarding her oral health status. They were as follows:

- Personal data
- Daily sugar consumption
- Level of education
- Socioeconomic status
- Type of interaction with the child while playing or feeding.
- Any deleterious habits.

Clinical examination

Clinical examination was carried out using a plain mouth mirror and an explorer. The child was made to sit comfortably on the dental chair under natural light, then a proper examination of the oral cavity was done, and then similarly for the mother. DMFT index of both the child and mother was recorded.

Statistical Analysis

After completing the clinical trial, the obtained data were subjected to statistical analysis; the data were analyzed using a Statistical Package for Social Science version 20.0. The level of significance was set at 95% ($P = 0.05$).

$P > 0.05$ was non-significant and $P < 0.05$ was significant.

The data of the present study were subjected to statistical analysis to interpret the differences and significance

among groups. Chi-square was used for statistical analysis.

RESULTS

Table 1 shows the study was performed on 150 children and based on the percentage distribution of gender shows that males were more affected (56%) than females (44%). Results showed (52.6%) of children were breastfeeding, (2%) of children were bottle feeding, and (45.3%) of children were both (breast/bottle) feeding. The frequency of bottle feeding in the daytime was (52%) when done 2–3 times, (38%) when done 3–5 times, (8%) when done 5–6 times, whereas (2%) of children were spoon-fed. The frequency of bottle feeding at night time was (62%) when done 1–2 times, (26%) when done 2–3 times, and the remaining (12%) no feeding was done at night time. The result shows that (80%) of children fall asleep with the nipple in their mouth, whereas the remaining (20%) do not use it while sleeping. The sugar intake in bottle milk was recorded with (82%) of children having one teaspoon of sugar, (4%) with 2–3 teaspoons, whereas (14%) of children did not consume sugar in the bottle of milk. (96%) of children had a habit of snaking between the meals, whereas (4%) of children lacked [Table 1].

Table 1: Percentage distribution of the children's feeding and eating habits

Category	Frequency *n* (%)	
Gender		
Boys	84	(56.0)
Girls	66	(44.0)
Type of feeding		
Breast	79	(52.6)
Bottle	3	(2.0)
Combination	68	(45.3)
Frequency of bottle feeding in the daytime		
2–3 times	78	(52.0)
3–5 times	57	(38.0)
5–6 times	12	(8.0)
Spoon feed	3	(2.0)
Frequency of bottle feeding at night time		
0 times	18	(12.0)
1–2 times	93	(62.0)
2–3 times	39	(26.0)
Sugar intake in bottle milk		
No sugar	21	(14.0)
1 teaspoon	123	(82.0)
2–3 teaspoon	6	(4.0)
Fall asleep with a nipple in mouth		
Yes	120	(80.0)
No	30	(20.0)
Use of pacifiers		
Yes	3	(2.0)
No	147	(98.0)
Snacking behavior		
Yes	144	(96.0)
No	6	(4.0)

Table 2 the result shows that (84%) of children brush their teeth once a day, (6%) of them brush twice a day, and (10%) were not brushing at all. It was reported that (96%) of the mothers were uneducated regarding the baby's oral health maintenance, (53.3%) declined to help their children during brushing, whereas (46%) agreed to it. In addition to that, (42%) of mothers did not know when to start maintaining the baby's oral hygiene; (48%) were aware to start it as all teeth erupt in the mouth, whereas 10% of mothers were educated to start it as soon as the baby is born. In our study, (68%) of the mothers reported that they made their child's 1st dental visit when they complained of pain; (32%) made it when they noticed decayed teeth, whereas none went for a routine check-up (0.0).

Table 3 shows the correlation between mothers' education and the DMFT score of children with a ($P = 0.088$), thereby depicting a non-significant difference between them [Graph 1].

Table 4 shows the correlation between the mother's caries experience and the child's caries experience; a significant positive correlation was found between the DMFT of the mother and DMFT of a child, with the *P*-value being (0.00), thereby showing a highly significant relationship between them [Graph 2].

Table 2: Percentage distribution of the children's oral hygiene habits

Category	Frequency *n* (%)	
Brushing		
No brushing	15	(10.0)
Once a day	126	(84.0)
Twice a day	9	(6.0)
Oral hygiene maintenance		
As soon as the baby born	15	(10.0)
When all the teeth erupt in the mouth	72	(48.0)
Don't know	63	(42.0)
Do you help your child in brushing?		
Yes	80	(53.3)
No	70	(46.0)
From where you get information for baby's oral health		
Don't know	144	(96.0)
From internet	6	(4.0)
From dentist	0	(0)
Does he/she sleep without brushing after a meal at night?		
Yes	139	(92.7)
No	11	(7.3)
When was your child's 1st visit to the dentist?		
For routine check-up	0	(0.0)
When noticed decayed teeth	48	(32.0)
When children complain about pain	102	(68.0)
Do you kiss your child on his/her lips?		
Yes	53	(35.3)
No	97	(64.7)

Table 3: Association between the education of the mother and the severity of decay

Education of mother	Child DMFT score								Chi-square	*P*-value	Inference
	Low		Moderate		High		Very High				
	n	%	*n*	%	*n*	%	*n*	%			
>10th pass	0	0.00	2	13.33	0	0.00	7	8.97	15.095	0.088	NS
10th pass	1	33.33	3	20.00	13	24.07	25	32.05			
12th pass	0	0.00	9	60.00	28	51.86	32	41.03			
Graduated	2	66.67	1	6.67	13	24.07	14	17.95			
Total	3	100.00	15	100.00	1	100.00	78	100.00			

Table 4: A significant correlation between DMFT of mothers and DMFT of children

Mother DMFT Score	Child DMFT score								Chi-square	*P*-value	Inference
	Low		Moderate		High		Very high				
	n	%	*n*	%	*n*	%	*n*	%			
Very low	3	100.00	0	0.00	3	5.60	3	3.80	71.556	0.000	HS
Low	0	0.00	3	20.00	3	5.60	18	23.10			
Moderate	0	0.00	9	60.00	39	72.10	48	61.60			
High	0	0.00	0	0.00	9	16.70	6	7.70			
Very high	0	0.00	3	20.00	0	0.00	3	3.80			
Total	3	100.00	15	100.00	54	100.00	78	100.00			

DISCUSSION

A variety of factors influence tooth decay, which is multifactorial in nature. The interaction of cariogenic microbes and suitable substrates, within a time frame, is influenced by broad social, economic, and cultural factors that contribute to the evolution of caries.[9]

Changing lifestyles and dietary patterns in developing countries like India have led to an increase in caries incidence. Mothers play a major role in promoting oral hygiene, as well as influencing the dietary habits and food preferences of their children. A pattern of behavior acquired during early childhood is deeply ingrained, and changes are difficult to introduce. As mothers play a crucial role in this area, thus, it can be assumed that increased knowledge of mothers will affect their self-care habits and dietary practices, leading to improvements in the dietary and oral hygiene habits of children, thereby improving their ability to prevent dental caries.[10]

In our study, males were more affected than females [Table 1]. Similar trends were reported by Al Hosani and Rugg-Gunn.[11] Studies conducted by O'Sullivan *et al.*[12] and Hattab *et al.*[13] reported no sex difference in caries prevalence.

In our study, most mothers reported that their children breastfeed to sleep during the night. Hattab *et al.*[13] and Dini *et al.*[14] in a study stated that children who were breastfed for a longer duration demonstrated a higher prevalence of caries. The American Academy of pediatric dentistry (AAPD)[15] considers breastfeeding on demand after tooth eruption to be a risk factor for the development of caries disease, which is in agreement with other studies.[16-18] However, it should be considered that the relationship between prolonged breastfeeding and the emergence of caries is complex and may be confused by other factors such as age, sucrose consumption between main meals, and quality of oral hygiene.[19]

In our study, the severity of decay was found to be higher among the children who showed an increased frequency of feeding than among the children who had a low frequency of feeding. Similarly reported by Retnakumari and Cyriac.[20] The severity of decay was higher among the children who fell asleep with nipples in their mouths than in those without. This corroborates with the findings of the study of AL-HSussyne and AL-Sadan.[21] In support of this study, Febres *et al.*[22] also stated that the incidence of caries was higher in children who slept with bottles than in those who did not.

In our study, the addition of sugar into the bottle of milk, as reported by the mothers [Table 1], are risk factors for ECC. A similar result was found in a study done by Corrêa-Faria *et al.*[23] Regarding children's diet, in the present study, it was found that most children have the habit of snacking between meals. A study done by Skafida and Chambers[24] stated that the frequent consumption of sugar-rich foods was associated with dental decay in children under 5. Lack of parental control over the number of sweets or chocolate that children consume also predicted dental decay.[24]

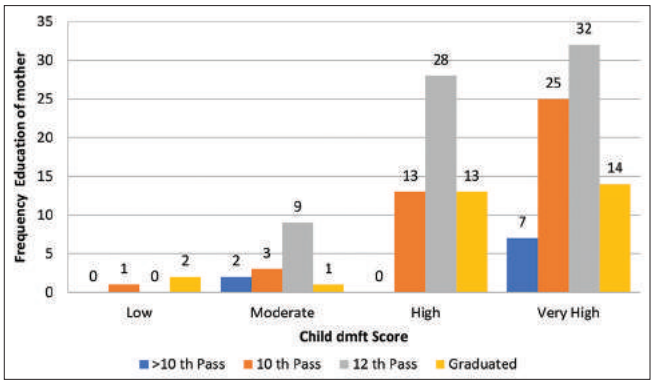
The age at which oral hygiene measures are commenced is of importance in establishing and maintaining the oral health of children. It is generally recommended to commence the tooth brushing as soon as the first tooth erupts. Melhado *et al.*[25] found that the application of dental care from the 1st year of life, mainly emphasizing the educational and preventive aspects, provides an important, if not the most important, means for an individual to reduce the possibility of contracting dental caries.

In our study, the severity of decay was found to be higher among the children in whom tooth brushing was started after 24 months of age, and the severity of dental caries was found to be lesser among the children who were brushed twice daily than among the children in whom brushing was done once daily [Table 1]. These findings are in conformity with the results of studies conducted by Mazhari *et al.*[26]

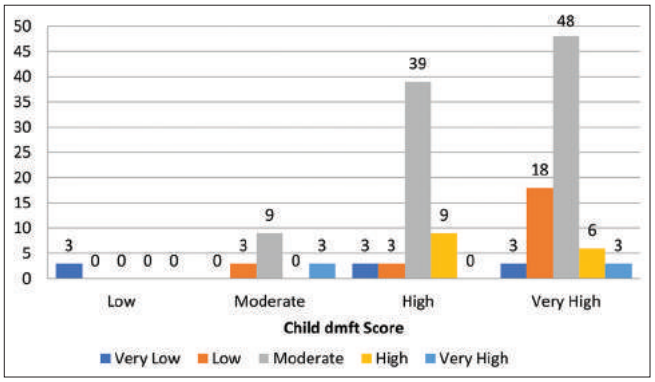
In our study, most of the mothers did not help their kids with brushing [Table 2]. In addition to that, mothers don't know when to start the baby's oral hygiene or when to visit the dentist for the 1st time [Table 2]. Studies prove the effectiveness of information in the fight against tooth decay since family knowledge about tooth decay is a protection factor against ECC. The AAPD recommends that the best time to start dental care is between the ages of 6 and 12 months.[15] In a study by Suresh *et al.*,[27] where most parents felt that they should brush their child's teeth when all the primary teeth have erupted. Similarly, Hallet and O'Rourke found that children who commenced tooth brushing earlier (age 12 months) had significantly lower ECC experience compared to children who commenced tooth brushing later.[28] Similarly, a study done at the University of Sao Paulo showed orientation/prevention as the predominant reason for seeking dental care; the second most common reason was caries/treatment, followed by dental trauma.[29]

In our study, the correlation between the education of the mother and the severity of decay was found to be non-significant ($P = 0.088$) [Table 3 and Graph 1]. Similar to the result of our study Brandão *et al.* also claimed that there was no relationship between the education of the mother and the severity of the decay.[30] Contrary to this, Elena and Petr[31] stated that mothers with a background of high education have more positive dental knowledge and attitudes.

In our study, a highly significant correlation was found between the DMFT of mothers' DMFT of children. ($P = 0.00$) [Table 4 and Graph 2]. The results of the study indicated a diminutive relationship between oral hygiene practices and the occurrence of dental caries. This corroborates with the findings of the study by Zanata *et al.*[32] who reported a strong positive association between



Graph 1: Association between the education of mother and severity of decay



Graph 2: Correlation between DMFT of mothers and DMFT of children

caries activity in mother-child couples. In the present study, a two-tailed correlation indicated that the mother's DMFT score was an impact factor for the caries experience.

Even though the multifactorial aspect of the etiology of ECC is now well established, the question of why its risk of occurrence is highest among some groups is unanswered. When considering possible explanations, dietary habits and sweetened food intake frequency may be likely contributing factors.

CONCLUSION

A high DMFS score as well as low socioeconomic factors were strong indicators of predisposition to caries for children.

There is a significant direct relationship between ECC severity and a child's feeding habits, such as frequency, type of feeding, falling asleep with nipples in their mouths, eating at night, in-between meal snacking, and duration of breastfeeding.

Despite being the main agents of transmission, most mothers are unaware of early caries disease and its risk

factors. It is, therefore, necessary to establish awareness programs for oral health in maternal-infant health units.

This study will help pediatric dentists to enhance their knowledge and understand the correlation of ECC in children with respect to their mothers. It will be of great importance to rule out the etiology for this majorly occurring disease in children nowadays and to find the possible cause and preventive measures for the ECC.

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Original Article

Comparative Evaluation of a Camera-based Monitoring Solution for Heart Rate, Heart Rate Variability, Respiratory Rate, Oxygen Saturation, and Blood Pressure Measurement vis-à-vis Regulated Contec Multipara Patient Monitor CMS 8000

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Abstract

This study aimed to evaluate the accuracy and reliability of a camera-based monitoring solution, vital scan, in measuring vital signs compared to established regulated medical devices. The study design involved simultaneous measurement of heart rate, respiratory rate, oxygen saturation, systolic blood pressure (BP), and diastolic BP using multiple devices, including smartphones and an HP laptop with a Logitech webcam. A total of 626 participants from diverse backgrounds were recruited for the study. Vital scan demonstrated a high correlation with the FDA-regulated Contec Multipara Patient Monitor CMS 8000 for all measured vital signs. The results suggest that the camera-based monitoring solution is feasible and accurate for assessing vital signs, potentially offering a non-invasive and convenient alternative in health-care settings. Further research and validation studies are needed to explore its integration into clinical practice and assess its cost-effectiveness and patient comfort benefits.

Key words: Blood pressure, Camera-based monitoring solution, Comparative evaluation, Heart rate, Oxygen saturation, Regulated medical devices, Respiratory rate

INTRODUCTION

Accurate and timely monitoring of vital signs, including heart rate (HR), respiratory rate (RR), oxygen saturation (SpO_2), and blood pressure (BP), is essential in health-care settings for effective patient care and early detection of critical conditions. Conventionally, regulated medical devices such as electrocardiograms (ECGs), pulse oximeters, and sphygmomanometers have been used to measure these vital signs. However, advancements in technology have introduced camera-based monitoring solutions that claim to provide non-invasive and convenient alternatives for vital sign measurement.[1-5]

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The camera-based monitoring solution utilizes computer vision algorithms and image processing techniques to analyze physiological parameters from video recordings or images captured by a standard camera. This technology has the potential to revolutionize vital sign monitoring by enabling remote and continuous measurements without the need for direct physical contact with the patient.[6-13]

This evaluation aims to critically assess the effectiveness and reliability of a camera-based monitoring solution in accurately measuring HR, RR, SpO_2, and BP when compared to established regulated medical devices. The evaluation will focus on evaluating the accuracy, precision, and consistency of the camera-based solution's measurements and comparing them to the gold standard provided by regulated medical devices.[1,4-9,14]

By conducting a comparative evaluation, health-care professionals and researchers can gain insights into the feasibility and potential limitations of adopting camera-

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based monitoring solutions in clinical practice. The results of this evaluation will inform decision-making processes regarding the integration of this technology into health-care settings, potentially improving patient monitoring efficiency, reducing health-care costs, and enhancing patient comfort.[1-6,10,12-14]

Contec CMS 8000

The Contec CMS 8000 is a multiparameter patient monitor commonly used in medical settings to continuously monitor the vital signs and other parameters of patients. It is designed to provide health-care professionals with real-time information about a patient's condition, allowing for timely interventions and improved patient care.

The Contec CMS 8000 typically monitors several key parameters, which may include in the study:

1. ECG: Measures the electrical activity of the heart, detecting irregularities and abnormalities in HR and rhythm.
2. SpO_2 (Peripheral SpO_2): Measures the SpO_2 level of hemoglobin in the blood, indicating how well oxygen is being carried to the body's tissues.
3. Non-invasive BP: Measures BP using a cuff on the patient's arm without the need for invasive procedures.
4. Respiration rate: Monitors the number of breaths per minute, helping assess respiratory function.
5. Temperature (TEMP): Measures the patient's body TEMP.
6. Pulse rate (PR): Monitors the HR by counting the number of pulses per minute.
7. Optional CO_2 monitoring ($EtCO_2$): Some versions of the CMS 8000 may also offer end-tidal carbon dioxide monitoring, which helps assess how well a patient is ventilating.

The patient monitor typically features a display screen that shows the real-time readings of the monitored parameters. Alarms and alerts are incorporated to notify health-care providers if any of the measured values fall outside preset safe ranges, allowing them to promptly respond to any critical changes in the patient's condition.

Hypotheses

1. The camera-based monitoring solution will provide measurements of HR comparable to those obtained from regulated medical devices.
2. The camera-based monitoring solution will accurately measure RR in line with the readings of regulated medical devices.
3. The camera-based monitoring solution will yield SpO_2 measurements similar to those obtained from regulated medical devices.
4. The camera-based monitoring solution will produce BP measurements that align with the readings of regulated medical devices.

By testing these hypotheses, we can determine the accuracy and reliability of the camera-based monitoring solution and its potential as a viable alternative for vital sign measurements.

Research Design

The study design involved simultaneous measurement of five vital signs: HR, RR, SpO_2, systolic BP (SBP), and diastolic BP (DBP). Multiple devices were utilized, including an HP laptop with a Logitech webcam, as well as smartphones (Samsung S23, OnePlus 11, iPhone 13, 14 Pro, and iPad Pro). This device diversity aimed to demonstrate that the results were not biased by a particular technology and could function effectively across different operating systems such as Android, iOS, Windows, and macOS.

To ensure standardized measurements, the devices were positioned 60 cm away from the subject's face and mounted on a tripod with a ring light source positioned in front of the subject, providing a minimum illumination of 250 lux. Reference measurements for HR and RR were obtained using Massimo mightiest devices, while OMRON/CIRCA MICRO LIFE/NIDEK multi-parameter monitors and pulse oximeters were used to obtain reference measurements for the other vital signs. Participants were instructed to remove glasses or any facial coverings and sit in a chair during the scans. They were advised to maintain stillness and gaze directly at the camera throughout the entire 60-s scan duration. All vital signs were measured once using the medical devices.

Participants

In this study, a total of 626 participants were recruited, consisting of 313 females and 313 males. The age range of the participants was 27–57 years, and they represented diverse skin colors, ethnicities, and medical statuses.

Data Collection

Prior to data collection, participants provided informed consent and underwent a brief orientation to the devices and the measurement protocol. Simultaneous measurements were conducted by positioning participants comfortably and ensuring adequate lighting conditions. For HR, RR, and SpO2 measurements, participants wore the necessary sensors as instructed by each device's manufacturer. Blood pressure measurements were obtained using appropriate cuffs and calibration techniques.

Data collection sessions were conducted in controlled settings by trained research assistants.At Actofit HQ. Each participant underwent two rounds of measurements, with a

resting period between rounds to minimize potential order effects. The order of device usage was counterbalanced to mitigate bias.

MATERIALS AND METHODS

This study aimed to assess the accuracy of remote health screening technology, specifically Vastmindz's 3.0 SDK, in measuring HR, RR, BP, and SpO_2. The objective was to compare the accuracy of these measurements obtained using Vastmindz's technology against gold standard vital signs monitors, which served as the reference method. It is important to acknowledge that the reference instruments themselves have inherent error, with possible deviations of up to ±3 units per parameter. This factor will be taken into consideration when interpreting the results.

The study methodology consisted of two main components: Onsite data collection and subsequent analysis. Data collection took place at hospitals, ensuring that the process was free from any external interference. The data collection device employed in this study was equipped with an app utilizing Vastmindz's technology. The app interface facilitated various functions such as face detection, landmark placement, and the creation of regions of interest (ROIs). Within each frame, the app collected the blue-green-red (BGR) components of each ROI, representing visual information. These BGR samples were securely stored in a cloud database for further analysis. Figures 1 and 2 provide an overview of the methodology employed in this study.

To analyze the collected data, a pipeline was developed to systematically process the samples. The pipeline involved parsing the samples, converting the BGR components into a 1D signal, and extracting the relevant physiological parameters. Subsequently, the extracted results were compared to the ground truth values obtained from medical devices.

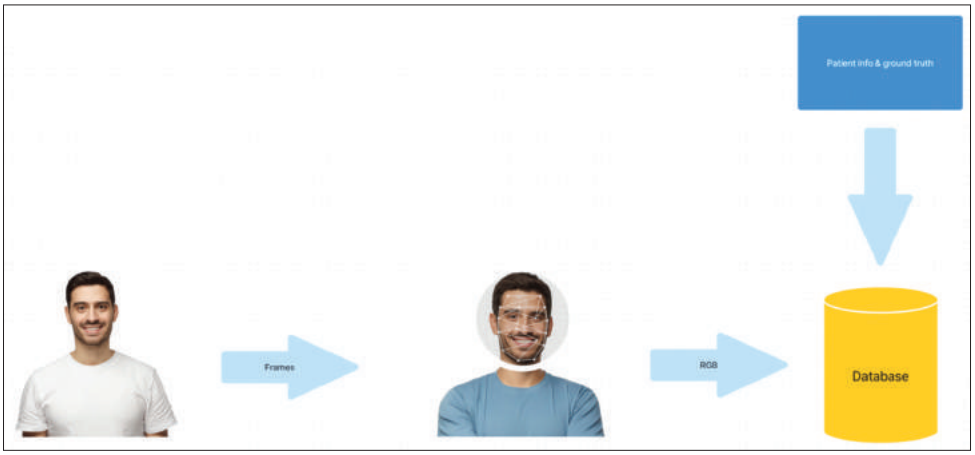


Figure 1: Study methodology: Data collection. RGB: red, green, and blue

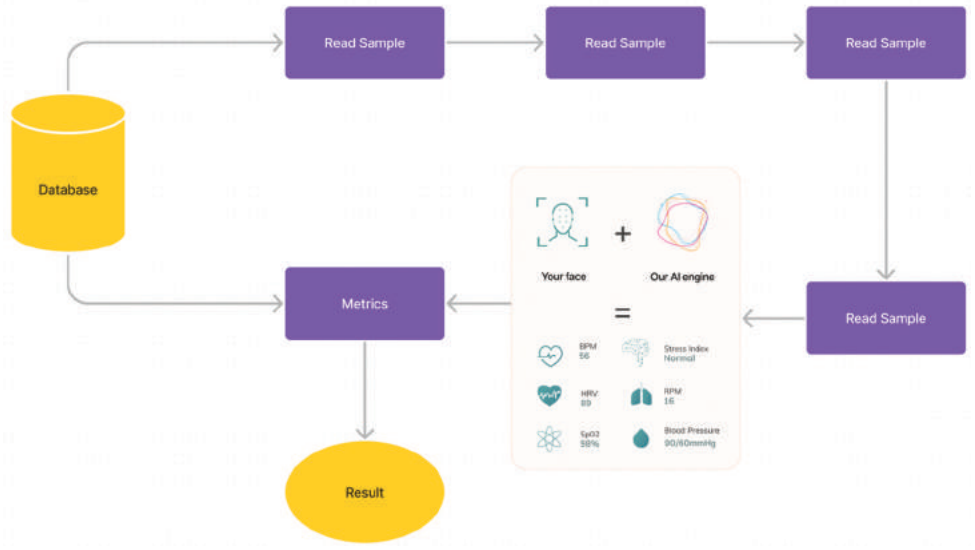


Figure 2: Study methodology: Analysis. BGR: Blue, green, and red, 1D: One-dimensional, rPPG: Remote photoplethysmography

Figure 3: Study methodology: Protocol

To assess the accuracy of the estimated values, several metrics were calculated, including the mean error, mean absolute error, root mean squared error, and root mean squared percentage error (RMSPE %). These metrics provide quantitative measures of the disparity between the estimated values and the ground truth values. Figure 3 provides a visual representation summarizing the workflow employed in this study.

RESULTS

In addition to assessing the technology across patients with diverse demographic characteristics, it is crucial to analyze individuals with varying baseline parameters, including resting PR, RR, BP, SpO_2, and HR variability (HRV). These baseline parameters provide reference values for comparison and evaluation. The summary of reference values is shown in Table 2.

Reference values were compared to estimated values using facial scanning. Table 7 presents sample sizes, ME, MAE, RMSE, and RMSPE for each vital sign. Results are categorized into three groups. Visual insights are available in Graphs 13 and 14, offering histograms of errors for RR, SpO2, HR, and BP (SBP, DBP) [Table 7].

Considering the comprehensive analysis of the results, graph 17 examines the effect of age on errors, while graph 18 explores the impact of height and weight. These figures provide insights into the relationships between these factors and the observed errors.

Additionally, acknowledging the presence of potential outliers that could influence statistical outcomes, this study employs box plots. These plots effectively illustrate quartile ranges and highlight outliers for each vital sign. Refer to graph 19 for a visual representation of these distributions [Graphs 1-20] and [Tables 1 and 3-6].

Table 1: Demographic characteristics of the data[1-4]

Characteristics	Mean (minimum-maximum)
Age	40.94 (27–57)
Height	168.38 (155–180)
Weight	70.38 (58–82)
BMI	24.79 (21.7–28)

BMI: Body mass index

Table 2: Vital scan ground truth[4-7]

Vital scan	Mean
Systolic BP (mmHg)	121.6
Diastolic BP (mmHg)	78.6
SpO2 (%)	97.45
Heart rate (bpm)	74.40
Respiratory rate (breaths/min)	15.35
HRV (ms)	68.15

HRV: Heart rate variability

Table 3: Mean and standard deviation graph of male, vital scan versus Contec Multipara Patient Monitor CMS 8000[4-7]

Device	Parameter	Mean	Standard deviation
Vital scan	Systolic BP (mmHg)	121.1789	3.68
	Diastolic BP (mmHg)	78.23323	2.94
	SpO_2 (%)	97.48243	1.02
	Heart rate (bpm)	74.05112	3.85
	Respiratory rate (breaths/min)	15.3099	1.01
	HRV (ms)	68.05751	1.92
Contec Multipara Patient Monitor CMS 8000	Systolic BP (mmHg)	121.130	4.40
	Diastolic BP (mmHg)	78.20	4.01
	SpO_2 (%)	97.408	2.28
	Heart rate (bpm)	74.00	4.00
	Respiratory rate (breaths/min)	15.30	1.22
	HRV (ms)	68.06	2.87

HRV: Heart rate variability

DISCUSSION

The discussion for graph mean and standard deviation graph of male, vital scan vs Contec Multipara Patient monitor Cms 8000 as follows:

For the vital scan software the parameter systolic BP (mmHg) has mean of 121.17 and standard deviation of 3.68 whereas for the device Contec multipara patient monitor the parameter of systolic BP (mmHg) has 121.13 and standard deviation of 4.40. For the vital scan software the parameter diastolic BP (mmHg) has mean of 78.23 and standard deviation of 2.94 whereas for the device Contec multipara patient monitor the parameter of diastolic BP (mmHg) has 78.20 and standard deviation of 4.01. For the

Table 4: Mean and standard deviation graph of female, vital scan versus Contec Multipara Patient Monitor CMS 8000[17-23]

Device/software	Parameter	Mean	Standard deviation
Vital scan	Systolic BP (mmHg)	121.9201	3.68
	Diastolic BP (mmHg)	78.83706	2.94
	SpO_2 (%)	97.35463	1.02
	Heart rate (bpm)	74.63578	3.85
	Respiratory rate (breaths/min)	15.39936	1.01
	HRV (ms)	68.24281	1.92
Contec Multipara Patient Monitor CMS 8000	Systolic BP (mmHg)	121.76	4.4
	Diastolic BP (mmHg)	78.82	4.02
	SpO_2 (%)	97.25	2.28
	Heart rate (bpm)	74.61	4.01
	Respiratory rate (breaths/min)	15.40	1.22
	HRV (ms)	68.15	2.87

HRV: Heart rate variability

Table 5: Correlation of vital scan versus Contec Multipara Patient Monitor CMS 8000 in female[7–11]

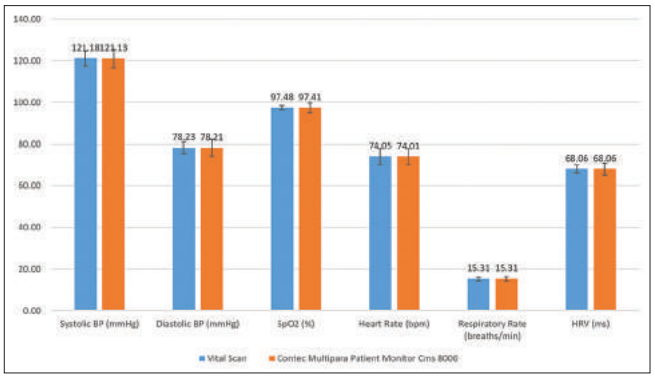
Parameter	Correlation value
Systolic BP (mmHg)	0.8707623141
Diastolic BP (mmHg)	0.8675261043
SpO_2 (%)	0.9370792407
Heart rate (bpm)	0.9303930157
Respiratory rate (breaths/min)	0.8940214791
HRV (ms)	0.9366756366

HRV: Heart rate variability

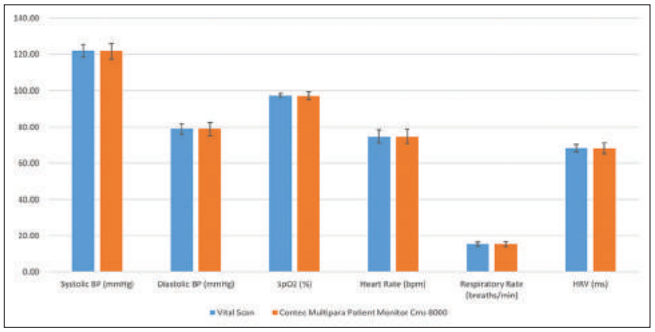
Table 6: Correlation of vital scan versus Contec Multipara Patient Monitor CMS 8000 in male

Parameter	Correlation value
Systolic BP (mmHg)	0.8726272693
Diastolic BP (mmHg)	0.896333088
SpO_2 (%)	0.9002112073
Heart rate (bpm)	0.9383255394
Respiratory rate (breaths/min)	0.9007170485
HRV (ms)	0.9229622818

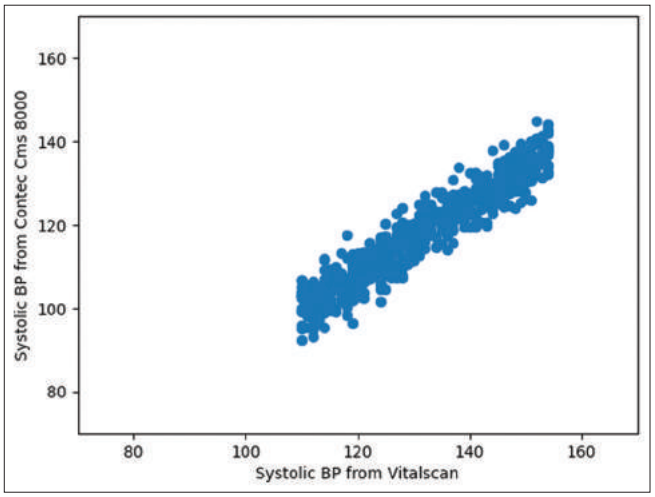
HRV: Heart rate variability



Graph 1: Mean and standard deviation graph of male, vital scan versus Contec Multipara Patient Monitor CMS 8000[4-7]



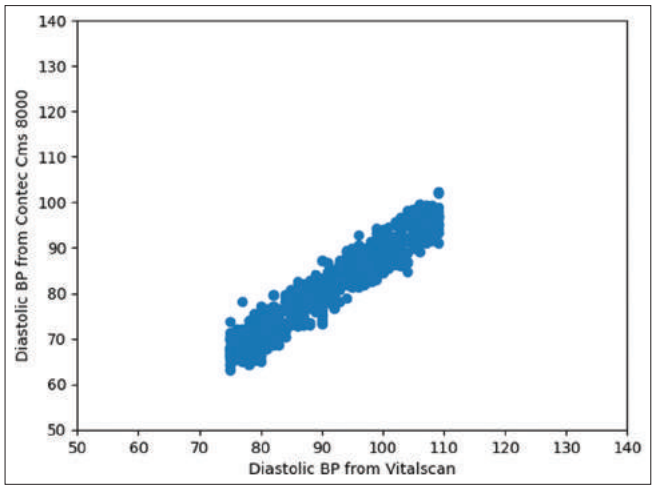
Graph 2: Mean and standard deviation graph of female, vital scan versus Contec Multipara Patient Monitor CMS 8000[4-7]



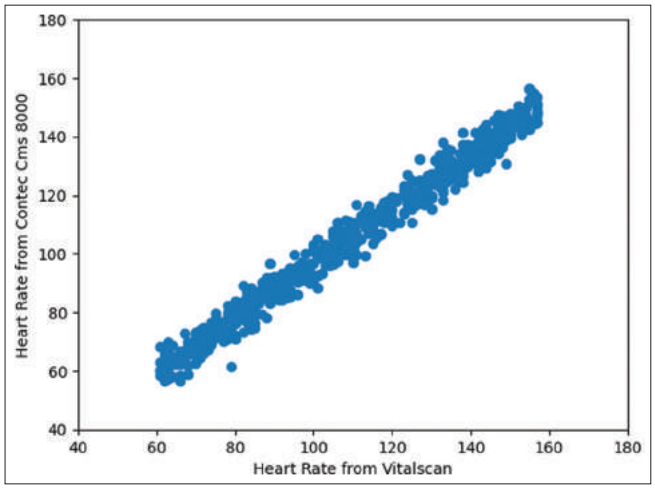
Graph 3: Systolic blood pressure female (Pearson correlation coefficient (r)=0.87, standard deviation=3.56)[7-11]

vital scan software the parameter SpO2 has mean of 97.48 and standard deviation of 1.02 whereas for the device Contec multipara patient monitor the parameter of SpO2 has mean of 97.40 and standard deviation of 2.28. For the vital scan software the parameter of heart rate (bpm) has mean of 74.05 and standard deviation of 3.85 whereas for the device Contec multipara patient monitor the parameter of heart rate (bpm) has mean of 74.00 and standard deviation of 4.00 . For the vital scan software the parameter of respiratory rate (breaths/min) has mean of 15.30 and standard deviation of 1.01 whereas for the device Contec multipara patient monitor the parameter of respiratory rate (breaths/min) has mean of 15.30 and standard deviation of 1.22. For the vital scan software the parameter of HRV (ms) has mean of 68.05 and standard deviation of 1.92 whereas for the device Contec multipara patient monitor the parameter of HRV (ms) has mean of 68.06 and standard deviation of 2.87.

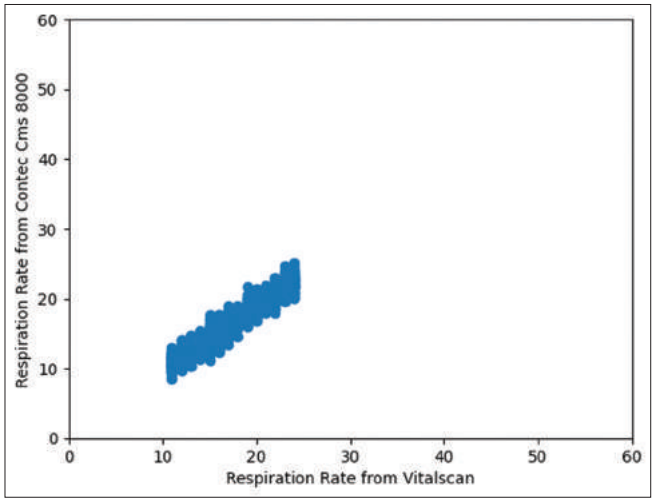
The discussion for graph mean and standard deviation graph of Female, vital scan vs Contec Multipara Patient monitor Cms 8000 as follows:



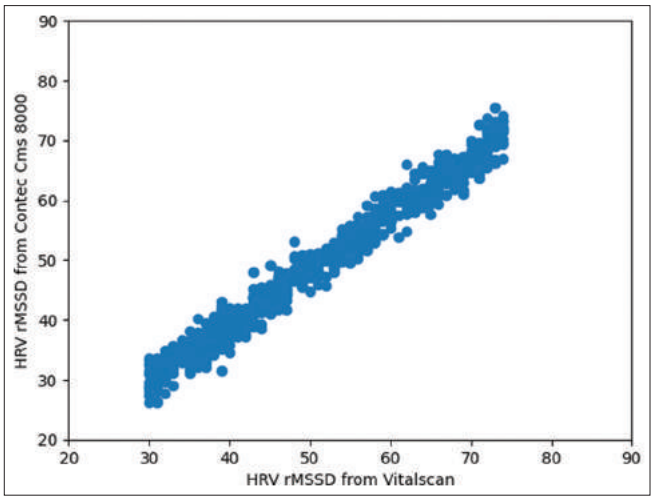
Graph 4: Diastolic blood pressure female (Pearson correlation coefficient (r) = 0.86 standard deviation = 2.80)[7-11]



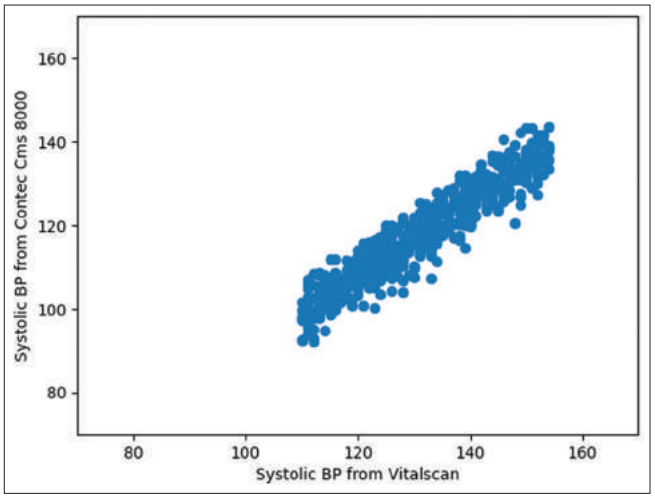
Graph 5: Heart rate female (Pearson correlation coefficient (r) = 0.93 standard deviation = 3.71)[4-9]



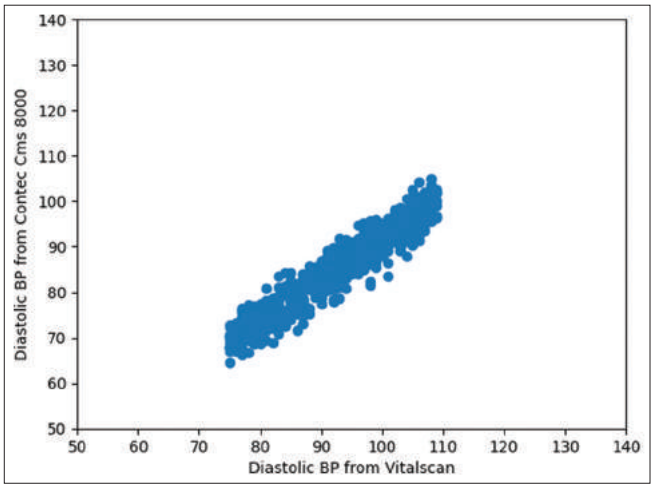
Graph 6: Respiration rate female (Pearson correlation coefficient (r) = 0.89 standard deviation = 1.09)[5-10]



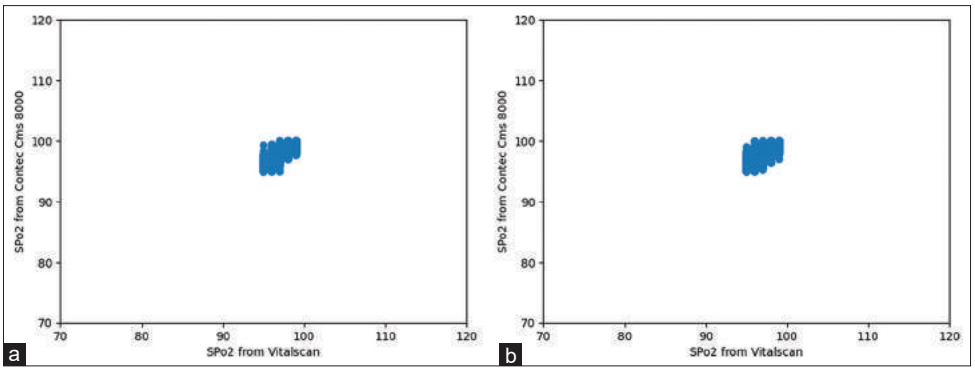
Graph 7: Heart rate variability rMSSD female (Pearson correlation coefficient (r) = 0.93 standard deviation = 1.95)[12-15]



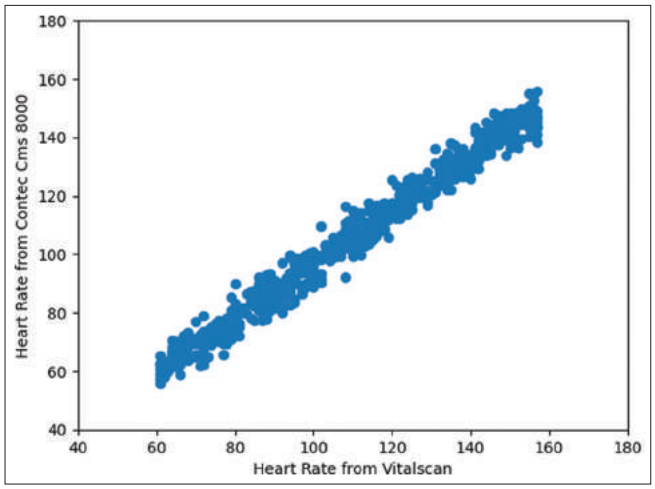
Graph 8: Systolic blood pressure male (Pearson correlation coefficient (r) = 0.87, standard deviation = 3.68)[7]



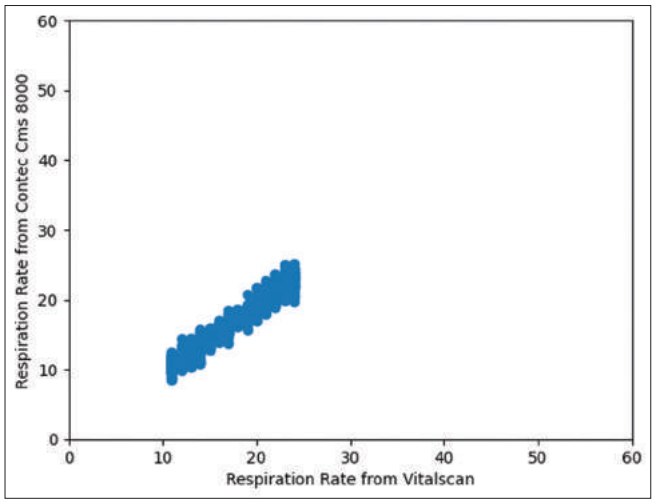
Graph 9: Diastolic blood pressure (Pearson correlation coefficient (r) = 0.98 standard deviation = 2.94)[7]



Graph 10: (a) SPO_2 female (Pearson correlation coefficient (r) = 0.93 standard deviation = 1.10) (b) SPO_2 male (Pearson correlation coefficient (r) = 0.90 standard deviation = 1.02)[17-25]

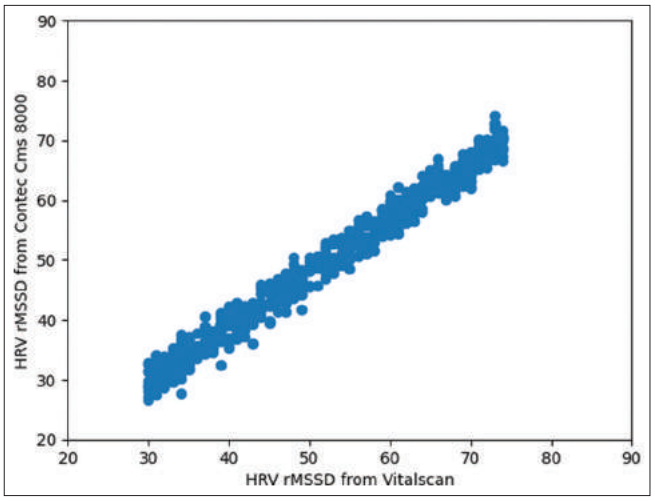


Graph 11: Heart rate male (Pearson correlation coefficient (r) = 0.93 standard deviation = 3.86)[17]



Graph 12: Respiration rate male (Pearson correlation coefficient (r) = 0.90 standard deviation = 1.01)[4]

For the vital scan software the parameter systolic BP (mmHg) has mean of 121.92 and standard deviation of 3.68 whereas for the device Contec multipara patient monitor the parameter of systolic BP (mmHg) has 121.76

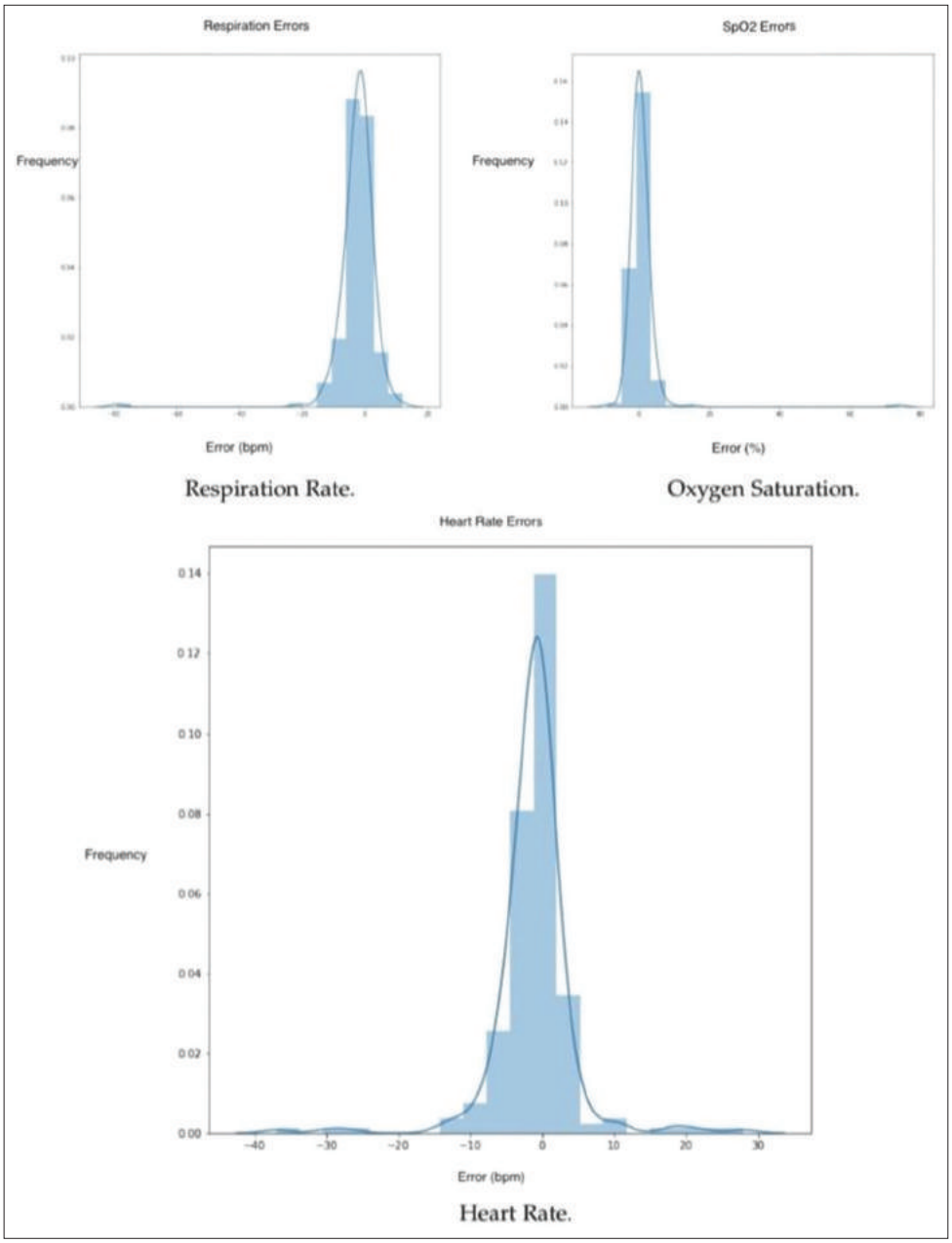


Graph 13: Heart rate variability rMSSD male (Pearson correlation coefficient (r) = 0.92 standard deviation = 1.93)[17]

Table 7: Differences between Reference and Estimated Values for Vital Signs

Vital Scan	Sample Size	ME	MAE	RMSE	RMSPE (%)
Heart rate (HR)	626	-1.19	3.09	5.72	7.43
HR≤60	46	1.94	2.88	5.51	10.48
60<HR≤100	501	-1.17	3.01	5.31	7.12
HR>100	79	-3.90	4.00	8.86	7.39
Oxygen saturation (SpO2)	608	0.30	1.21	1.77	1.85
90<SpO2≤95	78	3.64	3.64	3.80	4.06
SpO2>95	530	-0.15	0.88	1.26	1.29
Respiratory rate (RR)	576	-2.11	3.39	4.65	25.82
RR≤10	16	6.17	6.17	7.13	81.94
10<RR≤18	337	-0.48	2.02	2.70	17.94
RR>18	223	-5.41	5.46	6.58	28.22
Systolic blood pressure	613	-5.27	18.15	22.77	17.59
SBP≤90	3	38.33	38.33	38.48	45.62
90<SBP≤130	414	3.55	14.35	17.60	15.59
SBP>130	196	-22.13	24.69	29.68	19.93
Diastolic blood pressure	613	-3.95	10.49	13.71	17.38
DBP≤60	28	20.29	20.29	22.13	41.18
60<DBP≤90	509	-2.17 |	8.31	10.76	14.05
DBP>90	76	-20.68	20.68	23.10	23.47

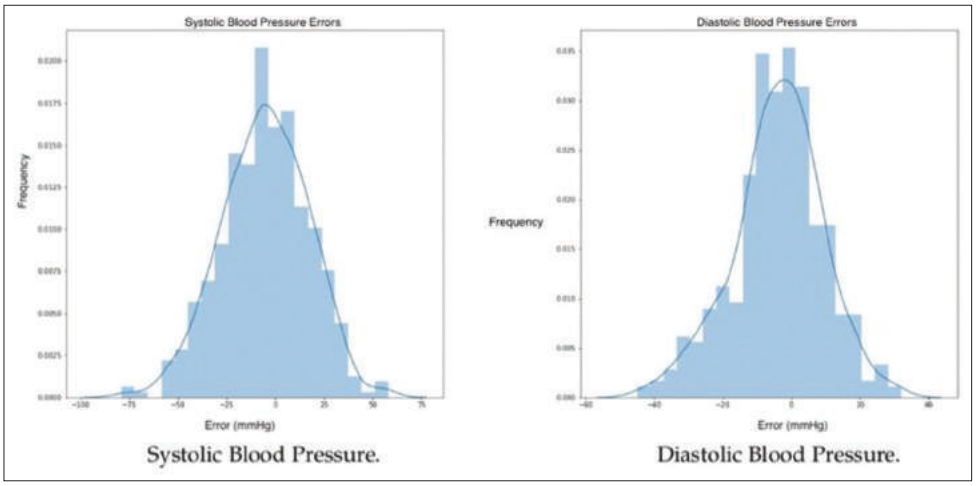
ME: mean error; MAE: mean absolute error; RMSE: root mean squared error; RMSPE: root mean squared percentage error



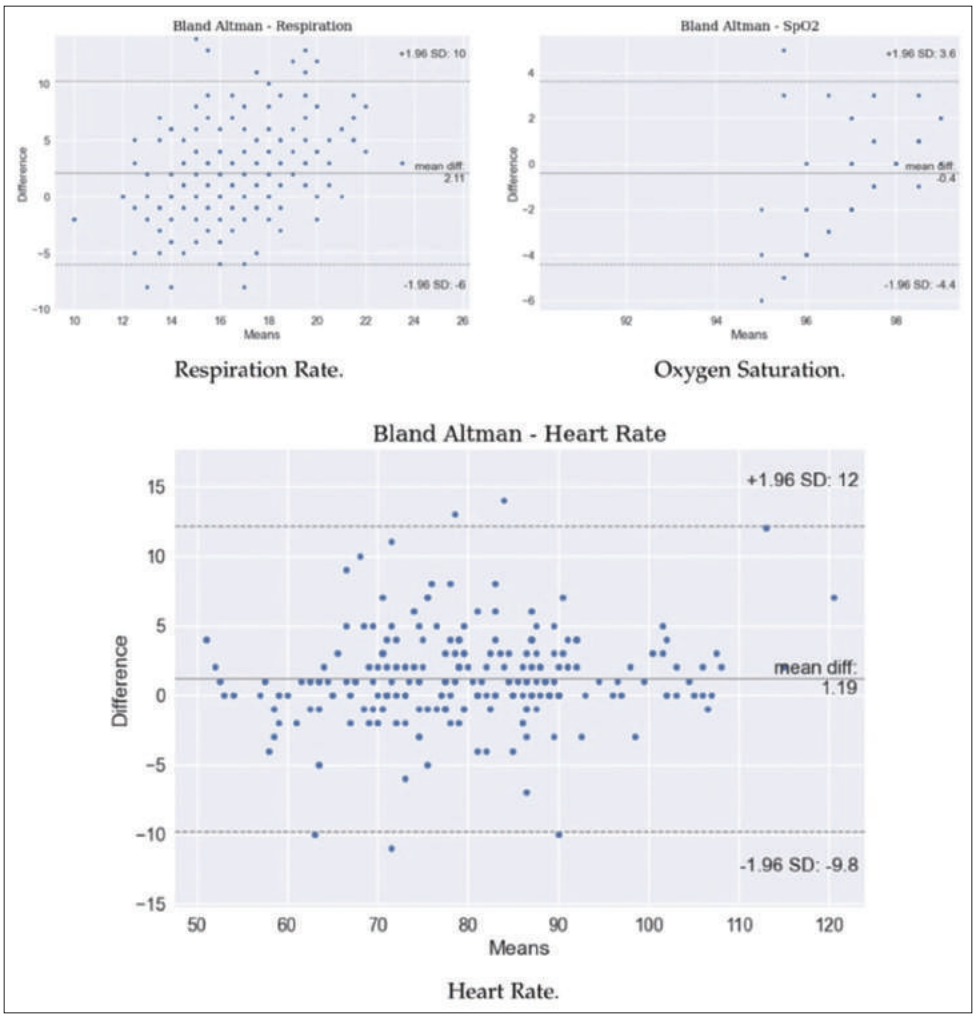
Graph 14: Histograms showing errors. (a) Respiration rate (RR), (b) oxygen saturation (SpO2), and (c) heart rate (HR)[17]

and standard deviation of 4.4. For the vital scan software the parameter diastolic BP (mmHg) has mean of 78.83 and standard deviation of 2.94 whereas for the device Contec multipara patient monitor the parameter of diastolic BP (mmHg) has 78.82 and standard deviation of 4.02. For the vital scan software the parameter SpO2 has mean of 97.35 and standard deviation of 1.02 whereas for the device Contec multipara patient monitor the parameter of SpO2 has mean of 97.25 and standard deviation of 2.28. For the vital scan software the parameter of heart rate (bpm) has mean of 74.63 and standard deviation of 3.85 whereas for the device Contec multipara patient monitor the parameter of heart rate (bpm) has mean of 74.61 and standard deviation of 4.01 . For the vital scan software the parameter of respiratory rate (breaths/min) has mean of 15.39 and standard deviation of 1.01 whereas for the device Contec multipara patient monitor the parameter of respiratory rate (breaths/min) has mean of 15.40 and standard deviation of 1.22 . For the vital scan software the parameter of HRV (ms) has mean of 68.24 and standard deviation of 1.92 whereas for the device Contec multipara patient monitor the parameter of HRV (ms) has mean of 68.15 and standard deviation of 2.87 .

The discussion for the graph of correlation of Vital Scan vs Contec Multipara Patient Monitor Cms 8000 in Female is as follows:

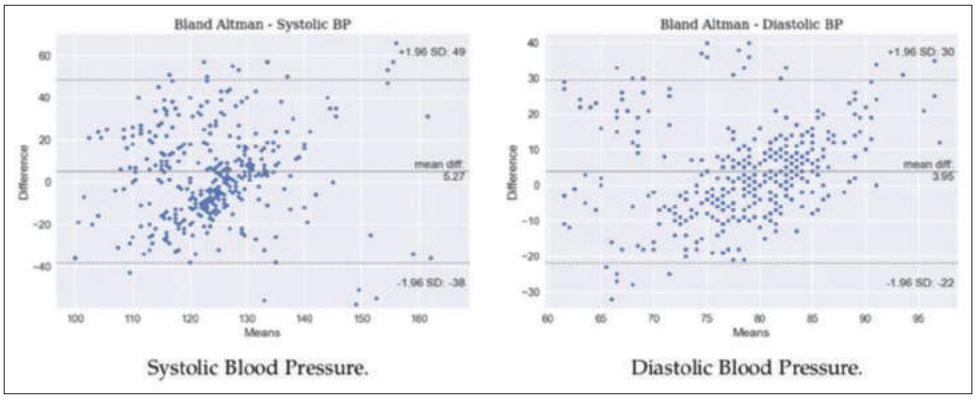


Graph 15: Histograms showing errors in blood pressure. In addition to histograms displaying error distribution, Bland-Altman plots provide an alternative evaluation method. These plots illustrate mean value versus difference for each data point. Graph 15 and graph 16 depict these plots for all vital signs[17]

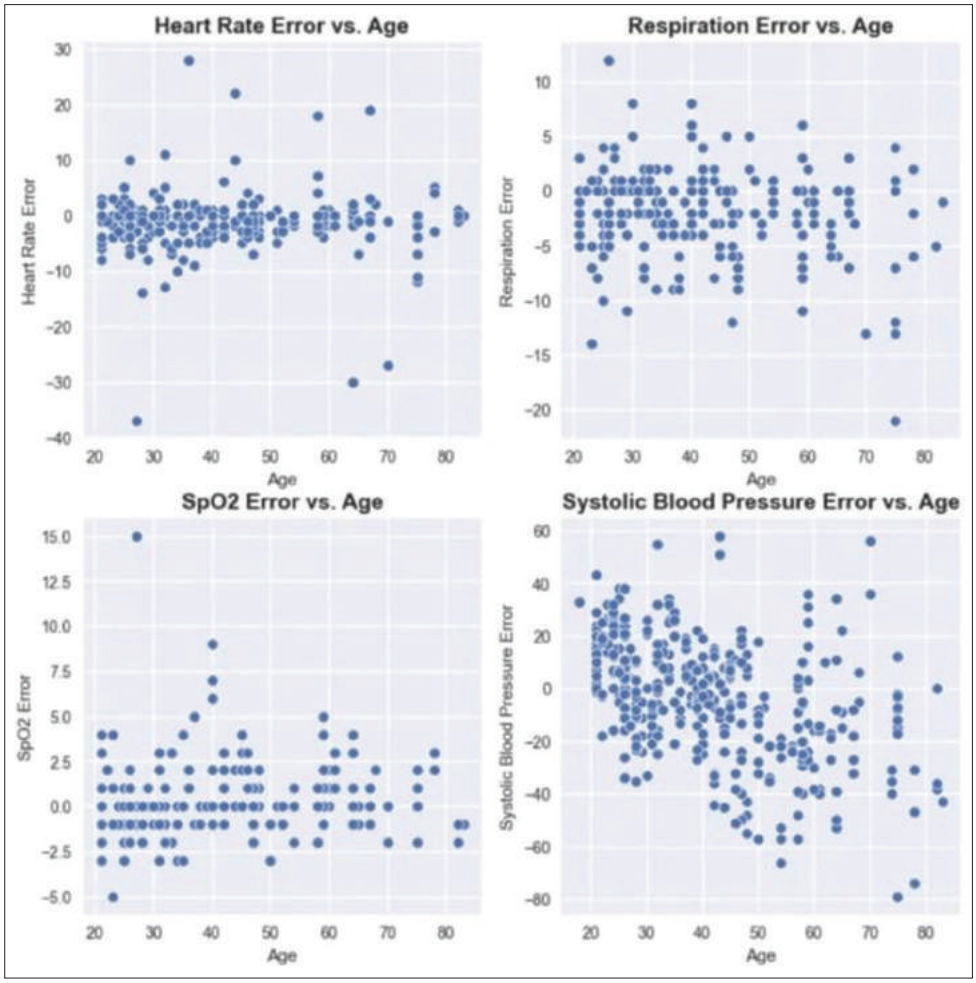


Graph 16: Bland-Altman plots. (a) Respiration rate, (b) oxygen saturation, and (c) heart rate[4]

The correlation value for systolic BP (mmHg) is 0.87.
The correlation value for diastolic BP (mmHg) is 0.86.
The correlation value for SpO2 is 0.937
The correlation value for Heart rate(bpm) is 0.930
The correlation value for Respiratory Rate (breaths/min) is 0.89
The correlation value for HRV (ms) is 0.93.



Graph 17: Bland-Altman plots. (a) Systolic blood pressure (SBP) and (b) diastolic blood pressure (DBP)[7]



Graph 18: Impact of age on vitals errors for heart rate, respiration, SpO2, and systolic blood pressure[5]

The discussion for the graph of correlation of Vital Scan vs Contec Multipara Patient Monitor Cms 8000 in Male is as follows:

The correlation value for systolic BP (mmHg) is 0.872

The correlation value for diastolic BP (mmHg) is 0.89.

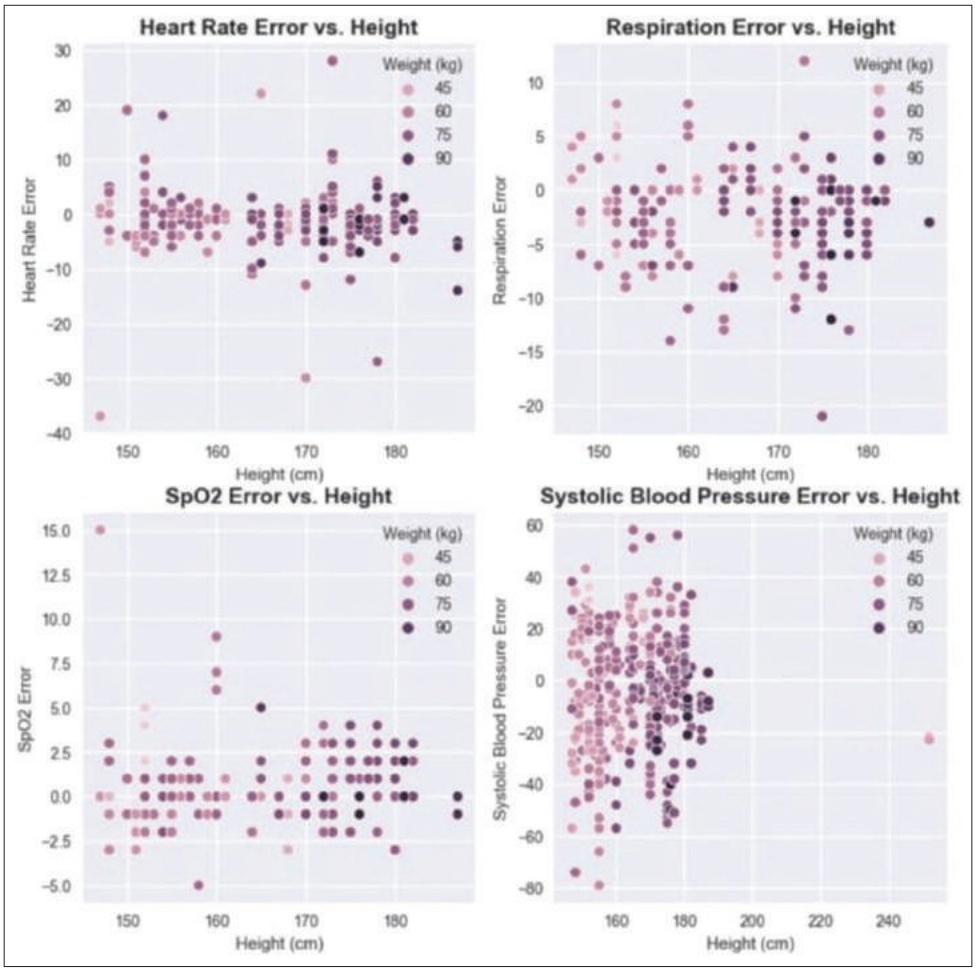
The correlation value for SpO2 is 0.90

The correlation value for Heart rate(bpm) is 0.938

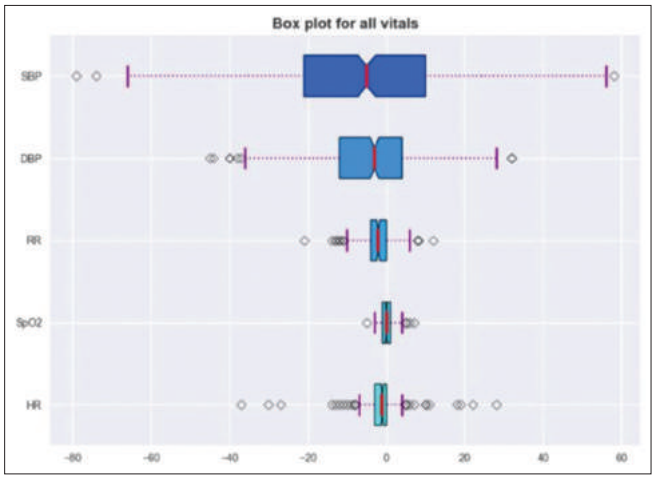
The correlation value for Respiratory Rate (breaths/min) is 0.90

The correlation value for HRV (ms) is 0.92 .

In the context of this study, the primary goal was to assess the performance of visual technology in comparison to established medical devices. It's important to note that



Graph 19: Impact of height and weight on vitals errors for heart rate, respiration, SpO2, and systolic blood pressure[4]



Graph 20: Box plot for all vitals. SBP: systolic blood pressure; DBP: diastolic blood pressure; RR: respiratory rate; SpO2: oxygen saturation; HR: heart rate[17]

the technology utilized in this investigation undergoes frequent software updates to enhance its capabilities. Consequently, recent studies are anticipated to exhibit improved performance compared to earlier ones. The study involved data collection from 626 participants, although complete vital sign data was not available for every individual. Notably, blood pressure (BP) was consistently measured for all participants, while other parameters were obtained from approximately 240 patients.[24,25]

The overall findings indicate a favorable agreement between camera-based visual monitoring technology (Vital Scan) and reference instruments. Specifically, heart rate (HR), respiratory rate (RR), and oxygen saturation (SpO2) all satisfied the preset hypothesis criteria of ±3 units in Mean Error (ME) for each parameter. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) also adhered to the requirement of ±10 units in ME. However, cautious interpretation is warranted due to the substantial standard deviation of errors among the results.[26]

An analysis of alternative metrics reveals that most algorithms maintained similar outcomes when using Mean Absolute Error (MAE), with the exception of SBP, which exhibited a significant absolute difference increase. The application of a quadratic function, such as Root Mean Square Error (RMSE), exposed errors that might be smoothed out by mean values. RMSE results indicated

acceptable performance in HR and SpO2, both in the average and within distinct groups. Nevertheless, RR, SBP, and DBP displayed the influence of pronounced errors when assessed through quadratic metrics.[27]

Notably, the HR estimation emerged as one of the most robust algorithms, maintaining the ±3 criteria across averages and within low and normal ranges. Instances of extremely high or low HR posed greater estimation challenges, potentially due to motion artifacts linked to stress and anxiety during image acquisition.

Regarding oxygen saturation (SpO2), a satisfactory agreement of 90% to 100% was observed, with a minimal ME of 0.3%. While there were limited instances of SpO2 below 90%, typically occurring in critical or high-altitude scenarios, future research aims to include more participants with hypoxia to validate performance at such low levels. It's worth noting that the technology's current scope is more aligned with preventive rather than diagnostic usage in such conditions.[28]

For respiratory rate (RR), optimal performance was within the normal range of 10 to 18 breaths per minute, exhibiting a mean error of -0.48. The most notable bias was apparent at very low rates of less than 10 breaths per minute.

However, blood pressure (BP), particularly SBP and DBP, posed the most intricate challenge. While the technology demonstrated favorable outcomes within its results and sample distribution, difficulties were prominent in extreme values, notably SBP higher than 150 mmHg and DBP higher than 90 mmHg.[29]

Histogram analyses highlight a tendency of results clustering around errors close to zero, implying frequent instances of low-level errors. However, the impact of outliers on statistical results must be acknowledged. Notably, the HR histogram displayed a classic normal distribution pattern.[30]

Bland-Altman plots, offering a robust perspective, indicate mean value vs. difference relationships. HR demonstrated a mean difference of 1.19 beats per minute, with a wider standard deviation of +12 to -10. RR exhibited a narrower standard deviation, although with a higher mean difference and more scattered errors. SpO2, as expected, revealed fewer data points due to grouped results, resulting in a lower mean difference. In the case of BP, consistent patterns of erroneous predictions were observed in extreme cases.[31]

Age did not exhibit a significant correlation with error across vital signs, suggesting the absence of age bias. Additionally, neither height nor weight appeared to influence outcomes, indicating that body weight and height relationships had minimal effect. The technology's performance remained unbiased in relation to demographic characteristics such as age, gender, height, or weight.[32]

A box plot analysis illustrated error distribution in quartiles and identified outliers. HR, RR, and SpO2 displayed narrow interquartile ranges, in contrast to DBP and SBP with broader ranges, aligning with the initial observation that BP exhibited a higher standard deviation. Outliers were observed in HR estimation, potentially impacting statistical outcomes, yet acceptable results were achieved even in their presence.[33]

Ethical Considerations

The consent was taken from the 626 participants who were recruited in this study, comprising 313 females and 313 males. The age range of the participants was 27–57 years, and they represented diverse skin colors, ethnicities, and medical statuses.

Limitations

Here are some limitations that can be identified for the given comparative evaluation:

1. Sample size: The study may have a limited sample size, which could affect the generalizability of the findings to a broader population.
2. Participant variation: While the study recruited a diverse group of participants, individual variations in physiology and health conditions could impact the accuracy of measurements for certain individuals or specific health conditions.
3. Device limitations: The camera-based monitoring solution may have its own limitations, such as the need for proper lighting conditions, distance from the camera, and potential inaccuracies in certain scenarios, which could affect the overall performance.
4. External factors: The study might not have accounted for all external factors that could influence the measurements, such as environmental conditions, movement artifacts, or interference from other electronic devices.
5. Controlled setting: The measurements were likely conducted in a controlled setting, which may not fully represent real-world situations and challenges that could arise in different health-care environments.
6. Interference: The presence of other people or objects in the camera's field of view might have introduced potential interferences, affecting the accuracy of measurements.
7. Specific vital signs: The accuracy of the camera-based solution could vary for different vital signs, and the study might not have explored this variation comprehensively.
8. Comparison devices: The performance of the

regulated medical devices used for comparison could also have their own limitations, which might influence the evaluation.

9. Duration of monitoring: The study might not have examined the long-term reliability of the camera-based solution for continuous vital sign monitoring over extended periods.
10. Scope of measurements: The study focused on specific vital signs; however, there are other vital signs and health parameters that the camera-based solution may not have been evaluated for.

It is essential to consider these limitations when interpreting the results and conclusions of the evaluation to ensure a comprehensive understanding of the camera-based monitoring solution's capabilities and potential applications in health-care settings.

CONCLUSION

The study encompassed comprehensive measurements of vital scan including heart rate (HR), respiratory rate (RR), oxygen saturation (SpO2), systolic blood pressure (SBP), and diastolic blood pressure (DBP) using a diverse range of devices such as smartphones (Samsung M32, OnePlus 9, iPhone 11, iPad 9) and an HP laptop with a Logitech webcam. This device diversity aimed to underscore the versatility of the results across various operating systems, avoiding technological bias. The utilization of Vital Scan software and the Contec Multipara Patient Monitor Cms 8000 device yielded valuable insights.

Through meticulous comparative analysis, Vital Scan demonstrated a strong correlation with the FDA-regulated Contec Multipara Patient Monitor CMS 8000, particularly concerning heart rate, respiratory rate, oxygen saturation, and blood pressure measurements. These findings affirm the precision and viability of camera-based monitoring for assessing crucial vital scan . However, the divergence observed in certain blood pressure readings underscores the need for further investigation.

With a dataset of 626 readings drawn from diverse demographics across facilities in India, the study substantiated the technology's ability to achieve acceptable agreement levels for mean error in HR, RR, SpO2, and BP measurements. Notably, while deviations were observed in some blood pressure readings, the overall acceptability of camera-based monitoring solutions for general health and wellness evaluation was evident.

As the study demonstrates the potential of this technology, its integration into clinical practice merits additional research and validation studies. Such endeavors could shed light on its cost-effectiveness, patient comfort, and broader utility. In essence, this study paves the way for a promising avenue of health assessment that leverages visual technology, fostering greater accessibility and insights into individual well-being.

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Original Article

Prevalence of Vitamin D Deficiency among Kashmiri Pregnant Females and its Impact on Maternal Outcome

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Abstract

Background: Vitamin D is a fat-soluble vitamin that is naturally present in few foods, added to others, and available as a dietary supplement. It is also produced endogenously when ultraviolet rays from sunlight strike the skin and trigger Vitamin D synthesis. The prevalence of Vitamin D deficiency has been reported to range from 15% to 80%. Research suggests that some of the damage done by Vitamin D deficiency is done in utero while the fetus is developing. Much of the damage may be permanent which cannot be fully reversed by taking Vitamin D after birth. In maternal Vitamin D deficiency, the maternal skeleton is also used as source of calcium for the developing fetus. This process is mediated by parathyroid hormone, which mobilizes calcium in a Vitamin D-dependent mechanism. Northern latitude especially winter or spring, limited sun exposure, regular use of sunscreens, African American or dark skin, obesity, extensive clothing cover, and malabsorptive syndromes (cystic fibrosis, cholestatic liver disease, inflammatory bowel disease, and short gut syndrome) are some of the risk factors for Vitamin D deficiency.

Aims and Objectives: This study aimed to find the prevalence of Vitamin D deficiency in pregnant women more than 28 weeks gestational age attending obstetric outpatient department (OPD) at Lalla Ded hospital for antenatal checkup and the cases were followed during antenatal, intrapartum, and neonatal period to find any fetomaternal correlation with Vitamin D deficiency and to know the prevalence of Vitamin D deficiency in pregnant Kashmiri women attending tertiary care hospital.

Materials and Methods: The study, entitled "The prevalence of Vitamin D deficiency in Kashmiri pregnant women and its impact on fetomaternal outcome – A tertiary care center study," is an observational study conducted in the Postgraduate Department of Obstetrics and Gynecology, Lalla Ded Hospital, an associated hospital of Government Medical College, Srinagar for 1½ years after obtaining clearance from the Institutional Ethical Committee. Based on the confidence level of 95%, the minimum sample size is 550. Proper written and informed consent was taken from pregnant women who were willing to participate in the study. They were requested to complete a questionnaire in their local language that covered sociodemographic data, obstetric history, lifestyle, dietary habits, and sunlight exposure. All singleton pregnant Kashmiri women aged between 18 and 35 years and more than 28 weeks of gestational age attending obstetric OPD at L.D Hospital for antenatal checkup were taken in study.

Results: The prevalence of Vitamin D deficiency was 60.2% (*n* = 331), 20.5% (*n* = 113) patients were Vitamin D sufficient while insufficient Vitamin D was observed in 19.3% (*n* = 106) patients. In patients aged between 26 and 30, Vitamin D deficiency was seen in 187 (59.9%) patients, insufficiency was observed in 60 (19.2%) patients while 65 (20.8%) had sufficient Vitamin D. In patients with 31–35 years of age, Vitamin D deficiency was observed in 93 (66.4%) patients, Vitamin D insufficiency was seen in 24 (17.1%) while 23 (16.4%) women were found to be Vitamin D sufficient. In women with <25 years of age, 51 (52%), 22 (22.4%), and 25 (25.5%) were Vitamin D deficient, insufficient, and sufficient. There were 189 (56.3%) primigravida compared to 142 (66.4%) multigravida women with Vitamin D deficiency. Vitamin D was insufficient in 65 (19.3%) primigravida compared to 41 (19.2%) multigravida. Sufficient Vitamin D was observed in 82 (24.4%) primigravida against 31 (14.5%) multigravida women. Statistically insignificant association was observed when Vitamin D status was compared with gestational age at delivery (*P* = 0.678) and gestational diabetes mellitus (*P* = 0.141). Mode of delivery, gestational hypertensive disorders, and maternal hypocalcemia had significant association with Vitamin D status.

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Conclusion: The present study provided significant information about the Vitamin D status of the Kashmiri pregnant women. Vitamin D deficiency has adverse effects on both mother and fetus, primarily preeclampsia, and maternal hypocalcemia. Increasing hours of sun exposure, Vitamin D supplementation during pregnancy could prevent some of the consequences. Effective educational programs should be initiated to elevate awareness among pregnant females about the importance of this vitamin and deficiency-associated complications.

Keywords: Maternal hypocalcemia, Preeclampsia, Vitamin D

INTRODUCTION

Vitamin D is a fat-soluble vitamin that is naturally present in a few foods, added to others, and available as a dietary supplement. It is also produced endogenously when ultraviolet rays from sunlight strike the skin and trigger Vitamin D synthesis. Vitamin D promotes calcium absorption in the gut and maintains adequate serum calcium and phosphate concentrations to enable normal bone mineralization and prevent hypocalcemic tetany. It is also needed for bone growth and bone remodeling. Vitamin D deficiency is an unrecognized epidemic which is common among children, adults, and pregnant women throughout the world.

The prevalence of Vitamin D deficiency has been reported to range from 15% to 80%. Research suggests that some of the damage done by Vitamin D deficiency is done in utero while the fetus is developing. Much of the damage may be permanent which cannot be fully reversed by taking Vitamin D after birth.[1,2] Its biological actions include an increase in intestinal calcium absorption, transcellular calcium flux, and opening gated calcium channels allowing calcium uptake into cells such as osteoblasts and skeletal muscle. Vitamin D has an increasingly recognized repertoire of non-classical actions such as promoting insulin action and secretion, immune modulation, and lung development. It inhibits parathyroid hormone (PTH) secretion and adaptive immunity while promoting insulin secretion and innate immunity. It also inhibits cell proliferation and stimulates their differentiation.[3]

Vitamin D Metabolism in Pregnancy

The most important source of Vitamin D is skin synthesis of Vitamin D from 7-dehydrocholesterol by UV – irradiation. It is transported in the blood by Vitamin D-binding protein. Vitamins D2 and D3 are 25-hydroxylated in the liver to produce major circulating Vitamin D metabolite in blood 25-hydroxy Vitamin D3 which undergoes further hydroxylation mainly in the kidneys to form the steroid hormone 1-alpha 25-dihydroxy Vitamin D. This hormone binds to intracellular Vitamin D-regulated genes all across the genome through epigenetic mechanisms. During pregnancy, maternal Vitamin D metabolism is altered to enable transfer of calcium across placenta to enable fetal skeletal development. Extra calcium is obtained mainly from increased maternal intestinal calcium absorption, a Vitamin D-dependent process, and increased renal hydroxylation. Transplacental transfer of calcium to the fetus is also facilitated by the expression of all key mediators of Vitamin D metabolism in the placenta.[4,5] In maternal Vitamin D deficiency, the maternal skeleton is also used as source of calcium for the developing fetus. This process is mediated by PTH, which mobilizes calcium in a Vitamin D-dependent mechanism. Further, adaptation occurs involving maternal PTH, PTH-related protein, and interaction of prolactin, estradiol, and some other hormones during breastfeeding after loss of placental influence on Vitamin D metabolism.[6]

A number of maternal health problems have been associated with maternal Vitamin D deficiency. In mother spontaneous preterm birth, an increased rate of cesarean section, preeclampsia, gestational diabetes mellitus (GDM), and muscle weakness have been described. Risk factors for Vitamin D deficiency: Northern latitude especially winter or spring, limited sun exposure, regular use of sunscreens, African American or dark skin, obesity, extensive clothing cover, and malabsorptive syndromes (cystic fibrosis, cholestatic liver disease, inflammatory bowel disease, and short gut syndrome).

The hallmark of preeclampsia is marked changes in Vitamin D and calcium metabolism as compared to normal pregnancy. Normotensive pregnant women have high 25(OH) Vitamin D levels than women suffering from preeclampsia.[7,8] The placenta itself expresses 1 alpha-hydroxylase and, thus, produces active metabolite 1,25 (OH)2D3.[9] In syncytiotrophoblasts from pre-eclamptic pregnancies, the expression and activity of 1 alpha-hydroxylase is limited implying a significant role of Vitamin D in placenta.[10] Vitamin D is a key regulator of target genes associated with implantation, trophoblast invasion, and implantation tolerance.[11] Vitamin D regulates the angiogenic processes through direct effects on angiogenesis by gene transcription, including vascular endothelial growth factor.[12]

The need of primary cesarean section is demonstrated to have an inverse association with the status of Vitamin D. Severely, Vitamin D-deficient women with levels of Vitamin D below 37.5 nmol/l delivered nearly 4 times as often by cesarean section than those with values more than 37.5nmol/l.[13]

Vitamin D is known to influence insulin secretion. Vitamin D regulates insulin secretion by pancreatic beta-cells and, thereby, affects circulating glucose levels, glucose intolerance, and features of metabolic syndrome in normoglycemic subjects. Vitamin D deficiency in early pregnancy sufficiently increases the risk of gestational diabetes in later pregnancy.[14]

Aims and Objectives

This study aimed to find the prevalence of Vitamin D deficiency in pregnant women more than 28 weeks gestational age attending the obstetric outpatient department (OPD) at Lalla Ded hospital for antenatal checkup and the cases were followed during antenatal, intrapartum, and neonatal periods to find any fetomaternal correlation with Vitamin D deficiency, to know the prevalence of Vitamin D deficiency in pregnant Kashmiri women attending tertiary care hospital, and to know the maternal outcome in these women.

MATERIALS AND METHODS

The study, entitled "The prevalence of Vitamin D deficiency in Kashmiri pregnant women and its maternal outcome – A tertiary care center study," is an observational study conducted in the Postgraduate Department of Obstetrics and Gynecology, Lalla Ded Hospital, an associated hospital of the Government Medical College, Srinagar for 1 ½ years after obtaining clearance from the Institutional Ethical Committee. Based on confidence level of 95%, minimum sample size is 550.

Proper written and informed consent was taken from pregnant women who were willing to participate in the study. They were requested to complete a questionnaire in their local language that covered sociodemographic data, obstetric history, lifestyle, dietary habits, and sunlight exposure. All singleton pregnant Kashmiri women aged between 18 and 35 years and more than 28 weeks of gestational age attending obstetric OPD at L.D Hospital for antenatal checkup were taken in study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Pregnant women with pre-existing medical disorders such as chronic hypertension, diabetes mellitus, renal disorder, and skin disorder
2. Previous history of lower-segment cesarean section (LSCS)
3. History of use of drugs interfering with Vitamin D metabolism such as anticonvulsants and corticosteroids.

Methodology

For this study, a 2 mL venous blood sample was taken during routine blood collection irrespective of fasting status. The sample for Vitamin D3 was protected from light, centrifuged, and stored at −20°C until analysis. Reliable Vitamin D3 was measured using a quantitative chemiluminescent immunoassay method (CLIA). Vitamin D status is best determined by measuring 25(OH) Vitamin D as it is the major circulating form and has longer half-life (2–3 weeks) than 1,25 dihydroxy vitamin D (5–8 h).

Results of the above laboratory investigations were recorded along with clinical data of the patient in pro forma. Subjects were classified as vitamin D insufficient, deficient, and sufficient. Values <20 ng/mL were the cutoff to define vitamin D deficiency.

The cases were followed in the antepartum period for any of these complications such as pregnancy induced hypertension (PIH), GDM, and maternal hypocalcemia. Gestational age at the time of delivery and mode of delivery was recorded in pro forma. The following parameters were calculated Vitamin D3 levels and maternal calcium levels.

Statistical Analysis

Data were entered in a Microsoft Excel spreadsheet. Results on continuous measurements were presented as mean±SD and results on categorical measurements were present in number (%). Chi-square test was used to find the significance of study parameters.

RESULTS AND OBSERVATIONS

The study patients were aged between 19 and 35 years with a mean age of 28.9 ± 3.64 years. Most common age group affected was 26–30 years in 312 (56.7%) patients followed by 31–35 years in 140 (25.5%) patients while 98 (17.8%) patients were aged <25 years [Table 1].

Out of 550 patients studied, 336 (61.1%) were primigravida while rest 214 (38.9%) were multigravida [Table 2].

Prevalence of vitamin D deficiency was 60.2% (n = 331), 20.5% (n = 113) patients were vitamin D sufficient while insufficient vitamin D was observed in 19.3% (n = 106) patients [Table 3].

In patients aged between 26 and 30, Vitamin D deficiency was seen in 187 (59.9%) patients, insufficiency was observed

in 60 (19.2%) patients while 65 (20.8%) had sufficient vitamin D. In patients with 31–35 years of age, Vitamin D deficiency was observed in 93 (66.4%) patients, Vitamin D insufficiency was seen in 24 (17.1%) while 23 (16.4%) women were found to be Vitamin D sufficient. In women with <25 years of age, 51 (52%), 22 (22.4%), and 25 (25.5%) were Vitamin D deficient, insufficient, and sufficient. The statistically insignificant association was observed between vitamin D status and age with $P = 0.269$ [Table 4].

Significant statistical difference was observed when patients were compared on the basis of vitamin D status and gravidity with $P = 0.014$. There were 189 (56.3%) primigravida compared to 142 (66.4%) multigravida women with Vitamin D deficiency. Vitamin D was insufficient in 65 (19.3%) primigravida compared to 41 (19.2%) multigravida. Sufficient vitamin D was observed in 82 (24.4%) primigravida against 31 (14.5%) multigravida women [Table 5].

Table 1: Age distribution of study patients

Age (years)	Number	Percentage
≤25	98	17.8
26–30	312	56.7
31–35	140	25.5
Total	550	100

Mean±SD (range)=28.9±3.64 (19–35 years)

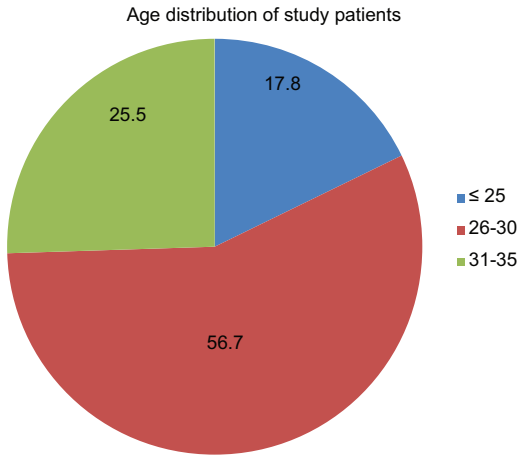

Table 2: Distribution of study patients as per gravid

Gravida	Number	Percentage
Primigravida	336	61.1
Multigravida	214	38.9
Total	550	100.0

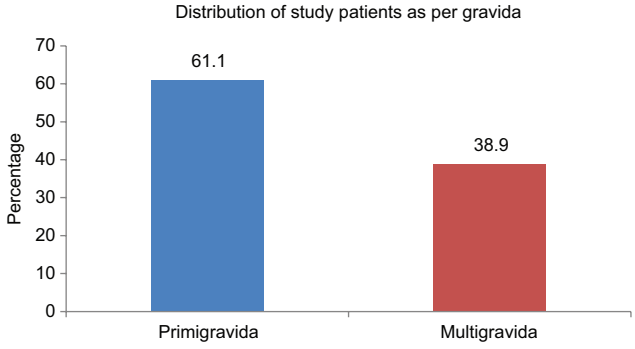

Table 3: Prevalence of Vitamin D deficiency in study patients

Vitamin D status	Number	Percentage
Deficiency	331	60.2
Insufficiency	106	19.3
Sufficiency	113	20.5
Total	550	100

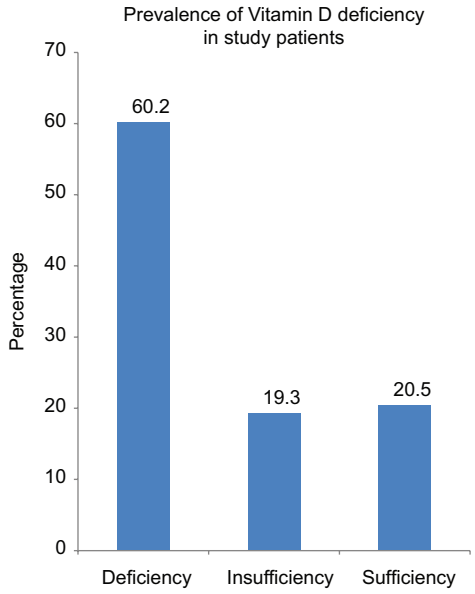

Table 4: Association of Vitamin D status with maternal age

Age (years)	Deficiency		Insufficiency		Sufficiency		*P*-value
	No.	%age	No.	%age	No.	%age	
≤25	51	52.0	22	22.4	25	25.5	0.269
26–30	187	59.9	60	19.2	65	20.8	
31–35	93	66.4	24	17.1	23	16.4	
Total	331	60.2	106	19.3	113	20.5	

Table 5: Association of Vitamin D status with gravid

Gravida	Deficiency		Insufficiency		Sufficiency		*P*-value
	No.	%age	No.	%age	No.	%age	
Primigravida	189	56.3	65	19.3	82	24.4	0.014*
Multigravida	142	66.4	41	19.2	31	14.5	
Total	331	60.2	106	19.3	113	20.5	

In patients with a gestational age of 37–40 weeks, majority, that is, 291 (59.9%) were vitamin D deficient, 91 (18.7%) had vitamin D insufficiency while 104 (21.4%) had vitamin D sufficiency.

In women with 34–36 weeks of gestation, 29 (63.0%), 11 (23.9%), and 6 (13.0%) were Vitamin D deficient, insufficient, and Vitamin D sufficient.

Vitamin D deficiency was observed in 11 (61.1%) patients, 4 (22.2%) had Vitamin D insufficiency while 3 (16.7%) were Vitamin D sufficient with gestational age of <33 weeks. The association between preterm delivery and vitamin D deficiency was insignificant. Moreover, as the majority of patients contacted the tertiary hospital near term, this association could not be made out.

Gestational hypertensive disorder was present in 132 (66.2%) patients with Vitamin D deficiency, 27 (16.0%) patients with Vitamin D insufficiency, and 30 (17.8%) patients with sufficient Vitamin D. GDM was present in 65 (65.7%) patients with Vitamin D deficiency, 12 (12.1%) patients with Vitamin D insufficiency, and 22 (22.2%) patients with sufficient Vitamin D.

Maternal hypocalcemia was present in 227 (76.9%) patients with Vitamin D deficiency, 38 (12.9%) patients with Vitamin D insufficiency, and 30 (10.2%) patients with sufficient Vitamin D [Table 6].

DISCUSSION

The present study entitled "Prevalence of Vitamin D deficiency in Kashmiri pregnant women and its impact on Fetomaternal outcome – A tertiary care center study" was a prospective observational study which was carried out in Lalla Ded Hospital, Government Medical College, Srinagar over a period of 1½ years from 2020 to 2021. Five hundred and fifty cases who fulfilled the criteria were recruited for the study.

The mean age of our study population was 26+3.64 years. The most common age group affected was 26–30 years in 56.7% of patients. In the study conducted by Al-Shaikh *et al.*,[15] 52% of Vitamin D deficient belonged to age group of 25–35 years which is comparable to our study. In study conducted by Gupta *et al.*,[16] the majority of patients were in age group of 21–25 years of age which is not comparable to our study. Yadav *et al.*,[17] in their study, found that mean age group affected with Vitamin D deficiency is 28.3 years which is comparable with the findings of the present study.

In our study, Vitamin D deficiency, insufficiency, and sufficiency were found in 60.2%, 19.3%, and 20.5% of subjects, respectively. Our study findings were consistent with the findings of Sharma *et al.*,[16]

Wherein Vitamin D deficiency was present in 84.8% of pregnant women and Vitamin D insufficiency was present in 12.44%. Dar *et al.*,[18] found Vitamin D deficiency in 68.5% of Kashmiri pregnant women and only 18% of subjects were Vitamin D sufficient which is comparable to our study. Kaur *et al.*,[19] in their study, found the prevalence of Vitamin D deficiency in pregnant women to be 79.8% which is comparable with the findings of the present study.

In our study, Vitamin D deficiency was more common in multigravidas (66.4%) as compared to primigravida (56.3%). These results were comparable with the study

Table 6: Association of Vitamin D status with maternal outcome

Variable	Deficiency		Insufficiency		Sufficiency		*P*-value
	No.	%age	No.	%age	No.	%age	
Gestational age at delivery (weeks)							
<33	11	61.1	4	22.2	3	16.7	0.678
34–36	29	63.0	11	23.9	6	13.0	
37–40	291	59.9	91	18.7	104	21.4	
Mode of delivery							
NVD	143	53.2	61	22.7	65	24.2	0.004*
LSCS	188	66.9	45	16.0	48	17.1	
Gestational hypertensive disorders							
Present	132	66.2	27	16.0	30	17.8	0.008*
Absent	199	52.2	79	20.7	103	27.0	
GDM							
Present	65	65.7	12	12.1	22	22.2	0.141
Absent	266	59.0	94	20.8	91	20.2	
Maternal hypocalcemia							
Present	227	76.9	38	12.9	30	10.2	<0.001*
Absent	104	40.8	68	26.7	83	32.5	

LSCS: Lower-segment cesarean section, GDM: Gestational diabetes mellitus

conducted by Al-Shaikh *et al.*,[15] who found that 66.8% of Vitamin D-deficient women were multiparous.

In our study, pregnant females who delivered at 37–40 weeks of gestation, 291 (59.9%) were Vitamin D deficient, 91 (18.7%) were Vitamin D insufficient while 104 (21.4%) were Vitamin D sufficient. In those pregnant women who delivered at <33 weeks gestation, Vitamin D deficiency was observed in 11 (61.1%) patients, 4 (22.2%) had Vitamin D insufficiency while 3 (16.7%) were Vitamin D sufficient. There was no significant correlation between Vitamin D deficiency and preterm birth. Yang *et al.*,[18,20,21] in their study, found that pregnant women with lower vitamin D (<20 ng/mL) had no significant increase in preterm birth risk which is comparable with our study.

In our study, gestational hypertensive disorder was present in 66.3% of Vitamin D-deficient pregnant women, 16 % of Vitamin D insufficient, and 17.8% of Vitamin D sufficient women. These results were comparable with the study conducted by Talukdar and Joshi[22] where hypertensive disorder was present in 63.6% of Vitamin D-deficient pregnant women and only 26.6% of Vitamin D-sufficient women. In study conducted by Bodnar *et al.*,[7] a positive correlation was found between Vitamin D deficiency and development of preeclampsia which is in accordance with our study.

In our study, only 65 out of 331 Vitamin D-deficient pregnant women had GDM which is comparable to a study conducted by Talukdar and Joshi[22] where only 9.1% of Vitamin D-deficient women had GDM while 90.9% were having normal sugars. The study conducted by Baker *et al.*,[19] showed no significant association of GDM with vitamin D deficiency which is in accordance with our study. The study findings of Hauta-Alus *et al.*,[23] were also consistent with our findings showing no significant association of GDM with Vitamin D deficiency. Rekha *et al.*, (2019) in their study, found that mean Vitamin D levels were lower in women with GDM as compared to normal pregnant women.

There is a strong association between Vitamin D deficiency and maternal hypocalcemia. In our study, 227 (76.9%) of Vitamin D deficient had hypocalcemia while 104 (40.8%) had normal calcium levels. In Vitamin D-sufficient group, 30 (10.2%) had hypocalcemia. Almaghamsi *et al.*,[24] found vitamin D deficiency as an important cause of maternal hypocalcemia. They found that vitamin D, calcitonin, and PTH interact to steadily maintain homeostatic ionic calcium control during pregnancy.

In our study, out of 331 women who were Vitamin D deficient, 188 (66.9%) delivered through LSCS while 143 (53.9%) delivered through normal vaginal delivery. In the study conducted by Prasad *et al.*,[25] 54% of study subjects who were Vitamin D deficient delivered through LSCS and 34% had normal vaginal delivery which is similar to our study. Our study findings were in accordance with Merewood *et al.*,[26] where they found that there exists an inverse association between cesarean section and serum Vitamin D levels. In their study, 28% pregnant women with Vitamin D deficiency had cesarean section compared to 14% pregnant women with sufficient Vitamin D levels.[27]

CONCLUSION

Vitamin D deficiency is an unrecognized epidemic that is increasing worldwide both in the general population as well as in pregnant women. Vitamin D is an important vitamin for the regulation of calcium metabolism and maintaining good health.

The present study provided significant information about the vitamin D status of Kashmiri pregnant women. Vitamin D deficiency has adverse effects on both mother and fetus. In our study of Kashmiri pregnant women, statistically significant association was observed between Vitamin D deficiency and mode of delivery, gestational hypertensive disorders, and maternal hypocalcemia. A statistically significant association was observed when Vitamin D status was compared with birth weight ($P = 0.002$), 1 min Apgar score ($P = 0.008$), respiratory infection, and neonatal hypocalcemia.

Increasing hours of sun exposure and Vitamin D supplementation during pregnancy could prevent some of the consequences. Effective educational programs should be initiated to elevate awareness among pregnant females about the importance of this vitamin and deficiency-associated complications.

As the majority of patients in our study contacted the tertiary care center for the 1st time near term (≥37 weeks) maternal and fetal outcome could not be prevented; therefore, serum analysis of Vitamin D should be done in pregnant females early in pregnancy and Vitamin D supplementation provided to prevent adverse maternal and fetal outcome.

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