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

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

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International Journal of Scientific Study

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International Journal of Scientific Study
May 2021 • Vol 9 • Issue 2

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International Journal of Scientific Study
May 2021 • Vol 9 • Issue 2

International Journal of Scientific Study
May 2021 • Vol 9 • Issue 2

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

Case Report

Familial Granular Corneal Dystrophy (Type 1) Involving four Members of a Single Family: A Case Report

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Abstract

Granular corneal dystrophy (GCD), Type 1 also known as corneal dystrophy Groenouw type I is a type of stromal corneal dystrophy. We report a series of four affected members of a family diagnosed with (GCD type 1). Our index case was a 45-year-old female with bilateral diminution of vision for the past 5 years. The diagnosis was established using clinical examination and anterior segment optical coherence tomography. Further screening of her family members revealed similar disease in her father and two siblings. The patient was not willing for deep anterior lamellar keratoplasty. Hence, she was managed conservatively with best-corrected visual acuity of 6/36 in the right eye and 6/18 in the left eye.

Key words: Anterior segment optical coherence tomography, Autosomal dominant, Granular corneal dystrophy

INTRODUCTION

Granular corneal dystrophy (GCD) (GCD type 1, also known as corneal dystrophy Groenouw type I) is a rare subtype of stromal corneal dystrophy, generally starts around puberty with a slow progression.[1,2] The patient may be asymptomatic for a prolonged period, though some may present with glare, photophobia, and/or recurrent erosions.[1] In this classic variant, there is bilateral involvement showing white, discrete, granular deposits of hyaline in anterior, and deep stroma with clear intervening stroma and sparing of the limbus.[1] Histopathological examination shows bright red amorphous deposits of hyaline material when stained with Masson trichome.[3,4] Definitive treatment for visually significant lesions includes deep anterior lamellar keratoplasty (DALK) or penetrating keratoplasty (PK) with good visual outcomes.[5]

A 45-year-old female presented in the eye clinic with chief complaints of diminution of vision in both eyes for the past 5 years. There was no trauma or associated ocular or systemic illness. Her uncorrected visual acuity was 6/60 in the right eye and 6/36 in the left eye. Slit-lamp biomicroscopy revealed mild epithelial erosion involving central cornea in both eyes (right eye > left eye). There were multiple, white granular deposits in the anterior and deep stroma of the central cornea with sparing of the limbus [Figures 1 and 2]. Rest of the anterior and posterior segment examinations were unremarkable.

Keratometry readings of the right eye (K1 = 43.75 D, K2 = 47.00 D; axis 94°) and left eye (K1 = 43.25 D, K2 = 44.50 D; axis =67°) were noted. Pachymetry revealed increased central corneal thickness readings (right eye =599 μm and left eye =564 μm). Anterior segment optical coherence tomography of both eyes revealed hyperreflective granular lesions extending from the bowman's layer to deeper stromal lamellae in both eyes (right > left eye) as shown in Figures 1 and 2. Patient was advised DALK but patient was not willing for surgical intervention, therefore was managed conservatively. Best-corrected visual acuity (BCVA) was 6/36 and 6/18 in the right and left eye, respectively.

In view of the autosomal dominant transmission of GCD type 1, a thorough screening of her family members was performed as shown in family chart [Figure 3]. We examined a total of 11 patients among which 4 (index patient, her father, and two younger

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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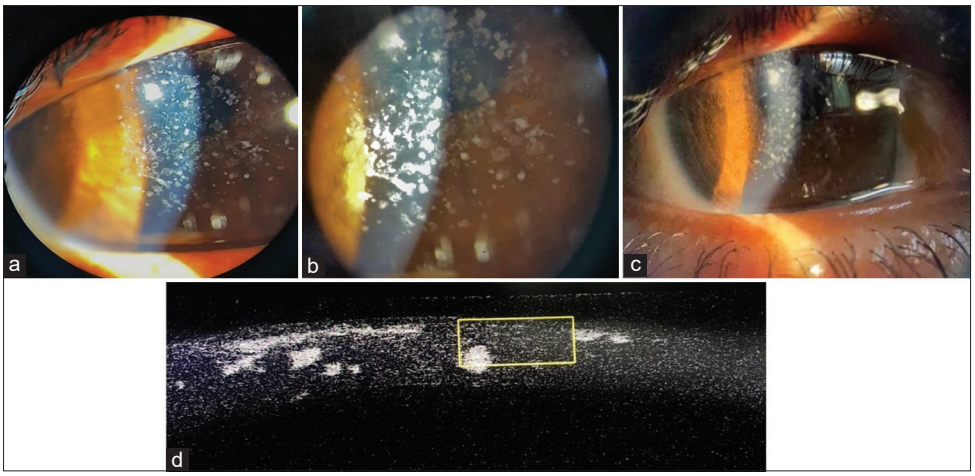

Figure 1: Slit-lamp photograph of the right eye (a-c) showing multiple, whitish granular deposits in the corneal stroma. Anterior segment optical coherence tomography (d) showed the presence of multiple anterior to mid stromal hyper-reflective opacities

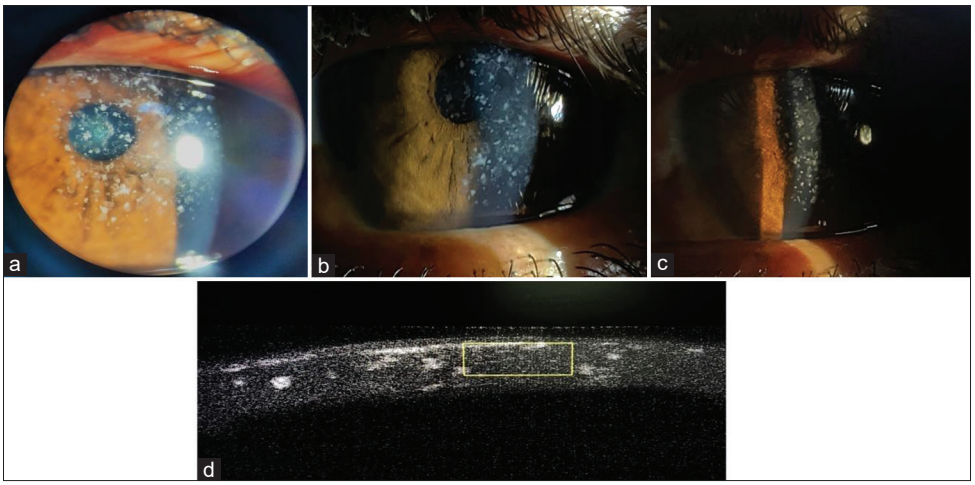

Figure 2: Slit-lamp photograph of the left eye (a-c) showing multiple, whitish granular deposits in the corneal stroma (less dense compared to right eye). Anterior segment optical coherence tomography (d) multiple anterior to mid-stromal hyper-reflective opacities in the central cornea

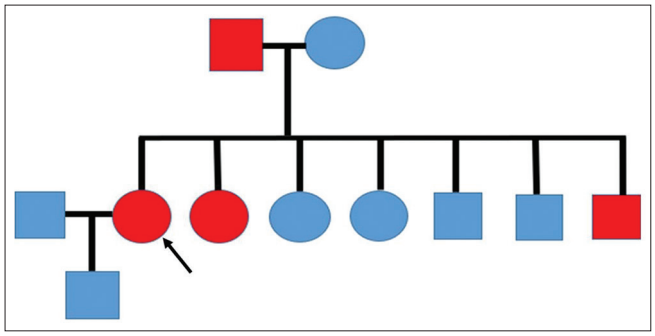

Figure 3: Family chart showing four affected family members shown as red square and red circle. These included the index case (female, 45 years), her father, and two siblings (one male and one female)

siblings) were detected to have GCD type 1 [Figure 4]. Her father had a presence of significant cataract in the right eye along with corneal stromal opacity and was planned for DALK and cataract surgery. The left eye was pseudophakic with BCVA of 6/12. Other two siblings also had complaints of diminution of vision for distant objects for which they were prescribed spectacles to correct the refractive error along with artificial lubricating eye drops [Figure 4].

DISCUSSION

GCD type 1 is an autosomal dominant inherited corneal stromal dystrophy.[1,4] We screened a family with GCD and found four members within varying stages of disease severity. Among 11 members, 4 (36.4%) were found to have GCD type 1. Genetic analysis forms the mainstay to identify and classify the disease.[1] However, in view of financial constraints, this was not performed in our study cohort. Although the majority of patients are asymptomatic

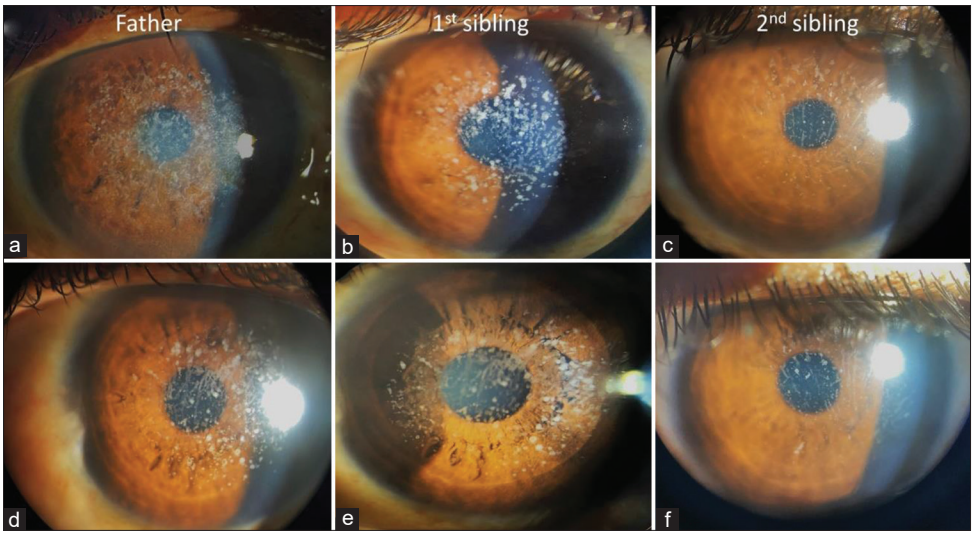

Figure 4: Slit-lamp photograph (diffuse illumination) of three other family members showing similar stromal opacities. Father (right eye – [a], left eye – [d]), 1st sibling (right eye – [b], left eye – [e]), 2nd sibling (right eye – [c], left eye – [f])

in initial stages, insidious progression heralds a multitude of ocular symptoms (diminution of vision, glare, and photophobia due to recurrent erosions). Whereas asymptomatic individuals benefit from refractive error correction and artificial tear substitutes alone, advanced cases may benefit from surgical procedures such as DALK or PK.[5,6]

CONCLUSION

To conclude, high index of suspicion and subsequent family screening is essential to diagnose corneal dystrophies such as GCD type 1 for early visual rehabilitation.

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How to cite this article: Guha S, Kumari R, Bhagat DK, Singh SR. Familial Granular Corneal Dystrophy (Type 1) Involving four Members of a Single Family: A Case Report. Int J Sci Stud 2021;9(2):1-3.

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

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

Review Article

A Focus on Soft Tissue Changes Around Implant vs Natural Tooth

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Abstract

Replacement of missing tooth marks the dawn of dentistry. Digging into the ancient times, man is persistently been working on the replacement of natural body parts, missing due to any congenital defect, any disease or injury, so as to regain a proper form and function. In the general population, dental implants have recently become established as a standard treatment protocol for replacing missing teeth. This article aims at sharing the knowledge about the difference between natural tooth and dental implants in an attempt to focus on the dilemma of using dental implants as an assured replacement to the natural tooth.

Key words: Implant, Natural tooth, Periodontium

INTRODUCTION

In daily practice, dental professionals routinely face the challenge of making difficult decisions in making a treatment plan for patients with compromised dentitions, the choice is often one of either building on the existing teeth or extracting teeth followed by restoration with implant-supported reconstructions.[1] To patients and practitioners alike, tooth extraction befits the final attempt when all other possible options fail. However, most recently dental implants have drawn practitioner's attention toward providing tooth substitutes, often hailed as equal or even superior to natural teeth, and many clinicians have been looking forward to embrace the placement of dental implant as the new standard treatment in the field of dentistry.[2] Thus, this review focuses on highlights on how soft tissues vary around implant and natural teeth and points out the anatomical and histological differences of the tissues.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

GINGIVAL EPITHELIUM AROUND TEETH

The gingival epithelium [Figure 1] is composed of three types of epithelium, namely, junctional epithelium (JE), oral epithelium (OE), and oral sulcular epithelium (OSE). JE is a non-keratinized epithelium having weak cell-cell contacts, making it more permeable to the inflammatory exudates, thus easily gets affected by exogenous factors.[3,4] The JE possess certain defense properties; (1) chemotactic activity leading to the endocytosis and decomposition of exogenous factors by neutrophils and JE itself, (2) self-cleansing and antibacterial action of gingival crevicular fluid, (3) exfoliation of JE cell layer.[3] Histologically epithelium attachment to the enamel is a complex structure and is composed of internal basal lamina and hemi-desmosome. Adhesion of epithelium to the enamel or cementum takes place mechanically through hemi-desmosomes while connective tissue possesses vertical mechanical and chemical attachment to tooth. JE is formed during the tooth eruption by the fusion of reduced enamel epithelium with OE, this primary JE gets replaced with secondary JE, similar in structure and function to primary JE.[3] OE being the thick mucosal epithelium forms a seal around the tooth protecting the soft and hard tissues. This seal extends from OSE to the top of alveolar bone comprising of both epithelial and connective tissues. This attachment structure is termed as biological width, usually ~2 mm in width. JE is approximately 0.5–1 mm in width and is a stratified squamous epithelium extending that attaches to the

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cervical layer of enamel in younger generations and extends gradually to the cementum layer around with patient's age.[4-14]

GINGIVAL EPITHEIUM AROUND IMPLANT

The peri-implant junction [Figure 1] is composed of three types of epithelium, namely, peri-implant epithelium (PIE), peri-implant sulcular epithelium, and OE. The peri-implant mucosa sealing the tooth is comparable to the natural teeth having a biological width of 3–4 mm, slightly longer than that around natural tooth.[3] According to the studies, the peri-implant mucosa resembles is well-keratinized from outer surface and its inner lining resembles the JE of the natural tooth.[4] Berglundh *et al*. in an experiment showed that the JE around implant extends 2 mm apically from the soft-tissue margin, facing the implant as result of wound healing with epithelial cells proliferating along the exposed implant surface until the restoration of epithelial continuity and integrity. The apical cells terminate nearly at 1–1.5 mm coronal to the bone crest, separated by collagen rich, cell poor connective tissue without any inflammation.[4] The PIE is 3–4 cell layer thin, formed from the cells OE within 2–3 weeks after implantation and mature barrier of epithelium is achieved after 6–8 weeks of healing.[15-17]

CONNECTIVE TISSUE AROUND TOOTH

According to the study of Berglundh *et al*., connective tissue around tooth is a complex structure having fan shaped arrangement of supra-alveolar fibers projecting from root cementum into the soft and hard tissues of the marginal periodontium running in lateral, coronal, and apical direction. Schoreder *et al*.[18] in his study described about the presence of dentogingival, dentoperiosteal, alveologingival, and periostogingival fibers attaching gingiva to teeth and bone, interpapillary fibers connecting the vestibular and oral interdental papillae, and circular or semicircular transgingival and transseptal fibers connecting adjacent teeth to one another.[4]

CONNECTIVE TISSUE AROUND IMPLANT

In contrast to the natural tooth, connective tissue around implant is different in cellular composition and fiber orientation having a poor mechanical resistance as compared to natural tooth [Figure 2].[4,6] The difference includes the orientation of collagen fibers in parallel direction around implant/abutment which also depends on the quality of mucosa where fibers tend to be perpendicular in keratinized mucosa and parallel in alveolar mucosa whereas in natural teeth fibers are arranged in perpendicular direction and tend to adopt a circular pattern,[4,6,16] whereas perpendicular direction of fibers is seen in certain studies in implants harboring porous surface [Figure 3].[6] Collagen fibers around implant extend between alveolar bone to mucosal margin. Studies have reported increased number of fibroblasts arranged in long axis parallel to the adjacent collagen fibers and to the implant surface, and this fibroblast rich barrier tissue plays an important role in maintaining an adequate seal against external environment. According to the study done on canine model by Berglundh *et al*. did a study on canine model and stated that peri-implant mucosa is formed after 4–6 weeks of healing and tissue maturation occurs between 6 and 12 weeks of healing. Tomas *et al*. in his study concluded that the peri-implant mucosal seal occurs completely within 8 weeks of healing and tends to be approximately 1.5 mm high lying supracrestaly.[4,16]

BIOLOGICAL WIDTH AROUND TOOTH

Biologic width is the term which describes the dimensional width of the dentogingival junction and was first described by Sicher in 1959 as "dentogingival junction". [15] Biological width is normally composed of connective tissue attachment (CTA) extending up to the apical extent of JE which includes 0.97 mm JE and 1.07 mm CTA [Figure 4]. [4,7] This natural seal may be defined as 'the total of supracrestal fibers, junctional epithelium and sulcus', which is essential for the maintenance of periodontal health and its violation leads to a damaged periodontium.[15]

Kois proposed three categories of biologic width which were based on the total dimension of attachment and the sulcus depth following bone sounding measurements which have been described Table 1.[15]

VIOLATION OF BIOLOGICAL WIDTH

It is the inadequacies of the tooth transition zone which is characterised by chronic progressive gingival inflammation around the restoration, bleeding on probing, localized gingival hyperplasia with minimal bone loss, gingival recession, pocket formation, clinical attachment loss and alveolar bone loss [Figure 8].[15]

Biological width assement can be done by using bone sounding method which includes probing under local anesthesia to the bone level and if this distance is less than 2 mm at one or more locations, a diagnosis of biologic width violation can be confirmed.[15]

BIOLOGICAL WIDTH AROUND IMPLANT

The implant-epithelium junction is similar to that of natural dentition. The difference includes the implant- epithelium junction is shorter and thinner than the tooth epithelium

junction and due to the absence of a cementum layer around an implant, most connective-tissue fibers in supracrestal region are oriented in a direction parallel to the implant surface.[15]

According to the study of Berglundh *et al*., biological width in peri-implant mucosa includes 2 mm of epithelial attachment and 1–1.15 mm of connective tissue attachment separating the epithelium from bone crest. According to the studies, similar mucosal barrier can be seen in submerged and non-submerged implants, making no difference in dimension and composition [Figure 5].[5] Difference between the biological width of implant vs natural tooth has been given in Table 2.

Considering the different characteristics; roughness, sandblasting, and polished, no difference was seen in healing pattern of peri-implant mucosa for three systems which was seen.[4,7] However, less bone loss was seen in roughened surface and has no impact on final location of most bone-implant contact.[4,7] Various studies concluded that titanium was the only material that showed consistent soft-tissue biocompatibility, zirconium and aluminum oxide demonstrated coronal favorable histological outcomes, whereas dental porcelain and gold were less biocompatible.[4,7] Types of implants include one piece and two piece implant including a horizontal mismatch (abutment is smaller in diameter as compared to implant diameter) and a horizontal match (implant and abutment having same diameter). Various studies prefer using horizontal mismatch pattern, as it leads to less marginal bone resorption as compared to the horizontal match pattern of implant abutment junction which leads to saucer-shaped bone defect[8]

BIOTYPE AROUND TOOTH

Gingival biotype signifies the thickness of gingiva which is basically of two types including thick biotype which means gingival thickness of >2 mm and thin biotype when gingival thickness is <1.5 mm. The term periodontal biotype introduced by Seibert and Lindhe categorizing the gingiva into "thick flat" and "thin scalloped" biotypes.[9] Thick biotype is characterized by broad zone of keratinized tissue and a thick flat bony architecture and is more prone to pocket formation due to inflammation of periodontium and showing more of the fibrotic changes, whereas thin biotype is characterized by thin band of keratinized tissue and a thin bony architecture and is more prone to gingival recession.[9,10] However considering the gingival thickness in various periodontal procedures which includes the following.[9,10]

- Root coverage procedures – thick biotype have shown to give more predictable results
- Extraction – thick biotype shows minimal ridge atrophy whereas thin biotype is likely to result in fracture of the labial plate and traumatic ridge resorption in the apical and lingual direction.
- Crown lengthening procedures – post-operative tissue rebound has been seen in thick biotype as compared to thin biotype.
- Orthodontic therapy – thin biotype shows more chances of recession with fenestration and dehiscence formation with tooth movement.
- Prosthesis esthetics – thin biotype is more prone to recession thus more caution should be exercised while planning subgingival margin.

BIOTYPE AROUND IMPLANT

According to variety of studies done, the mucosal biotype is mainly classified as thick biotype with high scalloping mucosa and a thick biotype with low scalloping mucosa [Figure 6]. Significance of biotype in implant selection suggests that – immediate implant – thick biotype is more preferable as thin biotype is mostly associated with more of the recession with increased risk of unfavorable outcomes.[8] Table 3 describe various studies related to the biotype with peri-implant mucosa.[14]

Delayed implant – more preferable for thin biotype gingiva.[8,9]

Flapless implant – includes thin biotype patients as according to studies, flapless implant has shown to decreases the papillary recession and bone loss.[8,9]

PAPILLA HEIGHT IN NATURAL TOOTH

Topographically gingiva is divided into three categories free, attached, and interdental gingiva which varies depending on the adaption of gingiva around tooth (Schroeder and Listgarten, 1997).[18] Interdental gingiva occupies the space interdentally, coronal to the alveolar crest. In the incisor region, papilla is pyramidal shape with the tip located immediately beneath the contact point, which is narrower, referred to as dental papilla. In the posterior region, it is broader, having a concave col or bridge shape (Cohen, 1959).[19] The interdental gingiva gains the attachment to the tooth by connective tissue and JE (Gargiulo *et al*., 1961),[20] lined in a coronal position by sulcular epithelium (Scrhoeder and Listgarden, 1997).[11] Table 4 describes the characteristics of different biotype.[14]

PAPILLA HEIGHT IN IMPLANT

The height of interdental papilla next to implant is one of the main parameters required for positive esthetic outcomes. Clinically, the presence of papilla between two teeth depends on the vertical distance between the alveolar and contact point of the adjacent teeth [Figure 7]. According to a clinical study:

- Vertical distance <5 mm – papilla present in 98% implant sites
- Vertical distance 6 mm – papilla present in 56% implant sites
- Vertical distance 7 mm – papilla present in 27% implant sites.

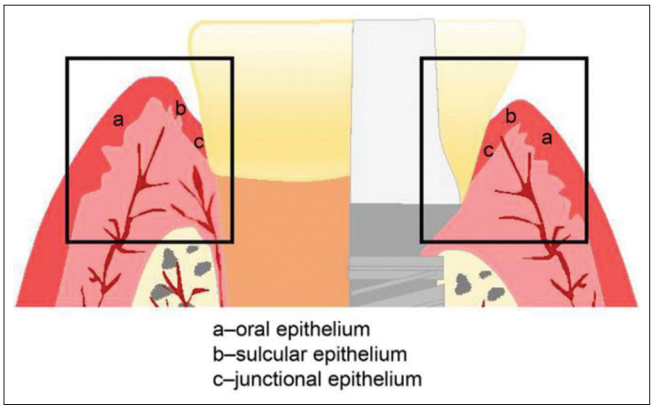


Figure 1: Epithelial components of dentogingival junction and peri-implant mucosa[5]

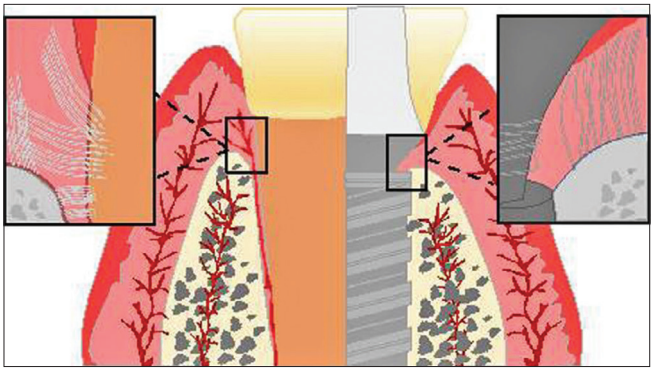


Figure 2: Connective tissue components of dentogingival junction and peri-implant mucosa. Perpendicular connective tissue attachment on tooth surface compared to longitudinal and circumferential fibers around the implant abutment surface.[5]

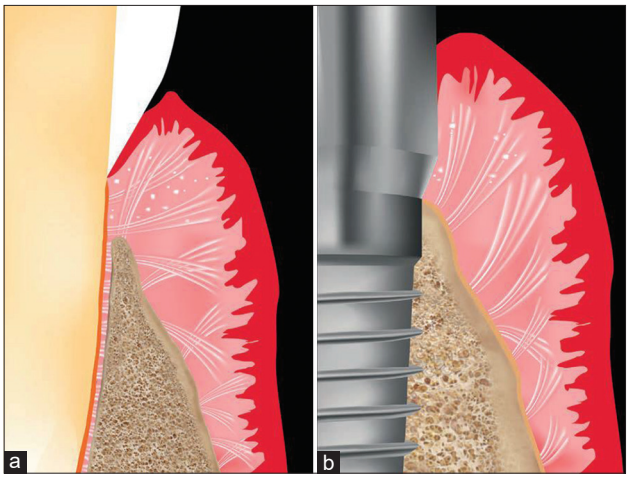


Figure 3: Illustrations of supracrestal tissues around a (a) natural tooth (b) titanium implant[16]

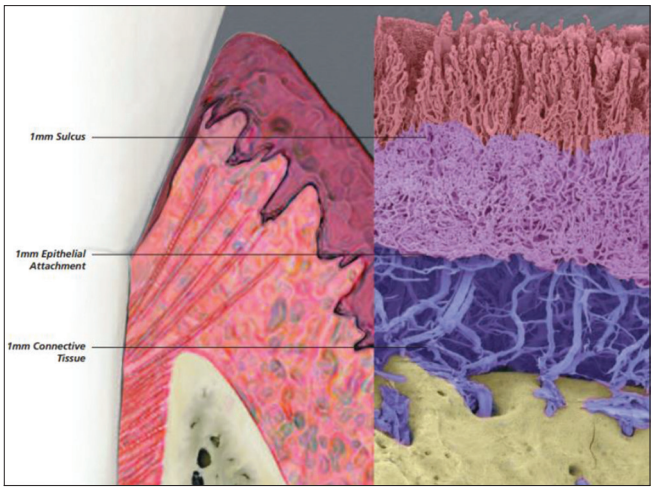


Figure 4: Biological width around natural tooth[12]

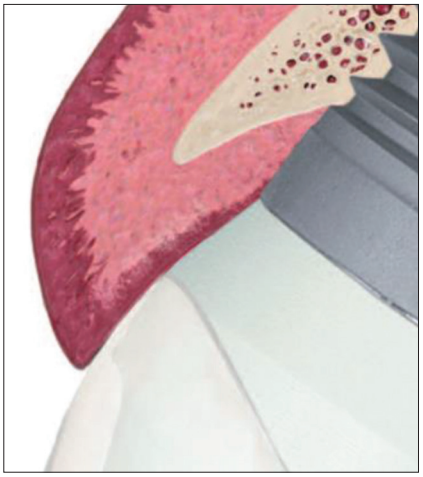


Figure 5: Illustration depicting the inherent thinning of the ridge following the development of the biologic width around standard two-stage implants. Note the increase in cortical bone and the reduction in cancellous bone[12]

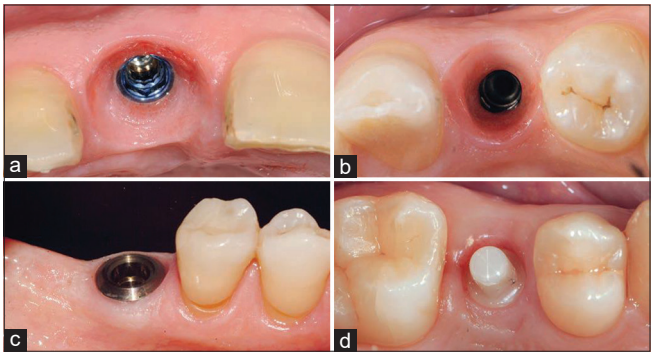


Figure 6: Physiologic appearance of peri-implant soft tissues around different implant types. (a and b) Bone level titanium implants. In these cases, the depth of the peri-implant mucosal tunnel, that is, the distance from the gingival margin to the implant connection, is greater. (c) Tissue level titanium implant. In these cases, the peri-implant mucosal tunnel is more shallow. (d) Single-component zirconia implant. With tissue level implants, the implant prosthetic platform is located closer to the surface in a juxtagingival or slightly subgingival position[16]

Table 1: Catergories of biological width

Crest	Mid facial measurement	Proximal measurement	Margins
Normal Crest (85%)	3.0 mm	3.0 mm to 4.5 mm	Margin of a crown should generally be placed no closer than 2.5 mm from alveolar bone.
High Crest (2%)	< 3.0 mm	< 3.0 mm	It is commonly not possible to place an intracrevicular margin because the margin will be too close to the alveolar bone.
Low Crest (13%)	>3.0 mm	>4.5 mm	These patients have been described as more susceptible to recession secondary to the placement of an intracrevicular crown margin.

Table 2: Summary of biological width around tooth versus dental implant[5]

Epithelial	Peri-implant epithelium Hemidesmosome attachment to Ti[21]	JE hemidesmosome attachment to enamel/cementum surface (Gargiulo *et al*., 1961)
Connective tissue attachment	Scar-like structure with abundant collagen but minimal vascularization, fibers run longitudinal, parallel, or circumferential fibers around the implant (Berglundh *et al*., 1994)	Well-organized perpendicular collagen fiber attach to root cementum[22]
Biological width	PIE=1.88 mm, CT=1.05 mm (Cochran *et al*., 1997)	JE=1.14 mm, CT=0.77 mm[23]

PIE: Peri-implant epithelium, JE: Junctional epithelium, CT: Connective tissue

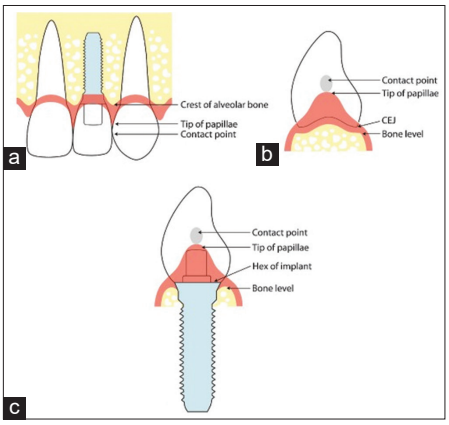


Figure 7: (a) Inter-dental/Inter-implant papillae; (b) inter-proximal view of inter-dental papilla in natural tooth; (c) inter-proximal view of inter-dental papilla in implant[12]

Compared to the natural teeth, the papilla height at implant site was reported to be shorter significantly and the mean papilla height between two implant was 3.4 mm, 1.5 mm less than a natural teeth, and an implant reported by an another study. However, a clinical study showed that for the presence of normal interdental paipilla, 3mm of interimplant distance is needed, as more crestal bone loss (1.04mm), was seen for interimplant distance <3mm and crestal bone loss was less (0.45mm) for imterimplant distant > 3mm.[8]

VASCULAR STRUCTURE OF GINGIVA AROUND TOOTH

Human gingival tissue is highly vascularized in nature.[4] In a clinical study, histological sections of the buccal periodontium in dogs showed that the oral surface of gingival tissue harbored a well-keratinized OE which was continuous with a JE that terminated at the cementoenamel junction. The connective tissue lateral to the JE was rich in collagen fibers and was devoid of accumulations of inflammatory cells.[13] The main source of gingival blood supply is large supraperiosteal blood vessels and vascular plexus of periodontal ligament (PDL) [Figure 7]. The vascular plexus of JE is rich in anastomoses anatomically extends from the coronal to the apical terminal ends of the JE, both vestibularly and orally including interdentally.[4] According to the study, the subepithelial oral plexus seems

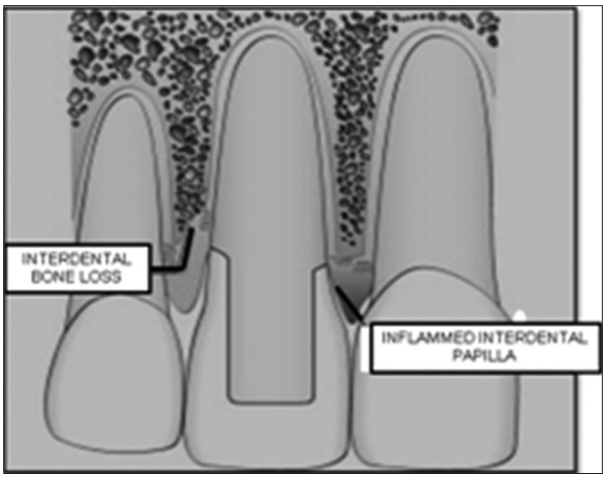


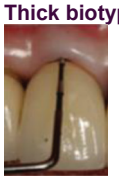
Figure 8: Ramification of biological width

to be as the terminal branches of the supraperiosteal plexus. The density of the vascular plexus was more in more in marginal gingiva and tends to increase all over during inflammation signifying the increase in capillary loops.[4,13] During inflammation, capillary venules of gingival plexus develop into high endothelial venules which proliferate, playing an important role against the selective entry of lymphocytes.[12] The vascular plexus consists of thin capillary loops projecting into the connective tissue papillae under the OE.

Table 3: Studies that correlated tissue biotype with peri-implant mucosa and the underlying bone[14]

Study	Study Design	N	Site	Definition of Biotype	Time of Measurement	Implant System	Observation Period	No. of Stages	Types of Prosthesis
Abrahamsson *et al*[34]	Animal Prospective	5 Beagle dogs 30 Implants	Mandibular premolars	Undefined	Abutment	Brånemark vs Astra Tech vs Bonefit	6 mo	1 and 2	Abutment connection and extension caps
Berglundh and Lindhe[41]	Animal Prospective	5 Beagle dogs 30 Implants	Mandibular premolars	Thin: 2.4 mm Thick: 3.3 mm	Abutment	Brånemark	6 mo	2	Abutment connection
Kan *et al*[21]	Retrospective	45 Patients 45 Implants	Maxillary anteriors	Thin: probe seen through tissue Thick: probe not seen through tissue	After prosthesis	Unknown	1 yr	2	Single crowns
Cardaropoli *et al*[38]	Prospective	11 Patients 11 Implants	Maxillary anteriors	Ultrasonic	Abutment connection	Brånemark	1 yr	2	Single crowns
Linkevicius *et al*[48]	Prospective	26 Patients 64 Implants	Unknown	Thin: ≤2 mm Medium: 2.1–3 mm Thick: >3.1 mm	Implant placement	BioHorizons	1 yr	1	Single crowns and fixed partial denture
Linkevicius *et al*[49]	Prospective	19 Patients 46 Implants	Unknown	Thin: ≤2 mm Thick: >2.5 mm	Implant placement	BioHorizons	1 yr	1	Single crowns and fixed partial denture
Linkevicius *et al*[50]	Prospective	4 Patients 12 Implants	Unknown	Thin: ≤2 mm	Implant placement	3i BioHorizons	1 yr	1	Splinted crowns and fixed partial denture
Blanco *et al*[39]	Animal Prospective	5 Beagle dogs 20 Implants	Mandibular premolars	Undefined	Unknown	Straumann	3 mo	1	Abutment connection

Table 4: Characteristics of different biotype[14]

Characteristics	Thin biotype	Thick biotype
		
Soft-tissue thickness	<2 mm	>2 mm
Facial height of peri-implant mucosa (equivalent biological width around tooth)	<3 mm	>4 mm
Impingement of peri-implant mucosa	Angular defect	Horizontal bone loss
Immediate implant placement in non-ideal position	More recession More papilla loss	Less recession Less papilla loss
Platform switching to minimize bone loss	No benefit	Potential benefit
Restorative components	Zirconium preferred	Zirconium preferred Titanium possible

The majority of these loops had a diameter which was about 7–10 μm.[13]

The vascular units coming as terminal branches of the supraperiosteal vessels, included vascular units consisting of thin vessels with a diameter of <7 μm and wider vessels with a diameter of 10 μm. The various vascular units formed in a mesiodistal direction a fine-meshed network of anastomosing structures; a "crevicular plexus." The vessels of the supracrestal connective tissue, lateral to the root cementum, were found to originate mainly from the vasculature of the PDL with a minor contribution from the larger supraperiosteal vessels. The vascular units close to the cementum were generally thin, but a few wider vessels could also be seen.[13]

VASCULAR STRUCTURE OF GINGIVA AROUND IMPLANT

The blood supply of peri-implant mucosa originates solely from the terminal branches of larger vessels of supraperiosteum from the vestibular border of alveolar ridge.[4] The peri-implant mucosa consists of JE facing the titanium abutment and a connective tissue present supracrestaly. This connective tissue is rich in supraperiosteal vessels which are similar to gingiva in location and configuration of arrangement. These vessels are present as thin capillary loops, having a diameter of 7–10 μm.[13] Lateral to the JE "cervical plexus" is present, at a distance of 50 μm from the basal layer of JE, suggesting the source of leukocyte migration and accumulation being same in both the tissues.[4,13] According to the dog study done by Berglundh, the root cementum of peri-implant mucosa is mainly devoid of vascular supply. However, the bone surrounding the fixture portion is richly vascularized

having vessels of varied diameter reaching the implant material, thus maintains the contact between the bone and implant material.[13]

CONCLUSION

These days, more and more patients are opting for dental implants after losing their teeth. Dental implants have made the life of patients easier as compared to other prosthetic restorations, in the following ways such as

- It is easier to eat with implant placement
- Gives a better alignment as each tooth relies on its neighbors to maintain proper alignment
- The body responds well to titanium as it gets easily osseointegrated to the bone
- Furthermore, implants are more durable, as results of various studies show 98% success rate for implant.

Moreover, the integrity of the tissue-implant interfaces can affect the success of dental implant treatment and success.

The integrity of the peri-implant soft-tissue seal is crucial for maintaining peri-implant tissue health. Although the transmucosal component of the restored implant shares some common features with teeth, namely, the presence of a JE and a connective tissue component, there are some important differences. A key difference is the nature of the relationship between the connective tissue and the implant surface, whereby there is "adaptation" of collagen fibers in a parallel orientation in relation to the implant, but insertion of fiber attachment perpendicularly into cementum in the case of teeth. This, combined with reduced cellularity and vascularity in the peri-implant connective tissue, may make them more susceptible to disease initiation and progression.[4]

In terms of disease etiology, dental plaque is the primary factor in both peri-implantitis and periodontitis. However, the presence of a subgingival connection between the implant and the abutment/ restoration poses some specific challenges, and the maintenance of the integrity of this connection is important in maintaining peri-implant tissue health. It should be noted that implant design features, such as the nature of the connection between the implant and the abutment, as well as the abutment and implant surface characteristics, may influence the maintenance of the soft-tissue integrity around implants. Iatrogenic factors, such as incorrect seating of the abutment and/or the restoration, and subgingival cement retention, will lead to loss of soft-tissue integrity and hence to peri-implant disease.[17]

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How to cite this article: Dhir S, Chauhan S, Sinha A, Sharma S. A Focus on Soft Tissue Changes Around Implant vs Natural Tooth. Int J Sci Stud 2021;9(2):4-10.

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

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

Review Article

Tobacco Use and Women in India

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Abstract

Tobacco consumption has become a cause of major concern globally. India has shown an increase in tobacco use not only among males but also tobacco use, especially smoking has been on a rise in urban Indian females over the past two decades. The use of smokeless tobacco (SLT) among the rural females has also been greatly increased. The major determinant for the SLT use has been the social and cultural acceptance of tobacco use and taboos among rural population. The lower SES population in India has shown an increased incidence of SLT use due to easy availability and access to these products. Furthermore, tobacco industries have a major stake in the economics of the country as well as in the employment of the population from lower SES strata. This paper reviews the statistics and determinants of tobacco use in Indian women along with tobacco addiction, tobacco use cessation strategies, and various tobacco control policies by the Government of India targeting the female population of the country.

Key words: COTPA, Smokeless tobacco, Smoking, Tobacco use cessation

INTRODUCTION

Tobacco consumption is a growing concern around the globe from many decades and has been regarded as one of the most common causes of morbidity and mortality. According to the International Classification of Diseases-10, "TOBACCO DEPENDENCE" has been recognized as a disease. Globally, about 6 million people die due to tobacco use annually. By 2030, unless urgent action is taken, this toll is expected to rise to more than 8 million. India is one of the largest producer and consumers of tobacco in the world. The prevalence of tobacco use among the adult Indian population is 34.6% overall, 48% of males and 19.3% of females, respectively.[1]

In well-developed countries, such as the United States and the United Kingdom, the rates of tobacco users among men and among women are nearly equal. In some Asian countries, only a small percentage of women smoke, while the majority of men are smokers. In India, smoking is not prevalent among women because of social disapproval, but smokeless tobacco (SLT) use has been widely accepted and is fairly common among women.

In India, about 18.4% (70 million) of adult women age 15 and above use SLT. In the country as a whole, the prevalence of SLT use is higher among men than women, but in most of the states in three regions (Eastern, Northeastern, and Southern), SLT use prevalence in women is about equal to or higher than in men. Women are more likely to use SLT products for oral application in some regions (Central, Eastern, and Western) than others, and prevalence of oral application is higher among women than men. In India, 24.1 million women use tobacco as a dentifrice or to alleviate oral problems.[1]

The data from diseases burden of India showed significant rise in tobacco-related health disparities.[2] While ischemic heart disease and chronic pulmonary obstructive disease that are etiologically linked to smoking[3,4] were ranked 6th and 8th, respectively; in disease burden in India during the 1990s, whereas they were in the first two positions in the data of 2016. Therefore, sensitization for tobacco control and tobacco use cessation has a substantial role in public health of India.

Access this article online

www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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At least 9–10 million women in India are engaged in underpaid or unpaid tobacco-related occupations, ensuring low production costs for tobacco companies but suffering serious health consequences.[5] Women have a major role as a caretaker in the house and can make a significant impact on the psyche of their children. Indulgence of women/mothers in tobacco use can influence the children at a very young age and initiate tobacco use among them at such a tender age. Tobacco use in women has been a neglected matter in India and relatively very little focus has been given for the current tobacco control scenario in India. Because tobacco use and its production create major issues for Indian women and subsequently the future generations, it is important to carefully document the impact of this use and production, and design policies and strategies to combat them.

TRENDS IN WOMEN TOBACCO USERS IN INDIA

Across the world, more and more women are taking to tobacco. In India, while the number of women using tobacco may be a small fraction of the total, it is nevertheless a large absolute number. Till quite recently, tobacco use among women was rare, especially in traditional households. Although rural women consumed tobacco, in some parts of India, tobacco use by women was not socially sanctioned. However, among urban women, smoking is now more often seen as a symbol of the emancipated, "modern" woman. These changing perceptions of women to smoke are due to a "cool" or "modern" image as educated young women and attractive models "light up." [6]

According to the National Family Health Survey 2005–2006, tobacco use is more prevalent in rural areas than in urban areas both among men and women.[7] Among women, 0.5% in urban areas and 2% in rural areas used smoking form of tobacco products and about 6% of urban women and about 12% of rural women used SLT. About 8% of Indian women aged 15–49 years chewed tobacco in the form of paan masala and gutka. About 5% of antenatal mothers and 10.8% of breastfeeding women use tobacco in some form.[8]

Most recently, GATS 16-17 data showed about 14.2% of women aged 15 years and older in India are using tobacco in some or other form on a daily basis. However, around 12.8% of women are indulged in use of a SLT. Among women, the three most commonly used tobacco products are betel quid with tobacco (2.0 crore), tobacco for oral application (2.0 crore), and khaini (1.0 crore). Looking at the GYTS 2009 data, there was exponential rise in use of smoking tobacco (6.1%) in below 15 years of aged girls across the country.[9]

Yet, the socioeconomic gradients for tobacco use are steeper for women than for men. The prevalence of smoking is higher among urban women and SLT use in rural women.

DETERMINANTS OF TOBACCO USE IN WOMEN

Most tobacco use begins in early adolescence – almost all first use occurs before the age of 18. In most countries, few people start smoking after the age of 21; however, in India, the mean age of initiation of tobacco use has been found to vary from 8 to 15 years.[10] The initiation of tobacco use is influenced by a complex interplay of personal, social, and cultural factors which can vary overtime and stage of development and may vary in impact on women.

Lower Socioeconomic Status

It characterized by lower education, unemployment, manual occupations, rural residence, living in poorer or slum neighborhoods, and other factors – was associated with higher prevalence of tobacco use.[11-13] Social disadvantage was also associated with lower age of tobacco initiation. According to GATS India 2009–2010, the mean age of initiation of tobacco use was 2 years lower among those with no formal education, in comparison to those with secondary or higher educations.[14]

In the Mumbai Cohort Study of over 8000 people, the odds ratios for SLT use after adjustment for age and occupation among illiterate women and men in comparison with the college educated were 21.02 (95% CI 16.63–26.56) and 7.75 (95% CI 6.55–9.18), respectively.[15]

Personal Factors

It characterized by different beliefs that tobacco use improves oral hygiene 3, weight reduction, ease gastric problems 65, reduce menstrual pain 66, freshen breath, alleviate fatigue 65, and for manifold other medicinal or imaginary benefits. However, use of SLT by women seems to have deeper underpinnings.[16,17]

Hunger Factor

For women who face economic difficulties, SLT can be a great value for the money. It is scientifically proven that the use of tobacco and/or areca nut causes a biological suppression of hunger and reduces caloric intake.[18-20] Women report that they use SLT to alleviate hunger and help them skip a meal or two.[17] (It should be noted that food is far more expensive than SLT.) In fact, a study of Mumbai pavement dwellers highlighted the fact that the poor choose tobacco over food.[21]

Psychosocial Stress

It is an important contributor to SLT use by Indian women. Women in India often lack equality with the men in the family, may have low levels of control over their lives, and may be frequently abused. Some 19% of ever-married women reported physical or emotional abuse in the family in an analysis of the NFHS-2 in 1998–99, and these women were more likely to use SLT than women who did not experience domestic violence (OR=1.36, 95% CI 1.28–1.44) after accounting for age, standard of living, caste, religion, residential and living environment, body mass index (BMI), employment, and pregnancy status in multilevel models.[22]

Easy Availability

A study in Mumbai (2009–10) reported in a typical low-income community, all residents could reach a tobacco outlet within 30–100 feet of their homes.[5] This study also documented that, in general, grocery shops selling SLT were much more numerous in the community than shops that only sold tobacco products. GATS India 2009–2010 showed that 64% of women (compared to 50% of men) purchased SLT products from stores that sell daily use commodities.[22]

In addition, tobacco-based toothpastes, toothpowders, and herbal dentifrices that contain tobacco are commonly available in "medical" or pharmaceutical shops, along with stocks of other toothpastes, toothbrushes, health drinks, muscle-building foods, and medicines.[23]

Low Self-Esteem

One of the studies on schoolchildren claimed that girls have lower self-esteem than boys. Moreover, a significant association was observed between low self-esteem and smoking behavior in girls only.[24,25]

TOBACCO USE AND HEALTH EFFECTS IN WOMEN

Underweight

Smoking as well as SLT has been closely related with lower body weight in Indian women. Low BMI is an independent determinant of all-cause mortality, however, low BMI associated with tobacco use to increase all-cause mortality, deaths due to tuberculosis, and cancer in women.[26] Maternal anemia and underweight in women of reproductive age are independent determinants of low birthweight, preterm birth, small for gestational age, and reduced fetal iron stores.[7,27] Experimental studies suggest biological plausibility of the association between SLT use, underweight, and anemia. Nicotine in SLT affects hypothalamic dopamine and serotonin, which reduces hunger.[28] Tobacco use increases production of free radicals and systemic oxidative stress 29'30 and reduces antioxidant levels, potentially damaging red blood cell (RBC) viability. A direct hemolytic effect of nicotine and cotinine on RBCs has been demonstrated.[29] Social disadvantage in women SLT users can prevent access to nutritious food, and reduced plasma levels of several antioxidant vitamins have been reported in SLT users.[30-32]

Oral Disease

Although pan masala and tobacco products are often advertised as mouth fresheners, women who use these products have severe oral health problems in comparison with non-users. Users experience more plaque and inflammation in the oral cavity, recession of gums, exposed root surfaces of teeth, increased periodontal pockets, and tooth loss.[33,34] Clinical loss of attachment of periodontal fibers increases with duration of SLT use.[35] Oral inflammation from tobacco and areca nut use further increases the risk of oral cancer, probably because of an increase in endogenous nitration and the formation of toxins.[36-38]

Women consuming tobacco products with areca nut can also develop an extremely debilitating and potentially malignant and precancerous condition called oral submucous fibrosis (OSF). Women may have more symptomatic difficulty associated with OSF than men – for example, difficulty opening the mouth, difficulty eating, burning sensation, altered taste sensation, and difficulty in swallowing.[39]

Cancer

Women who use SLT or pan masala have an increased risk of oral and pharyngeal cancers, and this risk increases with the duration and frequency of SLT use.[40] Women appear to be more vulnerable to the carcinogenic effects of SLT and pan masala than men.[41] In a meta-analysis that included 12 published studies of oral cancer, women had a substantially higher risk of oral cancer (OR=12.4 [5.7–27.1] compared to 4.7 in men [2.9–7.8]). Women's greater risks of oral cancer may have a variety of causes, which can only be hypothesized at this time.

Stillbirth/Pre-term Low Birthweight Child

Numerous studies suggested tobacco use by pregnant women results in a significantly higher risk of complications for the woman and the fetus. An interventional study on pregnant women in rural population reported a higher risk associated with pregnancy complications – including fetal distress, pregnancy-induced hypertension, antepartum hemorrhage, oligohydramnios, polyhydramnios, and postpartum hemorrhage – among users in comparison to non-users.[16]

Hence, tobacco users suffer increased episodes of hospitalization and out-of-pocket expenditures for health care, which threaten their financial well-being and their ability to provide essential nutrition for their families, which adversely affects family health.

TOBACCO: ADDICTION, WITHDRAWAL, AND CESSATION IN WOMEN

Women continue to smoke because of a complex interplay of factors, including physiological addiction to nicotine and psychological and social factors. It is well known that cigarettes and other forms of tobacco are addictive and that nicotine is the drug in tobacco that leads to addiction. Furthermore, withdrawal symptoms together with trying to managing life's extreme stresses make it doubly difficult for disadvantaged women to quit.

Several studies have suggested that women may have a harder time quitting smoking than men, which may be due in part to the greater tendency for women to smoke in response to negative affect, stress, or depression, or to control weight.[42,43] A recent study found that nicotine metabolism was faster among women than among men and faster among women taking oral contraceptives, which may have relevance for the efficacy of nicotine replacement medications for women.[44]

Women appear to be less interested in quitting tobacco use compared to men. According to GATS India 2009–2010, about 50% of tobacco user women were not interested in quitting, compared with 40% of males who were not interested in quitting. About 29% of daily user women had made an attempt to quit in the past 12 months, in contrast to 39% of males. Women also experience more anxiety and stress than men while trying to quit. They worry whether they will be able to continue their chores when they quit because they believe that using tobacco gives them energy and motivation and compensates for lack of food. They fear how difficult it could be to control the urge to chew when feeling depressed or depleted of all energy.[17]

GENDER-BASED TOBACCO CONTROL POLICIES

The increase in tobacco use among women has typically followed weakening social, cultural, and political constraints, which have been exploited by multinational tobacco companies. Recent estimates of tobacco use among youth show similar patterns among boys and girls in many areas of the world, suggesting that these differences may be narrowing. Although effective tobacco control policies are available, they could be optimized by understanding the factors that influence uptake and maintenance of tobacco use and how these factors may differ between boys and girls.[45]

It is recommended to develop culturally sensitive and gender-specific community programs to prevent initiation and cessation of tobacco use. Furthermore, to develop tobacco control strategies, one should take into consideration of the changing cultural, psychosocial, and environmental factors that influence initiation and cessation of tobacco use among girls and women of all ages as well.

CONCLUSION

The issues related to tobacco use among women are distressing. Well-organized and stringent women-centered policies are urgently required to curb and regulate the ease of availability and indirect advertisement. Despite higher pricing of tobacco products, lower SES population women are still exposed to substandard and raw tobacco products which ultimately affect the health and wealth of the entire family later on. Women-specific tobacco control policies are urgently required to enable India "Tobacco Free Nation" and improvement of the health status of its women and children.

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How to cite this article: Thakore D, Chavda M, Parmar G, Sheth T, Shah M. Tobacco Use and Women in India. Int J Sci Stud 2021;9(2):11-15.

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

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

Review Article

Levocetirizine – One of the Most Effective Antihistamines in Urticaria

Ganga Prasad[1], Jayakar Thomas[2], Madan Mohan[3], S Murugan[4], V Sampath[5], Sandeep Buddhadeo[6], Uday Kulkarni[7]

[1]Ex-Head of PMCH, Dhanbad, Jharkhand, India, [2]Emeritus Professor - Dermatology, The Tamil Nadu Dr. MGR Medical University, Chennai, Tamil Nadu, India, [3]Professor and Head, Department of Dermatology, Venereology and Leprosy, Dr. B. R. Ambedkar Medical College, Bengaluru, Karnataka, India, [4]Professor and Head, Department of Dermatology, Sri Ramachandra University, Chennai, Tamil Nadu, India, Consultant Dermatologist, Private Practitioner, Chennai, Tamil Nadu, India, [6]Senior Consultant Dermatologist Dr. Buddhadeo's Skin Care Clinic, Pune, Maharashtra, India, [7]Consultant Dermatologist, Pure Skin Clinic, Aurangabad, Maharashtra, India

Abstract

Levocetirizine is a R-enantiomer of racemic cetirizine, an antihistamine which has proven to be effective in mild as well as chronic form of urticarial. It has a more rapid onset along with longer duration of action than many other antihistamines available in market, with maximal inhibition of histamine-induced wheal occurring within 2 to 4 hours once the drug is administered. It also exhibits anti-inflammatory effects in patients with allergic disorders. This drug has no clinically relevant effect on cognitive function, psychomotor function and cardiovascular parameters. Levocetirizine as a drug of choice is generally well tolerated in adults, adolescents as well as children with allergic conditions.

Key words: Antihistamine, Levocetirizine, Urticaria

INTRODUCTION

Urticaria, a common skin condition, is a frequently disabling disease because of the persistence of clinical symptoms, the unpredictable course, and its negative influence on the quality of life.[1]

Elimination of detectable etiologic causes and avoidance of triggers constitutes the first step of treatment.[2] Many mechanistic studies have demonstrated histamine to be a major mediator involved in the development of symptoms of urticaria. This has led to the recommendation for the use of oral H1 receptor antagonists (H1 antihistamines).[3] Antihistamines bind to histamine receptors and prevent the formation of pruritus and urticarial plaques. The first-generation H1 antihistamines are less preferred due to their significant short duration of action, sedation, and associated side effects. The second-generation H1 antihistamines are first-line treatment for urticaria.[2]

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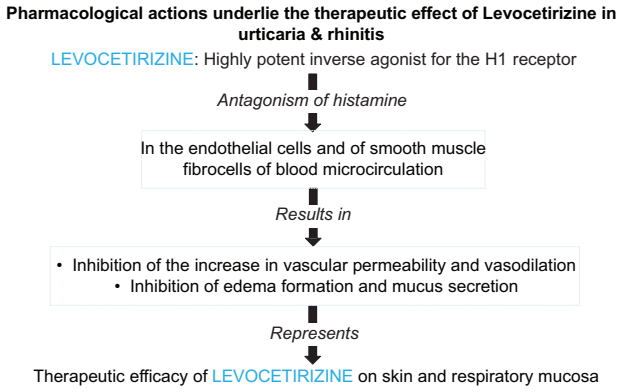
www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 05-2021
Month of Publishing : 05-2021

Levocetirizine, a second-generation H1 antihistamine, is a potent histamine H-1 receptor antagonist. It offers high power and specificity as inverse agonist for the H1 receptor.[4]

PHARMACOLOGICAL ACTION OF LEVOCETIRIZINE



THERAPEUTIC PROPERTIES OF LEVOCETIRIZINE

- Levocetirizine has the greatest anti-H1 activity, in suppressing skin reactivity to histamine, among other

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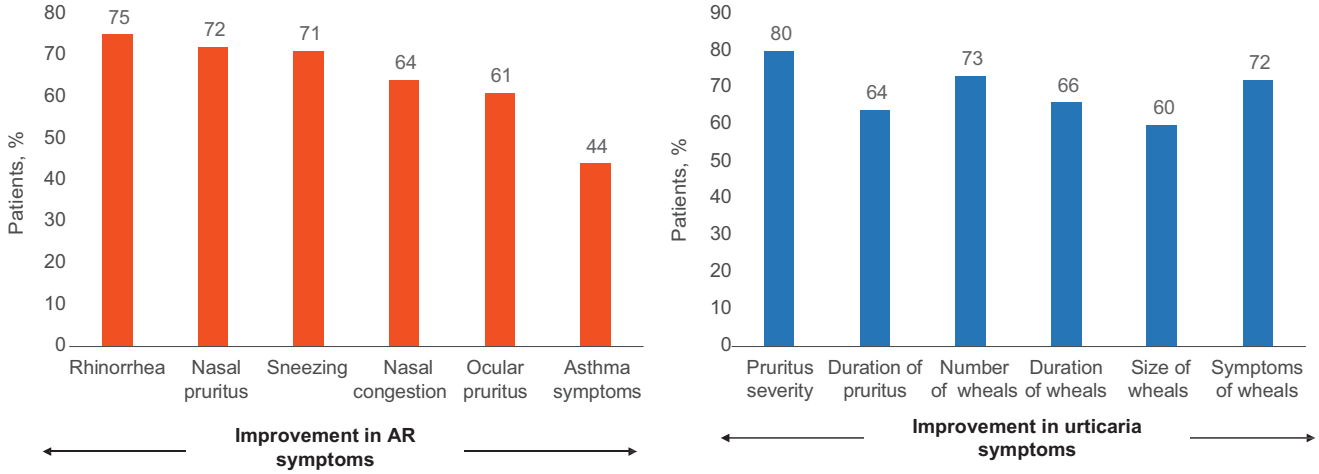
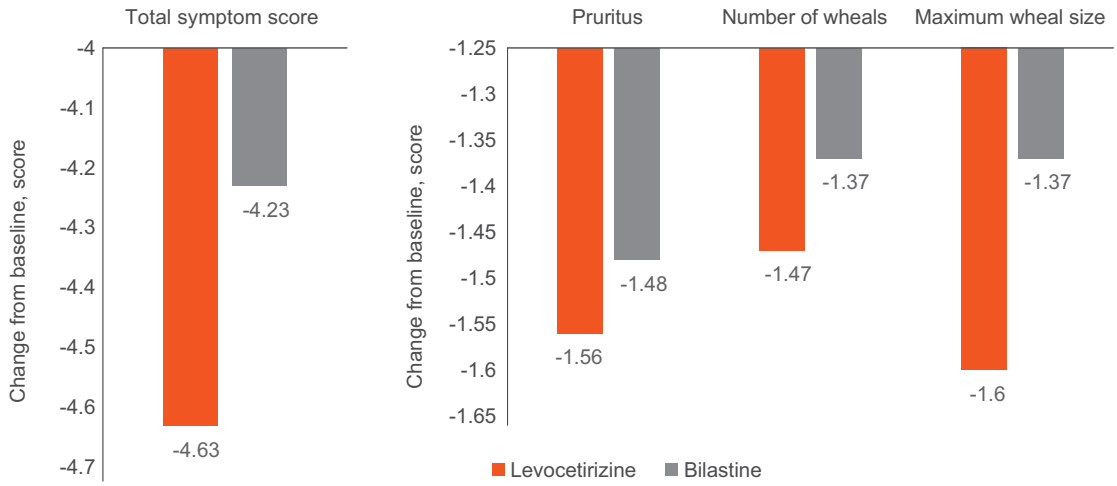
antihistamines, namely, fexofenadine, desloratadine, and mizolastine.[1]

- Levocetirizine has a rapid onset of action and more importantly, a sustained action for 24 hours.
  - In a study by Schoepke *et al.,* levocetirizine showed a faster onset of action (30–90 min vs. 2 h), shorter time to maximum effect (3–4 h vs. 3–6 h), and longer duration of action (at least 24 h vs. ~12 h) than fexofenadine on wheals, flare, and pruritus.[5]
  - In a comparative efficacy study, levocetirizine achieved a significant symptom reduction of rhinitis (AR) and urticaria; with up to 75% of AR patients and about 80% of urticaria patients reporting complete or marked improvements in individual symptoms.[3]
- Levocetirizine is significantly effective in reducing urticaria in children.[6]
  - Levocetirizine reduced number of urticarial episodes by 60% in atopic children.
  - Levocetirizine reduced exacerbations of concomitant urticaria in children with atopic dermatitis.
- Levocetirizine demonstrated higher efficacy and more prolonged action in inhibiting histamine induced wheal seasonal allergic rhinitis as early as the 1st hour, compared with 3 hours required for desloratadine to act; additionally, 24 hours after the first dose and just before receiving the second dose, symptom reduction was significantly higher in the patients treated with levocetirizine compared to desloratadine.[4]
- Levocetirizine shows favorable effect on overall severity of signs and symptoms of urticaria and allergic rhinitis.
- In a study conducted by Fang *et al.,* levocetirizine markedly improved the symptoms of allergic

Proportion of patients with improvement in symptoms of allergic rhinitis and urticaria



Change in total and individual symptom scores with Levocetirizine and Bilastine



formation than fexofenadine and desloratadine.[4]

- Levocetirizine showed slightly greater improvement in total symptom scores than bilastine in patients with chronic spontaneous urticarial.[7]
- Updosing of levocetirizine up to 4 times is effective and safe with respect to cardiovascular effects in difficult-to-treat urticaria patients.[8]
- Levocetirizine has a major role in improving the quality of life, showing noticeable improvement in Dermatology Life Quality Index score.[4]
- Levocetirizine has a good safety and tolerability profile: [4]
  - Levocetirizine has small volume of distribution which confers improved safety because of its lesser passage through the blood–brain barrier and low cerebral receptor binding.
  - Pharmacokinetic properties of levocetirizine are poorly modified by concomitant intake of other drugs.
  - Clinical trials have shown no modification on memory, attention, and motor skills in patients administered levocetirizine.
  - Levocetirizine safety is confirmed by the absence of cardiotoxic effects and the mild nature of the reported adverse reactions (fatigue, headache, dizziness, and dry mouth) during treatment, which do not generally interfere with the patient's well-being even in the case of chronic treatment.

Key Pointers

- Levocetirizine is an effective agent in patients with urticaria, as its action provides a rapid and satisfactory control of the associated symptoms with improved quality of life.
- Therefore, levocetirizine is an ideal choice for urticaria management.

Dr. Ganga Prasad
MD Dermatologist
EX HOD of PMCH, Dhanbad, Jharkhand

I have experienced more than 35 years in dermatology field. I have seen lots of patients of urticaria & my experience was that among all antihistamines, levocetirizine has been found to give 24 hours relief as compare with other antihistamines like fexofenadine, desloratadine and bilastine.

I have used levocetirizine for long terms & none of my patients reported any side effects. it's safe for my patients for long term .

I prescribed levocetirizine with other drugs & observed no drug to drug interactions with levocetirizine.

Dr. Jayakar Thomas
MD., DD., MNAMS., PhD., FAAD, FIAD, FIAP, FRCP (Edin), FRCP (Glasgow), FRCP (London), FRCP (Ireland), FRCPCH (London), DSc
Emeritus Professor - Dermatology, The Tamil Nadu Dr. MGR Medical University, Chennai

The response of levocetirizine to histamine and allergen-induced wheal and flare reactions is comparatively higher to currently available antihistamines such as fexofenadine, desloratadine and cetirizine.

Levocetirizine has a rapid onset of action and more importantly, a sustained action for more than 24 hours. Efficacy-wise, its anti-inflammatory property adds to its favorable effect, thereby improving the quality of life of patients using levocetirizine.

However, mild sedation is a limiting factor, and its use during the daytime is to be discouraged. This molecule has little effect on psychomotor functions and other subjective symptoms. Levocetirizine is among the first to be introduced for up dosing, and is can be administered up to four times the normal recommendation.

With a good tolerability profile, the treatment adherence and patient compliance is satisfactory.

Dr. Madan Mohan
M.B.B.S, MD (SKIN & STD)
Professor & HOD, Department of Dermatology, Venereology and Leprosy,
Dr. B. R. Ambedkar Medical College, Bangalore

It is quite a common skin problem, where the patient has itching skin associated with rashes. There are various skin problems associated with rashes and are classified into different types like physical urticaria, chemical urticaria, vibration urticaria & so on. To cater to these, there are different antihistaminics to treat the cause of urticaria.
I am of the opinion that levocetrizine can be used for these conditions. Levocetirizine like xyzal can be used. It is quite safe to use even 4 times the dose safely. It can also been found to be safe to be given to children.

Dr. S. Murugan
MBBS, MD (Dermatology)
Professor & HOD , Department of Dermatology,
Sri Ramachandra University, Chennai

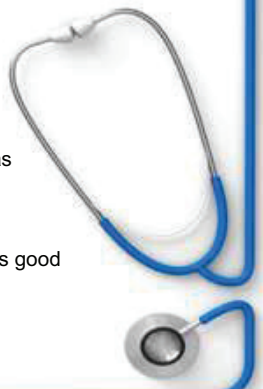
levocetirizine provides 4x better wheal inhibition.2x better flare inhibition than fexofenadine and desloratidine at 24 hours. It provides 5x better receptor occupancy at 24 hours than fexofenadine and desloratidine, and has excellent efficacy in providing relief in pruritus, urticaria, insect bite reactions, lichen planus and eczemas.

Levocetirizine causes improvement in urticaria specific quality of life and reduction in chronic urticaria associated discomfort, and has a positive impact with reduction in perception of somnolence and sedation. Excellent safety profile on updosing for urticaria upto 4x. Levocetirizine has excellent acceptance and tolerability and safety in all conditions with negligible interaction with other medications.

Patient adherence and compliance to treatment with levocetirizine is excellent with good patient satisfaction.

Dr. Sampath V
MBBS, MD Dermatology
Consultant Dermatologist, Chennai

I have been using Levocetirizine for more than 10 years now. It is an efficacious drug and non-sedative as well. It has a favourable effect on overall severity of symptoms. Compared to all other antihistamines, Levocetirizine has a faster onset of action. The tolerability is also good. I prefer using Levocetirizine over other antihistamines because of its good efficacy, tolerability & patient compliance.



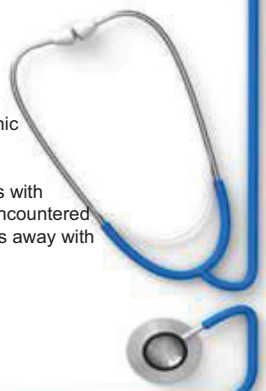
Dr. Sandeep Buddhadeo
M.B.B.S, MD - DVD

Levocetirizin, especially of a very good quality like Xyzal, is still an undoubtedly a gold standard in the management of acute and chronic urticaria

I have been treating patients with urticaria since more than 25 years with levocetirizine and have observed very good results. I have hardly encountered any side effects, and that includes mild sedation. This sedation goes away with continued usage.

Another thing is the cost of the treatment is less.

Levocetirizine is a time tested molecule



Dr. Uday Kulkarni
MBBS, MD (Skin & V.D.)

Levocetirizine is a potent H1 antagonist from 2nd generation antihistamines. It effectively blocks histamine induced wheal & flare reactions. Clinically, it seems to act much faster & for longer duration in comparison to fexofenadine & desloratidine.

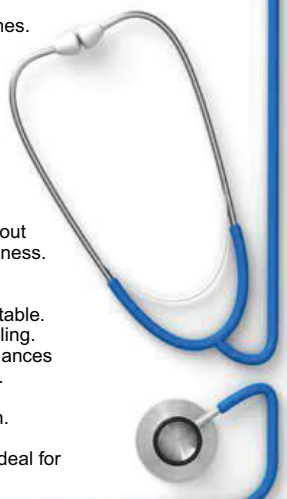
Clinically. it shows its onset of action within an hour & its effect lasts almost upto 24 hrs.In few cases it extends even beyond that. Shows favorable effect on overall severity of symptoms and signs of urticaria, and improves quality of life (QOL).

Definitely has a major role in improving QOL. Patients are able to carry out their daily routine undisturbed, except few who experience some drowsiness. Few patients experience sedation/drowsiness in variable degrees.

Due to immediate & long lasting results, patient feels very much comfortable. Minimum & no sedation adds to his /her mood elevation & energetic feeling. Up dosing is safe with respect to cardiovascular effects. Except few chances of drowsiness, Levocetirizine is found to be very safe in clinical practice.

Overall Levocetirizine is well tolerated even when used for long duration.

Single dosing ,immediate onset of action & long lasting effect makes it ideal for regular use & adherence to treatment Protocols.



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How to cite this article: Prasad G, Thomas J, Mohan M, Murugan S, Sampath V, Buddhadeo S, Kulkarni U. Levocetirizine – One of the Most Effective Antihistamines in Urticaria. Int J Sci Stud 2021;9(2):16-21.

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

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

Original Article

Study of Association of Level of Serum Uric Acid in Type 2 Diabetes Mellitus

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Abstract

Introduction: Diabetes mellitus (DM) is a group of metabolic disorder in which there are high blood sugar levels over a prolonged period. The prevalence of type 2 DM (T2DM) is a chronic metabolic disease that is a significant public health problem worldwide. Elevated serum uric acid (UA) concentration has been found to be closely associated with metabolic and other related syndromes.

Aim: This study aims to study serum UA levels in T2DM patients.

Materials and Methods: A total of 50 Type II diabetic patients were included in this study. Duration of diabetes, RBS, hemoglobin A1C (HbA1c), and serum UA level were collected. Results were analyzed statistically and discussed below.

Results: The study included 50 cases of T2DM, out of which there were 28 males and 22 females. The majority of the study population fell under the age group between 51 and 60 years. Based on the duration of diabetes, 7 patients had <5 years, 28 patients had between 6 and 10 years, and 15 patients had >11 years. Mean HbA1c was 7.1 ± 1.1, RBS was 168.24 ± 28.26, and serum UA was 8.62 ± 2.44. Seventeen patients had serum UA level <7.3, and 33 patients had >7.4.

Conclusion: DM is a chronic disease linked to cardiovascular and renal complications, as well as a variety of microangiopathies, including metabolic syndrome. In our study, DM is strongly associated with hyperuricemia. To avoid renal complications, it is recommended to monitor UA levels in people with type 2 diabetes.

Key words: Hemoglobin A1C, Serum uric acid, Type 2 diabetes mellitus

INTRODUCTION

Diabetes mellitus (DM) is a chronic disorder associated with cardiovascular complications, renal complications, and various microangiopathy types, including metabolic syndrome. The International Federation of Diabetes reported that around 415 million adults around all over the world have diabetes, and they estimated that the numbers are likely to reach about 642 million by 2040.[1]

Recent studies have demonstrated that serum uric acid (UA) levels are higher in subjects with pre-diabetes and early type 2 diabetes than in healthy controls.[2,3] Hyperuricemia has also been added to the set of metabolic abnormalities associated with insulin resistance or hyperinsulinemia in metabolic syndrome.[4-6]

UA is the end product of human purine metabolism. Hyperuricemia is a condition in which the subject has increased serum UA levels. Studies have noted that an elevated level of UA predicts diabetes, obesity, hypertension, and metabolic syndrome. People who had higher UA levels are more likely to get type 2 diabetes. The diabetic patients with increased serum UA level appear to be at increased risk of developing diabetic complication. Hyperuricemia is an independent risk factor for kidney dysfunction in diabetic patients. Hyperuricemia is probably associated with glucose intolerance due to various mechanisms. However, most important is an association between insulin a renal resistance to absorption of urate.[7]

Since hyperuricemia requires long-term management, patients must be informed about their diagnosis and

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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educated to achieve good patient compliance. The association between a chronic purine-rich diet, mainly of animal origin, and hyperuricemia or incident gout is well established.[8]

Aim

This study aims to study serum UA levels in type 2 DM (T2DM) patients.

MATERIALS AND METHODS

This prospective observational study was conducted in the department of general medicine in Type II diabetic patients. Patients diagnosed with type 2 diabetes were identified, and their hospital record in the department was studied. Selected sociodemographic, clinical, and laboratory data were elicited from the patients. A total of 50 patients were included in this study. Inclusion criteria include age above 18 years of both genders. Exclusion criteria include patients with renal failure and creatinine levels >1.5 mg/dl, renal stones, liver disease, and drugs affecting renal function. Results were analyzed statistically and discussed below.

RESULTS

The study included 50 cases of T2DM, out of which there were 28 males and 22 females [Table 1].

The majority of the study population, about 21 patients, fell under the age group between 51 and 60 years, 2 patients had age below 40 years, 13 patients had an age between 41 and 50 years, and 14 patients had more than 61 years [Table 2].

Based on the duration of diabetes, 7 patients had <5 years, 28 patients had between 6 and 10 years, and 15 patients had >11 years [Table 3].

Mean hemoglobin A1C was 7.1 ± 1.1, RBS was 168.24 ± 28.26, and serum UA was 8.62 ± 2.44 [Table 4].

Seventeen patients had serum UA level <7.3 in that 5 patients had a duration of diabetes of fewer than 5 years, 10 patients had between 6 and 10 years, and 2 patients had >11 years. Out of 33 patients had >7.4, 2 patients had a duration of diabetes <5 years, 18 patients had between 6 and 10 years, and 13 patients had >11 years [Table 5].

Table 1: Gender distribution

Gender	Frequency
Male	28
Female	22

Table 2: Age distribution

Age	Frequency	Percentage
<40	2	4.0
41–50	13	26.0
51–60	21	42.0
>61	14	28.0

Table 3: Duration of diabetes

Duration of diabetes	Frequency	Percentage
<5	7	14.0
6–10	28	56.0
>11	15	30.0

Table 4: Diseases parameters

Diseases parameters	Mean values
Hemoglobin A1C	7.1±1.1
RBS	168.24±28.26
Serum uric acid	8.62±2.44

Table 5: Distribution of duration of diabetes and uric acid level

Duration of diabetes	Serum uric acid		Total	*P*-value
	<7.3	>7.4		
<5				
Count	5	2	7	0.026
% within row	71.4	28.6	100.0	
6–10				
Count	10	18	28	
% within row	35.7	64.3	100.0	
>11				
Count	2	13	15	
% within row	13.3	86.7	100.0	
Total				
Count	17	33	50	
% within row	34.0	66.0	100.0	

DISCUSSION

Variations in UA levels have been increasingly associated with insulin resistance, hyperinsulinemia, and diabetes. Diabetic patients who are hyperuricemia appear to be at increased risk for developing diabetic complications, predominantly renal and cardiovascular disease. In Type 2 diabetes, hyperuricemia seems to be associated with insulin resistance syndrome, impaired glucose tolerance, and an early onset of nephropathy. In contrast, hypouricemia is associated with non-adequate metabolic control, hyperfiltration, and late-onset of overt nephropathy. Although one of the major antioxidants in circulation, UA can induce oxidative stress in various cells, including vascular smooth muscle cells, thus mediating cardiovascular disease progression. The pathogenic mechanism involves

decreased nitric oxide (NO) bioavailability in vascular smooth muscle and endothelial cells and direct scavenging of NO by UA. A decrease in endothelial NO production by UA has also been associated with endothelial dysfunction and insulin resistance. UA has been implicated in hypertension development, and elevated UA levels have been reported mainly in newly diagnosed hypertension. Hyperuricemia is also closely linked to the various metabolic syndrome components and represents a possible link between UA levels and cardiovascular morbidity and mortality.

In this current study, males were predominant compared to females. Prabhuswamy *et al.* and Prashant *et al.* quoted dominant males in their research, similar to the present analysis.[9,10]

In this present study, the majority fell under the age group between 51 and 60 years. Li *et al.*,[11] in their study, reported that the mean age was 65.57 ± 11.70 years. A survey by Ishizaka *et al.*[12] studied Japanese patients the mean age was 56.6 ± 10.4 years.

However, in the study reported by Rao and Sahayo,[13] the UA levels were higher only for pre-diabetes and not for people with diabetes. The studies done by Shabana *et al.*[14] reported a decreased UA level. As per our study, it was concluded that hyperuricemia was positively associated with hyperglycemia.

Patients having higher UA have the ability for more insulin secretion than patients having lower UA.[15] In a study by Zoppini in type 2 diabetic patients, hyperuricemia was an independent and vital risk factor for the development of chronic renal disease.[16] A study by Tanaka showed that UA increase results in declining renal function in diabetic patients.[17] A study by Siu had reported that as UA levels were lowered in renal disease patients with hyperuricemia, there was associated decrease in kidney disease.[18]

CONCLUSION

DM is a chronic disease linked to cardiovascular and renal complications and various microangiopathies, including metabolic syndrome. In our study, diabetes mellitus is strongly associated with hyperuricemia. To avoid renal complications, it is recommended to monitor UA levels in people with type 2 diabetes.

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How to cite this article: Manimekalai P, Ramalingam K. Study of Association of Level of Serum Uric Acid in Type 2 Diabetes Mellitus. Int J Sci Stud 2021;9(2):22-24.

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

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

Original Article

Open Reduction and Internal Fixation of Midshaft Clavicular Fractures with Pre-contoured Locking Clavicle Plate: A Prospective Study

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Abstract

Background: Fractures of clavicle constitute one of the most common fractures in orthopedic practice and till recently most of these fractures were treated conservatively. The advent of various implants for the fixation of these fractures along with safe surgical practices made the surgery more widely accepted and the definite indications for open reduction and internal fixation were formulated.

Materials and Methods: This prospective study conducted in Postgraduate Institute of Swasthiyog Pratisthan, Miraj, 35 patients operated for fracture midshaft clavicle with open reduction and internal fixation with pre-contoured locking clavicular plate. Patients followed for functional outcome and radiological and clinical union from June 2018 to June 2020. Results compared with other study in literature for validity.

Results: At 6 weeks, 25 (71%) patients fracture clinically united, at 3 months, all (100%) patients got clinically united and 28 (80%) patients radiologically united. At 3 months, Constant–Murley functional score was excellent in 71% of patients good in 26% and maximum patients 17 (49%) return to work in 6–8 weeks, 32 (91%) patients had an uneventful recovery, whereas 3 (9%) suffered one or several complications.

Conclusion: Operative treatment of fracture clavicle offers a definitive method of treatment in some specific instances. It reduces the time of union, stiffness of the adjoining joints and morbidity, and early return to work, patient satisfaction.

Key words: Midshaft clavicle fracture, Open reduction and internal fixation of clavicle, Pre-contoured locking clavicle plate

INTRODUCTION

The clavicle or collar bone is an S-shaped long bone, by its horizontal orientation, forms a strut between the sternum and the scapula, this bony link contributes to movements at shoulder. Clavicle fracture is a common traumatic injury around shoulder girdle due to their subcutaneous position.[1] It is caused by either low-energy or high-energy direct impact. Fracture of the clavicle accounts for approximately 2.6–5% of all fractures and up to 35% of injuries to the shoulder girdle. About 70–80% of these fractures are in the middle third of the bone and less often in the lateral third (12–15%) and medial third (5–8%).[1,2] Conservative treatment has been the treatment of choice for a long time. This treatment policy was based on two studies conducted in the 1960s, which stated non-union percentages <1% after conservative treatment, regardless of the degree of dislocation.[3,4] Although many methods of closed reduction have been described, it is recognized that reduction is practically impossible to maintain and a certain amount of deformity and disability is expected after conservative treatment. More recent data based on detailed classification of fractures, suggest that the incidence of non-union in displaced comminuted clavicular fractures in adults is between 10% and 15%. All fractures with initial shortening of >2 cm resulted in nonunion.[5,6] Several studies have examined the safety and efficacy of primary open reduction and internal fixation for completely displaced fractures

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www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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clavicle and noted high union rate with a low complication rate. There are various methods for treating clavicle midshaft fractures such as pre-contoured clavicular locking plates, reconstruction plates, dynamic compression plates, and intramedullary nails.[7] The purpose of this study is to gain experience with the open reduction and internal fixation of fresh displaced, comminuted, middle third clavicle fractures with pre-contoured locking clavicular plate and screws, and comparing study results with other various study in literature.

MATERIALS AND METHODS

Prospective observational study was conducted in GSK'S Fracture and Orthopaedic Hospital of Postgraduate Institute of Swasthiyog Pratishthan, Miraj, in the Department of Orthopaedics from June 2019 to June 2020. All willing patients attending outpatient department and emergency center of hospital with midshaft clavicle fracture were taken up for study. The patient included for the study was evaluated clinically and radiologically.

Inclusion Criteria

The following criteria were included in the study:

1. Age above 18 years
2. Closed fractures
3. No medical contraindication for anesthesia and surgery
4. Willing for surgery
5. Fracture specific[8]
    a. Displacement >2 cm
    b. Shortening >2 cm
    c. Increasing communition >3 fragments
    d. Segmental fractures
6. Floating shoulder (clavicle and glenoid neck fracture).

Exclusion Criteria

The following criteria were excluded from the study:

1. Age <18 years
2. Open fracture
3. Active infection at operative site
4. Medical contraindication to surgery and anesthesia
5. Non-displaced fracture.

Thirty-five patients were assessed carefully with detailed history and examined for deformity, swelling, and ecchymosis neurovascular deficit and other skeletal injuries were duly recorded in patient's pro forma. Patients were given appropriate analgesics and arm was immobilized with an arm pouch sling. Standard anteroposterior radiographic views of the clavicle of affected side were taken by carefully positioning the patient.

Fractures were classified using Robinson's classification system.[6] Hematological, biochemical, and other radiological investigation, chest X-ray, and electrocardiogram were done as per requirement for operative fitness, pre-anesthetic check-up and consent for surgery were taken.

Open reduction and internal fixation of indicated fracture done with curvilinear incision along the long axis of S shaped of clavicle, center over the fracture site. Side specific pre-contoured clavicular plate was used according to clavicle size and shape. Plate was placed over superior surface of clavicle.[9]

Rehabilitation of affected extremity was done according to the stage of fracture union and time duration from day of surgery. Pendulum movements exercise started soon after the pain tolerated postoperatively. Approx. 5th day postoperatively, after clinical union, the sling discontinued and unrestricted range of motion exercise allowed. More aggressive and physically demanding activities were started once bony union is evident on radiograph.

The patient was followed on the 14th post-operative day for the 1st time for suture removal after that they were called for follow-up on 6 weeks and monthly for 3 months and 6 months.

Clinical and Radiological Assessment of Fracture Union[10]

In follow-up, the patient evaluated for fracture union clinically as

1. Absence of pain or tenderness on palpation or examination
2. Absence of pain or tenderness when weight-bearing
3. The ability to bear weight.

For radiological union, plain radiograph evaluated for

1. Bridging of the fracture by bone, callus, or trabeculae
2. Bridging of the fracture at three cortices
3. Obliteration of the fracture line and/or cortical continuity.

Functional Assessment

Evaluation of results was carried out Constant–Murley shoulder score as assessment tool.[11]

The patient is assigned cumulative score out of 100 and graded as follows:

1. 0–55 – Poor
2. 56–70 – Moderate
3. 71–85 – Good
4. 86–100 – Excellent.

All data collected and find the correlation between the variables using Excel software.

RESULTS

A total of 35 patients with displaced or comminuted midshaft clavicular fracture were treated surgically with

open reduction and internal fixation with pre-contoured locking clavicular plate and followed for year. Fracture clavicle is common between 18 and 27 years (26%) and 48–57 years (26%) showing bimodal incidence. Mean age was 38 years. Demographic details about age distribution, sex and side predilection, most common mode of injury, and associated fracture given in table [Table 1]. Fracture segregation done with Robinson classification system [Figure 1]. The majority of fractures in the present study were displaced simple midshaft clavicle fracture Robinsons type 2 B1a in 20 patients (57%). Time required for completion of surgical procedure given in Figure 2. Time duration for completion of surgical procedure greatly reduced using pre-contoured plate, 14 (40%) patients took 71–80 min operation time. Maximum patients 17 (49%) return to work in 6–8 weeks, 7 (20%) in 9–11 weeks, and 11 (31%) in 12–15 weeks [Figure 3]. Fracture union studied clinically and radiologically. At the end of 6 weeks, 25 (71%) patients clinically united and 5 (14%) patients radiologically united. In 3 months, all patients (100%) clinically united and 28 (80%) patients got radiological union, other 7 (20%) patients got radiologically united at 6 months [Figure 4]. Functional outcomes assessment was done by Constant and Murley scoring system. At 6 weeks, score was good in 54% of patients and moderate in 37% of patients. At 3 months, score was improved and that was excellent in 71% of patients good in 26% [Figure 5].

Despite proximity of fracture site to neurovascular structures, none of patient got any iatrogenic neurovascular trauma and none non-union or malunion. There was 1 (3%) incidence of superficial infection which was managed by dressing and oral antibiotics, 1 (3%) patient had hardware irritation, after clinical and radiological union implant removal was done. One (3%) patient had hypertrophied scar formation.

Table 1: Demographic distribution of variable in clavicle fracture

Variable	No. of patients out of 35 (%)
Age distribution (highest)	
17–27 years	9 (26)
48–57 years	9 (26)
Sex distribution	
Male	29 (83)
Female	6 (17)
Side involvement	
Right	17
Left	18
Mode of injury	
RTA	29 (83)
Fall	6 (17)
Associated injury	
Scapula	3
Chest trauma	2
Wrist	1
No associated fracture	30

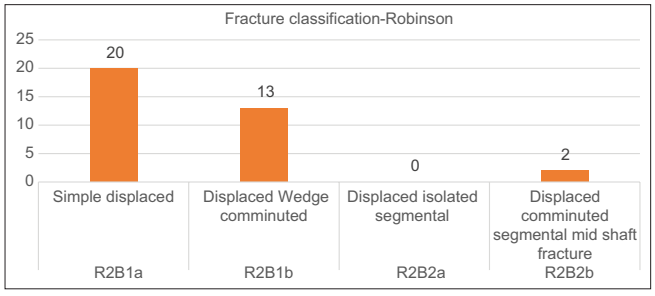

Figure 1: Fracture segregation with Robinson classification system

DISCUSSION

Clavicle fractures continue to be a common traumatic injury encountered by orthopedic surgeon and have received much attention recently. There is momentum growing toward the operative management of displaced fractures. Clavicle fractures are usually treated conservatively. The traditional view that the vast majority of clavicle fractures heal with good functional outcomes following non-operative treatment is no longer valid. Conservative treatment of displaced middle third clavicle fracture studied by Hill et al in1997, 12 Nordqvist *et al.* in 1998,[13] and Robinson *et al.* in 2013,[14] and found poor results following conservative treatment, reported higher non-union and malunion rates (14%-23%). These fractures should be viewed as a spectrum of injuries with diverse functional outcomes, each requiring careful assessment and individualized treatment.

Any displaced comminuted fracture is prone to the poorer outcome and hence operative stabilization is indicated. The patients treated with early, rigid fixation

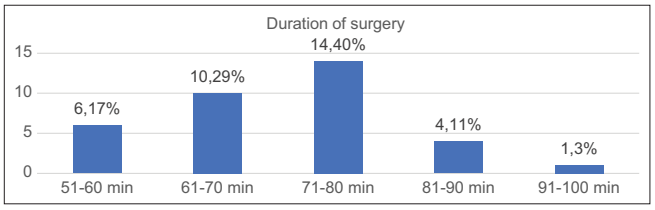

Figure 2: Chart showing the surgical time required for completion of surgery

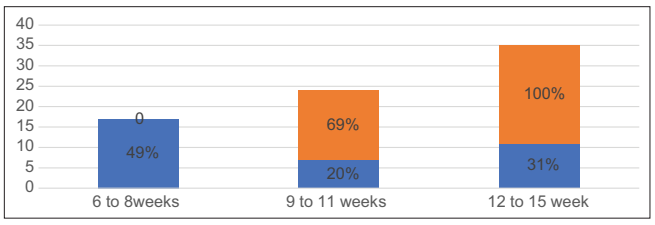

Figure 3: Bar diagram showing time required for no. of patient to return for work after surgery

of their clavicle fractures shared a high post-operative constant score, early pain resolution, early return to activity, and high patient satisfaction rating. Pre-contoured clavicular plating has the advantages of maintaining the length especially in comminuted fractures. Moreover, it anatomically pre-contoured which assists in restoring the original structure of the patient's anatomy with little or no bending of the plate by the surgeon at the time of surgery. Avoiding the need to bend a pre-contoured clavicle plate saves valuable operating room time during the operative procedure. There is little chance for hardware breakdown and migration.[15]

The present prospective study of 35 patients, male preponderance and bimodal age distribution seen (according to Nowak *et al*.[16] and Robinson[6] of epidemiological study, there was male predominance). At 3 months, all (100%) patients got clinically united and 28 (80%) patients radiologically united and functional score was excellent in 71% of patients good in 26% of patients. Maximum patients 17 (49%) return to work in 6–8 weeks. No major complication found in this study, 32 (91%) patients had an uneventful recovery, whereas 3 (9%) suffered some complications. One (3%) patient each had hardware irritation, superficial infection, and hypertrophied scar formation. Bostman *et al*.[17] infection rate was 7.8% and 23% suffered one or several complications. Other comparable studies of open reduction and internal fixation of clavicle fractures demonstrate similar short-term results with minimal complications and early recovery of shoulder functional outcome. Comparison of different study results and complication with the present study done in Table 2 and Table 3, respectively. This technique provides high fracture union rate, good functional outcome with early pain relief, early functional recovery and minimum complications, and less disability rate than does conservative treatment. Functional results improve when the normal bend of the clavicle is restored with pre-contoured plate.

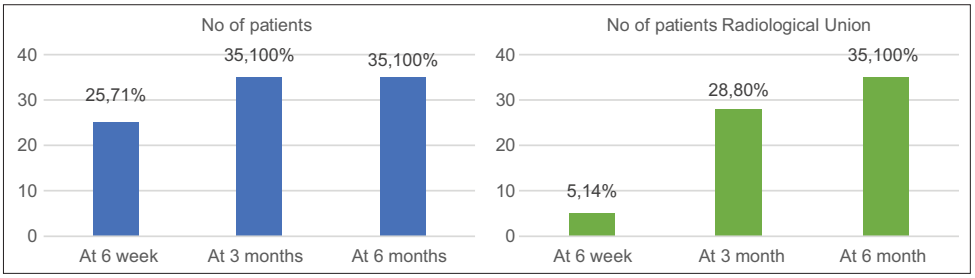

Figure 4: Bar diagram showing time required for no. of patient for clinical and radiological fracture union

Table 2: Comparison of different study results with the present study

Study	No. of cases	Study type	Average time of union	Follow-up duration	Constant score
Ethiraj *et al*., 2016[18]	60	Prospective	12 weeks	12 months	Excellent 76.7%
Kumar and Harsha, 2016[19]	20	Prospective	10–12 weeks	12 months	Excellent 80%
Mulmani *et al*., 2016[20]	20	Prospective	9.3 weeks	Till radiological union	Excellent 80%
Ramanathan and Kumar[21]	20	Prospective	9–13 weeks	11 months	ULCA score 31.35
Naidu and Anand, 2017[22]	50	Prospective	11–12 weeks	6 months	Excellent 32%
Ravi *et al*., 2017[23]	30	Prospective	12 weeks	6 months	Excellent 77%
Present study	35	Prospective	3 months Clinical –100% Radiological – 80%	6 months	At 3 months Excellent 71% Good in 26%

Table 3: Comparison of different study complication with the present study

Study	Infection	Non-union	Delayed union	Implant breakage	Implant irritation/ prominence	Screw loosening
Ethiraj *et al*., 2016	Nil	Nil	3	1	Nil	Nil
Kumar and Harsha, 2016	Nil	Nil	1	1	1	Nil
Mulimani *et al*., 2016	Nil	Nil	2	0	3	Nil
Ramanathan *et al*.	2	Nil	Nil	Nil	Nil	Nil
Naidu and Anand, 2017	Nil	Nil	Nil	Nil	Nil	Nil
Ravi *et al*., 2017	Nil	2	Nil	Nil	3	Nil
Present study	1	Nil	Nil	Nil	1	Nil

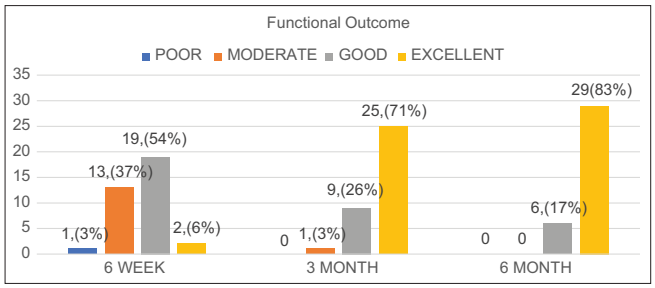

Figure 5: Bar diagram showing functional outcome in no. of patients with time duration

The success of pre-contoured locking compression plate for fractures of clavicle requires careful assessment of fracture pattern, selection of patients, meticulous operative technique, appropriate fixation, careful post-operative monitoring, and early rehabilitation because final functional result of treatment clavicle fractures depends on these parameters.

CONCLUSION

We inferred that open reduction and internal fixation with pre-contoured locking compression clavicular plate can be a good option in the treatment of displaced and/or comminuted clavicle fractures. With the data of this study and our experience of the present study, we recommend that this is a valuable option in management of clavicle fracture.

ACKNOWLEDGMENTS

Dr. G S Kulkarni for guiding at each step of the study and our physiotherapist Dr. Prasad Pawar.

ETHICAL APPROVAL

The study was approved by the Institutional Ethical Committee.

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How to cite this article: Kripalani S, Nagalwade S, Kulkarni V, Patil T, Jadhav S. Open Reduction and Internal Fixation of Midshaft Clavicular Fractures with Pre-contoured Locking Clavicle Plate: A Prospective Study. Int J Sci Stud 2021;9(2):25-29.

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

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

Original Article

Evaluation of Hepatic Function among Critically Ill Coronavirus-Infected Patients in a Tertiary Care Hospital of Tripura

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Abstract

Introduction: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been posing significant threats to public health since December 2019. Angiotensin-converting enzyme 2 (ACE2), the host cell receptor, has been demonstrated in mediating 2019-nCoV infection. Hepatic impairment was reported in majority of critically ill patients along with other system involvement. The median age of 40 enrolled patients was 53.6 years and 28 patients (70%) were men. The most common symptoms were fever, dry cough, headache, body ache, breathing difficulty, diarrhea, and fatigue. The present study also showed elevated aspartate transaminase (AST) in 85% intensive care unit (ICU) admitted patients and elevated alanine aminotransferase (ALT) in 90% of ICU patients. This paper provides an overview of hepatic function among critically ill coronavirus-infected patients.

Aims and Objectives: The study of evaluation of hepatic function among critically ill coronavirus-infected patients is important for various reasons. Studies on pandemic impact on liver are lacking. To estimate liver function, abnormality has great importance regarding treatment aspect among critically ill coronavirus disease (COVID) patients admitted in Agartala Government Medical College and GBP Hospital.

Materials and Methods: A cross-sectional hospital-based evaluation of hepatic function of critically ill COVID-19 patients admitted in ICU at AGMC & GBP Hospital.

Results: The median age of 40 enrolled patients was 53.6 years and 28 patients (70%) were men. The most common symptoms were fever, dry cough, headache, body ache, breathing difficulty, diarrhea, and fatigue. The present study also showed elevated AST in 85% ICU admitted patients and among them 50% had more than 2 times raised AST. Elevated ALT in 90% of ICU patients and among them 35% had more than 2 times raised ALT and 25% had more than 5 times raised ALT. Majority of patients had normal serum bilirubin and alkaline phosphatase.

Conclusion: Hepatic injury among coronavirus-infected critically ill patients might be directly caused by the SARS-COV-2 through binding to ACE2. ALT, AST, and diagnostic biomarker for hepatic injury have been elevated in this existing COVID-19 study. Liver damage in severe COVID-19 is transient or permanent needs a follow-up. Increased mortality had been observed in COVID-19 infected person with pre-existing liver disease. Immune dysfunction – including lymphopenia, reduce cluster differentiation4+ T-cell levels, and abnormal cytokine levels, might be a critical factor associated with disease severity and mortality. This study has shown us that special care of liver dysfunction should be installed in treating 2019-nCoV patients during the hospitalization. Further research should focus on the severity of liver injury and progression toward chronic liver disease in COVID-19.

Key words: Hepatic, Patient, Virus

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is the illness caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Older adults and people with chronic liver disease, including hepatitis B and hepatitis C, and those have serious underlying medical conditions might be at

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higher risk for severe illness from COVID-19. Genomic sequence shown that both SARS-CoV and SARS-CoV-2 infect cells through the angiotensin-converting enzyme 2 (ACE2) receptor.[1-4] ACE2 was abundantly expressed on the surface of the lungs and the small intestine epithelium, and occasionally on the bile ducts.[5] About 59.7% of cholangiocytes and 2.6% hepatocytes expressed ACE2.[6] One study (2004) showed that 43 cases of COVID-19 had higher alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level.[7] Wang *et al*. found that 23 had elevated ALT (33%) and 19 had elevated AST (28%).[8] A recent autopsy case also found moderate microvesicular steatosis and mild lobular activity in the liver, indicating either SARS-CoV-2 infection or drug-induced liver injury.[9] In this study, we evaluated hepatic function of critically ill coronavirus affected patients.

Aims and Objectives

The study of evaluation of hepatic function among critically ill coronavirus-infected patients is important for various reasons. Studies on pandemic impact on liver are lacking. To estimate liver function, abnormalities have great importance regarding treatment aspect among critically ill COVID patients admitted in intensive care unit (ICU) at AGMC and GBP Hospital.

MATERIALS AND METHODS

A cross-sectional hospital-based evaluation of hepatic function of critically ill COVID-19 patients admitted in ICU at AGMC and GBP Hospital.

Study Population

Patients, both male and female, having SARS-COV-2 positive on RT-PCR or rapid antigen test admitted in ICU at AGMC and GBP Hospital following inclusion and exclusion criteria will be included in the study.

Sampling Technique

Census sampling. As it is decided to include all the COVID-19 patients who will be admitted in ICU at AGMC and GBP Hospital.

Sample Size

All the COVID-19-infected patients admitted in ICU at AGMC and GBP Hospital following inclusion and exclusion criteria will be included in the study.

Inclusion Criteria

All the COVID-19-infected patients admitted in ICU at AGMC and GBP Hospital were included in the study.

Exclusion Criteria

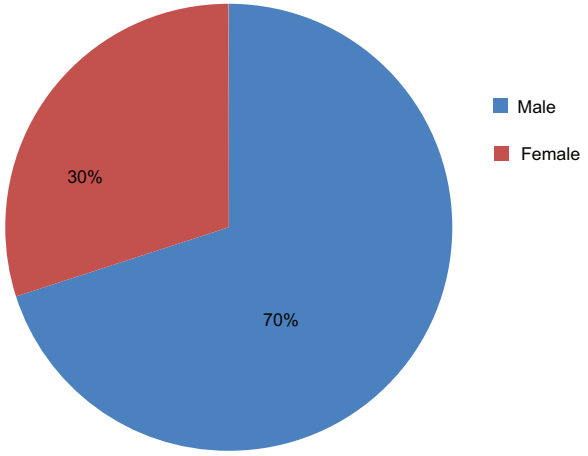
The following criteria were excluded from the study:

- Viral hepatitis
- Alcoholic liver disease
- Diagnosed with non-alcoholic fatty liver disease
- Presently taking hepatotoxic drugs.

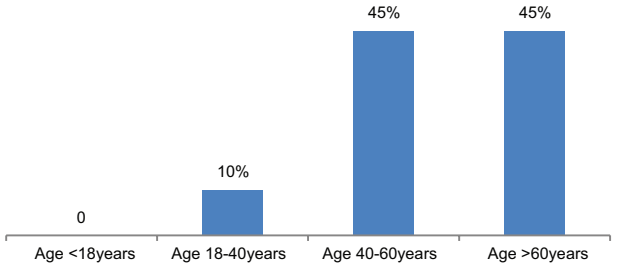
Data were analyzed by SPSS software ver. 15 using appropriate statistical tests.

RESULTS

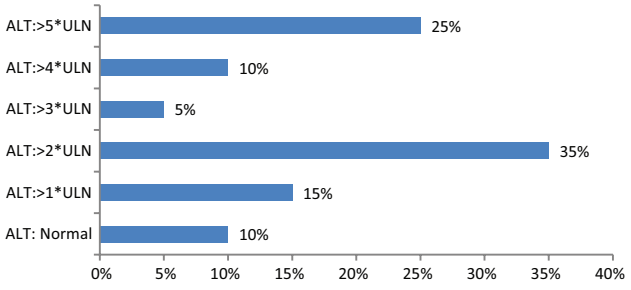
Sex-Wise Distribution



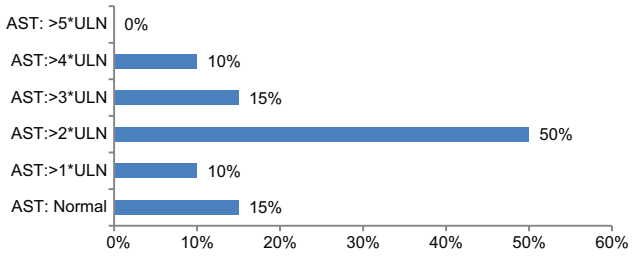
Age-Wise Distribution



ALT: Normal ALT for males: 29–33I U/L, normal ALT for females: 19–25 IU/L.



AST: Normal AST for both males and females: 5–35 IU/L.



DISCUSSION

The median age of 40 enrolled patients was 53.6 years (IQR 30.0–84.0), and 28 patients (70%) were men. The most common symptoms were fever, dry cough, headache, body ache, breathing difficulty, diarrhea, and fatigue.

Study conducted by Guan *et al*. among 1099 corona-infected patients revealed that elevated AST in 56 (39.4%) of 142 patients with severe disease. Elevated levels of ALT were observed in 38 (28.1%) of 135 patients with severe disease[10] and male preponderance was seen.

The present study also showed elevated AST in 85% ICU admitted patients and elevated ALT in 90% of ICU patients. Among them 35% had more than 2 times raised ALT and 25% had more than 5 times raised ALT. Male preponderance also observed in this study.

Huang *et al*. observed that elevated AST in 62% ICU admitted severe COVID-19 patients.[11] Here our study showed elevated AST in 85% icu patients. Among them, 50% had more than 2 times raised AST.

Majority of the patients had normal range of serum bilirubin, alkaline phosphatase, gamma-glutamyltransferase, and prothrombin time. Few elderly patients had low total protein and low albumin.

CONCLUSION

Hepatic injury among coronavirus-infected critically ill patients might be directly caused by the SARS-COV-2 through binding to ACE2.[12] However, few study shows virus might directly bind to ACE2-positive cholangiocytes and cause damage or might be due to systemic inflammatory response induced liver injury.[7] ALT, AST, and diagnostic biomarker for hepatic injury have been elevated in this existing COVID-19 study. Liver damage in severe COVID-19 is transient or permanent needs a follow-up. Chronic liver disease, an immunocompromised state, represents a major burden globally. Increased mortality had been observed in COVID-19 patients with pre-existing liver disease. Immune dysfunction – including lymphopenia, reduce cluster differentiation 4+ T-cell levels, and abnormal cytokine level, might be a critical factor associated with disease severity and mortality. This study has shown us that special care of liver dysfunction should be installed in treating 2019-nCoV patients during the hospitalization. Further research should focus on the severity of liver injury and progression toward chronic liver disease in COVID-19 patients.

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How to cite this article: Sarkar P, Paul S, Das M. Evaluation of Hepatic Function among Critically Ill Coronavirus-Infected Patients in a Tertiary Care Hospital of Tripura. Int J Sci Stud 2021;9(2):30-32.

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

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

Original Article

Comparative Evaluation of Fracture Resistance of Newer Restorative Materials with Conventional Amalgam in Class II Cavity Preparation

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Abstract

Introduction: Cavity preparation weakens the tooth structure and makes it susceptible to fracture. Thus, an ideal restoration in a tooth should be able to maintain the esthetics, function, preserve the remaining tooth structure, and prevent microleakage. Amalgam is very strong in bulk section, but its slow setting process, mercury content, and unpleasant color, has led to its decline in the recent years. Since then, many newer materials have been developed as an alternative.

Objectives: The objectives of the study were to evaluate and intercompare the fracture resistance of resin composite, fiber-reinforced composite, and dual-curing restorative material with conventional amalgam.

Study Design: The study was conducted in the department of pediatric and preventive dentistry in collaboration with mechanical engineering department on a sample size of 80 teeth. The samples included freshly extracted premolar teeth, free of caries, craze lines, fracture, or restoration.

Methodology: Standard Class II cavities were prepared in all the teeth which were divided into four equal groups. Samples of Group I, II, III, and IV were restored with amalgam, conventional composite, fiber-reinforced composite, and Cention N, respectively. Fracture resistance was calculated when the samples were subjected to a compressive load in a universal testing machine.

Results: The mean fracture resistance of Group 3 was the highest, followed by Group 4, Group 1, and Group 2 the least.

Conclusion: For Class II cavity preparation, among restorative materials studied, fiber-reinforced composite (Group 3) was found to be the best material as it exhibited the highest fracture resistance.

Key words: Fracture resistance, Amalgam, Ever X, Cention N

INTRODUCTION

One of the most prevalent oral diseases in modern civilization due to change in the lifestyle is dental caries. Its successful long-term treatment is the area of concern for dentists across the world.[1]

In posterior tooth restorations, physical and mechanical properties play a dynamic role as they are subjected to heavy occlusal loads. Due to the stress concentration at the axiopulpal line angle under masticatory load, restoration fracture mainly occurs at the isthmus of a Class II restored cavity. Hence, materials with high fracture resistance are highly recommended in cases where they are subjected to heavy load as seen in cases of Class II carious teeth.[2]

Access this article online

www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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Conventionally, amalgam has been used as the best core build-up material as it is strong in bulk section. Its slow setting process, mercury content, and unpleasant color are some of the reasons why alternative restorative materials were developed. The major drawback of amalgam, however, is its inability to bond to dental hard tissues which demands the use of macromechanical retentive features. This, in turn, causes further weakening of the remaining tooth structure.

At present, resin composites are the most widely used materials in restorative dentistry. It has micromechanical property that makes composite more suitable for filings even in small cavity. Synthetic resins evolved as a restorative material since they were insoluble, adhesive to the tooth structure, have tooth-like appearance, insensitive to dehydration, easy to manipulate, and reasonably inexpensive. The inherent drawback encountered while using composite resin was polymerization shrinkage and insufficient fracture resistance (Madley *et al.*, 1976).

To overcome this disadvantage, fibers were incorporated into the resin composite to enhance its mechanical adhesive and the flexural properties. Ever X flow is a fiber-reinforced composite designed to replace dentin and reinforce restorations. The short glass fibers of ever X flow material strength restorations and prevent them from cracking. Cention N (a dual cure restorative material) is another inventive restorative material for substituting lost tooth structure in posterior teeth. Cention N offers tooth-colored esthetics along with high flexural strength. The alkaline filler present balances the pH value during acid attacks by increasing the release of hydroxide ions. As a result, demineralization can be limited. Moreover, the release of substantial amount of fluoride and calcium ions assists in remineralization of dental enamel.

Since there is a paucity of information available on fracture resistance of these materials, this study was thus planned to compare and evaluate the fracture resistance of conventional composite, fiber-reinforced composite, and Cention N with amalgam in Class II cavity preparations.

MATERIALS AND METHODS

The study sample comprised 80 human premolar teeth with intact root, extracted for orthodontic purposes. All the teeth (80 premolars) were cleaned of debris and soft-tissue remnants and were stored in formalin until used. Before the teeth were used, they were washed with tap water to eliminate formalin. To simulate periodontium, root surfaces of the selected teeth were first dipped into melted wax to a depth of 2 mm below the cement-enamel junction to produce a thin layer and then vertically embedded in polyvinyl cylinders with self-cure acrylic (to simulate the alveolar bone). The wax spacer was later substituted with light body addition silicone (to simulate the periodontal ligament).

Class II cavity preparation (mesio-occlusal) was done on all the mounted teeth using high-speed bur and water spray. The cavities were prepared with gingival margin located 1.0 mm above the cementoenamel junction, 2 ± 0.2 mm pulpal width, 2 ± 0.2 mm gingival width, and 3 ± 0.2 mm buccolingual width and were verified using periodontal probe. The facial and lingual walls of the occlusal segment were prepared parallel to each other. All the teeth after cavity preparation were randomly divided into four groups for 20 teeth each. Teeth in Group 1 were restored with amalgam, in Groups II, III, and IV were restored with conventional composite (3M, Ivoclar), Ever X flow, and Cention N, respectively. All the restorations were done according to the manufacturer instructions.

After restoration, the samples were thermocycled for 500 times at 5°C and 55°C with each cycle corresponding to a 15 s bath at each temperature. Fracture resistance was tested when samples subjected to a compressive load with cross-head speed of 1 mm/min in a Universal Testing Machine. The force was applied in the center of the restoration contacting only the buccal and lingual cusp inclines of each tooth and parallel to the long axis of the tooth [Figure 1]. Peak load to fracture was recorded in Newtons (N) for each specimen and the data collected were sent for statistical analysis.

RESULTS

Data were summarized in Mean ± SE (standard error of the mean). Groups were compared by one factor analysis of variance (ANOVA) and the significance of mean difference between (inter) the groups was done by Tukey's HSD (honestly significant difference) *post hoc* test after ascertaining normality by Shapiro–Wilk test and homogeneity of variance between groups by Levene's test. A two-tailed ($\alpha = 2$) $P < 0.05$ was considered statistically significant. Analysis was performed on SPSS software (Windows version 22.0).

The fracture resistance of four groups (Group 1, Group 2, Group 3, and Group 4) is summarized in Table 1 and also depicted in Figure 2. The fracture resistance of Group 1, Group 2, Group 3, and Group 4 ranged from 1305 to 1660, 1300 to 1645, 1855 to 2260, and 1770 to 2010 Newton, respectively, with mean (± SE) 1530.75 ± 22.26, 1489.45 ± 22.63, 2044.50 ± 30.06, and 1893.50 ± 16.96 Newton,

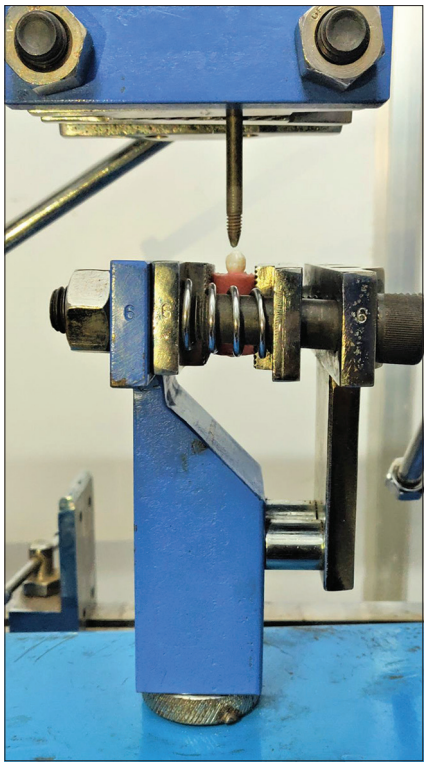

Figure 1: Sample subjected to compressive load in a universal testing machine

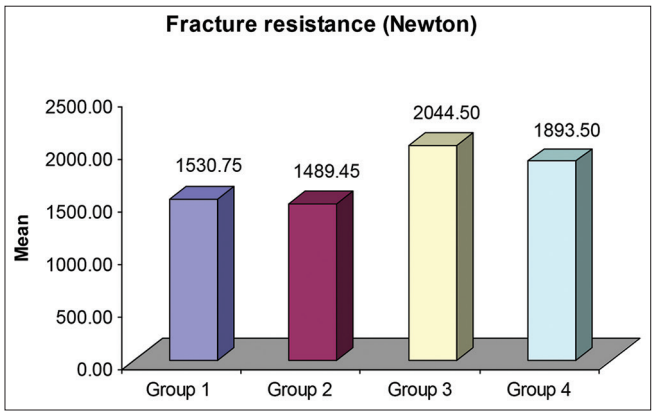

Figure 2: Bar graphs showing mean fracture resistance of four groups

Table 1: Fracture resistance (Newton) of four groups

Group	*n*	Mean±SE	F value	*P* value
Group 1	20	1530.75±22.26	135.20	< 0.001
Group 2	20	1489.45±22.63		
Group 3	20	2044.50±30.06		
Group 4	20	1893.50±16.96		

The fracture resistance of four groups was summarized in Mean±SE and compared by ANOVA (F value)

respectively, and median 1548, 1493, 2045, and 1893 Newton, respectively. The mean fracture resistance of Group 3 was the highest, followed by Group 4, Group 1, and Group 2 the least (Group 2 <Group 1 <Group 4 <Group 3).

Comparing the mean fracture resistance of four groups, ANOVA showed significantly different fracture resistance among the groups (F = 135.20, $P < 0.001$) [Table 2].

Further, comparing the difference in mean fracture resistance of Group 1 with other groups (Group 2, Group 3, and Group 4), Tukey test showed significantly different and higher fracture resistance of both Group 3 (25.1%) (1530.75 ± 22.26 vs. 2044.50 ± 30.06, mean difference = 513.75, q = 21.91, $P < 0.001$) and Group 4 (19.2%) (1530.75 ± 22.26 vs. 1893.50 ± 16.96, mean difference = 362.75, q = 15.47, $P < 0.001$) as compared to Group 1 but not differ between Group 1 and Group 2 (1530.75 ± 22.26 vs. 1489.45 ± 22.63, mean difference = 41.30, q = 1.76, $P > 0.05$) though it was found 2.7% higher in Group 1 as compared to Group 2

Similarly, comparing the difference in mean fracture resistance of Group 2 with other groups (Group 3 and Group 4), Tukey test showed significantly different and higher fracture resistance of both Group 3 (27.1%) (1489.45 ± 22.63 vs. 2044.50 ± 30.06, mean difference = 555.05, q = 23.68, $P < 0.001$) and Group 4 (21.3%) (1489.45 ± 22.63 vs. 1893.50 ± 16.96, mean difference = 404.05, q = 17.24, $P < 0.001$) as compared to Group 2

Similarly, comparing the difference in mean fracture resistance between Group 3 and Group 4, Tukey test showed significantly different and higher (7.4%) fracture resistance of Group 3 as compared to Group 4 (2044.50 ± 30.06 vs. 1893.50 ± 16.96, mean difference = 151.00, q = 6.44, $P < 0.001$).

DISCUSSION

Fracture resistance is the inherent property of a material by virtue of which it resists plastic deformation under a particular load. Masticatory forces tend to deflect the cusps under stress, whether the tooth is restored or unrestored. It is, therefore, important that any restorative material that is used to repair a missing tooth structure should also reinforce the tooth and minimize the risk of fracture of its cusp.[2]

In dentistry, silver amalgam is the utmost common and time tested material being used for the restoration of posterior teeth.[3] In the hands of an experienced clinician, even today, it is still the cheapest, easy to use, most durable, and satisfactory material.[4] However, the discoloration exhibited by this material has shown to be a major disadvantage. Lack of adhesion to the tooth structure involves removal of the sound tooth structure, thus reducing the strength of the tooth is another disadvantage of using amalgam as a restorative material.

Table 2: Comparison of difference in mean fracture resistance (Newton) between groups by Tukey test

Comparison	Mean diff.	Mean diff. (%)	q value	*P* value	95% CI of diff.
Group 1 versus Group 2	41.30	2.7	1.76	*P*>0.05	45.98–128.60
Group 1 versus Group 3	513.75	25.1	21.91	*P*<0.001	426.50–601.00
Group 1 versus Group 4	362.75	19.2	15.47	*P*<0.001	275.50–450.00
Group 2 versus Group 3	555.05	27.1	23.68	*P*<0.001	467.80–642.30
Group 2 versus Group 4	404.05	21.3	17.24	*P*<0.001	316.80–491.30
Group 3 versus Group 4	151.00	7.4	6.44	*P*<0.001	63.72–238.30

Diff: Difference, CI: Confidence interval, q value: Tukey test value

This led to the evolution of adhesive restorations which included resin composite and glass ionomer cement. Later, fibers were incorporated into the resin composite to enhance its mechanical properties. Another recent material which provides conservative tooth preparation as well as fluoride release is Cention N.

Solomon *et al.*[3] in their study had shown that bulk composite resin placed in horizontal increments showed lesser fracture resistance than silver amalgam. Pretronjevic *et al.*[5] found no significant difference in the fracture resistance of premolars restored with resin composite and amalgam

In the present study, standard Class 2 cavities were outlined and prepared on all the samples to decrease the potential effect of amount of tooth structure loss on the strength of those teeth. Precautions were taken to minimize the variabilities.

Stresses induced due to the variations in the elements of the Class 2 cavity preparation design (depth of the cavity, width of the isthmus, and thickness of the remnant interaxial dentin) have been discussed.[6] Granath and Svensson found that the extent of width of cavity and depth was directly related to cusp displacement, that is, an increase in width of cavity and depth means an increase in cuspal displacement during loading and vice versa. It has been observed clinically that after some years of Class 2 restoration of premolar teeth, cuspal failures are quite common. After periodontal disease and caries, tooth loss from fracture ranks third and is especially common in people over 40 years of age.[7]

In the present study, fracture resistance of amalgam was compared with resin composite, fiber-reinforced composite, and Cention-N. Fracture resistance of fiber-reinforced composite (2044.50 ± 30.06) was found to be highest followed by Cention N (1893.50 ± 16.96), amalgam (1530.75 ± 22.26), and then conventional composites (1489.45 ± 22.63). The increased fracture resistance of fiber-reinforced composites restored in Class II cavity can be attributed to large filler particle which strengthens physical properties (Magne *et al.*, 2009). Other factor besides filler size which can be responsible for low fracture resistance is filler loading and stress transfer from resin matrices to filler particles (Magne, 2009; Magne *et al.*, 2008; Zhao *et al.*, 1997; Ferracane *et al.*, 1998; Kim *et al.*, 2000; Bonilla *et al.*, 2001, and Kim, 2002).

Fracture resistance of Cention N was found to be higher than amalgam and conventional composite. This may be attributed to the fact that Cention N releases a large number of fluoride and calcium ions which form a sound basis for remineralization of the dental enamel the highly cross-linked polymer structure is responsible for the high flexure strength (Chowdhury *et al.*, 2018).

Kumar *et al.*[1] evaluated the fracture resistance of fiber-reinforced composite, core build up material, and flowable composite and reported that fiber-reinforced composite showed maximum mean fracture toughness. This was statistically significant when compared to other tested restorative materials. A study of Garoushi *et al.*[8] showed that short fiber fillers could stop the crack propagation and provided increase in fracture resistance of composite resin.

Jayashankara *et al.*[9] and Chowdhury *et al.*[2] compared Cention-N and nanocomposite Filtek Z350 for resistance to fracture in Class II cavities. They found that Cention-N and Filtek Z350 materials have higher resistance to fracture in Class II cavity restoration and dental amalgam showed comparatively inferior results.

CONCLUSION

For Class II cavity preparation, among restorative materials studied, this study found fiber-reinforced composite (Group 3), the best material as it exhibited the highest fracture resistance. However, findings of this study may be further validated on larger sample size and comparisons with other different restorative materials.

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How to cite this article: Naik NS, Sharma K, Sharmaa S, Vashisth P, Deepshikha, Murry JN. Comparative Evaluation of Fracture Resistance of Newer Restorative Materials with Conventional Amalgam in Class II Cavity Preparation. Int J Sci Stud 2021;9(2):33-37.

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

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

Original Article

Effect of Different Denture Soft Liners on Mandibular Ridge Resorption in Complete Denture Wearers: An *In-vivo* Study

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Abstract

Introduction: Soft lining materials can be defined as soft polymers that can be added to the denture fitting surface to decrease and distribute occlusal loads more uniformly on the underlying mucosal tissues.

Purpose: The purpose of the study was to evaluate the effect between conventional denture, acrylic-based denture soft liner, and silicone-based denture soft liner on mandibular ridge resorption after 6 and 9 months of denture insertion in complete denture wearers.

Materials and Methods: Thirty completely edentulous patients between 45 and 60 years of age with well-formed ridges in class I jaw relations were selected. The patients were divided into 3 groups each containing 10 patients. Group I was given conventional dentures, Group II was given acrylic-based soft-lined dentures, and Group III were given silicone-based soft-lined dentures. Vertical measurements were made on orthopantomograph and analyzed using Adobe Photoshop 7.0 software at five points, one at central incisor and two points at right and left first premolars, and two in each first molar region.

Results: All three groups showed a significant change in bone height after denture delivery ($P < 0.05$). Participants in Group II and Group III showed lesser bone loss in all three regions compared to Group I over a period of 9 months. The comparison of bone height between the three groups in different regions at various time intervals showed a significant difference in bone levels ($P < 0.05$) at baseline to 6 months and baseline to 9 months' period ($P < 0.01$).

Conclusion: The use of soft denture liner significantly reduces the residual ridge resorption in complete denture wearers as compared to conventional denture wearers (without denture liner) over a period of 9 months of denture insertion.

Key words: Complete denture, Edentulous ridge, Residual ridge resorption, Soft liner

INTRODUCTION

Bone is a dynamic tissue capable of adaptation to meet compression or tensional forces falling upon it.[1] Bone loss varies from patient to patient, but more significant changes are evident in the mandibular arch. The mean ratio of anterior maxillary to anterior mandibular residual ridge reduction (RRR) is 1:4. Mandibular ridge is more prone to resorption as it bears higher functional forces transferred through the dentures than the maxillary ridge. Its smaller area and less advantageous shape of the mandibular basal seat contribute to this phenomenon.[2]

Despite the strong desire of the patient to obtain well-fitting dentures, as well as clinicians who diligently strive to produce gratifying dentures, edentulous patients are still there who suffer while having their daily meals with wearing their conventional complete dentures. One plausible reason why patients encounter difficulties while masticating may be

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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attributed to atrophic and thin mucosa that bear the stress caused by occlusal force.[3] Soft liners aid in distributing more evenly the forces of mastication to the underlying tissues by absorbing some of the forces. Soft liners have the ability to enhance comfort to denture patients with ridge atrophy, thin and non-resilient mucosa, bony undercuts, and bruxomania.[4]

Several authors have reported that resilient denture liners distribute the stress derived from occlusal force.[5-7] Due to the cushioning effect provided by soft liners, a lesser amount of forces are transferred to the underlying bone during various functions as compared to without soft liners leading to a reduction in residual ridge resorption.[2] As intraoral environment is the most precise testing, clinical studies are a must to draw definitive conclusions. Various qualitative and quantitative indices and approaches have been used to explain the resorptive changes in the mandible.[1]

At present, there is less literature available regarding the evidence of the effect of resilient liners on residual ridge resorption in complete denture wearers. Therefore, this study was intended to evaluate the effect of soft denture liners on mandibular ridge resorption in complete denture wearers up to the 9th month of their application.

MATERIALS AND METHODS

This study is an interventional *in-vivo* study conducted in the Department of Prosthodontics and Crown and Bridge, Institute of Dental Sciences, Bareilly. Patients who were edentulous for the last 6 months, having class I jaw relation with well-developed ridges, firm mucosa, and with no previous denture experience were included in the study. Patients who had Class II or III jaw relationship, any general systemic conditions related to bone pathology, and severely resorbed ridges were excluded from the study.

Methodology

Study population

Thirty completely edentulous patients aged between 45 and 60 years were selected randomly from the out-patient department of Prosthodontics and Crown and Bridge. The selected patients were explained about the whole procedure, the need for follow-up visits, radiographs required. Written informed consent was obtained and ethical committee approval was taken. Participants were divided into three groups; 10 participants were enrolled in each of the three groups as per stratified block randomization, which was based on computer-generated numbers given by the statistician. A thorough case history of the patient was taken. Clinical examination of the patient was done to meet the inclusion criteria and rule out the exclusion criteria. Group 1 represents the control group (n = 10), where conventional maxillary and mandibular complete dentures were fabricated in heat-cured acrylic resin (Trevalon, Dentsply India, Mumbai, India). Group 2 represents the experimental group (n = 10) where maxillary dentures were fabricated in heat-cured acrylic resin (Trevalon, Dentsply India, Mumbai, India) while mandibular denture was lined with acrylic-based soft liner (Permasoft, Dentsply International, USA). Group 3 represents the 2nd experimental group (n = 10), where maxillary dentures were fabricated in heat-cured acrylic resin while mandibular dentures were lined with silicone-based denture soft liner. (Molloplast B, (Detax, GMBH & CO, Germany).

The primary impression was made using an impression compound and a primary cast was poured. Custom trays were fabricated using tray material. Border molding was done with green stick compound and the final impression was made using zinc oxide eugenol impression paste. Occlusion rims were constructed on the master cast, vertical dimension of occlusion and centric relation was recorded. Acrylic artificial teeth of semi anatomic form were used for teeth arrangement and try-in of the dentures was done. After dewaxing, radiopaque markers were placed over the tooth surfaces in mandibular dentures at five different points (one in central incisor region and one in 1st premolar and 1st molar region on both sides) and secured in position. Then the mold was packed in heat-cured acrylic resin. In Group II and III, spacer of two mm thickness was adapted over the mandibular cast and the remaining space was packed with heat-cured acrylic resin. Spacer was replaced after trial closure with either heat-cured acrylic or silicone soft denture liner and denture was cured using the standard procedure. Dentures were finished, polished, and delivered to the participants. For each participant, three panoramic radiographs (OPG) were taken immediately after denture insertion, at 6 months and at 9 months after denture insertion to assess the amount of bone resorption [Figures 1-3]. To ensure the reproducibility between successive films, all the radiographs were taken on same machine (OPG machine details) by a trained radiographer using a standard protocol. For the measurements, a reference plane was drawn, touching the inferior border of the mandible. On this line, 90° tangents were drawn from the lower border of the radiopaque markers in five different regions; 2 in 1st premolar, 2 in 1st molar, and 1 in midline. The distances from the radiopaque markers to the reference plane were measured with the help of Adobe Photoshop 7.0 (Adobe Systems, San Jose, CA, USA). Measurements recorded immediately after denture insertions were considered as baseline values, and measurements made at 6 months and 9 months were also recorded.

The data were entered on a Microsoft Excel spreadsheet and imported into Statistical Package for the Social Sciences (SPSS) version 22 for statistical analysis. The results were present in the form of mean and standard deviation. The student paired *t*-test was used to find the significant difference within the group at different visits, for compare more than two groups for continuous variables between the groups one-way ANOVA was used A $P < 0.05$ was considered statistically significant.

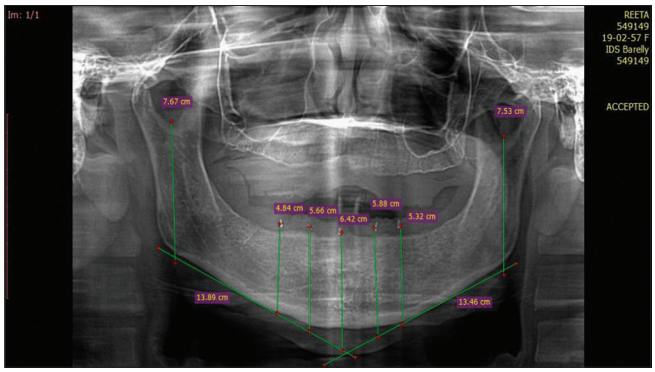


Figure 1: Osteoprotegerin at baseline

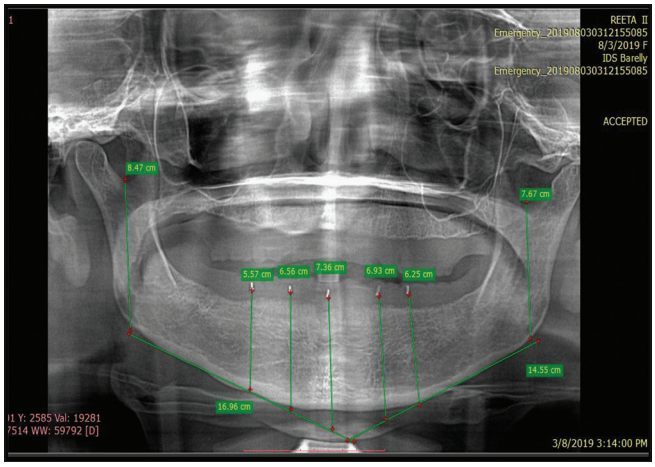


Figure 2: Osteoprotegerin at 6th month

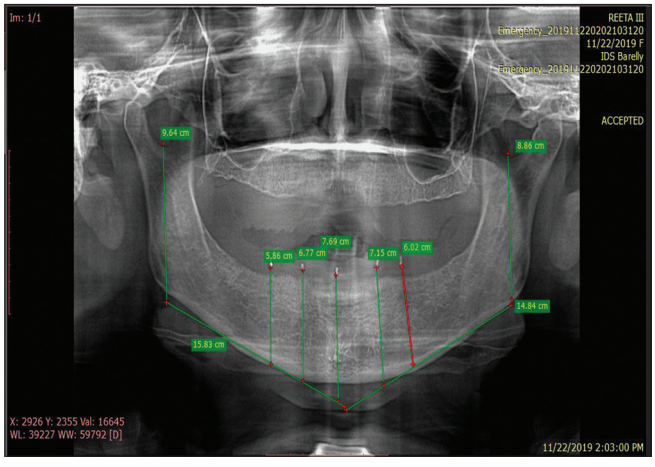


Figure 3: Osteoprotegerin at 9th month. (measurements from lower border of radio opaque marker to the reference line.)

RESULTS

The comparison of bone height between the three groups in different regions at various time intervals showed a significant difference in bone levels ($P < 0.05$) at baseline to 6 months and baseline to 9 months' period ($P < 0.01$) [Table 1].

Mean bone loss at the right posterior from baseline to 6 months in Group 1 (Conventional) was 2.84 ± 1.62, in Group 2 was 0.48 ± 0.34 and in Group 3 was 1.26 ± 0.39. Mean bone loss at right posterior in Group 1 was maximum and in Group 2 was minimum at baseline to 6 months, 6–9 months, and baseline -9 months. There was a significant difference in mean bone loss at the right posterior at different time intervals between Group 1, Group 2, and Group 3 [Graph 1].

Mean bone loss at anterior-incisor from baseline to 6 months in Group 1 (conventional) was 2.98 ± 1.75, in Group 2 was 0.59 ± 0.54, and in Group 3 was 1.37 ± 0.38, mean bone loss at anterior-incisor in Group 1 was maximum and in Group 2 was minimum at baseline to

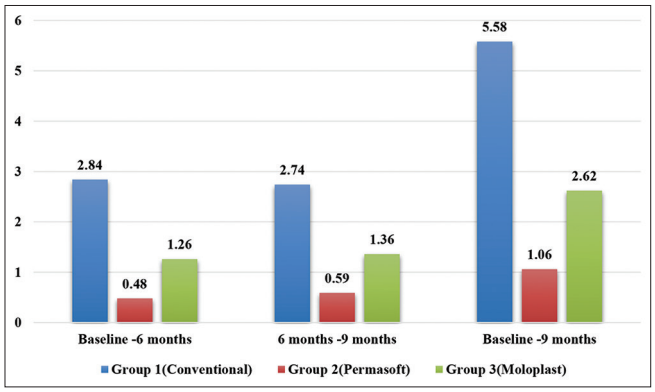
Table 1: Comparison of mean bone loss (mm) at different points in between Group 1 (conventional), Group 2 (Permasoft), and Group 3 (Molloplast-B) at a different time interval

Time interval	Group 1 (Conventional)	Group 2 (Permasoft)	Group 3 (Molloplast-B)	P-value
	Mean±SD	Mean±SD	Mean±SD	
Right posterior				
Baseline -6 months	2.84±1.62	0.48±0.34	1.26±0.39	<0.001*
6 months -9 months	2.74±1.71	0.59±0.42	1.36±0.49	<0.001*
Baseline -9 months	5.58±2.57	1.06±0.68	2.62±0.63	<0.001*
Anterior-incisor				
Baseline -6 months	2.98±1.75	0.59±0.54	1.37±0.38	<0.005*
6 months -9 months	2.83±2.27	0.56±0.92	1.38±0.51	<0.001*
Baseline -9 months	5.81±3.14	1.15±1.14	2.75±0.6	<0.001*
Left posterior				
Baseline -6 months	3.07±1.69	0.6±0.4	1.42±0.56	<0.001*
6 months -9 months	2.77±1.95	0.83±0.43	1.47±0.4	<0.004*
Baseline -9 months	5.84±3.29	1.43±0.6	2.89±0.630	<0.001*

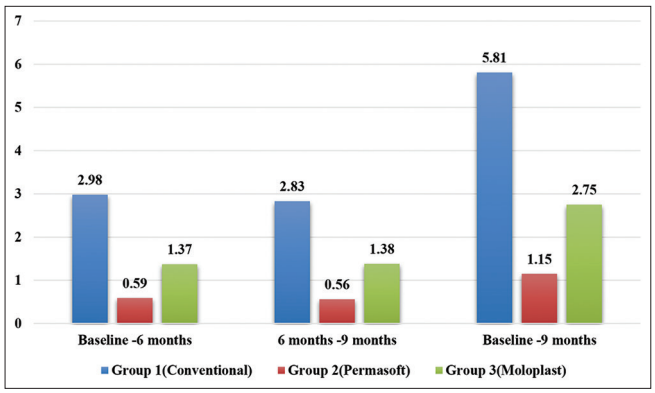
*Statistically significant

6 months, 6–9 months, and baseline -9 months. There was a statistically significant difference in mean bone loss at anterior-incisor at different time interval in between Group 1, Group 2, and Group 3 [Graph 2].

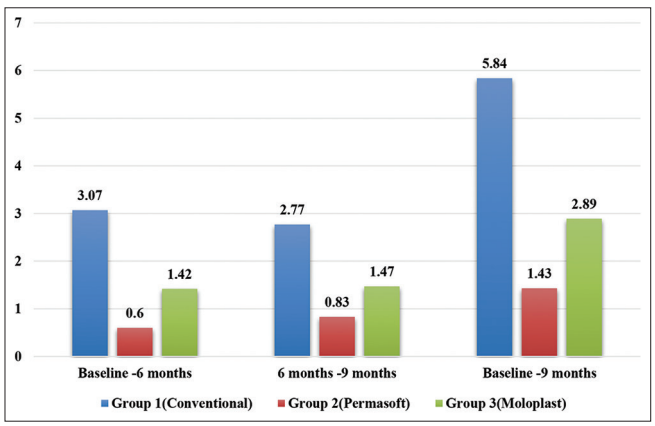
Mean bone loss at left posterior from baseline to 6 months in Group 1 was 3.07 ± 1.69, in Group 2 was 0.6 ± 0.4, and in Group 3 was 1.42 ± 0.56, mean bone loss at left posterior



Graph 1: Mean bone loss (mm) at right posterior in different groups



Graph 2: Mean bone (mm) loss at anterior-incisor in different groups



Graph 3: Mean bone loss (mm) at left posterior in different groups

in Group 1 was maximum and in Group 2 was minimum at baseline to 6 months, 6–9 months, and baseline -9 months. There was a statistically significant difference in mean bone loss at the left posterior at different time intervals between Group 1, Group 2, and Group 3 [Graph 3].

DISCUSSION

The reduction of residual ridges (RRR) is a major unsolved oral disease that causes physical, psychological, and economic problems for millions of people all over the wor1d.[8] One of the most important factors regarding bone is its accelerated resorption by excessive stress.[9] RRR is almost universal but with wide individual variations. Hence, what is important is the amount. However, since the amount is cumulative, a single examination does not reveal the current rate of resorption. Since the resorption is slow, lengthy longitudinal studies are required. Repeated readings at intervals are required to reveal resorptive changes. Hence, the recordings were taken at 0, 6th, and 9th months in the current study.

This study was conducted among the age group of 45–60 years who were edentulous for the last 6 months. It was observed that mandibular resorption rate was greatest in the earlier stages of edentulism and slowed with the longevity of edentulism. i) This is in accordance with Tallgren, who stated that RRR was greater during the first few months after the tooth extraction than later.[10]

In the current study, laboratory-processed acrylic-based soft liner (Permasoft) and silicone-based denture soft liner (Molloplast-B) were used. The thickness of soft-liner material was kept 2 mm, because a thickness of 2.5 mm resulted in a slightly higher level of stress. A possible explanation of the above could be the instability of the prosthesis over the reliner material above a certain height of the same which is in agreement with data presented by Kawano *et al*.[11] and Lima *et al*.[9] The thickness of the soft liner plays a significant role in the stress distribution especially in the patient with thin mucosa.[11]

Resorption of the residual ridge has been estimated with various radiographic techniques such as lateral cephalometric and panoramic radiographs. Panoramic radiography was used in this study because an image of both the jaws can be produced on one film quickly and conveniently with relatively lesser radiation exposure.[2] Magnification is one of the major problems with panoramic radiography. Larheim and Svanaes[12] investigated the precision of measurements of mandibular linear dimensions in panoramic radiographs and found that the variability of vertical measurements made from repeated

panoramic radiographs is small when patients are properly positioned in the panoramic apparatus.

In the current study, a reference line was drawn touching the inferior border of the mandible. From this line, vertical lines were drawn to the lower border of the radiopaque markers in five different regions. According to Xie *et al*., if reference lines and measured points are located in the same vertical plane or approximately the same plane as the teeth, variations in vertical measurements in the mandible and maxilla are within a small range.[13]

Enlow *et al*. described the distribution of surface fields of resorption and deposition in all parts of the edentulous mandible and stated that residual ridge resorption is usually more rapid in the premolar and molar region than the anterior region of the mandible due to the lower position of the reversal line in the posterior region. Hence, it is especially important to record the resorption in the anterior and posterior region of the mandible.[14]

There is a statistically significant difference in the bone loss between conventional and soft-lined dentures ($P < 0.05$). Less resorption with acrylic-based soft-liner as compared to silicone-based soft liner may be because acrylic resin shows viscoelastic behavior and higher levels of cushioning effect. Similar results were obtained by Elcharkawi and ElMahdy, when the bone loss in the mandible after 6 months of denture delivery was compared with and without soft liners.[14] Babu *et al*. also obtained the same results when comparing bone loss in mandible after 6 and 12 months of denture insertion with and without soft liners.[2] ii) Taguchi *et al*.[7] stated that acrylic resilient liner material showed a higher viscoelastic behavior than silicone material after applying the stress and have the ability of stress distribution or stress relaxation. Contrary to this study, Al-Noori and Said[1] found no significant difference in bone resorption with and without soft liner in complete denture patients.

Although ridge reduction has occurred in all three groups, the rate of ridge reduction under dentures incorporating a resilient material is apparently much less than that which occurred under conventional dentures. This reduction is attributed to the effect of the resilient materials sandwiched within the denture base. Thus, the use of the resilient reliner material considerably minimized the stress in the alveolar bone and mucosa.

The main limitation of this study is the short study period. Cushioning effect of soft liner decreases over time, so they have to be replaced repeatedly. Further studies may be validated on a larger sample size and comparisons with other different relining materials.

CONCLUSION

Acrylic-based resilient denture liners are beneficial for both the patients and clinicians, as problems affecting the mucosa during the first denture adjustment session following the initial fitting of the dentures are the severest and the most annoying for complete denture wearers. Although acrylic denture liner bonds chemically to denture base, only problem that arises is the longevity of the denture liner and its long-term maintenance. The risk-benefit ratio should be analyzed before the use of this material.

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How to cite this article: Kouser M, Nair C, Khurana A, Saifi D, Budakoti V,Shukla AK. Effect of Different Denture Soft Liners on Mandibular Ridge Resorption in Complete Denture Wearers: An *In-vivo* Study. Int J Sci Stud 2021;9(2):38-42.

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

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

Original Article

Emergence from Anesthesia in Children – A Prospective Comparative Study between Volatile Induction and Maintenance Anesthesia and Total Intravenous Anesthesia

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Abstract

Background: Two anesthetic techniques are frequently used in day care surgery, total intravenous anesthesia (TIVA) and volatile induction and maintenance anesthesia (VIMA). They have been extensively used and studied. These mainly involve the induction phase and maintenance phase. The rapid redistribution of intravenous agent could lead to lightening of anesthesia before an adequate depth is achieved with the inhalational agent. This has promoted the rediscovery of single agent anesthesia, which avoid problems related with the transition phase.

Materials and Methods: This randomized controlled trial was conducted in 120 pediatric age group population undergoing inguinal herniotomy under the age group of 2–10 years of the American Society of Anesthesiologists I, II physical status. Patients were randomly divided into two groups of 60 each. Group P received i/v propofol 2–3 mg/kg for induction and 100–400 mcg/kg/min infusion for maintenance. Group S received 8% sevoflurane in 33% of oxygen for induction and 2–3% sevoflurane in 33% oxygen for maintenance. Both the groups received ilioinguinal iliohypogastric block using 0.2% ropivacaine. In both the groups, patients were kept on spontaneous ventilation using Jackson Rees modification of Ayre T piece.

Results: Patients of Group S (VIMA) had early recovery with near-complete achieved modified Aldrete score and pain-discomfort score. Group P patients were relatively calm and less agitated when compared to Group S.

Conclusion: In our study on emergence from anesthesia in children a prospective comparative study between VIMA and TIVA, we found early emergence in VIMA with early cry, early eye opening, and early movement of all four limbs with more incidence of post-operative nausea and vomiting (PONV), while delayed emergence less agitation and no incidence of PONV associated with TIVA with above-mentioned limitations.

Key words: Propofol, Sevoflurane, Total intravenous anesthesia, Volatile induction and maintenance anesthesia

INTRODUCTION

The ideal anesthetic technique for pediatric anesthesia should provide a rapid, smooth induction of anesthesia, stable hemodynamics with superior operating conditions, intraoperative amnesia and analgesia, and prompt awakening at the end of the procedure.[1] In view of this, fast induction and emergence from anesthesia is essential.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

Two anesthetic techniques are frequently used in day care surgery, total intravenous anesthesia (TIVA) and volatile induction and maintenance anesthesia (VIMA). They have been extensively used and studied. These mainly involve the induction phase and maintenance phase. The rapid redistribution of intravenous (IV) agent could lead

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to lightening of anesthesia before an adequate depth is achieved with the inhalational agent. This has promoted the rediscovery of single agent anesthesia, which avoid problems related with the transition phase.

We undertook to study the efficacy of these techniques on spontaneously breathing pediatric patients for short duration surgery. Propofol is short-acting general anesthetic agent and is used extensively for TIVA because of its favorable induction properties and quick clearance due to its high metabolic clearance rate. The patient rapidly regains consciousness after discontinuation of the propofol infusion and may be discharged with minimal residual sedation after short outpatient procedure.

VIMA facilitates anesthesia without the need for IV drugs. Sevoflurane is ideal inhalational anesthetic for its properties of being an agent for VIMA leading to faster elimination from body and quicker recovery from anesthesia.[2] These properties make sevoflurane, especially suitable for day surgery in children.

This study was designed to compare emergence and quality of recovery from anesthesia using TIVA with propofol and VIMA with sevoflurane, in children undergoing inguinal herniotomy.

MATERIALS AND METHODS

This study was conducted in the Department of Anaesthesiology in Pediatric Operation Theater at NSCB Medical College and Hospital, Jabalpur. This prospective, randomized, double-blind study included 120 patients of the American Society of Anesthesiologists Grade I and II, age 2–10 years who underwent inguinal herniotomy. Prior ethical permission was taken from our the Institutional Ethical Committee and Review Board and written informed consent was obtained from all parents on behalf of the patients enrolled in the study.

Careful pre-anesthetic evaluation was done and it was made sure that the patients meet the inclusion and exclusion criteria. The patients were randomized on the day of surgery into two groups by sealed envelope method.

Group P allotted 60 patients and 60 patients were allotted in Group S randomly.

- Group P: Group P received propofol 2–3mg/kg IV for induction and 100–400 μg/kg/min IV infusion for maintenance of anesthesia and was oxygenated through face mask using Jackson Rees modification of Ayres T piece. Ilioinguinal and iliohypogastric nerve block was given with 0.2% ropivacaine (0.4 ml/kg) as a measure to achieve post-operative analgesia
- Group S: Group S received inspired concentration (through a facemask) of sevoflurane 8% in 33% oxygen with 66% nitrous oxide for induction and 2–3% of sevoflurane in 33% oxygen with 66% nitrous oxide for maintenance of anesthesia. Ilioinguinal and iliohypogastric nerve block was given with 0.2% ropivacaine (0.4 ml/kg) as a measure to achieve post-operative analgesia.

Jackson Rees modification of Ayre's T-piece circuit was used for the delivery of gases to the patients during anesthesia through facemask. Patients were allowed spontaneous breaths and were adjusted to keep normoxia with oxygen saturation ≥98%.

After the completion of surgical procedure, the propofol infusion and sevoflurane were stopped and 100% oxygen administered.

- The following was recorded by an anesthetist blind to the anesthetic technique used: Time from discontinuation of anesthetic to the movement of the limbs
- Time from discontinuation of anesthetic till the child started crying or was able to state own name
- Recovery characteristics and the quality of emergence was compared using: Modified Aldrete score
- Pain-discomfort scale.

These were recorded by an anesthetist blind to the anesthetic technique, for every 3rd min till 15 min in the recovery.

The "Modified" Aldrete scale

Respiration	2 Able to take deep breath and cough	1 Dyspnea/shallow breathing	0 Apnea
02 saturation	2 Maintains >92% on room air	1 Needs 02 inhalation to maintain 02 saturation >90%	0 Saturation <90% even with supplemental 02
Consciousness	2 Fully awake	1 Arousable on calling	0 Not responding
Circulation	2 BP a 20 mmHg pre-operative	1 BP a 20–50 mmHg pre-operative	0 BP a 50 mmHg pre-operative
Activity	2 Able to move 4 extremities voluntarily or on command	1 Able to move 2 extremities voluntarily or on command	0 Able to move 0 extremities voluntarily or on command

Pain-discomfort scale (FLACC)			
	Scoring		
Items	**0**	**1**	**2**
Blood pressure	>10% of pre-operative level	>20% of pre-operative level	>30% of pre-operative level
Crying	Not crying	Crying but responds to tender loving care	Crying and does not respond to tender loving care
Movement	Mild	Restless	Thrashing
Agitation	None	Patient asleep or calm	Hysterical
Posture	No special posture	Flexing legs and thighs	Holding scrotum or groin
Complaints of pain (When appropriate states no pain by age)	Asleep, or	Cannot localize	Can localize

OBSERVATION AND RESULTS

Values are number (%) of TIVA and VIMA. There were 37 (60%) males in P group while 34 (57.5%) males in S group. Both the groups were comparable in terms of patients demographic data, duration of surgery, and duration of anesthesia [Table 1].

Emergence from anesthesia occurred significantly earlier in the S group as compared to P group as evident by time to eye opening, time to move all four limbs, and time to cry/stating name ($P = 0.0054$) [Table 2].

Similarly, more patients in the S group scored maximum points in the modified Aldrete score at 10 min ($P = 0.0026$) and 20 min ($P = 0.013$) and 30 min ($P = 0.019$) and 40 min ($P = 0.0185$). This study again indicated an early recovery in sevoflurane VIMA group. However, at 50 min ($P = 1$), the difference was insignificant [Table 3].

Similarly, more no. of patients in sevoflurane group scored maximum points in pain-discomfort scale at 10 min ($P = 0.08$), 20 min ($P = 0.223$), and 30 min ($P = 0.006$), while at 40 min onward, none of the patients in either group scored maximum points in the pain-discomfort scale [Tables 3 and 4] [Graphs 1-4].

DISCUSSION

This study was designed to compare emergence and quality of recovery from anesthesia using TIVA with propofol and VIMA with sevoflurane in children undergoing inguinal herniotomy.

In this study, induction with both propofol and sevoflurane was well tolerated. Children in the sevoflurane VIMA group opened their eyes, cry/stating their names, moving all four limbs, interacted with the environment, and scored maximum points on the modified Aldrete scale earlier than in the propofol (TIVA) group.

This study all demographic variables (age, weight and height of patient) and duration of surgery and duration of anesthesia were comparable in both groups with no significant difference. Time of induction in our study was 3.1 ± 1.9 min in Group P and 5 ± 2.3 min in Group S ($P < 0.001$) which is in concordance with the study of Chen *et al*.[3] in which early induction was observed with propofol than sevoflurane which was 34.8 ± 2.4 s in comparison to 81.6 ± 4.7 s, ($P < 0.001$). In concordance with our study, Chen *et al*. also notified more incidence of agitation with sevoflurane in induction and in emergence as well. In our study, agitation was observed in 10 (16.67%) patients in induction phase and in 3 (5%) patients in emergence in Group P. In Group S, agitation was observed in 24 (40%) patients in induction phase and in 33 (55%) patients in emergence. Similarly, in a study of Uezono *et al*.,[4] total incidence of agitation was 38% in sevoflurane group while no agitation was reported in patients using propofol. TIVA consumes lesser time for induction and better stress response which was observed in the form of hemodynamic variables with lesser undesired adverse event. Meanwhile, Guedel second stage of inhalation anesthesia is more apparent in VIMA. Komatsu *et al*. reported electrical seizures in pediatric patient in sevoflurane induction. While using VIMA as induction and maintenance technique, heart rate and mean arterial pressure (MAP) variations were observed in pediatric population age group.[3] Although the same induction and maintenance techniques was employed in adult population, it revealed insignificant variation in heart rate and MAP.[5-7]

Prolong induction in Group S was assumed to be one of cause for agitation. Sevoflurane is pleasant and smooth so preferred as inhaled agent in pediatric group of population. In our study, patients have more anxiety due to separation from parents, intolerance, to NBM duration and restraint with mask while using VIMA method. In Group P, where TIVA method was used, cause of agitation is thought be pain on injection propofol. Unlike to our study in some other, they used IV lignocaine along with propofol which might be a source of error/bias in study. Pre-operative benzodiazepines and other sedatives are recommended to alleviate the agitation in pediatric patient which was not used in our study. In concordance with our study, Welborn *et al*.[8] reported more emergence agitation in sevoflurane anesthesia. In the present study, emergence agitation was significantly higher in Group S, 33 (55%) than Group P which is observed only in 3 patients (5%), it was due to

lesser solubility of sevoflurane which causes early recovery from anesthesia causing anxiety.

Table 1: Demographic data, duration of surgery, and anesthesia

Demographic data	Propofol group (*n*=60)	Sevoflurane group (*n*=60)	*t*-test	*P*-value+
Age (years) (mean±standard deviation)	5.2±2.1	5.8±1.8	1.68	0.095
Weight (kg) (mean±standard deviation)	21.6±6.5	22.2±6.2	1.38	0.06
Height (cm) (mean±standard deviation)	116±22.2	122±24.3	1.41	0.161
Duration of surgery (min) (mean±standard deviation)	36.8±11.5	30±10.1	1.92	0.057
Duration of anesthesia (min) (mean±standard deviation)	42.6±12.8	40.8±9.8	0.86	0.389

Table 2: Induction time, time to spontaneous eye opening, time to move all four limbs, and crying/stating name

Induction and emergence times (min)	P group (*n*=60) Mean±SD	S group (*n*=60) Mean±SD	*P*-value
Induction time	3.1±1.9	5.0±2.3	<0.001
Time to eye opening	9.5±5.1	4.9±2.7	<0.001
Time to move all four limbs	14.2±6.9	11.2±4.8	0.0066
Time to crying/stating name	15.3±7.1	12.1±5.1	0.0054

Similarly, Liao *et al*.[9] concluded early emergence and increased excitement in sevoflurane volatile induction in comparison to propofol/remifentanil i/v anesthesia in foreign body removal in children with $P < 0.05$. Gil *et al*.[10] study was consistent with our study in which rapid emergence was reported with sevoflurane than propofol in pediatric patients in infraumbilical surgeries. Likewise, Ledowski *et al*.[11] stated better inhibition of neuroendocrinal stress in TIVA than sevoflurane. Similar to our study, Hugo *et al*.[12] reported more rapid recovery in prolonged neurological procedures in sevoflurane maintenance anesthesia than propofol, that is, 3 min and 4 min, respectively ($P = 0.01$).

In our study, time to eye opening in Group P was 9.5 ± 5.1 min and 4.9 ± 2.7 min in Group S ($P < 0.001$) which is supported by Pasha *et al*.[13] who reported significantly earlier eye opening in group S than in Group P ($P = 0.043$). Similarly, Viitanen *et al*.[14] also demonstrated early eye opening, early cry/sound in sevoflurane group. In our study, after 20 min of discontinuation of anesthesia, 75% of patients achieved full Aldrete score in sevoflurane group and in 54% in Group P, which is also supported by Viitanen *et al*.[14] who demonstrated that more children acquired full Aldrete score in sevoflurane group than propofol group in the first 20 min after anesthesia ($P < 0.05$). Likely, Pasha *et al*.[13] also concluded similarly that 80% of patients in Group S achieved full Aldrete score in initial 20 min after discontinuation of anesthesia whereas it is achieved in only 57.5% of patients in Group P ($P = 0.03$). Likewise, the study of Maidatsi *et al*.[15] and Peduto *et al*.[16]

Table 3: Number of patients achieving maximum scores after discontinuation of anesthetic drug

Time after discontinuing drugs (min)	Modified Aldrete score full/max (10)						Pain-discomfort scale full/max (10)					
	Propofol (*n*=60)		Sevoflurane (*n*=60)		Z statistics	*P*-value	Propofol (*n*=60)		Sevoflurane (*n*=60)		Z statistics	*P*-value
	n	%24.5	*n*	%			*n*	%	*n*	%		
10	10	17	25	42	3.01	0.02	6	9.8	13	22	1.75	0.22
20	32	54	45	75	2.47	0.03	4	70	8	13	1.22	0.13
30	40	67	51	86	2.35	0.05	0	0	7	12	2.73	0.11
40	47	78	56	94	2.36	0.06	0	0	0	0	1	1
50	60	100	60	100	2.32	1	0	0	0	0	1	1

Table 4: Adverse reactions

Reaction	TIVA (*n*=60)			VIMA (*n*=60)		
	Induction	Maintenance	Emergence	Induction	Maintenance	Emergence
Coughing	0	0	14 (24%)	0	0	24 (40%)
Laryngospasm	0	0	0	0	0	0
Nausea	0	0	0	0	0	0
Vomiting	0	0	0	0	0	2 (3.33%)
Bronchospasm	0	0	0	0	0	0
Agitation	10 (16.67%)	0	3 (5%)	24 (40%)	0	33 (55%)
Other	0	0	0	0	0	0

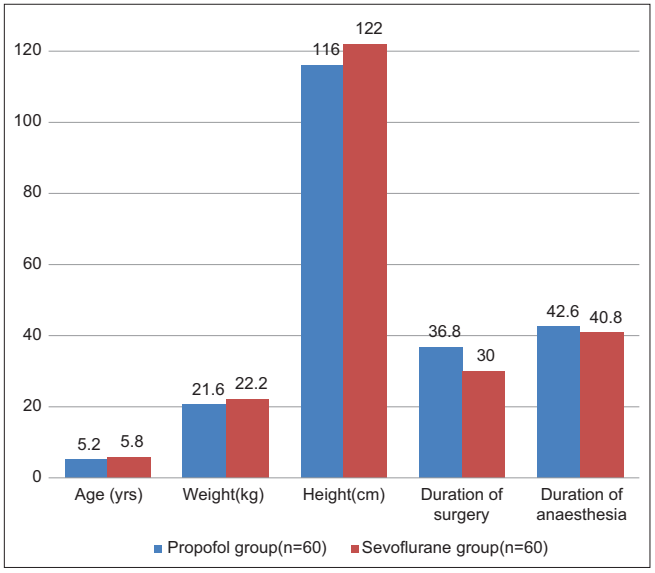
TIVA: Total intravenous anesthesia, VIMA: Volatile induction and maintenance anesthesia

also reported early recovery in sevoflurane anesthesia than propofol with fentanyl anesthesia for day care surgery. In contrast to our study, Magni *et al*.[17] reported no significant difference in emergence time and early cognitive function between sevoflurane/fentanyl and propofol/remifentanil in intracranial surgery. In our study, no incidence of post-operative nausea and vomiting (PONV) was reported in Group P and in Group S only 2 (3.3%) patients reported PONV, which was in concordance with the study of Fredman *et al*.[18] and study of Nathan *et al*.[19] They also reported increased incidence of PONV in sevoflurane anesthesia. PONV is one of the reasons for prolonged stay in recovery, delay discharge, and unanticipated overnight stay in day care surgeries specially in pediatric group of population.[20,21] Early recovery is one of the leading factors associated with good hospital turnover and offers an economic advantage in a day care unit.[22,23] Lesser incidence of PONV in propofol group patients in various studies is due to antiemetic property of propofol. In concordance with our study, Moore *et al*.[24] observed significantly higher nausea in sevoflurane group (11 episodes) and in six patients in propofol with halothane group. In a study of Uezono *et al*.,[4] only 2 cases/(6.25%) episodes of PONV reported in sevoflurane anesthesia in ward which is similar to the present study.

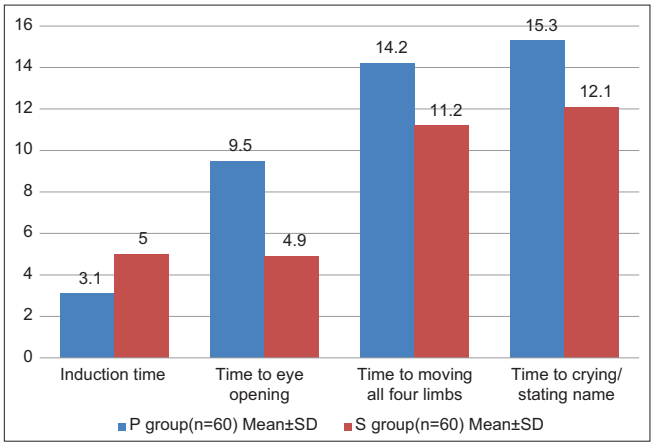
In a study of Pasha *et al*.,[13] higher pain-discomfort score was achieved by patient in sevoflurane group at different time interval after discontinuing the anesthetic agent than propofol group, but it was statistically insignificant. In Viitanen *et al*.[14] study, higher pain-discomfort score was achieved in sevoflurane group at 10 min after discontinuation of anesthesia but it was statistically significant. ($P = 0.04$) but the same was insignificant at interval of 20 min after discontinuation of anesthetic agent. ($P = 0.06$). Although in same study time to emergence, making sound and interaction were earlier in sevoflurane group which is in concordance with our study. Another study by Hugo *et al*.[4] also stated that there were no significant difference in visual analog scale score for the assessment of pain in either group using sevoflurane and propofol. Uezono *et al*.[4] also delivered the same conclusion about the post-operative pain in sevoflurane versus propofol in pediatric population that no additional analgesic required in post-anesthesia care unit (PACU) in either group of patients.

All these studies were similar to our observations in which we observed higher pain-discomfort score in Group S than Group P at 10, 20, and 30 min after discontinuing anesthesia (27.27% vs. 10%), (13.3% vs. 6.66%), and (12% vs. 0%), respectively, but all these were statistically insignificant with $P > 0.05$. Modified Aldrete scoring system and pain-discomfort score both were used to assess the recovery from anesthesia and quality of emergence by Hanallah *et al*.[24]

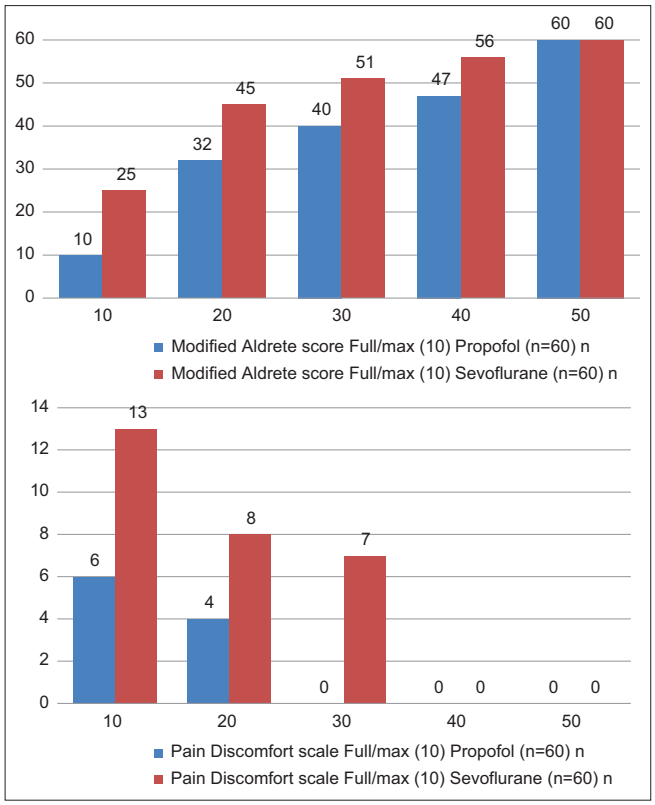
In the present study, time to spontaneous eye opening after discontinuation of anesthesia in Group P and Group S was 9.5 ± 5.1 min and 4.9 ± 2.7 min, respectively ($P < 0.001$), which was similar to the study of Uezono *et al*.[4] who observed significantly early eye opening in sevoflurane group at 19 ± 8 min than propofol group at 32 ± 16 min ($P < 0.05$). Similarly, early eye opening was there in a study by Hugo *et al*.[12] ($P < 0.001$). Likewise, Pasha *et al*.[13] also witnessed the same in their study, in which early eye opening was there in sevoflurane group at 4.7 ± 2.6 min and at 8.3 ± 6.9 min in propofol group ($P = 0.017$). In same study, time to cry/stating the name was also earlier in sevoflurane group at 11.3 ± 4.6 min than propofol group at 14.7 ± 7.2 min ($P = 0.039$) which is in concordance with the present study. In our



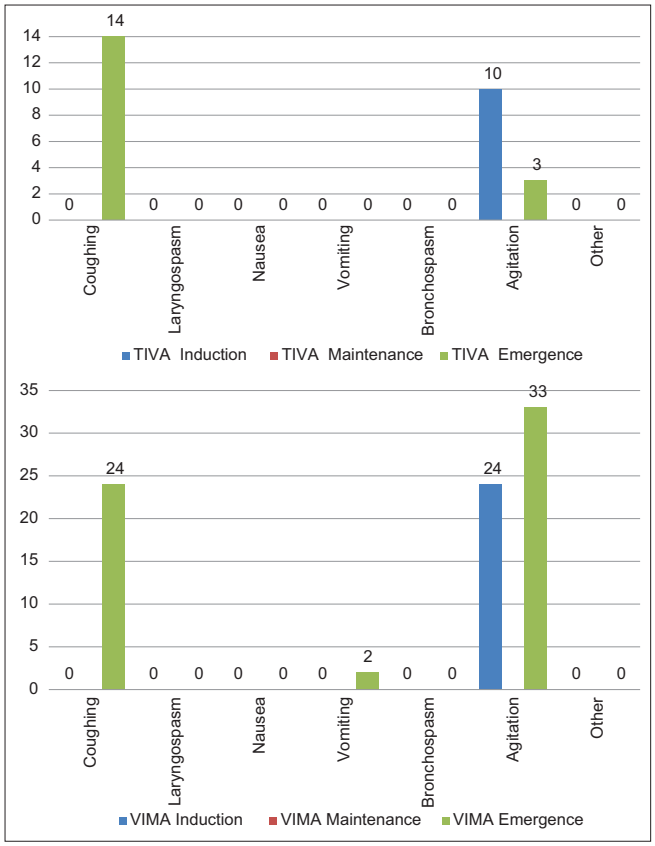
Graph 1: Demographic data, duration of surgery, and anesthesia



Graph 2: Induction time, time to spontaneous eye opening, time to move all four limbs, and crying/stating name



Graph 3: Number of patients achieving maximum scores after discontinuation of anesthetic drug



Graph 4: Adverse reactions

study, time to cry/stating the name in Group P patient was 15.3 ± 7.1 min and it was 12.1 ± 5.1 min Group S patients ($P = 0.005$). In a study of Viitanen *et al*.,[14] early recovery variables were observed in sevoflurane patients, in which making sound was noticed in sevoflurane group at 10 ± 4 min and at 15 ± 7 min in propofol group ($P = 0.002$), although early recovery using different variables was observed in our study in Group S patients but in other studies such as Aono *et al*.[25] and O'Kelly *et al*.[26] showed greater incidence of emergence delirium during recovery from sevoflurane anesthesia in preschool population. Sevoflurane anesthesia in preschool population, which may be due to the age effect of the studied population and unfamiliar surroundings. Westrin *et al*.[27] also found that post-anesthetic agitation was related to age of children and not to the perception of pain. It had been also suggested by O'Kelly *et al*.,[26] shorter time to emergence may contribute to post-operative delirium.

Many studies had notice early recovery in sevoflurane anesthesia predominantly in day care anesthesia.[28] Even in prolonged duration of anesthesia in neurological procedures, same was observed by Hugo *et al*.[12]

In our study, other adverse events as laryngospasm and coughing were not observed either at induction or emergence in both groups. Emergence agitation may lead to threaten complication such as inadvertent movement, falling from operation table, and accidental removal of drain catheter or i/v cannula or self-injury, so while dealing with preschool population in operation rooms, it is necessary for anesthesiologist, surgeons, and other care providers to keep continuous and intensive alertness. Comparison of inhaled and i.v anesthetic in such scenario is much complicated. In our study, clinical crude variables were used for the assessment of emergence agitation, no monitoring of depth of anesthesia using BIS devise or other was there. For pain, ilioinguinal iliohypogastric block was given by surgeon using 0.2% ropivacaine (0.4 ml/kg) immediately after induction with land mark technique. Authenticity of all these methods is not so much reliable, so all these were limitation of our study because depth of anesthesia and pain stimulus may be contributor to emergence agitation.

Despite early emergence in Group S patients leading good case turn over, minimum stay in PACU, and other economical benefits, it failed to gain parent satisfaction. Because this is not surprising, maximum parents are unaware of duration of PACU stay, if they were allowed to be in PACU, no one like to see his/her child to be agitated. Instead a slower but smoother course of recovery after propofol anesthesia is more appealing to parents. PONV was also more associated with sevoflurane anesthesia.

CONCLUSION

In our study on emergence from anesthesia in children a prospective comparative study between VIMA and TIVA, we found early emergence in VIMA with early cry, early eye opening, and early movement of all four limbs with more incidence of PONV, while delayed emergence less agitation and no incidence of PONV associated with TIVA with above-mentioned limitations. There is more to explore in this scenario, especially in pediatric group of population.

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How to cite this article: Rawat K, Sharma SN, Maravi GS, Rajoriya K, Sethi A, Narang N, Agrawal V. Emergence from Anesthesia in Children – A Prospective Comparative Study between Volatile Induction and Maintenance Anesthesia and Total Intravenous Anesthesia. Int J Sci Stud 2021;9(2):43-49.

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

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

Original Article

A Study of Surgical Management of Distal Humerus Fractures

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Abstract

Introduction: Distal humeral fractures are uncommon injuries that account for fewer than 2% of all adult fractures. The complex shape of the elbow joint, the adjacent neurovascular architecture, and the sparse soft tissue envelope combine to make these fractures difficult to treat. The quality of elbow function following intercondylar fractures of humerus is related to the degree to which normal anatomical relationship are restored.

Purpose: The purpose of this study was to determine the functional outcome of various surgical methods of distal humeral fractures in adults.

Materials and Methods: This study consists of 36 patients with fracture of distal humerus treated by open reduction/close reduction and internal fixation with K-wires, reconstruction plate, and cannulated cancellous screws. Postoperatively, patients were reviewed every 2 weeks for the first 2 months and monthly for the next 2 months, then every 2 months until fracture healing or full range of motion was regained. Postoperatively elbow function was evaluated using physician-based elbow scoring systems using Mayo Elbow Performance Index (MEPI).

Results: In this study, significant difference was found between gender and mode of injury, including road traffic accident (RTA) and falls (P = 0.003) with most cases occurring because of RTA. A significant difference existed in the mean duration of union for implants used (P = 0.048). K wire + recon plate + cancellous screw gave the highest MEPI mean score of 94.86 ± 33.39. However, the K wire group showed the least mean MEPI score of 61.36 ± 22.03. A significant association was observed between implants used and the outcome (P = 0.038).

Conclusion: Reconstruction plate alone or a combination of reconstruction plates and cannulated cancellous screws offers excellent results in the distal humeral fracture in adults and can be considered as the first-line of management.

Key words: Fracture, Humerus, Mayo elbow performance index, Open reduction

INTRODUCTION

We live in a society with a growing elderly population and a young population in which extreme sports and high-speed motor transportation are popular; therefore, the incidence of distal humeral fractures is likely to increase. In young adults, most distal humerus fractures occur from high-energy trauma, sideswipe injuries, motor vehicle accidents, falls from height, and gunshot wounds. In elderly persons with more osteoporotic bone, most of these injuries occur from falls.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

Distal humeral fractures are uncommon injuries that account for fewer than 2% of all adult fractures. The complex shape of the elbow joint, the adjacent neurovascular architecture, and the sparse soft tissue envelope combine to make these fractures difficult to treat. So the complex nature of the unstable distal humeral fracture has promoted a global interest in more precise treatment for this diverse group of injuries. Acceptable results have been reported in most patients treated by open reduction and internal fixation.[1] The only reliable method for restoring the normal alignment and contour of distal humerus is operative exposure and direct manipulation of fractures and fragments. Surgical treatment for these fractures has evolved significantly in the last 30 years. In the 1960's and 1970's, most surgeons

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condemned surgical treatment due to high failure rates with loss of fixation, non-union, and elbow stiffness.[2] In the 1970s, treatment began to shift from casting and the "bag of bones" technique to surgical intervention with limited internal fixation. Again, results generally were poor due to a lack of adequate stabilization for early motion.

In the early 1980s, the AO-ASIF group reported good and excellent results in 27 of 39 patients with communited fractures of the distal humerus.[3] These were the best results reported in the treatment of these difficult fractures at that time. This led to increased enthusiasm for surgical reduction and fixation. A surgeon treating a healthy active patient with a fracture distal humerus should make every attempt to reconstruct and preserve the distal humerus. The quality of elbow function following intercondylar fractures of humerus is related to the degree to which normal anatomical relationship are restored. Residual elbow stiffness remains the worst complication of intercondylar fractures as it is poorly tolerated because of a lack of compensatory motions in adjacent joints.

Hence, improved understanding of the complex pathoanatomy of unstable distal humerus fractures in adults has prompted a global interest in more precise treatment for this diverse group of injuries. Surgeons who treat fracture of the distal humerus frequently have realized the challenges that arise relate to poor bony quality, distal separation of the articular fragment from the columns of the distal humerus, and fragmentation of the articular surface in one or more planes. Varying patterns of distal humeral fractures are common in adults. Malunion is also common. Even minor irregularities of the joint surface of the elbow usually cause some loss of function. The purpose of this study was to determine the functional outcome of various surgical methods of distal humeral fractures in adults.

MATERIALS AND METHODS

This study was conducted among 36 patients with fracture of distal humerus, treated by open reduction/close reduction and internal fixation with K-wires, reconstruction plate, and cannulated cancellous screws between April 2015 and August 2016 after obtaining the clearance from ethical committee at Vinayaka Missions Kirupananda Variyar Medical College Hospital, Salem. Out of all the above, 21 treated by open reduction and internal fixation with reconstruction plates (3.5 mm), cancellous screws, K-wires, and 9 patients were treated by closed reduction and internal fixation with K wires.

Most of the patients presented to hospital within 24 h of injury of distal humerus. Only 7 patients presented within a week after sustaining the injury. About 90% of the patients presented with injured forearm supported with hand, while 10% patients came with their injured limb immobilized with plaster of Paris slab. On admission of the patient, careful history was elicited from the patient or attendants to reveal the mechanism of injury. The patients were examined clinically for signs of fracture displacements, deformity, neurovascular status associated injuries, and for vital signs.

According to the AO classification, 14 patients belong to Type A, 7 patients Type B, and 14 patients Type C (5 Type C1, 6 Type C2, and 3 Type C3).[4] After thorough clinical evaluation X-ray of the affected forearm was taken in both anteroposterior and lateral view, including shoulder and elbow joints. The limb was immobilized in the above elbow slab with positioning the forearm in supination or mid prone according to the site of fracture with sling. The surgery was done and post-operative care given.

The patient comes for follow-up on 14th post-operative day. The sutures were removed. In patients with rigid fixation, active gentle motion of involved limb several times a day in concurrence with the pain was advised. All patients had to demonstrate >40° of range of motions within a month. He can be subjected for active physiotherapy after 1 month and full activity after 3 months. Full activity was allowed at 3–4 months as fracture consolidation occurred. Postoperatively, patients were reviewed every 2 weeks for the first 2 months and monthly for the next 2 months, then every 2 months until fracture healing or full range of motion was regained.

Postoperatively, elbow function was evaluated using physician-based elbow scoring systems using Mayo Elbow Performance Index (MEPI).[5]

The data were collected in Microsoft Excel and analyzed using SPSS version 16. All study variables were analyzed using descriptive statistical methods such as frequencies and percentages for categorical variables and mean with standard deviation for continuous variables. The various factors and their relation were studied using Chi-square tests and Fischer's exact test to find associations. Analysis of variance (ANOVA) was used to find the significant difference between mean values of multiple variables under study. P <0.05 was considered significant.

RESULTS

The distribution of age of the study population is from 18 to 70 years. Out of the 36 patients, 16 patients (44.0%)

were between the age group of 18–30 years, eleven patients (31.0%) between 30 and 50 years, and 9 patients (25.0%) between 50 and 70 years. A significant difference existed between the mean age of males and females (t = 4.09; P = 0.001). Female patients were found to have significantly higher age (mean =51.91 years) compared to males (mean =31.40 years). Maximum cases were recorded in the age group of below 30 years (44%) and least was in the age group below 70 years.

The pattern of distribution of cases of male and female patients in different modes of injury was statistically different, where male patients had more of road traffic accidents (RTA) while female patients had more of falls. When gender and mode of injury were considered, a significant Chi-square (Chi-square =8.96; P = 0.003) value was observed, revealing that frequencies of mode of injury differed significantly with gender. Maximum cases were reported in RTA, followed by fall.

Equal number of injuries was reported in both right (18) and left side (18). A non-significant association was observed between age group and mode of injury (P = 0.301), indicating that the pattern of injury in different age groups is statistically the same. Table 1 shows the distribution of the samples by type of fracture.

A non-significant association was observed between sex and type of fractures (Chi-square =5.88; P = 0.208), as well as between type of fracture and associated injuries (Chi-square =13; P = 0.369). There was no significant association between type of implant used and age groups (Chi-square =12.64; P = 0.396) and between type of implant used and gender (Chi-square =2.80; P = 0.834). Table 2 shows the distribution of the sample by the side of injury and the implant used.

A significant difference existed in the mean duration of union for implants used (Chi-square=2.41, P = 0.048) [Table 3]. K-wire + Recon plate with cancellous screws and Recon plate (10 weeks) alone had taken least duration for union while Recon plate + cancellous screw + Tension Band Wiring (TBW) had maximum duration (30 weeks).

Table 4 shows mean flexion-extension, flexion contracture, supination and pronation, and MEPI. The flexion-extension arc had a mean value of 94.86 ± 33.39. The MEPI had a mean value of 72.64 ± 21.46.

A non-significant difference was found in the mean flexion extension values of different implants used as ANOVA value revealed a non-significant value of 1.498 with P = 0.214. Flexion contracture showed a non-significant result in different implants used as ANOVA revealed a non-significant value (ANOVA =0.901; P = 0.508). Similarly, pronation (ANOVA =0.764; P = 0.604) and

Table 1: Distribution of sample by type of fracture

Fracture type	Frequency	Percent
Supracondylar	13	36.1
Supracondylar with intercondylar	10	27.8
Lateral condyle	4	11.1
Intercondylar	7	19.4
Medial condyle	2	5.6
Total	36	100.0

Table 2: Distribution of the sample by the side of injury with implant used

Implants used	Left (%)	Right (%)	Fischer's Exact value	*P*-value
K-wire+recon plate+cancellous screw	0 (0.0)	1 (100.0)	11.02	0.888
K-wire+cancellous screw fixation	2 (20.0)	8 (80.0)		
K-wire	7 (64.0)	4 (36.0)		
Recon plate	1 (50.0)	1 (50.0)		
Recon plate+cancellous screw	8 (80.0)	2 (20.0)		
Recon plate+cancellous screw+TBW	0 (0.0)	1 (100.0)		
Recon plate+K-wire	0 (0.0)	1 (100.0)		
Total	18 (50.0)	18 (50.0)		

TBW: Tension band wiring

Table 3: Mean duration of union with different implants

Implants used	*n*	Union in weeks			ANOVA	*P*-value
		Mean	SD	Std. Error		
K-wire+recon plate+cancellous screw	1	10.00	–	–	2.41	0.048*
K-wire+cancellous screw fixation	10	14.50	8.29	2.62		
K-wire	11	11.82	2.99	0.90		
Recon plate	2	10.00	0.00	0.00		
Recon plate+cancellous screw	10	12.10	1.52	0.48		
Recon plate+cancellous screw+TBW	1	30.00	–	–		
Recon plate+K wire	1	12.00	–	–		

TBW: Tension band wiring

Table 4: Descriptive statistics for the flexion-extension, flexion contracture, supination, pronation, and MEPI

Parameters	Minimum	Maximum	Mean	SD
Flexion extension arc	35	140	94.86	33.39
Flexion contracture	5	60	26.39	16.93
Supination	5	71	56.69	20.02
Pronation	5	84	66.53	23.96
MEPI	35	95	72.64	21.46

MEPI: Mayo elbow performance index

supination (ANOVA =0.780; $P = 0.592$) showed a non-significant result in different implants used.

MEPI values of different implants used showed a non-significant result (ANOVA =1.119; $P = 0.376$). Comparatively, K-wire + recon plate + cancellous screw gave the highest MEPI mean score of 95. However, the K-wire group showed the least mean MEPI score of 61.36 ± 22.03. K-wire had maximum stiffness of 55% and patients treated with recon plate alone did not show any complications. Furthermore, combinations with recon plates had the least complications.

A significant association was observed between implants used and the outcome (Fisher's Exact value =29.95; $P = 0.038$) [Table 5]. K-wire + recon plate + cancellous screw implant, Recon plate + cancellous screw, and Recon plate implant had the better results in treatment compared to K-wire implant.

DISCUSSION

Functional elbow is very essential for an individual for social and economic well-being. Fractures of the distal humerus may affect the functional movement of elbow, especially intercondylar (intra-articular) fracture. The relationship of the radiohumeral joint and ulnohumeral joints must be perfect for functional outcome.

The restoration of elbow function is dependent on three salient features: Exposure, fixation, and post-operative rehabilitation, with later two are of primary consideration. Adequate exposure is necessary for visualization of the bone injury and fixation of the fracture fragments. The optimal exposure is provided by posterior approach with extra-articular osteotomy of the olecranon. This allows complete examination of the articular surfaces of trochlea, capitellum, olecranon, and radial head. It also gives access to the medial and lateral supracondylar ridges. Full evaluation of the fragments of the fracture and reduction can then be performed. Although non-union of the extra-articular osteotomy may be regarded as a potential complication of this exposure, TBW of the osteotomy has provided sufficient stability of the olecranon for immediate use of the elbow through a secure range of motion without the occurrence of non-union.

The distal humeral fractures were observed to be more common between 18 and 70 years and number of cases decreased linearly as age increases. The minimum age was 18 years and maximum age was 70 years (mean age of 31.40 for males and 51.91 for females). The age distribution could be compared to earlier studies done by Holdsworth and Mossad[6] in which the mean age for males was 33.4 years and for females was 42.4 years. Majority of our patients were males attributable to their activity and exposure to vehicular and other accidents.

In our study, the incidence of right- and left-sided fracture was equal. Among the distal humeral fractures, the most common was supracondylar fracture with 13 cases (36.1%). The study reported equal number of injuries in both right (18) and left (18) sides. In this study, commonly encountered complications were elbow stiffness in 8 cases (22%), delayed union in 2 cases (6%) and delayed union with pin tract infection in 1 case (3%) and non-union in 1 case (3%). Pin tract infections were treated by regular dressing and oral antibiotics. Physiotherapy was given for elbow stiffness.

In our study, 11 patients were treated with K-wire, out of which 5 sustained injury by RTA and 6 by fall. In the 11 cases, 6 patients had a fracture left distal humerus and 5 patients had right side. The fracture type was supracondylar in 5 patients, intercondylar in 2 patients, supracondylar with intercondylar in 1 patient, lateral condyle in 2 patients, and medial condyle in 1 patient. Union of fractures in 11 patients was between 8 and 16 weeks with mean of 11.82 weeks. The flexion and extension range of movements in 11 patients is 50°–140° with a mean of 75.91°. By MEPI scoring system, 1 had excellent result, 4 had good result, 1 had fair result, and 5 had poor results.

In our study, 10 patients were treated with K-wire and cannulated cancellous screws, out of which 5 sustained injury

Table 5: Distribution of sample by implants used and the outcome

Implant used	Results				Fischer's exact value	*P*-value
	Poor (%)	Fair (%)	Good (%)	Excellent (%)		
K-wire+recon plate+cancellous screw	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	29.95	0.038
K-wire+cancellous screw fixation	2 (20.0)	3 (30.0)	2 (20.0)	3 (30.0)		
K-wire	5 (45.5)	1 (9.1)	4 (36.3)	1 (9.1)		
Recon plate	0 (0.0)	0 (0.0)	0 (0.0)	2 (100.0)		
Recon plate+cancellous screw	1 (10.0)	0 (0.0)	0 (0.0)	9 (90.0)		
Recon plate+cancellous screw+TBW	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)		
Recon plate+K-wire	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)		

TBW: Tension band wiring

by RTA and 5 by fall. The fracture type was supracondylar in 4 patients, supracondylar with intercondylar in 3 patients, lateral condyle in 2 patient, and intercondylar fracture in 1 patient. Union of fractures in 10 patients was between 10 and 30 weeks with mean of 14.50 weeks. The flexion and extension range of movements in 10 patients was 50°–140° with mean of 92.50°. By MEPI scoring system, 3 had excellent result, 2 had good result, and 3 had fair result and 2 had poor results.

In our study, 10 patients were treated with reconstruction plate and cannulated cancellous screw. The fracture type was supracondylar with intercondylar in 5 patients, intercondylar in 3 patients, medial condyle in 1 patient, and supracondylar in 1 patient. Union of fractures in 9 patients was between 10 and 15 weeks with mean of 12.10 weeks. The flexion and extension range of movements in 10 patients were 35°–140° with mean of 111°. By MEPI scoring system, 9 had excellent result and one had poor result.

One patient treated with a reconstruction plate and K-wire had supracondylar fracture following RTA with right elbow involvement. Fracture united in 12 weeks with mean flexion of 100°. MEPI scoring system patient had given good result.

In our study, the correlation we found between the functional results and the type of fracture confirms the prognostic value of AO classification. The elderly patients regained less movement, but none of them had instability. In one case, olecranon osteotomy was used for reduction of fracture but we had no complication regarding the union by olecranon osteotomy and been fixed by a cancellous screw and TBW. We found tingling in ulnar nerve distribution even after prophylactic anterior transposition. However, the nerve was returned to its normal course at the end of the operation.

In our study, the lateral or radial plate (reconstruction plate) was posterior and, therefore, at right angles to the medial or ulnar plate which enhanced stability. This was possible because the articular surface of the capitellum was entirely anterior and distal. The posterolateral plate required little contouring; the medial plate needed to be very heavily contoured in two planes. Hence, the "pelvic reconstruction" plate, though slightly less strong, was often useful. We have not removed implants as a routine unless their prominence in thin patients caused issues. K-wire with cancellous screws showed an excellent result when compared to K-wire alone.

In the case of reconstruction plate and cannulated cancellous screws, the value of compression while obtaining union was noted. The union occurred between 12 and 15 weeks with mean of 12.10 weeks. One patient who had elbow stiffness was corrected by physiotherapy.

By compression, the fracture united by primary bone healing if the fragments were rigidly fixed with their blood supply disturbed as little as possible. Under these conditions, resorption and bone formation occurred simultaneously in fracture treated with rigid fixation. When the fracture gap was obliterated or greatly diminished by a compression plate, the capillaries were able to grow into the medullary callus at an early stage in the healing process.

Functional results were of more importance than anatomical results, functional recovery was rapid and complete in relatively fresh cases in our series is by absolute stability[7,8] and contact healing.[9] Plate removal was not done in the study since none of the patients had symptoms associated with plate. Although the long-term effects of these retained plates are not known and there is no need to remove plates as such.[8]

CONCLUSION

Reconstruction plate and reconstruction plate with cannulated cancellous screws showed stable fixation and allowed immediate mobilization than K-wires when used exclusively. Excellent results were achieved in terms of mobility and union without deformity. Reconstruction plate alone and reconstruction plates and cannulated cancellous screws offer excellent results in distal humeral fracture in adults.

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How to cite this article: Majeed TA, Latheef S. A Study of Surgical Management of Distal Humerus Fractures. Int J Sci Stud 2021;9(2):50-54.

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

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

Original Article

A Prospective Study of Role of Preoperative Testosterone in Hypospadias Repair

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Abstract

Background: Hypospadias is a congenital anomaly of the male urethra that causes significant morbidity in the paediatric male population. The mainstay of treatment is hypospadias repair surgery. To improve the surgical results, preoperative hormonal stimulation has been recommended since it is believed that it temporarily promotes phallic growth, which makes the correction easier and results in less early and late postoperative complications and better postoperative outcome. Our objectives were to evaluate the effect of preoperative parenteral testosterone on stretched penile length (SPL), circumference of penile shaft, thickness of penile shaft skin and vascularity of penile skin.

Material and Methods: In this study, 25 patients of hypospadias between the ages of 1-12 years were included. All patients received preoperative intramuscular testosterone injection at dose of 2mg/kg body weight and serial penile measurement were taken.

Results: The mean stretched penile length before testosterone injection was 5.2 ± 0.91 and after first dose of testosterone was 5.88 ±0.78. The mean circumference of penis before giving testosterone was 4.28±0.54 and after first dose was 4.68±0.95. On comparison, the difference was statistically significant.

Conclusion: Almost all patients have shown significant increment in stretched penile length and circumference and decreased early and late postoperative complications.

Key words: Stretched penile length, Preoperative, Testosterone, Circumference, Urethrcutaneous, Fistula, Vascularity, Postoperative

INTRODUCTION

Hypospadias is one of the most common congenital anomalies of male genitalia. Hypospadias term is derived from the Greek word Hypo means under and spadon means a fissure.[1] The mainstay of treatment for hypospadias is surgical correction to achieve a straight penis with the urethral opening as close to the ventral tip of the penis as possible with uninterrupted urinary flow and creating a straightened penis (upon erection) that is similar in appearance to a normal circumcised penis. The general consensus among pediatric surgeons is to perform elective surgery on male genitalia between 6 and 18 months of age as it is believed that a boy will be aware of his genitalia by the age of 18 months.[2] Hormonal stimulation before hypospadias correction has been accepted as a relatively common practice for few decades.[3,4] Testosterone use was first reported in 1971[5] and it has been applied as the hormone of choice for the preoperative hormonal stimulation in hypospadias repair. Our objectives were to evaluate the effect of preoperative parenteral testosterone on stretched penile length (SPL), penile circumference and thickness of penile skin, and vasculature of penile shaft skin.

Access this article online

www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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MATERIALS AND METHODS

In this study, 25 patients of hypospadias between the ages of 1 and 12 years were included in the study. All patients received preoperative intramuscular testosterone injection at dose of 2 mg/kg body weight. All patients received 1–2 intramuscular testosterone injection at 1–3 weeks interval. When patient came for follow-up in outpatient department after first dose we clinically assessed the patients and took measurements of penile length and circumference with the help of measuring tape or vernier calipers. If the length and circumference were found adequate the surgery was planned. If the size of the penis was still small and inadequate for hypospadias repair, we gave second dose of testosterone injection. We can give up to three doses of testosterone. In this study, most of the patients received two doses of testosterone. Various surgical techniques were used in hypospadias repair but the most common was Snodgrass procedure. Basic steps for a successful hypospadias outcome: (a) orthoplasty (straightening), (b) urethroplasty, (c) meatoplasty and glanuloplasty, and (d) skin coverage. Postoperative follow-up after 7–10 days then at 1, 3, and 6 months.

OBSERVATIONS AND RESULTS

Twenty-five patients of hypospadias were included in this study. All patients received 1–2 doses of preoperative intramuscular testosterone injection and followed up timely.

Age distribution		Type of hypospadias		Type of surgery	
Age (years)	Frequency (%)	Type	Frequency (%)	Type	Frequency (%)
<2	16	Distal penile	68	Snodgrass	56
2–5	56	Mid penile	16	Snodgrass with chordee correction	24
>5	28	Proximal penile	8	2 stage urethroplasty	12
		Penoscrotal	8	Meatal advancement surgery	8
Total	100		100		100

In this study, most of the children belonged to the age group of 2–5 years and most common type of hypospadias is distal penile 68%.

Penile measurements	SPL (cm)				Circumference of the penis (cm)			
	n	Mean	SD	*P*-value	*n*	Mean	SD	*P*-value
Before testosterone	25	5.20	0.91	<0.0001	25	4.28	0.54	0.001
After first dose	25	5.88	0.78		25	4.68	0.95	

SPL: Stretched penile length

Most common surgery performed is tubularized incised plate (TIP) or Snodgrass urethroplasty in 80% of cases, out of which 24% cases also needed chordee correction.

Out of 25 patients, only nine patients presented with chordee rest 16 patients were presented with without chordee.

Effect of Testosterone on SPL and Circumference after First Dose

Paired *t*-test is applied for SPL. The mean SPL before testosterone injection was 5.2 ± 0.91 and after first dose of testosterone was 5.88 ± 0.78. The mean circumference of the penis before giving testosterone was 4.28 ± 0.54 and after first dose was 4.68 ± 0.95. On comparison, the difference was statistically significant.

Effect of testosterone on SPL after two doses

Repeated measure ANOVA Test for SPL was applied to only those patients who received repeated dose (at least two doses) of testosterone injection.

SPL (cm)	*n*	Mean	SD	*P*-value
Before giving testosterone	19	5.11	0.99	<0.0001
After first dose	19	5.84	0.90	
After second dose	19	6.26	0.73	

SPL: Stretched penile length

The mean length of the penis before giving testosterone was 5.11 ± 0.99 and after first dose was 5.84 ± 0.90. Mean difference in SPL was –0.737. That is mean increment in SPL is 0.73 cm. On comparison, the difference was found to be statistically significant. The mean length of the penis after first dose 5.84 ± 0.90 and the mean length after second dose 6.26 ± 0.73 and mean difference is –0.421, the difference is found to be significant with $P = 0.006$. We observed that the penile length significantly increased after testosterone injection and also that, increment in penile length is more after first dose as compare to increment after second dose of testosterone injection.

Effect of Testosterone on Circumference after Two Doses

Circumference of the penis (cm)	*n*	Mean	SD	*P*-value
Before testosterone	19	4.32	0.58	<0.0001
After first dose	19	4.79	0.98	
After second dose	19	5.11	0.99	

Mean circumference of the penis before giving testosterone was 4.32 ± 0.58 and mean circumference after first dose was 4.79 ± 0.98 and mean difference was –0.474. On comparison, the difference was found to be statistically significant with $P < 0.002$. The mean circumference of the penis in centimeter after first dose 4.79 ± 0.98 and the mean circumference after second dose 5.11 ± 0.99 and mean

difference is –0.316, the difference is found to be significant with $P = 0.030$. We can see that the penile circumference significantly increased after testosterone injection and we also observed that, increment in circumference is more after first dose as compare to increment after second dose of testosterone injection. We had also observed clinically that the thickness of penile skin and the vascularity of the penile shaft is also increased in all patients who have received preoperative testosterone injection. We did not find any adverse effects such as gynecomastia, the appearance of pubic hairs, and growth spurt.

Postoperative Complications

Early complications	Frequency	Late complications	Frequency
Edema	16	Urethrocutaneous fistula	20
Bleeding, hematoma	16	Meatal stenosis	4
Urinary retention	12		
Superficial skin blackening	8		
Wound dehiscence	4		
local infection	4		

Meatal stenosis as a late complication was observed in one patient which was corrected with the help of urethral dilator.

Final Outcome

Out of 25, urethrocutaneous fistula developed in 20% of patients and 80% of patients had successful outcome.

DISCUSSION

Hypospadias is a common pediatric congenital anomaly but it is challenging problem due to wide variation in local anatomical factors. Hormone therapy preceding surgical correction of hypospadias has been proposed to obtain better surgical conditions, such as a bigger penis, and to reduce surgical complications.[6] Testosterone has been widely used for penile enlargement before hypospadias reconstructive surgery.

Teckchandani and Bajpai observed that mean SPL at 2–3 years of age was approximately 5.01 ± 2SD and at 4–5 year was approximately 5.82 ± 2SD, in the Asian population. In our study >50% of patients belong to age between 2 and 5 years with mean SPL is 5.2 ± 0.91 which is similar to results of above mentioned study.[7]

Nuininga *et al*.[8] noted a 54% long-term complication rate in 126 patients who underwent primary hypospadias repair. In our study, 20% of patients developed urethral fistula and meatal stenosis was seen in 4% of cases as a long-term complications. Aisuodionoe-Shadrach *et al*.[9] reported urethrocutaneous fistula as the most common complication in 37.5% followed by meatal stenosis in 12.5% of cases. In our study, urethrocutaneous fistula was the most common late complication seen in 20% of patients and meatal stenosis in 4 % of cases. Barakoti *et al*.[10] noted that urethrocutaneous fistula occurred in 15 (33.33%) patients which are slightly higher than our study. Khan *et al*.[11] noted the most common chronic complication was UCF which was initially observed in 38.8% of cases, meatal stenosis observed in 5.6% of patients. These complications are slightly higher than this study. Nema and Varia[12] observed in their study, 25% of patients developed wound infection, 16% developed edema, urethral fistula developed in 15% of patients, 34% developed skin necrosis. In our study, we noted wound infection in only 4% of patients, edema developed in 16% of patients, urethral fistula developed in 20% of patients, skin blackening developed in 8% of patients.

Paiva *et al*.[13] in their study observed a significant increase in penile length, the diameter of the penis and glans were observed after 30 days in those using 1% testosterone propionate. The most frequent side effects were appearance of pubic hair and darkening of the genital skin. Asgari *et al*.[14] observed in his study an increase in penile length (from 28.1 ± 2.2 mm to 38.5 ± 2.6 mm) ($P = 0.001$) and penile circumference (from 35.1 ± 1.6 mm to 45.5 ± 2.2 mm) ($P = 0.001$) were noticed in all but four children in the testosterone group, the TIP urethroplasty was performed with an overall complication rate of 9.34%. In our study, we observed that SPL and circumference significantly increased after first dose of testosterone injection with $P < 0.0001$ and <0.002, respectively, and there was no side effect of testosterone observed.

CONCLUSION

In this study, all patients responded well to preoperative intramuscular testosterone injection, we found that the preoperative testosterone therapy is effective in achieving our primary and secondary objectives. Some previous studies reported that there were some transient side effects of testosterone but there were no side effects of testosterone injection seen in our study. From this study, we can conclude that the intramuscular injection of testosterone significantly increases penile length and circumference in prepubertal boys, thereby provide better conditions for operative procedure and reducing the postoperative early and late complications, thus we can get better post-operative outcome and reduces the requirement for reoperation. Apart from increment in penile length and circumference, vascularity of penile shaft and thickness of penile skin also increase. Nevertheless, there is still a

large scope for improving our knowledge about the use of hormonal treatment before surgery, which will require further studies with large study group and longer follow-up.

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How to cite this article: Sharma SS, Lahoti BK, Kumar M, Laddha A, Sharma A, Shukla RM. A Prospective Study of Role of Preoperative Testosterone in Hypospadias Repair. Int J Sci Stud 2021;9(2):55-58.

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

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

Original Article

Dosimetric Comparison of Three-dimensional Conformal Radiotherapy versus Intensity Modulated Radiotherapy Following Breast Conservation Surgery in Early Stage Breast Cancer

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Abstract

Introduction: Breast cancer is the most frequent cancer among women. Radiotherapy is integral in the management of breast cancer. The purpose of this study was to compare two different types of treatment planning, standard wedged tangential-beam three-dimensional (3D) conformal radiotherapy (CRT), and dynamic intensity modulated radiotherapy (IMRT), in early breast cancer patients who have undergone breast conservation surgery. We aimed to improve dose distribution homogeneity in the breast and decrease the dose of organs at risk (OAR), that is, heart and ipsilateral lung.

Materials and Methods: This study is conducted using treatment plans done on the computed tomography (CT) simulation data sets of 20 patients. These patients were already treated with breast conservation surgery, consisting of removing the primary tumor with a margin followed by 3D CRT at the Department of Radiotherapy, Government Medical College, Kozhikode from 2015 to 2017. A CT scan was taken with the patient in treatment position from the level of the C6 vertebra to below the level of the diaphragm. The breast clinical target volume was contoured according to Radiation Therapy Oncology Group guidelines and reference radio-opaque wires placed. The same CT data set with target volumes and OAR volumes were used for the IMRT study. Plans were compared according to cumulative dose-volume histogram analysis in terms of planned treatment volume (PTV) and volume parameters of OARs.

Results: Our study 3D CRT gives a much better dosimetry coverage for breast PTV and reduces the dose to the OARs than IMRT. IMRT is more cardiac sparing at higher doses than 3D CRT, especially at v25 and the dose receiving 33% of heart is less on IMRT. Hence, IMRT may be beneficial in patients with a high risk of cardiac events. The ipsilateral lung dose parameters were observed to have higher values in the IMRT technique than the 3DCRT technique.

Conclusion: 3D CRT enables better dose distribution in the PTV and reduces OARs in breast cancer radiotherapy compared to IMRT.

Key words: Breast cancer, Dynamic intensity modulated radiotherapy, Organs at risk, Three-dimensional conformal radiotherapy, Whole breast irradiation

INTRODUCTION

Breast cancer is the most frequent cancer among women; most patients with breast cancer are diagnosed at an early stage (61.1%), largely because of widespread mammography screening programs. The standard of care for these patients is lumpectomy or mastectomy plus lymph node sampling followed by adjuvant radiotherapy (RT) to the tumor bed or the whole breast as indicated. RT is integral in the management of breast cancer. Long-term data establish the efficacy of RT in the adjuvant management of breast cancer the 25-year results of NSABP B04 published in 2002 indicate radiation leads to less extensive surgeries while maintaining relapse-free and overall survival.[2] Meta-analyses show that locoregional control as well as

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www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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breast cancer mortality benefit from adjuvant radiation therapy following breast conservation surgery or following mastectomy with node-positive disease.[1,2]

The focus has now shifted from just treatment to high-quality, precise treatment delivery to reduce long-term treatment-related toxicity. Radiation to the breast, with or without additional fields for nodal coverage, has the potential to negatively impact long-term cosmetic outcome of the treated breast. It can also cause rare but severe complications due to incidental dosage to the heart, lungs, and contralateral breast. In fact, cardiac mortality is reported to be higher in left-sided breast cancer patients than in right-sided breast cancer patients because higher incidental cardiac radiation doses were delivered in patients with left-sided breast cancer.

Due to the proximity of the lung beneath the breast tissue, this organ receives the highest incidental dose in women receiving radiation for breast cancer. The mean total lung dose has been reported as 5.7 Gy using modern three-dimensional (3D) conformal techniques. The contralateral breast is also an important organ at risk (OAR) due to its exposure to scattered radiation. While we have established the indispensable role of RT in the management of breast cancer, it is also important to deliver this at the lowest possible, most effective dose to ensure patient safety. Furthermore, the best mode of delivery of RT must be established. It was either used as tangential preoperative treatment of the breast or as post-operative treatment of the chest wall during the initial years.

In the 1980s, breast-conserving surgery (BCS) started and post-operative treatment of the remaining breast tissue became standard. Prospective randomized trials have confirmed that long-term mortality from breast cancer and overall patient survival are comparable for BCS plus radiation treatment and for mastectomy[3] the past decade has seen considerable advances in the delivery of post-operative radiation that aim to optimize the treatment for each person's anatomy and reduce acute or long-term toxicity. 3D planning with a computed tomography (CT) simulator and either field-in-field three-D conformal radiation therapy (CRT) (forward planning) or intensity-modulated radiation therapy (IMRT) (inverse planning) has replaced the simple 2-D tangential treatment. By reducing dose non-homogeneity, these advances in techniques are associated with lower rates of complications, such as acute skin desquamation, edema, late fibrosis, or negative cosmetic effects on the breast.[6,7] In addition, techniques involving the prone position and deep-inspiration breath-holding are now used for left-side breast cancer or larger breast size to reduce toxicity, particularly cardiac dose sparing.[8,9]

This study aims to compare the dosimetry characteristics of IMRT and 3D RT techniques and evaluate each modality's characteristics when applied to whole breast radiation therapy in early-stage breast cancer.

MATERIALS AND METHODS

Patients with left-sided breast cancer who have already been undergone breast conservation surgery and post-operative RT from Government Medical College, Calicut, from 2015 to 2017 were included in the study after informed consent and ethical clearance obtained from the Institutional ethics committee, Medical College Kozhikode. At the time of recruitment, the following data were collected: Name, age, address, menopausal status, parity, presence of comorbid illness, stage at diagnosis, histopathological report, details of surgery performed, and chemotherapy are taken. RT was planned and administered after obtaining informed consent. Dose volume histogram (DVH) data were collected from the Treatment Plans of individual patients.

Simulation and Treatment Planning

External Beam Radiation using the 3D Conformal technique 3D CRT was used. The patient was placed in the supine position with both the arms flexed and abducted to more than 90°. Both hands were made to hold the handgrip placed on the board above the head. The arms were held in position by arm supports which were also attached to the board and the head was turned to the right. Headrest and hip rest were also used to aid in the patient's position reproducibility.

The field borders were determined clinically and marked by radio-opaque wires. The medial border was 1 cm from the mid-line, the superior border was at the caudal border of the clavicular head, the inferior border was 1 cm below the inframammary fold and the lateral border was at the mid-axillary line. A contrast-enhanced CT scan was taken with the patient in the treatment position from the level of the C6 vertebra to below the level of the diaphragm. The chest wall or breast clinical target volume, the regional lymphatics, and the supraclavicular field (when indicated) were contoured according to the Radiation Therapy Oncology Group guidelines.

CT data were exported to a computerized treatment planning system (Eclipse, Version13.6). Beam weights and wedges were optimized based on the dose distribution for the central axis plane. All patients were planned with 6MV photons. Field borders were not modified to reduce or avoid cardiac irradiation and cardiac shielding was not used. All patients were treated with a tumor dose of 50Gy to the isocenters in 25 fractions, 5 days/week.

The dose distribution was calculated with full 3D CT density information, including lung correction using the Anisotropic Analytical Algorithm algorithm. In the IMRT technique, the fluence-based sliding window IMRT optimized plans were generated to achieve the same objectives described for the 3D CRT plans, the number of beam segments was not restricted during optimization.

The planned treatment volume (PTV) for IMRT was the same as used for the 3D CRT plans. The ECLIPSE 15.1 treatment planning system was used to analyze the PTV's mean, maximum and minimum doses and for organs at risks (OARs) mean, maximum, minimum doses, percentage of volume receiving 3000 cGy (V30), percentage of volume receiving 2000 cGy (V20), percentage of volume receiving 1000 cGy (V10), and isodose volumes for 50%, 30% and 10%. The OAR that was assessed was the heart and lungs. The heart is contoured with the aid of a heart contouring atlas "Development and Validation of a Heart Atlas to study Cardiac exposure to Radiation following treatment for Breast Cancer".[10] For each treatment plan, DVHs for the heart and lungs, with a 1-cm radial margin, were generated. The superior limit of the heart included the right and left atria and excluded the pulmonary trunk, ascending aorta, and superior vena cava. The caudal border of the myocardium was taken as the inferior limit of the heart. For each OAR, the mean and maximum dose was assessed for each patient. For each of these quantities, the average value for all assessed patients (referred to as mean) was calculated with its standard deviation (SD).

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using the SPSS version 23.0 software and analyzed with the help of descriptive statistics such as mean, SD, percentage, and statistical tests such as the Independent *t*-test.

RESULTS

Twenty patients with post BCS status who satisfied the inclusion criteria were selected and data were analyzed. The majority of the women enrolled in the study were in the age group 31–40 years, comprising 40% of the study population. The mean age of the population was 40.3 years. About 80% of the study population (16 patients) was postmenopausal and 10% (2 patients) were nulliparous. Most women (95%) enrolled into the study had no pre-existing cardiac disease. About 15% were hypertensive. About 50% were found to be Luminal subtype A and 25% constitute triple negative. Nine patients (45%) in our study presented with T1 stage while most of the patients (55%) had T2 disease. Ten patients (50%) received chemotherapy with AC, followed by Taxol.45% of patients received FAC schedule and 5% received FEC.

Comparison of PTV

This study shows that the mean of maximum dose and minimum dose received by PTV is high in IMRT planning than 3D CRT with a statistically significant *P* value. However, the mean dose received by PTV is less with IMRT planning.

Comparison of Heart Dose

The dosimetry comparison between 3D CRT and IMRT shows that the mean of the maximum dose and minimum dose received by heart was higher in IMRT planning than 3D CRT. The mean of v25 dose and dose received by 33% of heart is more on 3D CRT when compared to IMRT. Thus, IMRT is more cardiac sparing.

Comparison of Lung Dose

This data analysis shows that the mean of v10, v20, and v30 doses received by lung is less on 3D CRT when compared to IMRT [Table 1] and this is found to be statistically significant with a *P* value of 0.001 as per *t*-test. Similarly,

Table 1: Comparison of dose distribution of PTV and OAR in 3D CRT versus IMRT

Group		Mean	Std.Deviation	*P*-value
PTV				
Max dose	3D CRT	5553.095	49.04559	0.049
	IMRT	5584.255	48.05061	
Min dose	3D CRT	1422.68	59.1518	0.001
	IMRT	2631.327	239.91481	
Mean dose	3D CRT	5259.25	85.81385	0.001
	IMRT	4998.635	96.51326	
Heart				
Max	3D CRT	4521.25	85.72546	0.001
	IMRT	4666.9	72.5084	
Min	3D CRT	41	4.66792	0.001
	IMRT	347.45	19.67225	
Mean	3D CRT	1159.75	79.02956	0.001
	IMRT	1537.65	76.44212	
33% Vol	3D CRT	1480.3	54.65885	0.001
	IMRT	1077.8	60.60624	
V25	3D CRT	23.7	2.51522	0.001
	IMRT	15.914	1.16765	
V10	3D CRT	33.35	3.01357	0.001
	IMRT	48.321	5.3049	
Lungs				
V5	3D CRT	50.785	3.27242	0.001
	IMRT	59.85	5.66322	
V20	3D CRT	32.2	2.10488	0.001
	IMRT	37.25	1.05954	
V30	3D CRT	26.78	0.89006	0.001
	IMRT	28.39	1.44072	
V10	3D CRT	41.9	2.72261	0.001
	IMRT	55.07	5.08218	
Mean dose	3D CRT	1043.35	46.1511	0.001
	IMRT	1489.35	108.14185	

PTV: Planned treatment volume, OAR: Organ at risk, CRT: Conformal radiotherapy, IMRT: Intensity-modulated radiation therapy

the mean dose is also less with 3D CRT (1043.35 cGy) than IMRT plans (1489.35 cGy). So from this study, we can see that more lung volume is irradiated with IMRT than 3D CRT planning.

DISCUSSION

BCS plus radiation treatment is associated with very high local control rates (90–95%). These rates are comparable to those obtained with mastectomy, with more women having a good or excellent cosmetic result.[4,5] In India, BCS is preferred mostly by young women, whereas most older women undergo mastectomy. Since our study included only women who received radiation after BCS, we have a study population with a majority of them in their forties.

This study aimed to quantify the radiation dose received by ipsilateral breast, heart, and ipsilateral lung. All the patients included in this study had left-sided disease and all of them had undergone BCS.

Out of the 20 patients studied, only two patients (10%) were nulliparous, while 18 patients (90%) were multiparous. In our study population, 15% had a history of hypertension which is also a risk factor for coronary artery disease. One patient (5%) already had a history of heart disease, increasing their chances of developing radiation-induced coronary artery disease. All of the patients had received anthracycline-based chemotherapy, which on its own is a known cardiotoxic drug. This increases cardiac morbidity and mortality in addition to radiation-induced cardiac disease.

Dosimetry analysis shows that in the 3D CRT plan, the maximum dose received by PTV is 5553.09 cGy (111%), whereas, in the IMRT plan, it is 5584.25cGy (111.68%). This proves that IMRT has a higher maximum dose exposure because IMRT is known to cause focused areas of hot spots, causing more radiation on the breast tissue.

In the 3D CRT plan mean minimum dose received by PTV is 1422.68cGy (28.4%), while in the IMRT plan mean minimum dose received by PTV is 2631.32cGy (52.62%). Hence, our study showed that the IMRT plan achieved high minimum doses. These minimum doses are only point doses in PTV explained by the fact that we can only achieve the prescribed dose delivery for more than 90% of the prescribed isodose to encompass greater than 95% of the PTV, so at some points in every plan, there will be doses lesser than mean doses. These results are comparable with the previous studies by Ashraf *et al*.[10]

The present study mean of maximum dose received by heart is 4521.25 cGy y with 3D CRT plan, while in IMRT plan; it is 4666.9 cGy, which means maximum dose received by heart much higher by IMRT plan. Similarly, the mean minimum dose received by the heart is 41 cGy with 3D CRT, whereas the heart in IMRT is 347.45 cGy. Hence, the mean minimum dose received by the heart is more on the IMRT plan.

This data analysis shows that the mean of v25 dose received by the heart is 23.7% and 15.91% for 3D CRT and IMRT plans. This is significant with a $P = 0.001$.

Hence, mean V25 dose received by the heart is lesser using IMRT planning. The mean dose received by 33% of the heart is also less with IMRT. From this data, we can infer that IMRT is more cardiac sparing at higher doses compared to 3D CRT.

Different studies show that the mean dose received by the heart ranges from 0.8 Gy to 13.3 Gy.[11-14] In our study, the mean cardiac dose received is 14.89 Gy which is higher with IMRT. Higher doses on the heart in IMRT may be because we were not using breath-holding/respiratory gating techniques in IMRT planning.

In the case of the lung, the mean dose is 1043.3 cGy in the 3D CRT plan in contrast to the IMRT plan, where the mean dose received by the lung is 1489.3 cGy. Hence, it can be concluded that the mean dose received by the lung is more on the IMRT plan. The v5, v10, v20, and v30 doses received by lung in 3D CRT is 50.7%, 41.9%, 32.2%, and 26.8%, respectively, whereas they are 50.85%, 55.07%, 37.25%, and 28.39%, respectively, in IMRT plan with a statistically significant $P = 0.001$. This shows that more lung is exposed in IMRT planning at low doses and higher doses. At low doses, it can increase the risk of radiation-induced second malignancies. The risk of radiation pneumonitis is related to the volume of lung irradiated at higher doses.

CONCLUSION

3D CRT gives a much better dosimetry coverage for breast PTV and reduces the dose to OARs than IMRT. At higher doses, IMRT is more cardiac sparing than 3D CRT, especially at V25 A dose receiving 33% of heart is less in IMRT. Hence, IMRT may be beneficial in patients with a high risk of cardiac events. The ipsilateral lung dose parameters were observed to have higher values in IMRT techniques than 3D CRT. The risk of Radiation-Induced Pneumonitis is related to the volume of ipsilateral lung irradiated.

However, the quality of the treatment plan depends on the patient geometry and technology available in a RT center, such as treatment planning system, beam energy, and TPS

algorithm. The selection of treatment techniques for whole breast irradiation is an important factor in sparing the adjacent normal structure and determining the associated risk. The IMRT technique delivers a modestly higher dose to adjacent normal tissues. The main concern with this is the increased risk of late secondary malignancy.

Quantification of dose to OARs may be useful for clinicians as they counsel women with early-stage breast cancer about their treatment options. The IMRT plans contribute a modestly higher dose to adjacent normal tissues. The main concern with this is the increased risk of late secondary malignancy. 3D CRT technique is superior in better coverage of PTV volumes and delivering lower dose to adjacent normal tissue, and treatment time.

ACKNOWLEDGMENTS

We want to thank Dr. Praveen Kumar RD, Radiation Physicist and Assistant Professor Department of Radiation Oncology, Government Medical College Kozhikode, for his valuable support in dosimetric evaluation.

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How to cite this article: Shafi KM, Bindu G, Ajayakumar T, Induprabha Y, Suseelan S, Mahadevan R. Dosimetric Comparison of Three-Dimensional Conformal Radiotherapy versus Intensity Modulated Radiotherapy Following Breast Conservation Surgery in Early Stage Breast Cancer. Int J Sci Stud 2021;9(2):59-63.

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

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

Original Article

Predicting the Coronavirus Disease 2019 Severity in Patients with Diabetes using Hemoglobin A1c

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Abstract

Aim: The current study aimed to evaluate the association between the levels of HbA1c with the severity of COVID-19 among T2DM patients.

Materials and Methods: This is a retrospective, observational study included post COVID-19 T2DM patient's aged ≥18 years with preexisting comorbid conditions in India, from March 2020 to October 2020. The demographic and clinical characteristics were recorded accordingly.

Results: A total of 120 Post COVID T2DM patients were included in the study, of which 102 were hospitalized and the 18 were home quarantined based on the severity of COVID-19. Among hospitalized patients majority of them were males with various preexisting comorbid conditions such as HTN, Heart problem etc., The current study finding highlighted that the levels of HbA1c and comorbid conditions such as hypertension, heart problems, Thyroid and Dyslipidemia showed higher risk of hospitalization which is significantly associated with diabetes.

Conclusion: Thus the study suggested that the prognosis of COVID-19 severity in diabetic patients showed higher risk based on the level of HbA1c ≥ 9%. Uncontrolled T2DM might be responsible for an overall higher hospitalization for COVID-19 infection. Thus focusing on the preexisting comorbid risk factors among diabetic patients can be used in the management of COVID-19 severity and can minimize socio-economic burden.

Key words: Comorbid conditions, Coronavirus infectious disease 2019, Hemoglobin A1c

INTRODUCTION

The novel coronavirus disease 2019 (COVID 19) is caused by a severe acute respiratory syndrome, which mainly affects the lungs and the immune system. It was first recognized in the city of Wuhan in China and spreads worldwide. The current pandemic situation has caused a large number of deaths in many parts of the world. The COVID-19 confirmed cases were increasing worldwide. India, is a nation already been the diabetes capital of the world, further the dual burden of COVID worsens the current situation.[1] Some of the evidence showed that the socioeconomic status and those who lacks the access to routine health care leading to cause morbidity and mortality. A recent study showed that there is a bidirectional relationship between COVID-19 and hyperglycemic which might be postulated, irrespective of the underlying mechanisms, poor prognosis associated with hyperglycemia.[2]

People with diabetes and COVID-19 may need special attention and clinical care.[3] Recent studies highlighted that the severity and the mortality associated with COVID-19 was related to age and comorbid conditions such as diabetes mellitus (T2DM), Hypertension (HTN), cardiovascular disease (CVD) and cerebrovascular disease.[4,5] Diabetes and CVD are the major underlying comorbidities condition which might increase the risk of mortality in COVID patients.[6-10]

Diabetes is the second comorbidity after HTN in patients with COVID-19 disease. Insulin is the standard therapy to control hyperglycemia in hospitalized patients.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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Metformin could also be continued in mild cases of COVID-19 in absence of contraindications. The anti-diabetic effect of hydroxyl chloroquine can be virtually beneficial in COVID-19 patients with T2DM.[11] Recent study highlighted that Hyperglycemia is an independent factor which is associated with severe prognosis in people hospitalized for COVID-19.[12] Further the impact of HbA1c control on the management of COVID-19 infection[13] also played a major role. Since diabetes has been reported to be associated with poor prognosis of COVID-19, the management of HbA1c for patients with both T2DM and COVID-19 has gained considerable attention.[14,15] There are evidences that better glycemic control is closely associated with improvement in clinical outcomes in COVID-19 patients.[16,17] Perhaps, still there is no clear understanding, whether COVID-19 contributes to hyperglycemia. In India the prevalence of T2DM is high and there is a paucity of literature on the association of T2DM with COVID-19, thus there is a need to identity the possible responsible factor for severe outcome among T2DM patients. Thus the current study was designed to evaluate the association between the levels of HbA1c with the severity of COVID-19 among T2DM hospitalized COVID affected patients.

MATERIALS AND METHODS

The present retrospective, observational study was conducted among post COVID-19 patients with diabetes in Chennai. A consecutive 120 post COVID T2DM individuals (hospitalized due to COVID/ home quarantined due to mild COVID-19 infection), were recruited during the period of March to October 2020. The study subjects were recruited base on inclusion and exclusion criteria, Diabetic patients who were mentally oriented, aged between 18 and 80 years and took treatment for COVID-19, T2DM patients with preexisting comorbid conditions were included in the study. Those individuals who were on alternative treatment for COVID-19 and other serious illness pregnant women were excluded from the study. Demographic and clinical characteristics including age, gender, HbA1c, pre-existing conditions such as Hypertension, Cardiovascular disease, Dyslipidemia and Thyroid were recorded accordingly.

Means and proportions of the given data for each variable were calculated. For the comparison between groups t test was used for continuous variables and Chi-square tests were used for categorical variables. Multivariate regression was used to estimates the odds ratios (OR) and 95% CI for the independent association between the following clinical characteristics age, HbA1c ≥ 9%, Hypertension, Dyslipidemia and COVID-19 disease severity has assessed by the need for hospitalization. Multivariate regression was used to identify the factors associated with COVID -19 hospitalization among T2DM patients. The multivariate analysis with an HbA1c cutoff of >7% or with HbA1c as a continuous variable was observed. Statistical significant was determined at p value less than 0.05 <0.05. STATA 12 software was used to assess the data.

RESULTS

Of 120 T2DM patients who were tested for COVID-19 positive were diagnosed with the pre-existing disease and recovered from COVID. Of 120 patients enrolled in the study, 93 were male and 27 were females. The study participants had a mean age of 54.65 (±14.33) years and ranged from 21 to 80 years. About 53.79 % of the patients were greater than 50 years of age. Among preexisting comorbid conditions majority of the patients had Hypertension (35.0%), followed by Dyslipidemia (31.6%), heart problem (5.83%) and Thyroid (8.33%). The demographic characteristics of the study patients were presented in Table 1. With reference to HbA1C level, Majority of the patients had HbA1C level > 9%, followed by 8-8.9%, 7-7.9% and <7% respectively. Among 120 post covid- 19 patients with diabetes, 102 were hospitalized and 18 were home quarantined. Table 2 shows the clinical characteristics of post COVID hospitalized and non-hospitalized patients with diabetes. The Multivariate analysis, controlling for multiple prior clinical conditions showed the significant higher risk of hospitalization, among the patients with HbA1c ≥ 9% with adjusted Odds ratio of 6.21 (P < 0.01) (Table 3). Furthermore, an

Table 1: Demographic characteristics of Post COVID 19 T2DM patients

Variable	COVID-19 n=120
Mean age, years (CI)	54.65 (52.9-53.8)
20-40	23(19.1)
40-60	51(42.5)
60-80	46(38.3)
Gender	
Male n (%)	93(77.5)
Female n (%)	27(22.5)
Mean HbA1c% (CI)	9.0(8.52.-9.35)
HbA1c	
≤ 7%	36 (30.0%)
7% -7.9%	27(22.5%)
8.0% -8.9%	29(24.1%)
≥9%	28(23.3%)
Comorbid conditions	
Hypertension	42(35.0)
Heart Problems	7 (5.83)
Dyslipidemia	38(31.6)
Thyroid	10(8.33)

increased risk for hospitalization was observed in patients with prior congestive heart failure and a reduced risk for hospitalization. In the later analysis, any increase in HbA1c by 1% above a 5% baseline was associated with an OR for hospitalization of (95% CI; P < 0.05) (Table 4).

DISCUSSION

Using pre-infection glycemic control data, we found HbA1c as a clear predictor of COVID-19 severity.[18] Other clinical characteristics which were significantly linked to hospitalization included female gender, age, pre-existing conditions like Obesity, HTN, Thyroid and CVA.[14] Unexpectedly obesity and male were not associated with hospitalization despite being suggested as risk factors in earlier studies.[19] In a multivariate regression analysis adjusting for multiple potential risk factors and comorbid conditions which may have an effect on disease outcomes (including age, gender, hypertension, CVA, obesity, Thyroid and TB), only HbA1c ≥ 9% remained a significant predictor for hospitalization.[20] HbA1c remained a strong predictor of hospitalization due to COVID-19 when the model was repeated with an HbA1c cutoff of >7% as a continuous variable.[21] Association between the glucose levels in hospital and disease severity suggested linked glycemic control studied in previous studies. The improvement in glycemic control failed in hospitalized patients rather than COVID-19 severity outcome.[22.23] The current study finding suggested that the HbA1c level is a predictor to find the COVID-19 severity in patients with T2DM. Patients with long term uncontrolled HbA1c level (greater than 9%) needs more attention. However, who are at greater risk of COVID-19 severity will be critical to determine till the vaccine is available to overcome this disease.

Table 2: Clinical characteristics of T2DM patients hospitalized due to COVID-19

Variable N (%)	Hospitalized n=102	Not Hospitalized n=18	P-value
Mean age, yrs	25.5	4.50	P<0.001
20-40	19(18.6)	6(33.3)	P<0.001
40-60	47(46.0)	8(44.4)	0.132
60-80	36(35.2)	4(22.2)	P<0.05
Gender			
Male n (%)	89(87.2)	7(38.8)	0.051
Female n (%)	13(12.7)	11(61.1)	0.032
Mean HbA1c % (CI)	8.21(7.65)	8.0 (7.23)	P<0.005
co-morbid condition			
Hypertension	35(34.3)	6(33.3)	P<0.001
Heart Problems	7(6.86)	3(16.6)	P<0.05
Dyslipedemia	38(37.2)	4(22.2)	0.05
Thyroid	10(9.80)	5(27.7)	0.043

Table 3: HbA1c of T2DM patients hospitalized due to COVID-19

Variable (HbA1c)	Hospitalized, n=102	Not Hospitalized, n=18	Crude OR (95% CI) for COVID-19	P-value
<7%	24 (29.3)	7(22.2)	1.00	-
7%-7.9%	17 (20.7)	5(11.1)	3.25	0.046
8.0%-8.9%	23 (28.0)	2(27.7)	4.32	p<0.05
≥9%	38 (37.2)	4(38.8)	6.21	P<0.01

Abbreviations: CI, confidence interval; odds ratio.

Table 4: Multivariate logistic regression analysis, controlling for comorbid conditions accessing the OR for hospitalization in patients with diabetes and COVID-19

Variable	Adjusted OR (95% CI)*	P-value
HbA1c≥9	4.32	<0.01
Age	1.07	0.06
Male	0.50	0.52
Female	0.36	0.48
Hypertension	0.78	0.03
Heart Problems	0.42	0.07
Dyslipedemia	0.25	0.14
Thyroid	1.87	0.32

Abbreviations: CI, Confidence interval; OR, odds ratio
*Adjusted for age, gender and co-morbidities.

CONCLUSION

In the current retrospective study, we have considered 120 post COVID-19-infected patients with T2DM and characterized with biochemical and other clinical parameters. From the various observations, it can be concluded that uncontrolled diabetes mellitus might be responsible for hospitalization of T2DM patients and severity of COVID-19 infection.

The timely intervention to control HbA1c is required for patients along with the treatment regimen of COVID 19 during the pandemic. There is a need for more research data from other vulnerable population. As the COVID-19 pandemic situation continues, the present study finding helps in planning a comprehensive support strategies for individuals with diabetes in the health care sector. To conclude, the study findings highlighted that regular monitoring of HbA1c should be encouraged along with the specific screening strategies for COVID patients with diabetes.

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How to cite this article: Vijayam B, Balaji MS, Balaji T, Veerasamy S, Devaraj S. Predicting the Coronavirus Disease 2019 Severity in Patients with Diabetes using Hemoglobin A1c. Int J Sci Stud 2021;9(2):64-67.

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

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

Original Article

Role of Clinical Examination (Bulbocavernosus Reflex, Anal Tone Assessment and Perianal Sensation) and Uroflowmetry Studies in Evaluating Post-Operative Prognosis in Patients of Benign Prostatic Hyperplasia

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Abstract

Aims and Objectives: Benign prostatic hyperplasia (BPH) is a very common problem of older age group leading to the lower urinary tract symptoms (LUTS). It is difficult to differentiate whether the LUTS are due to bladder outlet obstruction or detrusor underactivity without urodynamic study which is not always possible. Hence, surgery may or may not improve the voiding efficiency. This study aims to evaluate the role of Bulbocavernosus Reflex, Anal Tone Assessment, Perianal Sensation, and Uroflowmetry studies in evaluating the prognosis after surgical treatment in patients of BPH.

Materials and Methods: Cases of BPH operated in the Department of General Surgery, MGM Medical College, Indore, were included in the study. Pre- and post-operative reflexes and uroflowmetry parameters were recorded. Improvement in LUTS was determined.

Results: A total of 400 patients were included with study period of 1.5 years. Follow-up period was 6 months. Out of these, 352 patients had good pre-operative reflexes and 48 patients had weak/absent reflexes. All the patients had poor uroflowmetry parameters. Out of 352 patients having good reflexes and normal anal tone, 336 patients (95.45%) showed good improvement in the uroflowmetry parameters and voiding efficiency after surgery. Out of 48 patients with absent reflexes or decreased anal tone, 46 patients (95.83%) showed no improvement in the uroflowmetry parameters and LUTS still persisted among them.

Conclusion: Patients with good reflexes, that is, intact S2, S3, and S4 showed improvement after surgery and those with absent reflexes, that is, the patients with pre-operative detrusor underactivity did not show improvement in their symptoms even after surgical intervention. Uroflowmetry alone is not reliable in predicting the post-operative prognosis in patients of BPH.

Key words: Anal tone assessment, Perianal sensation, Benign prostatic hyperplasia, Bladder outlet obstruction, Bulbocavernosus reflex, Detrusor underactivity, Lower urinary tract symptoms

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a very common condition affecting men in older age group. It is one of the most common causes of the lower urinary tract symptoms (LUTS). It may or may not be associated with bladder outlet obstruction (BOO). BPH is benign enlargement of the prostate gland that may lead to symptoms in men termed as LUTS. This condition affects the quality of life (QOL) significantly in many patients.[1] Histologically, there is proliferation of smooth muscle and epithelial cells within the prostatic transition zone to variable degrees.[2,3] The pathological process in BPH is hyperplasia (and not hypertrophy) which affects both the stromal and glandular elements of this gland.

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www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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The exact etiology is unknown; however, BPH may result from a reinitiation of embryonic induction processes in adulthood.

Several theories[4] have been proposed. These include:
1. Age-related tissue changes
2. Hormonal alterations – The presence of androgens is needed for the pathogenesis
3. Metabolic syndrome - There is association between metabolic syndrome and the development of BPH
4. Inflammation – It may be due to an inflammatory-based disorder.

LUTS can be due to two reasons:
1. Direct BOO from enlarged tissue (static component)
2. Increase in the smooth muscle tone and resistance within the enlarged gland (dynamic component).

Detrusor over activity leads to the storage symptoms seen in LUTS.[5]

In men who developed BPH, acute retention of urine is a severe symptom. It is defined as a sudden and painful inability to void voluntarily.[6,7] BPH is the most common cause of urinary retention.

MATERIALS AND METHODS

Four hundred cases of BPH operated in the Department of General Surgery, MGM Medical College, Indore, were included from the study. Pre- and post-operative reflexes and uroflowmetry parameters were recorded. Improvement in the LUTS was determined. All patients which were included in study had some degree of LUTS. A cautious physical examination digital rectal examination (DRE) and some urological investigations were done for the diagnosis of BPH in each patient. Patients also got an uroflowmetry done. Clinical reflexes (Bulbocavernosus reflex, anal tone assessment, and perianal sensation) were also checked. Patients undergone transurethral resection of the prostate or open prostatectomy depending on various factors.

Post-operative irrigation continued through triway Foley's catheter for sometime until bleeding stopped. Traction was released after few hours. Foley's removal done after 2–3 days and patient observed for urinary retention post Foley's removal. Patient was asked for persistence of any LUTS. Patient was then discharged and advised for follow-up after 1 month. On follow-up, the reflexes were checked again and uroflowmetry got done. These findings were compared with the pre-operative findings. Patient was asked for persistence of any LUTS again to see the relationship amongst the pre- and post-operative clinical reflexes, uroflowmetry findings, and any symptoms post-surgery.

RESULTS

Table 1 shows the distribution of patients according to post-operative symptoms in different groups (patients having good reflex and patients having weak/absent reflex preoperatively).

Out of total 352 patients having good reflexes preoperatively, 336 (95.45%) patients showed improvement in their symptoms and 16 (4.55%) patients had persistence of symptoms after surgery.

Out of total 48 patients having weak/absent reflexes pre operatively, two (4.17%) patients showed improvement in their symptoms and 46 (95.83%) patients had persistence of symptoms after surgery.

Table 2 shows the distribution of patients according to clinical reflexes in different age groups pre operatively (patients having good reflex and patients having weak/absent reflex).

Table 3 shows the distribution of patients according to post-operative symptoms in different age groups in patients having good pre-operative clinical reflexes.

Table 4 shows the distribution of patients according to post-operative symptoms in different age groups in patients having weak/absent pre-operative clinical reflexes.

Table 1: Distribution of patients according to post - operative symptoms in different groups (Pre - operative good clinical reflex group & weak/absent clinical reflex group)

Reflex (Pre-op) Symptoms persist		Symptoms (%)		Total (%)
		Symptoms persist	Symptoms relieved	
Weak/Absent	Count	46 (95.83)	02 (4.17)	48 (100)
Good	Count	16 (4.55)	336 (95.45)	352 (100)
Pearson Chi-square		268.758	*P*-value	<0.0001 (Sig.)

Table 2: Distribution of patients according to pre - operative clinical reflexes in different age groups

Age Good		Reflexes (%)		Total (%)
		Good	Weak/Absent	
40–60 years (*n*=151)	Count	134 (88.74)	17 (11.26)	151 (100)
61–80 years (n=246)	Count	216 (87.80)	30 (12.20)	246 (100)
>80 years (*n*=3)	Count	02 (66.67)	01 (33.33)	03 (100)

Table 3: Distribution of patients according to post - operative symptoms in different age groups in patients having good pre - operative clinical reflexes

Age	Good reflex (%)		Total (%)
	Symptoms persist	Symptoms relieved	
40–60 years	05 (3.73)	129 (96.27)	134 (100)
61–80 years	10 (4.63)	206 (95.37)	216 (100)
>80 years	01 (50)	10 (50)	02 (100)
Total	16 (4.55)	336 (95.45)	352 (100)

P=0.007

Table 4: Distribution of patients according to post - operative symptoms in different age groups in patients having weak/absent pre - operative clinical reflexes

Age	Weak/Absent reflex (%)		Total (%)
	Symptoms persist	Symptoms relieved	
40–60 years	16 (94.12)	01 (5.88)	17 (100)
61–80 years	29 (96.67)	01 (3.33)	30 (100)
>80 years	01 (100)	00 (0)	01 (100)
Total	46 (95.83)	02 (4.17)	48 (100)

P=0.89

DISCUSSION

One hundred and fifty-one (37.8%) patients were in the age group 40–60 years, 246 (61.5%) patients were in the age group 61–80 years, and three (0.8%) patients were in the age group >80 years. Majority of the patients were in the age group of 61–80 years.

Wu *et al*.[8] in their study reported a median age of 74.4 ± 10 years. Three hundred and fifty-two (88.0%) patients were having good clinical reflexes preoperatively and 48 patients (12.0%) were having weak/absent reflexes.

Wu *et al*. in their study reported that patients with successful outcome had a higher baseline detrusor pressure (P =.029), that is, good clinical reflexes and greater maximum flow rate (P = 0.034) than the non-recovery group.

Kuo *et al*.[9] reported that urodynamically obstructive BPH proven by a high voiding pressure and constrictive flow pattern predict a satisfactory outcome. The unfavorable factors always come from a small adenoma, uncertain irritative symptoms, and detrusor underactivity.

Rademakers *et al*.[10] reported that patients with detrusor underactivity have an unfavorable outcome after prostatic surgery and do not have better long-term results than untreated detrusor underactivity patients.

Out of total 400 patients in study, there was persistence of symptoms in 62 (15.5%) patients postoperatively and in 338 (84.5%) patients symptoms were relieved after surgery.

Out of 352 patients having good reflexes preoperatively, 336 (95.45%) patients showed improvement in their symptoms and 16 (4.54%) patients had persistence of symptoms after surgery.

Out of 134 patients in 40–60 years age group having good reflexes preoperatively, 129 (96.27%) patients showed improvement in their symptoms and 5 (3.73%) patients had persistence of symptoms after surgery. Similarly, out of 216 patients in 60–80 years age group having good reflexes preoperatively, 206 (95.37%) patients showed improvement in their symptoms and ten (4.63%) patients had persistence of symptoms after surgery. Similarly, out of two patients in >80 years age group having good reflexes preoperatively, one (50%) patient showed improvement in his symptoms and one (50%) patient had persistence of symptoms after surgery.

Out of total 48 patients having weak/absent reflexes preoperatively, two (4.16%) patients showed improvement in their symptoms and 46 (95.83%) patients had persistence of symptoms after surgery.

Out of 17 patients in 40–60 years age group having weak/absent reflexes preoperatively, one (5.88%) patient showed improvement in his symptoms and 16 (94.12%) patients had persistence of symptoms after surgery. Similarly, out of 30 patients in 60–80 years age group having weak/absent reflexes preoperatively, one (3.33%) patient showed improvement in his symptoms and 29 (96.67%) patients had persistence of symptoms after surgery. Similarly, out of one patient in >80 years age group having weak/absent reflexes preoperatively, and one (100%) patient showed persistence of symptoms after surgery.

There was significant improvement in uroflowmetry parameters in 352 patients who were having good clinical reflexes preoperatively and no significant improvement in uroflowmetry parameters in 48 patients who were having weak/absent clinical reflexes preoperatively.

Wu *et al*. reported that patients with DU and small TPV might also benefit from prostatic surgery if they had a higher detrusor pressure which is reflected by good clinical reflexes and maximum flow rate at baseline.

Rademakers *et al*. reported in their study that careful assessment of voiding dysfunction to discriminate between detrusor under activity and BOO should be done with pressure-flow studies, can avoid unsuccessful prostate surgery and helps in counseling patients.

Andrade *et al*.[11] in a study showed that a urodynamic study revealed a hyposensitive bladder (first sensation at 450 ml), normal compliance (35 mL/cm H_2O), and absent voluntary detrusor contraction. The remainder of the workup was unremarkable. Patient was started an alpha blocker (tamsulosin) and intermittent catheterization, every 4 h, preceded by a voiding attempt and no surgery was done. After a few weeks, he was able to void by schedule with negligible residual volumes.

CONCLUSION

For the management of BPH, we had analyzed the role of clinical examination and uroflowmetry studies. Pre-operative and post-operative clinical reflexes were checked and uroflowmetry done. The results obtained from the study show that there was a significant improvement in the LUTS after surgery in patients whose clinical reflexes were good preoperatively, that is, intact S2, S3, and S4 and also there was improvement in uroflowmetry study parameters. There was no significant improvement in the LUTS after surgery in patients whose clinical reflexes were weak/absent pre operatively and also there was no improvement in uroflowmetry study parameters.

These clinical reflexes give an idea about detrusor activity. Patients with weak/absent reflexes give an idea about detrusor underactivity which may be due to various underlying neurological conditions.

Majority of the patients who are having weak/absent clinical reflexes do not improve even after surgery since they have underlying detrusor underactivity.

This study concludes that there is no benefit of surgery in patients having weak/absent clinical reflexes preoperatively, that is, in patients having detrusor underactivity.

Uroflowmetry alone is not reliable in predicting the post-operative prognosis in patients of BPH. Furthermore, not all the patients having pre-operative poor uroflowmetry parameters will improve after surgery. The improvement depends on the pre-operative clinical reflexes.

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How to cite this article: Mahajan S, Ghanghoria A, Arora S, Yadav JS, Patidar A. Role of Clinical Examination (Bulbocavernosus Reflex, Anal Tone Assessment and Perianal Sensation) and Uroflowmetry Studies in Evaluating Post-operative Prognosis in Patients of Benign Prostatic Hyperplasia. Int J Sci Stud 2021;9(2):68-71.

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

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

Original Article

Renal Resistive Index in Unilateral Obstructive Nephropathy – A Study to Assess Current Role and Future Possibilities

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Abstract

Introduction: Gray scale ultrasonography is the initial investigation for the anatomical assessment of the renal system. CTIVU and diuretic renogram are the investigations of choice for functional assessment of the kidneys. Recently, the role of color Doppler to determine renal resistive index (RI) and RI ratios (RIRs) has been suggested for functional assessment of kidneys at the time of disease presentation as well as for follow-up after corrective surgeries.

Aims: This study aims to determine the role of RI and RI ratio in the functional assessment, diagnosis, and follow-up of unilateral hydronephrotic/obstructive kidney.

Materials and Methods: Thirty patients who presented to our outpatient department/emergency department with unilateral hydronephrosis were selected and pre-operative RI of diseased and normal kidneys and RIR were determined. Individualized surgical interventions were performed for the relief of hydronephrosis in these patients and 3 months post-operative, the RI and RIR were measured again. The values of the RI in normal and hydronephrotic kidneys, pre-operative and post-operative RI and RIR were compared. Student's t-test was applied to determine the *P* value.

Results: The value of RI in hydronephrotic kidneys was significantly higher as compared to normal kidneys, but when the established cutoff of 0.7 was used, the sensitivity was found to be very low. There was also a significant decrease in the pre- and post-operative RI values of the abnormal kidneys.

Conclusions: Even though color Doppler is much cheaper and readily available technique, it is user dependent and the sensitivity to determine functional compromise of the kidney is not high, especially in mild-to-moderate hydronephrosis. It may have a role as an adjuvant investigation but not as an alternative of diuretic renogram.

Key words: Colour doppler, Obstructive hydronephrosis, Renal resistive index ratio, Renal resistive Index

INTRODUCTION

Gray scale ultrasonography has been the most routinely performed investigation for the evaluation of renal pathologies. In spite of marked improvement in the technology, it gives us the information regarding the anatomy of kidney and dilatation of the pelvicalyceal system. Functional assessment of the renal units cannot be performed through it.

Thus, the use of Doppler sonography was established to provide better diagnostic information as well as the functional status of the kidneys. With the calculation of the renal resistive index (RI), one can show the degree of resistance within the renal vasculature. Its use has been indicated in the diagnostic evaluation and follow-up of various renal pathologies, including obstructive diseases. At present, diuretic renography is the most widely accepted non-invasive procedure to assess renal function in an obstructed pathology of kidney. However, it has the disadvantages of being expensive, it uses ionizing radiation and having 10–15% rate of false-positive and indeterminate

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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results. The non-invasive and non-radiation nature of measurement and easy availability of Doppler give RI considerable appeal in potential application to patients with obstructive uropathy.

MATERIALS AND METHODS

A prospective study was conducted at a tertiary center. A total of 30 cases which underwent treatment for unilateral hydronephrosis were included in the study.

All patients who presented to the emergency department and surgery outpatient department above the age of 12 years with the clinical symptoms of renal colic (flank pain, nausea, vomiting, hematuria, and burning micturition) were evaluated by proper history taking, physical examination, and thereafter, blood investigations (complete blood count and renal function test) and radiological investigations such as ultrasound of the KUB region and plain radiograph KUB. Those patients diagnosed clinically with unilateral hydronephrosis (either due to a calculus or pelviureteric junction [PUJ] obstruction) with a normal contralateral kidney were included in the study. After explaining the details of the study including the benefits and risks, those patients that gave informed and written consent were selected for the study. The patients with contralateral kidney involvement, patients with single kidney, patient lost to follow-up, and those who refused to undergo surgical intervention for their cause of hydronephrosis were excluded from the study.

Patients were further evaluated by performing renal color Doppler of both kidneys and thus determining the pre-intervention renal RI of normal and abnormal kidneys and RI ratio. Other investigations such as CTIVU and DTPA were conducted in a few patients with severe hydronephrosis. Depending on the functional status of the kidney and the level and type of obstruction in the urological tract, individualized interventions were planned for each patient such as percutaneous nephrostomy, percutaneous nephrolithotomy, and open or laparoscopic pyeloplasty. On recovery, the patients were discharged and asked to come for follow-up. Three months post-operative, each of these patients was asked to undergo the basic blood investigations and ultrasound with renal color Doppler again. Post-operative RI of both the kidneys was noted and RIR calculated. The pre-operative RI of normal and obstructive kidneys and pre- and post-interventional renal RIR were compared in every patient. Student's *t*-test was applied to determine *P* value.

RESULTS

In this research, we have endeavored to study renal vascular resistance in terms of Doppler waveforms in renal obstruction. The study comprises 30 patients, aged from 12 to 60 years, and eventually planned for surgery for diagnosed PUJ obstruction, either from an anatomical or physiological defect or secondarily from calculi.

In our study, the mean age of presentation was 33.7 years with the mean age of PUJ obstruction cases being 30.23 years and PUJ calculus group being 36.35 years. Out of 30 subjects, 20 were males making 66.66% of total patients, while 10 were female making 33.33% of the total. PUJ obstruction, either from an anatomical or physiological defect, was the cause of pathology in 13 out of 30 patients (43.33%), while obstructive calculus at pelvic-ureteric junction/upper ureter was the cause in the rest 17 (56.66%). While the left kidney was pathologically affected in 46.66% of cases (14 patients), the right kidney was affected in the rest 53.33% (16 patients).

The calculation of RI of both the renal systems was done by color Doppler technique.

Preoperatively, the mean RI in healthy kidney was 0.599 while in the pathological kidney was 0.673 [Figure 1]. This difference between the two was found to be statistically significant. However, if we take into account the established threshold value for RI in pathological kidney of 0.7, then the sensitivity came out to be only 20% and specificity was 100%.

Postoperatively, the mean RI in healthy kidney was measured as 0.57 and in the pathological kidney was measured as 0.65 [Figure 1]. This decrease in mean RI values of pathological kidneys was found to be statistically significant ($P < 0.001$) on applying paired *t*-test.

Preoperatively, the mean RIR in this study of 30 patients was 1.11. This value was reduced to 1.08 postoperatively [Figure 2], the difference was found to be significant on applying paired t-test. However, if the threshold value of 1.1 is being considered, then the sensitivity was found to be only 56.66% in this study.

DISCUSSION

The hemodynamic changes that occur in an obstructed kidney have been studied extensively. The initial phase of increase in the renal blood flow is due to pre-glomerular vasodilation followed by the second phase in which decline in flow is observed.[1,2] The extent of the blood flow changes is dependent on the extent or severity of obstruction. In case of chronic obstruction, the renal blood flow may reduce or may be essentially the same as that of a normal kidney,[3] the reasons for which are unclear. These hemodynamic responses can be measured by the renal RI.

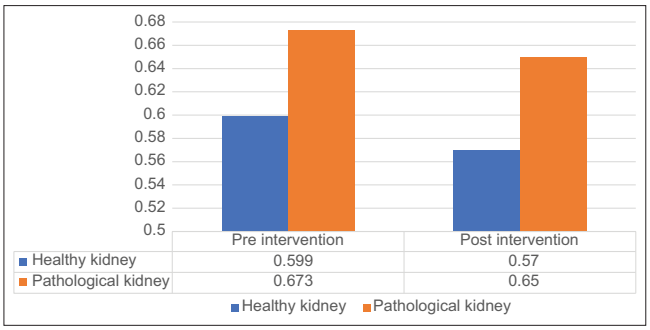

Figure 1: Bar chart comparing mean resistive index in pre- and post-operative healthy and pathological kidneys

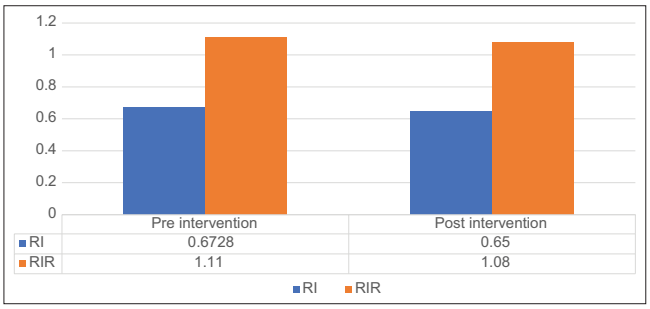

Figure 2: Bar chart comparing pre- and post-operative resistive index in pathological kidneys and pre- and post-operative renal index ratio values

Various studies have been done on the usefulness of this index and its reliability in studying functional compromises of an obstructed kidney.

0.70 being considered the upper limit for a normal mean intrarenal RI,[4,5] the sensitivity of RI to differentiate between obstructive and non-obstructive hydronephrosis was 92% and 100% in the series of Platt *et al*.[4] and Gottlieb *et al*.,[5] respectively. Brkljacić *et al*.[6] found RI <0.70 in six of 21 unilaterally obstructed kidneys (28.6%), the sensitivity was 71.4% when RI ~0.70 was used as a cutoff value in diagnosing obstruction.

With this upper limit, the sensitivity was found to be only 20% in our study. Many other studies failed to show a high sensitivity of RI in obstructive pathologies. Chen *et al*.[7] found a sensitivity of 52% in their study, which they attributed to the fact that mildly obstructed kidneys had little change in the RI values. Tublin *et al*.[8] observed a sensitivity of 44% in their study. They concluded that when the RI is elevated and one is suspecting acute obstruction clinically it is highly specific. However, if one relies solely on an elevated RI to diagnose obstruction, the sensitivity is such that many cases of obstruction would be missed.

Deyoe *et al*.[9] found that only three obstructed kidneys out of 10 showed an elevation in RI. None of the partially obstructed systems had in increase in RI. Only 30% of their patients with complete obstruction exhibited an elevated or asymmetric RI. de Toledo *et al*.[10] reported a sensitivity of 91.8% in patients with complete obstruction but only 48.1% in those with partial obstruction. Li *et al*.[11] concluded in their study that pre-operative RI and post-operative decrease in RI were not independent predictors of renal functional recovery in their patients. Elevation of pre-operative RI was associated with poor recovery of post-operative renal function. Their study was the first to use RI to predict the recoverability of post-operative renal function in patients with chronic hydronephrosis. They demonstrated that lower pre-operative RI and a greater decline in post-operative compared with pre-operative RI were associated with better outcomes in patients younger than 35 years.[11]

In acute obstruction, the sensitivity of RI drops substantially after 48 h, renal Doppler US is useful for diagnosing acute renal obstruction 6–48 h after the onset of symptoms.[12] In unilateral hydronephrosis, a RI ratios (RIR) of >1.1 indicates obstruction and is predictive of the need for surgery.[13] This index is of more significance in children as compared to adults, since unlike the RI, it is unaffected by the age of the child.[14] Brkljacić *et al*.[6] showed that RI comparison between obstructed and contralateral kidneys in a patient with unilateral obstruction is more useful than the application of a 0.70 RI threshold value in diagnosing urinary tract obstruction. In our study, the sensitivity of RIR when the upper limit of 1.1 was considered was found to be 56.66%. In contrast, Ulrich *et al*.[15] reported an RI ratio of 1.15 to be 100% sensitive and specific for acute obstruction.

There are many limitations of our study, one being a very small sample size, too small to define a threshold RI value for renal obstruction. We also did not perform the Whitaker test; so the significance of obstruction could not be accurately assessed on the basis of ultrasonographic findings. Another limitation of RI is that its value may be affected by various other factors such as hypertension, diabetes mellitus, arteriosclerosis, or pulmonary system diseases, which may also affect its efficiency and feasibility for predicting postoperative renal function.[16] Even though, currently, the role of RI is limited and only has a supportive role, it can be of help in situations in which intravenous contrast administration is undesirable such as pregnancy, contrast agent allergy, and renal dysfunction. Furthermore, it has a role in assessing the presence of obstruction and if functional compromise is present in pyelocaliectasis of a symptomatic kidney.

In institutions at which sonography is used as a primary technique for evaluating acute renal colic, the addition of a Doppler study will improve the sensitivity for early obstruction and will provide functional information regarding an obstructed kidney.

CONCLUSIONS

Renal obstruction produces a change in the Doppler waveform causing elevation of RI by causing increase in renal vascular resistance. Duplex Doppler sonography is an insensitive technique for the detection of patients with renal obstruction. Multiple factors that directly or indirectly affect renal arterial resistance limit its use as a screening examination. Decrease of a previously elevated RIR to significant values can be used as an early indicator that recovery of renal function is likely and hence helps in evaluating the success of surgical intervention. After relief of obstruction, renal function is regained that is associated with decrease in mean RI and RIR. RI and RIR values provide corroboration of the initial diuretic renogram and can be used as a non-invasive modality for monitoring the dilated collecting system. Doppler ultrasound being a physiological investigation cannot be used to determine precise anatomical details and should not be used alone to evaluate a patient with hydronephrosis. However, it can be used for monitoring hydronephrotic kidney under observation obviating the need for frequent radioisotope scintigraphy. The non-invasive nature of renal color Doppler gives it considerable appeal in the diagnosis and follow-up of patients with hydronephrosis. This method provides a non-invasive modality for monitoring patients after reconstructive surgery of the upper urinary tract. More work needs to be conducted to establish the role of RI and RIR in diagnosing and follow-up cases of renal obstruction in adults.

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How to cite this article: Shukla S, Sharma SS, Sharma A, Kumar M. Renal Resistive Index in Unilateral Obstructive Nephropathy – A Study to Assess Current Role and Future Possibilities. Int J Sci Stud 2021;9(2):72-75.

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

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

Original Article

Pulmonary Toxicity in Patients with Carcinoma Breast Treated With Post-operative Chest Wall Irradiation

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ABSTRACT

Background: Radiation plays a very important role in the multimodality treatment of breast cancer. As overall survival increases, the long-term toxicity due to radiation also increases. This study intends to evaluate the incidence and assess pulmonary toxicities in patients undergoing post-operative radiation with conventional radiotherapy techniques.

Materials and Methods: Patients with invasive breast cancer who have completed surgery and chemotherapy were selected and given radiation to the chest wall and regional lymph nodes, when indicated, using a conventional simulator and Co-60 Tele Cobalt Therapy machine to a dose of 50 Gy in 25 fractions and boost radiation for Breast Conservation Surgery patients. These patients were followed up at 3 and 6 months following radiation with the help of chest X-ray, Contrast-Enhanced Computed Tomography. Thorax if indicated, and pulmonary function tests. Clinical symptoms were recorded.

Results: The incidence of symptomatic radiation pneumonitis is low in our study population. This study showed a significant decrease in Forced Expiratory Volume in 1 s following radiation. This reduction was associated with central lung distance (CLD) and locoregional lymph node irradiation.

Conclusion: The CLD is the main factor affecting radiation toxicity. The majority of patients show some reduction in pulmonary function even though symptomatic radiation toxicity is rare.

Key words: Breast cancer, Chest wall radiation, Co^{60} teletherapy, Central lung distance, Pulmonary toxicity

INTRODUCTION

Breast cancer is the most common type of cancer seen among females in Kerala. The management of breast cancer consists of the integration of surgery, chemotherapy, radiotherapy, hormonal therapy, and biological therapy. Each mode of treatment is tailored according to the stage and characteristics of the particular patient's disease.

Access this article online

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

Radiotherapy plays an important role in the multimodality treatment of breast cancer.[1] It is given to prevent local recurrence and also helps in palliation. Radiation treatment is given after breast conservation surgery (BCS) and in patients undergoing Modified Radical Mastectomy (MRM), if there are certain adverse features.[1,2] It is delivered to the breast, chest wall, and regional lymph nodes in the curative setting. Since breast cancer patients may survive for years, the toxicity of a particular treatment manifests as long as the patient survives. Radiation therapy (RT) is not without consequences. It causes short-term and long-term toxicities. Since the radiation portal partly passes through the underlying lung, there is a chance that it may manifest as short-term and long-term pulmonary damage.

This study tried to assess the incidence and factors associated with pulmonary toxicity and quantitatively and

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qualitatively measure it with pulmonary function tests (PFT), chest X-ray, and contrast-enhanced computed tomography.

Aims and Objectives

The aim of the study was to study the pulmonary toxicity following post-operative RT using conventional radiotherapy techniques in patients with carcinoma breast and to evaluate the incidence of radiation pneumonitis (RP) in this study population. This study also aimed to assess radiation toxicity with PFT quantitatively.

MATERIALS AND METHODS

This hospital-based prospective study was conducted in the Department of Radiotherapy, Government Medical College Hospital, Kozhikode, Kerala. The study population consisted of 40 female patients registered from July 2013 to December 2013 with histological diagnosis of carcinoma breast who were candidates for post-operative RT and were willing to undergo follow-up according to the study guidelines with informed consent. Those patients with ages between 18 and 65 years, Stage 1–3, with Eastern Cooperative Oncology Group performance status ≤2 and with no history of the previous pulmonary disease were included in the study. The study was conducted after obtaining ethical clearance from the ethical committee. Patients were enrolled after obtaining written informed consent. Privacy and confidentiality were maintained.

At the time of recruitment, the following data were collected: Name, age, address, socioeconomic status, menopausal status, hematological and biochemical parameters, previous comorbidities, site of the primary tumor, stage at diagnosis, histopathological report, details of surgery performed, chemotherapy taken, and whether hormonal agents were being used.

Radiotherapy was planned and administered after obtaining informed consent. All patients were asked to undergo a PFT to get a baseline value.

Radiation was scheduled to begin within 3 weeks after chemotherapy. A dose of 50 Gy in 25 fractions was planned using gamma rays from a Cobalt 60 machine using medial and lateral tangential fields. Patients were treated in the supine position with the ipsilateral arm abducted, externally rotated, and placed above the head. The tangential field borders were determined clinically and marked by radio-opaque wires. The medial border was 1 cm from the mid-line or the medial end of the mastectomy scar. The superior border was at the caudal border of the clavicular head. The inferior border was 1 cm below the inframammary fold, and the lateral border was at the mid-axillary line. The supraclavicular fossa was treated separately if indicated. Boost doses of 10 Gy in 5 fractions were given to patients who had undergone BCS. During the simulation, the central lung distance (CLD) values for each patient were recorded.

Every patient was monitored at 3 months and 6 months following radiation with chest X-ray and PFT. A detailed history was taken and a clinical examination was done to assess pulmonary toxicity. High-resolution computed tomography was taken for those patients with doubtful chest x-ray findings. Clinical symptoms, X-ray findings, and forced expiratory volume in 1 s (FEV1) values were recorded.

Data were entered into Microsoft Excel and analysis was performed using the SPSS version 20.0 software and analyzed with the help of descriptive statistics such as mean, standard deviation (SD), percentage, and statistical tests such as Independent *t*-test, one-way ANOVA test, and Chi-square test applied appropriately.

RESULTS

Forty patients had participated in our study, with the mean age being 47.6 years. Twenty-two patients in our study presented with early disease (55%) and 18 patients with locally advanced disease (45%). Only four patients (10%) had undergone BCS, while 36 patients (90%) had undergone mastectomy (MRM). Thirty patients (75%) had received regional nodal radiation, while ten patients (25%) did not. Table 1 shows categorization of patients according to the CLD, with majority of patients in category 3 (17 patients).

In our study, we found a low incidence of symptomatic RP. There was no case of radiation fibrosis or radiation-induced bronchiolitis obliterans organizing pneumonia (BOOP). We have only one patient with symptomatic RP. She was a 65-year-old lady with Stage III_B breast cancer. She received chest wall irradiation and regional lymph node radiation with a CLD of 2.8 cm. She had a 22.8% reduction in FEV1. She complained of dry cough and dyspnea on exertion, and her X-ray showed diffuse haziness, which any other disease could not explain. FEV1 values were recorded at baseline, that is, before chemotherapy or radiation and

Table 1: Patient categorization according to CLD

Category	CLD (cm)	Number of patients
1	≤1.5	2
2	1.6–2	9
3	2.1–2.5	17
4	2.5–3	12

at 3 months and 6 months after completion of RT. Our study population had a baseline mean FEV1 of 1.93 L. The mean FEV1 of our study population at 3 months after RT showed a significant decrease to 1.78 L. At 6 months, the mean FEV1 of our study population decreased to 1.67L ($P = -0.012$) [Table 2].

The mean FEV1 values progressively decreased after RT. Although we had only one patient with symptomatic RP, the FEV1 values showed a uniform decrease following RT. Even though the PFT values showed deterioration in most patients, clinically symptomatic RP is rare. The percentage decrease in FEV1 was compared with CLD.

There is a statistically significant relationship between the percentage decrease in FEV1 and CLD. $P = 0.23$ [Graph 1].

The mean percentage decrease in FEV1 was compared in the group receiving locoregional lymph node radiation and the group that did not receive nodal RT.

There is a decrease in pulmonary function in patients with locoregional RT, but the relation is not statistically significant. $P = 0.52$ [Graph 2].

DISCUSSION

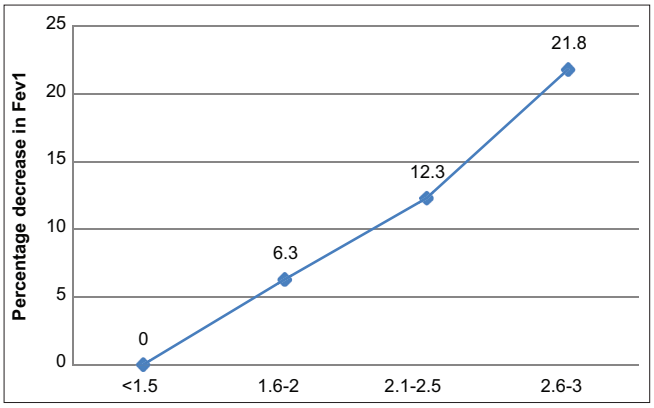
Pulmonary Function After RT

Fall in lung function parameters after radiotherapy for breast cancer is well described. Ooi *et al.* demonstrated that FEV1, Forced Vital Capacity (VC), VC, Total Lung Capacity, and Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) progressively declined after radiotherapy and remained irreversible at 12 months ($P < 0.05$).[3] Tokatli *et al.* found a significant reduction in FEV1 and VC at 6, 16, and 52 weeks after radiotherapy compared with baseline.[4]

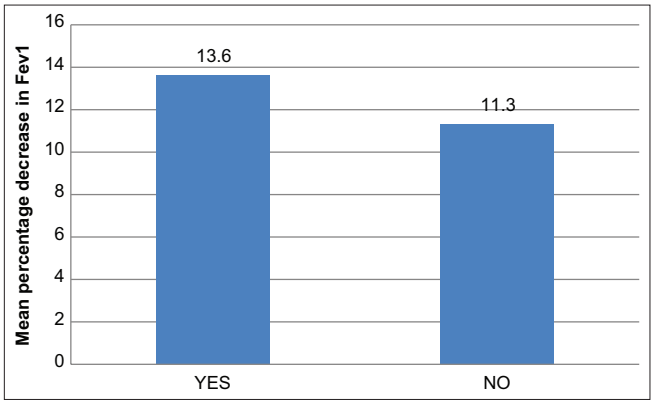
In our study, mean FEV1 reduced from 1.93 L (SD 0.288) at baseline to 1.67 L (SD 0.258) 6 months after RT.

Table 2: Comparison of FEV1

FEV1	Baseline	3 months	6 months
Mean	1.9378 L	1.7898 L	1.6785
Std. deviation	0.28803	0.24617	0.25892
Median	1.9000 L	1.7950 L	1.67
Mode	1.92 L	2.20 L	1.42



Graph 1: Mean percentage decrease in forced expiratory volume in 1 s compared to each category of central lung distance



Graph 2: Relationship between locoregional lymph node irradiation and mean percentage decrease in forced expiratory volume in 1 s

Pulmonary Toxicity After Radiation

Radiation lung injury typically presents three distinct clinical stages, namely, RP, fibrosis, and BOOP.[5]

RP is an early inflammatory reaction that occurs 4–12 weeks after completion of thoracic irradiation, while radiation fibrosis is observed beyond 6 months.[6,7] Pulmonary fibrosis is a late injury that can take months to years to evolve and is characterized by progressive fibrosis of the alveolar septa and pleura.

Among pulmonary injuries following RT of the whole breast, the most clinically significant pulmonary disorder is RT-induced BOOP syndrome. It is characterized by infiltrating shadow expansion outside the RT field of the lung. Crestani described the following factors for diagnosing BOOP.[8]

- RT to the chest within past 12 months.
- General and or respiratory symptoms are lasting for more than 2 weeks.
- Radiographic lung infiltration outside the RT port.
- No evidence of a specific cause.

Incidence of Pulmonary Toxicity

The reported frequency of RP in breast cancer ranges from 1 to 80%. This wide range of incidence across studies is due to variations in simulation techniques, treatment

schedules, treatment portals, total dose, use of photons or electrons, and the use of various grading systems and endpoints and types of tools to access it.[4-9] A recent meta-analysis on the incidence of early lung toxicity with three-dimensional conformal radiation for breast cancer identified ten different studies and reported the overall incidence of clinical and radiological RP as 14% and 42%, respectively.[10]

In our study, population of 40 patients, we had only one case of symptomatic RP. She had haziness in her chest X-ray and dyspnea on exertion, which developed 5 months after RT. She is a 65-year-old lady who took chest wall and locoregional lymph node irradiation with CLD of 2.6 (category 4). Our study showed a low incidence of RP, that is, 2.5%. We had no cases of BOOP syndrome.

Role of CLD

CLD is useful for assessing the amount of lung volume included in the radiation portal. CLD is directly proportional to the lung volume exposed to RT. Bornstein *et al.* identified CLD as the best predictor of ipsilateral lung volume when using tangential fields.[11] A CLD of 1.5 cm predicted that about 6% of the ipsilateral lung would be included in the tangential field, a CLD of 2.5 cm about 16%, and a CLD of 3.5 cm about 26% of the ipsilateral lung with a mean 90% prediction interval of ±7.1% of ipsilateral lung volume. The CLD helps predict the irradiated lung volume; 0.6%/mm and 0.5%/mm for the left and right lungs.

Our study showed a consistent decrease in pulmonary function as CLD increases. There is a statistically significant relationship between the percentage decrease in FEV1 and CLD.

Role of Locoregional Lymph Node Irradiation

Lymph nodal irradiation increases the irradiated lung volume and the radiation dose to the lung. Studies have demonstrated an increased risk of RP with local and regional radiotherapy compared to that of local radiotherapy alone.[12]

We assessed the percentage decrease in FEVI in those patients with lymph node RT and those without lymph node radiation. There is more reduction in FEV1 in the group in which lymph node radiation was given. This result was not significant statistically because we had only few patients who did not take RT to regional lymph nodes.

CONCLUSION

Even though we use conventional methods for simulation using conventional X-ray simulators and two-dimensional radiotherapy using Tele cobalt unit, the incidence of RP is low. However, we found out that there is a statistically significant decrease in FEV1 after radiotherapy. This study also showed that there is a decrease in FEV1 with the increase in CLD.

Further studies with more sample size, long duration of follow-up, and more variables with probable association with the number of lung injuries should be conducted in the future.

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How to cite this article: Jose AC, Bindu G, Amina A, Ajayakumar T, Jayaraman MB. Pulmonary Toxicity in Patients with Carcinoma Breast Treated With Post-operative Chest Wall Irradiation. Int J Sci Stud 2021;9(2):76-79.

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

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

Original Article

Study on Correlation between Ultrasonographic and Surgical Findings in Acute Appendicitis

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Abstract

Introduction: Acute appendicitis is an acute inflammation of the vermiform appendix, which is a blind-ended tube arising from the cecum. It is a vestigial organ but it can become diseased. Appendicitis is a surgical emergency, and if it is left untreated, the appendix may perforate and cause potentially fatal complications, especially in children and the elderly. This is a study on correlation between ultrasonographic and surgical findings in acute appendicitis.

Materials and Methods: A prospective study was conducted for a period of 1 year from 2018 to 2019. A total of 60 cases were taken for detailed study from Government Headquarters Hospital, Tirupur.

Results: Out of 60 total cases, 48 cases were acute appendicitis histopathologically, out of them, 39 (81.25%) were male and 09 (18.75%) were female. An increased leukocyte count was found in 65% of cases of histopathologically diagnosed acute appendicitis. Self-localization was found to be useful in diagnosis by ultrasound in our study. About 80% (48 cases) showed ultrasound findings suggestive of acute appendicitis.

Conclusion: Ultrasonography has a definite role in acute appendicitis. It is more useful in female patients whenever there is associated pelvic pathology and in children and also in obese patients where acute appendicitis is in dilemma.

Key words: Appendicitis, Histopathology, Ultrasonography

INTRODUCTION

Acute appendicitis refers to acute inflammation of the vermiform appendix, which is a blind-ended tube arising from the cecum. It is a vestigial organ but it can become diseased. Appendicitis is a surgical emergency, and if it is left untreated, the appendix may perforate and cause potentially fatal complications, especially in children and the elderly. One of the most frequent causes of surgical emergencies and abdominal pain is acute appendicitis. Patients with appendicitis present with a wide variety of clinical manifestations, which may mimic symptoms of other diseases.[1] If not diagnosed early, it can rapidly develop severe acute abdominal complications such as perforation, abscess formation, sepsis, bowel obstruction, and general peritonitis. Prompt diagnosis is essential to minimize morbidity and mortality. Therefore, surgeons have been performing appendectomy, in cases where the diagnosis was only probable, thus elevating the rate of removal of normal appendices. The classic presentation of a patient with appendicitis has a typical sequence of symptoms (poorly localized periumbilical pain). This classic presentation occurs in only 50–60% of patients, and the diagnosis may be missed or delayed when atypical patterns of disease are encountered.[2]

Patients with acute appendicitis typically present with central abdominal pain shifting to the right lower quadrant (RLQ) or may present with generalized abdominal pain. Vomiting is common in children. Clinical examination reveals signs of acute intra-abdominal process, for example, local and rebound tenderness, muscle guarding, rigidity, cutaneous hyperesthesia, and tenderness on rectal examination. About one third of patients with acute appendicitis present with atypical symptoms.[3] Differential diagnosis is diverse and includes gastroenteritis, mesenteric lymphadenitis, ovarian and tubal disorder, renal colic, peptic ulcer, and acute cholecystitis.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 05-2021
Month of Publishing : 05-2021

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Ultrasonographic criteria of acute appendicitis include blind-ended, non-compressible, aperistaltic tube, with diameter more than 6 mm, arising from the tip of cecum with a gut signature. Visualization of an appendix with an appendicolith, regardless of appendiceal diameter, is also regarded as a positive test. However, a normal appendix can also be visible on ultrasound. Normal appendix is compressible with wall thickness of ≤3 mm. The size of the appendix can differentiate normal from acutely inflamed appendix. The threshold level for the diameter of the appendix above which acute appendicitis is very likely 6 mm.[4]

Appendicitis represents one of the most common causes of abdominal pain of adult patients referred to the emergency department. To prevent high morbidity and mortality, most of the surgical authorities have advocated timely surgical intervention (early appendicectomy), accepting that a significant number of normal appendices will be removed.[3,5] The diagnosis of appendiceal inflammation cannot be accurately made, based on a single symptom, sign, or diagnostic test in all cases. The diagnosis of acute appendicitis can be established accurately in over 80% of the cases by some experienced senior surgeons.[6,7] Abdominal ultrasonography (USG) has a definitive role in the diagnosis of acute appendicitis, establishes an alternative diagnosis in patients with acute right lower abdominal pain, and reduces the number of negative laparotomies.[8-10]

MATERIALS AND METHODS

It is a prospective study. Material for this study was obtained from the patients admitted in the Department of General Surgery, at Government Headquarters Hospital, Tirupur, who were suspected of having appendicitis. The study was conducted for a period of 1 year, from 2018 to 2019. A total of 60 cases were taken for detailed study.

Inclusion Criteria

1. Patients admitted with acute abdomen with clinical diagnosis suggestive of acute appendicitis irrespective of age and sex
2. Patients who underwent surgery were only taken for the study.

Exclusion Criteria

1. Patients admitted with hollow viscous perforation with peritonitis
2. Patients proved to have other causes of pain in the right iliac fossa such as renal colic, pelvic inflammatory disease (PID), ovarian cyst, appendicular abscess, and appendicular mass.

A detailed history was taken from all patients regarding presenting complaints, their duration, severity, sequence of onset of symptoms, mode of onset, progression, change in pattern at the time of presentation, etc. Each patient was examined regarding built, nourishment, hydration, general appearance, and presence of any systemic illness. Vital signs were recorded in each case. CVS and RS were examined as routine special attention was paid to abdominal examination and per rectal examination.

In this study, the diagnosis of appendicitis was mainly clinical depending on history and physical examination. All patients underwent ultrasound examinations of the abdomen. Relevant investigations which were done in this study included blood – hemoglobin percentage, total count, differential count, RBS, urea, S. creatinine, blood grouping and Rh typing, urine examination, and gynecological opinion in some female patients. Routine investigations were performed to know the fitness for anesthesia in elective cases. Ultrasonographic examination was performed, initially with a handheld 3.5 MHZ sector probe, in which the entire abdomen was scanned to exclude possible differential diagnosis of acute appendicitis. A 5 MHZ sector probe scan of the RLQ using graded compression technique was followed.

Operative Treatment

Most of the cases of acute appendicitis were treated with:

a. Emergency appendectomy
b. Laparoscopic appendicectomy
c. Conservative management followed by interval appendicectomy – either laparoscopic or open.

Data Analysis

The analysis of the 60 cases of acute appendicitis who underwent surgery was studied, clinical diagnosis was correlated with USG abdomen and histopathology between 90% and 92% is presented here.

RESULTS

Table 1 shows spectrum of complaints. Out of 60 patients, 55 (91.66%) had RLQ tenderness, 31 (51.66%) had rebound tenderness, 12 (20%) had fever, and 43 (71.66%) suffered from loss of appetite. About 80% (n = 48) of the patients had complaints of nausea and vomiting. About 36.66% (n = 22) of patients had shift in pain, 39 (65%) patients suffered from leukocytosis, and 26 (41.66%) patients had left shift.

Table 2 shows a spectrum of diseases mimicking acute appendicitis. Appendicular masses were found in three patients. One female and five males had RT. acute

pyelonephritis and RT. ureteric calculus, respectively. One patient each suffered from twisted ovarian cyst and ILEO-cecal TB. Three patients had CA cecum and five with NAD. A total of 39 patients were diagnosed with acute appendicitis, out of which 31 patients were male and eight females.

Table 3 shows sex incidence of acute appendicitis and appendicular mass. A total of 39 patients were diagnosed with acute appendicitis, out of which 31 patients were male and eight were female. Appendicular mass was found in two males and a female.

Table 4 shows a spectrum of appendicitis and diseases mimicking acute appendicitis. Sonographic diagnosis showed 48 positive results and 12 negative reports in patients with disease.

Table 5 shows the percentage of position of appendix in the present study. Thirty-eight (79.16%) cases had appendix in retrocecal position, 6 (12.5%) cases in pelvic position. Each patient had appendix in subcecal, pre-ileal, post-ileal, and subhepatic positions.

DISCUSSION

In our study, out of 60 total cases, 48 cases were acute appendicitis histopathologically, out of them, 39 (81.25%) were male and 09 (18.75%) were female, male-female ratio was 4.3:1 and mean age was 29.64 years. The most common age group was 18–30 years followed by 31–40 years. In a study by Sigdel *et al.*[11] done in Kathmandu, mean age was 27.5 years and male-to-female ratio was 2.6. In most other studies too, there is male preponderance.[12] Our study was supported by Berry and Malt.[13] In his study of 246 cases, there was male predominance with 60.2% of males and 39.5% of females. In a study by Khattak *et al.*,[14] out of 663 cases, 447 were male and 216 were female with male-female ratio of 2:1. Peak incidence was in the 2nd and 3rd decade which is also comparable to our study. In another study by Omran *et al.*,[15] 58% of patients were male and age-specific incidence of acute appendicitis followed a similar pattern for male and female which is also comparable to our study. In our study, increased leukocyte was found in 65% of cases of histopathologically diagnosed acute appendicitis. However, increased leukocytosis is not a reliable indicator. Our study was supported by several other studies.[16-18]

For ultrasound examination, graded compression, as described by Puylaert,[19] was used in our study to displace bowel loops from the right iliac fossa, the aim being to oppose the external abdominal musculature with the psoas muscle. The cecum and the external iliac vessels were found to be useful anatomic landmarks. Graded compression was, surprisingly, well tolerated by patients, in contrast to the extreme pain of sudden compression. Jeffrey *et al.*[8] could perform a successful ultrasound examination on 95% of their patients. Sonographic

Table 1: Spectrum of complaints

Complaints	*n*	Percentage
RLQ tenderness	55	91.66
Rebound tenderness	31	51.66
Fever	12	20
Loss of appetite	43	71.66
Nausea, vomiting	48	80
Shift in pain	22	36.66
Leukocytosis	39	65
Left shift	26	41.66

RLQ: Right lower quadrant

Table 2: Spectrum of diseases mimicking acute appendicitis in our study

Disease	Males	Females	Total
Acute appendicitis	31	08	39
Appendicular mass	2	1	3
RT. acute pyelonephritis	–	1	1
RT. ureteric calculus	5	–	5
PID	–	1	1
Twisted ovarian cyst	–	1	1
ILEO–Cecal TB	2	–	2
CA cecum	3	–	3
NAD	5	–	5
Total	48	12	60

PID: Pelvic inflammatory disease

Table 3: Sex incidence of acute appendicitis and appendicular mass in our study

Disease	Males	Females	Total
Acute appendicitis	31	08	39
Appendicular mass	2	1	3

Table 4: Spectrum of appendicitis and diseases mimicking acute appendicitis in our study

Sonographic diagnosis	Patients with disease	Patients without disease
Positive	48	–
Negative	12	–

Table 5: Percentage of position of appendix in our study

Position of appendix	No. of cases	Percentage
Retrocecal	38	79.16
Pelvic	6	12.5
Subcecal	1	2.08
Pre-ileal	1	2.08
Post-ileal	1	2.08
Subhepatic	1	2.08
Total	48	100

self-localization of the exact site of pain has been reported by Chesbrough *et al*.[20] as a valuable adjunct to diagnosis. They found self-localization to be possible in 85% of patients with acute appendicitis in contrast to 15% of the patients with some other intra-abdominal pathology. Self-localization and elicitation of a "Sonographic Mc. Burney's sign reduce the time of examination and are lost in perforation of the appendix."

Although self-localization was not independently studied, it was found to be useful in diagnosis by ultrasound in our study. About 80% (48 cases) showed U/S finding suggestive of acute appendicitis. Non-compressibility had an accuracy of 96% Fakhry *et al*.[21] who had described a target lesion to be characteristic of lesions of the bowel and the stomach. Puylaert[19] had found a non-compressible target lesion, which could be elongated to a blind end to be specific for appendicitis. Kang *et al*.[22] had found 100% specificity for periappendiceal collection while Puylaert[19] reported a diagnostic accuracy of 89% for appendicular abscess. John *et al*.[23] found ultrasound to be particularly useful in detecting peri-appendiceal collection, with all four cases in their series being diagnosed by ultrasound. In our study Retro-caecal was found in 38 cases and pelvic position appendix in 6 cases.

CONCLUSION

USG has a definite role and best non-invasive method in acute appendicitis in adjuvant to clinical findings. It is more useful in female patients whenever there is associated pelvic pathology, children and also in obese patients where acute appendicitis is in dilemma.

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How to cite this article: Ali VAMM, Saravanan KK. Study on Correlation between Ultrasonographic and Surgical Findings in Acute Appendicitis. Int J Sci Stud 2021;9(2):80-83.

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

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

Original Article

A Prospective Study on the Contamination of Mobile Phones among Health care Workers in a Tertiary Health-care Setup

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Abstract

Background: Mobile phones (MPs) are extensively used by health care workers (HCWs) in tertiary health-care centers for faster communication. Studies in the past have revealed that MPs were invariably contaminated with microorganisms and often go disinfected. The objective of our study was to find out the percentage of MPs of our health-care personnel contaminated with microorganisms and also to find out the microbial profile of such contaminated MPs.

Materials and Methods: On a random day, swabs from MPs of about 100 randomly chosen HCWs working in Government Medical College and Hospital, Pudukkottai, were collected for culture. The collected samples were cultured under strict laboratory conditions, the microorganisms grown were identified, and compilation of the microbial profile was done.

Results: Among 100 HCWs, MPs of 70 subjects were found to be contaminated. Out of the 70 contaminated MPs, only one had been contaminated with multiple microorganisms, while the remaining 69 MPs were contaminated with only one microorganism. The most common contamination was found to be coagulase-negative *Staphylococcus*, while the least common organisms were *Pseudomonas aeruginosa* and *Enterococcus*, with one contamination each.

Conclusion: Infection seen in about 70% of MPs is quite an alarming number. If proper measures to disinfect the MPs are not taken, then it might lead to increased number of infections among HCWs. Hence, we conclude that disinfection of MPs must be made mandatory both while entering and leaving a health-care setup.

Key words: Contamination, Health care workers, Mobile phones

INTRODUCTION

Mobile phones (MPs) and mobile hand-held devices (MHDs) help accelerate in-hospital flow of medical information and information sharing and querying, and contribute to communications in the event of emergencies through their application and access to wireless media technology.[1,2] As technology in this area has evolved, MHDs that provide laboratory and imaging results, patient data, and photographic images are being used by physicians during bedside rounds to engage clinicians, residents, and students. Health care workers (HCWs) access pharmaceutical knowledge and literature by MPs and MHDs, which facilitates learning and clinical performance.[3,4]

However, the MP, which we often carry in our pocket and hold with clean or dirty hands, can lead to potential risks, such as noise, distractions, loss of concentration, data safety, disturbance of patient privacy, and transfer of microorganisms possibly leading to nosocomial infections.[5,6]

The infection potential of telephones was first suggested by Aronson in 1977.[7] Then, in 1978, Cozanitis reported that telephones could pose a risk of transmitting infections within the intensive care unit.[8]

White-Raffery published study on telephones as a potential source of infection in the early 1980s.[9,10] Health care-

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www.ijss-sn.com

Month of Submission : 04-2021
Month of Peer Review : 04-2021
Month of Acceptance : 05-2021
Month of Publishing : 06-2021

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associated infection (HAI) is a leading cause of morbidity and mortality among patients in health-care facilities and cause significant financial burden on the state. HCWs are routinely contaminated by pathogens. MPs in the past decade and a half have emerged as a potential source of HAI.[11]

MPs are used at every possible place, home, kitchen, washroom, and market place exposing them to different types of microorganisms. They are rarely cleaned being electronic gadgets. There are reports of colonization of bacteria on cell phones exposing our patients to nosocomial infections through contact.[12]

Aims and Objectives

The objective of our study was to find out the percentage of MPs of our health-care personnel contaminated with microorganisms and also to find out the microbial profile of such contaminated MPs.

MATERIALS AND METHODS

This was a case cross-sectional study carried out in the Department of Microbiology, Government Medical College and Hospital, Pudukkottai, Tamil Nadu, India.

Study Population

The study was conducted on December 24, 2019. A total of 100 HCWs who carry and utilize their personal MPs in the hospital premises were enrolled for the study. HCWs included doctors, staff nurses, and paramedical students from different medical specialties and units. Informed written consent was obtained from each participant before the start of the study. Subject selection was made on a random basis.

Sampling Technique

Samples were collected aseptically with sterile swabs moistened with sterile normal saline and by rolling over the exposed surfaces of the MPs. Maximum care was taken to ensure that all the buttons of the keypad, screen, mouthpiece, earpiece, sides, and back of the mobiles were properly swabbed since these areas are the most frequent spots, in contact with the fingers. The samples were labeled and safely transported to the Microbiology Laboratory of Government Medical College, Pudukkottai, for culture, analysis, and identification of different microorganisms.

All laboratory analyses were done within 1 h of sample collection. The swabs collected were directly inoculated on blood agar and nutrient agar. The pair of inoculated media was incubated aerobically at 37°C for 24 h and then examined for bacterial growth according to standard protocol (Cheesbrough, 2012). The isolated bacteria were identified by colony characteristics and Gram staining, and by testing for catalase, coagulase, and bile esculin hydrolysis for Gram-positive bacteria. Other biochemical tests included oxidase, indole production, citrate utilization and urease activity, triple sugar iron agar tests, and motility for Gram-negative bacteria.

OBSERVATION AND RESULTS

As given in Table 1, we found that no microbial growth was seen in 30 samples, coagulase-negative *Staphylococcus* (CoNS) was the most common contamination accounting for 27% of contaminations. Methicillin-resistant *Staphylococcus aureus* (MRSA) was seen in two swabs, methicillin-sensitive *Staphylococcus aureus* (MSSA) was seen in seven samples. *Klebsiella pneumoniae* and *Bacillus* contaminations were found in nine MPs each. Acinetobacter was found in three MPs and Micrococcus was the second most common contamination found in 12 samples. *Pseudomonas aeruginosa* and *Enterococcus* contaminations were the least common ones with each contaminating one MP. This is depicted in Figure 1.

Table 2 shows the percentage of single and multiple contaminations. About 99% of MPs in our study were contaminated by only single microorganism, while only 1% was contaminated by multiple microorganisms. It was contaminated by both *Klebsiella pneumoniae* and CoNS. This is depicted in Figure 2.

Table 1: Microbial profile

S. No.	Microorganism	No. of samples in which the organism was present	Percentage
1.	Methicillin-resistant *Staphylococcus aureus*	2	2
2.	Methicillin-sensitive *Staphylococcus aureus*	7	7
3.	*Klebsiella pneumoniae*	9	9
4.	*Pseudomonas aeruginosa*	1	1
5.	*Acinetobacter*	3	3
6.	*Enterococcus*	1	1
7.	*Micrococcus*	12	12
8.	*Bacillus*	9	9
9.	Coagulase-negative *Staphylococcus*	27	27
10.	No growth	30	30

Table 2: Single and multiple contaminations

S. No.	Contamination	Number of mobile phones	Percentage
1.	Single contamination	99	99
2.	Multiple contaminations	1	1

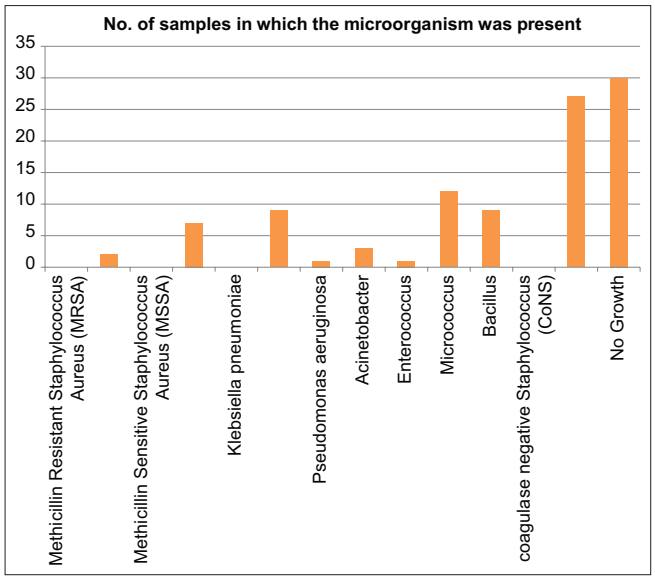

Figure 1: Microbial profile

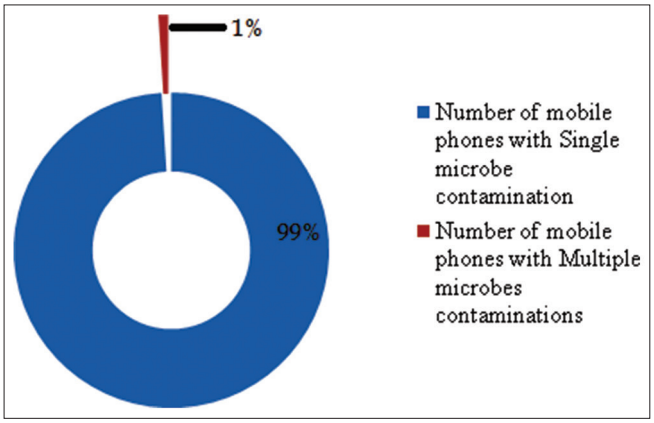

Figure 2: Single and multiple contaminations

DISCUSSION

In this modern world of technology, MP is a part of our day-to-day life. It has become practically impossible to live without this device. We tend to carry the MPs to almost everywhere in a health-care set up barring a few places such as operation theatres. Hence, the risk of contamination and transmission of pathogens are tremendous. Therefore, we decided to carry out this study to find out the percentage of MPs of HCWs contaminated with microbes and also to find out the microbial profile of such contaminations.

Out of the 100 samples collected from MPs of 100 HCWs, about 70% of samples were found to be contaminated with microbes. This percentage was less when compared to a study done by Siddiqui *et al*. whose study revealed that 92% of samples were contaminated.[13]

Among the microbes to contaminate the MPs in our study, CoNS accounted for the most common contamination with 27%. Our results are in accordance with the study done by Brady *et al*. which revealed CoNS to be the most common microorganism isolated from MP swabs.[6]

MRSA was seen in 2% of swabs which is comparable to the results of study by Brady *et al*.[6] which revealed a 2–10% contamination by MRSA.

MSSA was seen in seven out of 100 samples. A study by Morubagal *et al*. revealed that MSSA was seen in 16.64% of samples,[14] while in our study, it was less and found to be only 7%.

Acinetobacter was found in swabs collected from three MPs accounting for 3%. This is similar to review by Brady *et al*.[6] who quoted 1–12%. Pal *et al*.[15] have found Acinetobacter to be occurring at 5.93% which is slightly higher than our findings.

In our study, we isolated microorganisms such as *P. aeruginosa* and *Klebsiella pneumoniae*, and *Enterococcus faecalis*. This is similar to a study done by Akinyemi *et al*.[5] In our study, *P. aeruginosa* and *Enterococcus* contaminations were the least common ones with each contaminating one MP accounting for 1% each. *P. aeruginosa* was found in only 1% of our samples, this is contrary to results of study by Pal *et al*.[15] which revealed *P. aeruginosa* to be present in 6.67% swabs which is higher than that of our findings. *Klebsiella pneumoniae* contamination was found in nine MPs accounting for 9%, this is higher than the 4% found in the study done by Ramesh *et al*.[2] In our study, we found out that *Bacillus* contamination was also found in 9% of MPs.

Micrococcus was the second most common microorganism in our study, contaminating about 12% of MPs, this is higher than the findings from a study done by Siddiqui *et al*. which showed that combined contaminations including aerobic spore-bearing Gram-positive rods, *Moraxella* species, and micrococci accounted for only 2.5%.[13]

CONCLUSION

Contamination of MPs has reached alarming levels. We recommend all HCWs to disinfect their MPs both while entering the health-care facility and also while leaving the facility. Our study has a small sample size, nonetheless, it throws light on the fact that enormous number of mobiles phones used by HCWs is contaminated. Studies involving larger samples would give us further insight into the problem.

ACKNOWLEDGMENT

The authors would like to thank the HCWs, Government Medical College and Hospital, Pudukkottai, who took part

in this study. They also acknowledge the immense help received from the scholars whose articles are cited and included in the references of this article.

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How to cite this article: Sarasu VP, Girija K, Suganya PH. A Prospective Study on the Contamination of Mobile Phones among Health care Workers in a Tertiary Health-care Setup. Int J Sci Stud 2021;9(2):84-87.

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

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

Original Article

Assessing the Changes in Sodium and Potassium in Newborns Following Phototherapy for Neonatal Hyperbilirubinemia

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Abstract

Introduction: Hyperbilirubinemia can be treated either by phototherapy or exchange transfusion, or pharmacologic agents. Phototherapy plays a significant role in the prevention and treatment of hyperbilirubinemia.

Aim: This study aims to study the changes in sodium and potassium in newborns following phototherapy for neonatal hyperbilirubinemia.

Materials and Methods: This observational study was conducted in the Department of Paediatrics, Government Headquarters Hospital, Dindigul, from January 2019 to June 2019 in term neonates admitted in the neonatal intensive care unit receiving phototherapy. Pre- and post-phototherapy bilirubin, serum sodium, and potassium levels were measured.

Results: In 50 neonates included, the mean duration of phototherapy was 42.21 h. Pre-phototherapy, total bilirubin was 15.27 ± 2.51 mg/dl; indirect bilirubin was 12.61 ± 2.98 mg/dl. Post-phototherapy, total bilirubin was 9.02 ± 1.28 mg/dl and indirect bilirubin was 7.14 ± 2.12 mg/dl. Pre-phototherapy, serum sodium was 144.12 ± 3.24 mEq/L and serum potassium was 4.61 ± 0.91 mEq/L. Post-phototherapy, serum sodium was 135.24 ± 4.21 mEq/L and serum potassium was 4.11 ± 0.41 mEq/L.

Conclusion: The following phototherapy, serum sodium, and potassium levels significantly lower. When the length of phototherapy is longer, the frequency of sodium and potassium changes is more significant.

Key words: Hyperbilirubinemia, Newborn, Phototherapy, Potassium, Sodium, Term

INTRODUCTION

Neonatal jaundice is a yellowish discoloration of the skin, conjunctiva, and sclera from elevated serum or plasma bilirubin in the newborn period. The term jaundice is from the French word "jaune," which means yellow. Neonatal jaundice in most newborns is a mild and transient event. However, it is imperative to identify newborns with jaundice that do not follow this pattern, as failure to do so may lead to long-term sequelae.[1]

Neonatal jaundice is noted in >50% of newborns. It is more often physiological; however, sometimes serum bilirubin levels cross the normal range (as per the recommended guidelines by the American Academy of Pediatrics [<1–2 mg/dl/4 h]) to become pathological.[2]

Nevertheless untreated, severe unconjugated hyperbilirubinemia is potentially neurotoxic and conjugated hyperbilirubinemia is a harbinger of underlying severe illness. Neonatal hyperbilirubinemia is a reflection of the liver's immature excretory pathway for bilirubin. It is the most common reason for readmission of neonates in the 1st week of life in the current era of postnatal discharge from the hospital. Neonatal hyperbilirubinemia is a cause of concern for the parents as well as for the pediatricians.[3]

Phototherapy is started based on risk factors and the serum bilirubin level on the nomogram. Bilirubin absorbs light optimally in the blue-green range (460–490 nm) and is either photoisomerized and excreted in the bile or converted into lumirubin and excreted in the urine.[4]

Access this article online

www.ijss-sn.com

Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

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As any treatment has its side effects, phototherapy also has its adverse effects such as electrolyte changes. A few studies are currently available that depict the adverse effects of phototherapy on serum sodium and potassium.

Aim

This study aims to study the changes in sodium and potassium in newborns following phototherapy for neonatal hyperbilirubinemia.

MATERIALS AND METHODS

This observational study was conducted in the Department of Paediatrics, Government Headquarters Hospital, Dindigul, from January 2019 to June 2019 in term neonates admitted in the neonatal intensive care unit receiving phototherapy. Inclusion criteria: Full-term neonates with unconjugated hyperbilirubinemia requiring phototherapy. Exclusion criteria: Newborns with perinatal asphyxia, with congenital anomalies, with jaundice lasting more than 14 days of life, any comorbidities, and neonates with conjugated hyperbilirubinemia were excluded from the study.

All neonates included in the study had a complete medical history and physical examination. Demographic and clinical variables of the infant were recorded at the time of admission and phototherapy duration. Maternal risk factors such as hypertension, diabetes mellitus, oligohydramnios, anemia, epilepsy, fever, any rash, and any medicine intake during pregnancy other than iron and folic acid supplementation were excluded from the study.

Blood specimens were obtained primarily by heel punctures. The minimally dangerous method to collect blood samples of neonates is the heel puncturing method. Merely, the micro amount of serum or plasma is needed for tests by the analyzers. Data were analyzed as pre-phototherapy and post-phototherapy using the Student's *t*-test.

RESULTS

In this study, 50 neonates were included, 26 male and 24 female babies with the mean gestational age of 37.54 weeks. The mean birth weight of neonates was 3.12 kg, 28% of neonates are low birth weight and 72% are normal birth weight. Out of 50 neonates, 14 (28%) were low birth weight babies, and 36 (72%) were normal birth weight babies. All neonates have undergone phototherapy in a mean duration of 42.21 h [Figures 1 and 2].

Before phototherapy, the total bilirubin was 15.27 ± 2.51 mg/dl; indirect bilirubin was 12.61 ± 2.98 mg/dl. Post-phototherapy, total bilirubin was 9.02 ± 1.28 mg/dl and indirect bilirubin was 7.14 ± 2.12 mg/dl. The difference between direct bilirubin and indirect bilirubin was statistically significant ($P < 0.0001$), respectively [Figure 3].

Before phototherapy, serum sodium was 144.12 ± 3.24 mEq/L and serum potassium was 4.61 ± 0.91 mEq/L. Post-phototherapy, serum sodium was 135.24 ± 4.21 mEq/L

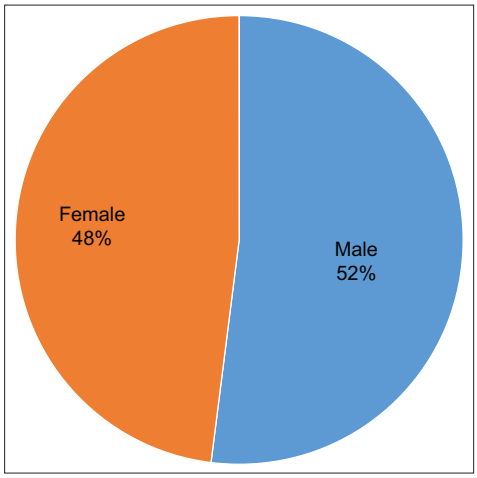

Figure 1: Gender distribution

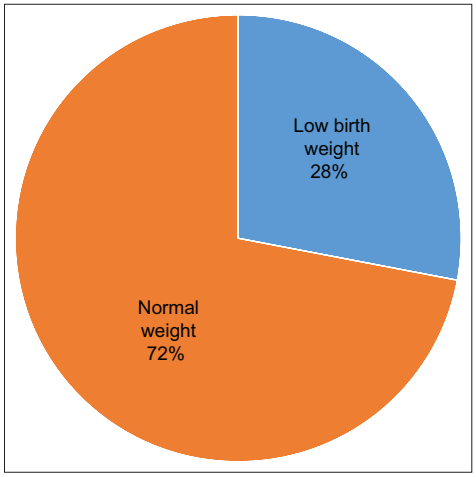

Figure 2: Birthweight distribution

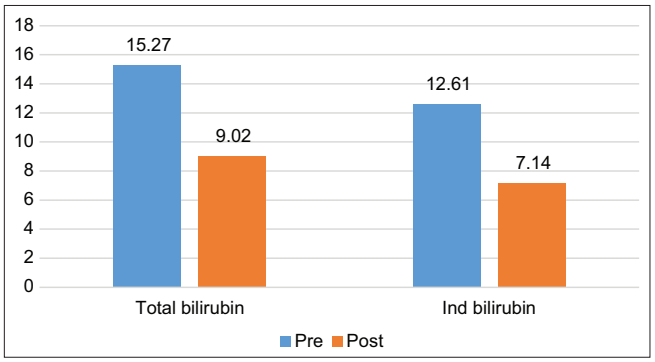

Figure 3: Bilirubin level distribution

and serum potassium was 4.11 ± 0.41 mEq/L. The difference between serum sodium and potassium was statistically significant ($P < 0.0001$), respectively [Figures 4 and 5].

DISCUSSION

Phototherapy has a significant function in the prevention as well as in managing hyperbilirubinemia.[5] Side effects of phototherapy are insensible water loss, watery diarrhea, hypocalcemia, bronze baby syndrome, hyperthermia, tanning of the skin, intolerance to feed, retinal damage, genotoxicity, erythema, and increased blood flow to the skin.[6] One of the side effects is diarrhea. A very small number of studies currently depict the side effects of phototherapy on sodium levels in serum. Since diarrhea causes a change in electrolyte levels in this study, we determine the levels of serum sodium and potassium and compare these levels before and after phototherapy in full-term neonates with unconjugated hyperbilirubinemia.[7]

Hyponatremia, a very common electrolyte abnormality, is a serum sodium level <135 mEq/L. Both total body sodium and total body water determine the serum sodium concentration. Hyponatremia exists when the ratio of water to sodium is increased. Similarly, body water can be low, normal, or high. Hypokalemia is defined as a serum potassium level below 3.5 mEq/L. Curtis *et al.* studied diarrhea in jaundiced neonates treated with phototherapy. The study showed that absorption of sodium, chloride, and potassium was significantly impaired in the patients receiving phototherapy.[8] Beresford and Conolly stated that babies under phototherapy could have sodium imbalances due to insufficient fluid replacements.[9] The differential effect of other electrolytes with phototherapy has not been studied by other workers except that for Curtis *et al.* study which stated that absorption of water, sodium chloride, and potassium was significantly impaired in the patients receiving phototherapy.[8] Tan and Jacob, a study in healthy full-term neonates, demonstrated a transient raise in potassium levels after phototherapy, which was in contrast to the present study.[10] Reddy *et al.*, the study showed that sodium changes are significant, potassium and chloride changes were insignificant, which is in contrast to the present study where both sodium and potassium changes are significant.[11] In another study conducted by Bezboruah and Majumder to show the "Electrolyte imbalance in neonates after Phototherapy," it was seen that 38.83% of the population were low birth weight neonates and 61.17% were normal birth weight, neonates.[12]

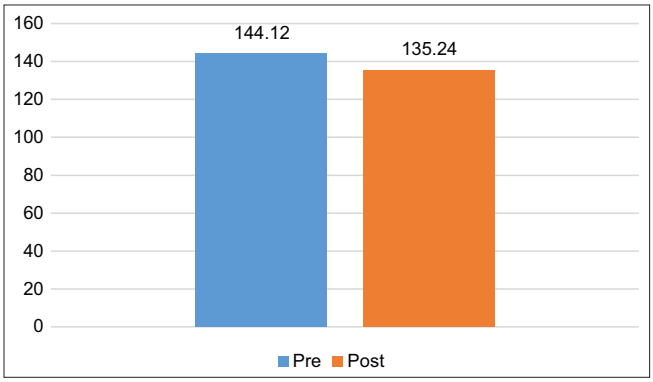

Figure 4: Serum sodium level distribution

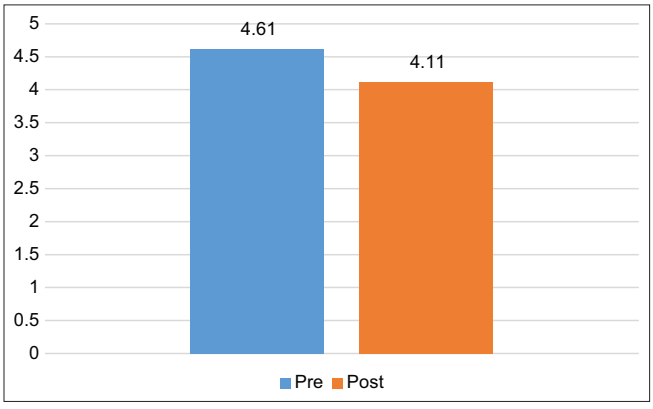

Figure 5: Serum potassium level distribution

CONCLUSION

The following phototherapy, serum sodium, and potassium levels significantly lower. When the length of phototherapy is longer, the frequency of sodium and potassium changes is more significant. As a result, we strongly recommend measuring serum sodium and potassium in neonates before and after phototherapy.

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How to cite this article: Thirunavukkarasu V. Assessing the Changes in Sodium and Potassium in Newborns Following Phototherapy for Neonatal Hyperbilirubinemia. Int J Sci Stud 2021;9(2):88-91.

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

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

Original Article

Diagnostic Value of St Depression in Both Exercise and Recovery Phase of Treadmill Test

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Abstract

Background: Despite the current availability of diagnostic image tests with excellent diagnostic and prognostic accuracy, Treadmill test (TMT) remains as the procedure most commonly used for the evaluation, diagnosis and risk stratification of patients with coronary artery disease (CAD).

Objectives: To investigate the diagnostic value of ST segment depression limited to the recovery phase of an exercise stress test, as compared with that of ST segment depression (ST-d) appearing during exercise only and with ST depression in both exercise and recovery.

Material and Methods: Clinical data and TMT from 142 patients with positive stress test were analyzed. All patients had significant ST- segment depression and were divided into three groups: Group A, 81 patients with significant ST- depression during exercise; Group B, 33 patients with borderline ST- depression during exercise which became significant during the recovery phase: Group C, 28 patients with ST- d only during the recovery phase. Clinical and angiographic data were compared in each group.

Results: A diagnosis of significant CAD was made in 68 patients in group A (83.9%), in 28 patients in group B (84.8%) and in 22 patients in group C (78.5%) (p = 0.10). Patients in group C were older and higher prevalence of single vessel disease (p=0.04). There was no statistical significant difference in terms of normal coronaries, significant CAD, double and triple vessel disease (p >0.05).

Conclusion: The diagnostic value of ST segment depression limited to the recovery phase of an exercise test is largely similar to that of ST segment depression induced duringeffort.Patient with recovery only ST segment depression are more likely to have single vessel disease on coronary angiogram compared to exercise phase ST changes.

Key words: Coronary artery disease, St depression, Treadmill test

INTRODUCTION

Exercise induced ST segment depression is considered a valuable ECG finding for the diagnosis of obstructive CAD[1,2]. It has also been associated with a worse prognosis for patients with a known CAD[3]. However, while the diagnostic value of ST - d occurring during the active phase of exercise test is well known, only a few studies have evaluated the clinical significance of ST -d appearing only during the recovery phase of exercise testing[4-7]. Thus, in this study we aimed at evaluating the diagnostic power of recovery-only ST -d in a sufficiently large group of consecutive patients who were referred for exercise testing because of suspected or known CAD and who underwent coronary angiography within six months of the stress test.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

MATERIALS AND METHODS

Study population

An observational prospective study was conducted with patients over 18 years old who developed significant ST changes on TMT and underwent coronary angiogram subsequently for evaluation of suspected coronary artery disease in the department of cardiology of a tertiary hospital, in the period between september, 2019 and september, 2020. This study consist of three different group of population,in which group A (n = 81), B (n=33) and

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C (n = 28) consist of patients who developed significant ST depression prominently in exercise irrespective of ST changes in recovery, ST depression developed in exercise but prominent in recovery and significant ST depression in recovery phase only respectively. Indications for an exercise stress test were diagnostic assessment for suspected angina pectoris, follow up assessment of patients with a known history of CAD (for example, previous angina, myocardial infarction (MI), or coronary revascularisation procedures), and predischarge evaluation of patients admitted for unstable angina. Patients were excluded if they presented with one or more of the following features: recent (6 months) acute MI; ECG abnormalities at rest that could have interfered with ST segment analysis, including left ventricular hypertrophy, atrial fibrillation, baseline ST segment depression (. 0.5 mm), left bundle branch block, and pacemaker rhythm; and clinical evidence of non- coronary heart disease, including valvular heart disease and cardiomyopathy.

For every patient we obtained information about their age, sex, clinical diagnosis, history of diabetes, previous MI or coronary revascularisation procedures, use of anti-ischaemic drugs, and left ventricular ejection fraction (LVEF) measured by two dimensional echocardiography within two months of the exercise test.

Exercise Stress Test

All patients underwent a symptom and sign limited treadmill test according to either a Bruce or modified Bruce protocol. Indications for interruption of the test were crescendo angina, ST segment changes >1.5 mm compared with baseline, clinically significant arrhythmias, hypotension (. 20 mm Hg reduction in systolic blood pressure compared with a previous measurement) or hypertensive (systolic blood pressure. 220 mm Hg or diastolic blood pressure > 120 mm Hg) response to exertion, and other potentially serious clinical conditions (such as arrhythmias or dyspnoea). Three ECG leads (II, V2, and V5) were continuously monitored during the test. The recovery phase of exercise always lasted six minutes, but it was prolonged if clinically indicated. ST segment depression was considered to be significant when it was > 1 mm at 0.08 seconds from the J point and was either horizontal or down sloping.

The patient clinical characteristics including age, sex, smoking status, diabetes mellitus and hypertension were recorded. All the routine blood investigations,ECG, Echocardiography, TMT followed by coronary angiogram were done. Indication for CAG was either the presence of typical angina and positive TMT in patient groups. Group A, B and C were consist of total 142 patients. These groups were compared for clinical characteristics and coronary artery distribution. Written consents were taken from all the patients.

HTN was defined as previous use of antihypertensive medications, systolic pressure > 140 mm Hg or diastolic pressure > 90 mm Hg in at least two separate measurements. Diagnosis of DM was based on previous history of diabetes with or without drug therapies or fasting blood glucose ≥ 126 mg/dL. Hyperlipidaemia was defined as total cholesterol of ≥ 200 mg/dL or current statin therapy. Body mass index (BMI) was calculated as weight [kg]/height [m^2]. A BMI of ≥ 30 kg/m2 was defined as obese. Current smokers were defined as those who had smoked for some period during the past year. Echocardiography (VIVID S-5 General Electric Medica System 3.6 MHz) was performed according to the American Society of Echocardiography guidelines, and LVEF was evaluated using the visual assessment.

Coronary Angiography

All patients underwent CAG within six months of the TMT. Coronary stenoses were assessed visually by two experienced angiographers independently. A stenosis > 50% of the lumen diameter in a major epicardial coronary artery was considered to be obstructive.

Statistical Analysis

Continuous variables had a normal distribution, are expressed as mean ± standard deviation, and were analyzed with the ANOVA test to compare three groups. When differences were found among the groups, post-hoc test was used to determine which groups had the statistically significant difference.

Categorical variables are expressed as frequency and percentage, and they were evaluated with the chi square test, and partitioning chi squares with degrees of freedom. P value < 0.05 was considered significant.

RESULTS

This study included a total of 142 patients. Patients were divided into three groups. Group A (Patients with prominent ST depression in exercise), Group B (ST depression in exercise but prominent in recovery) and Group C (ST depression in recovery only) had 81, 33 and 28 patients respectively. Mean age of group C patients was relatively older as compared to group A and B but not statistically significant different (C: 58.53 ± 8 years; B: 56.18 ± 8 years, and A: 54.6 ± 9 years; p 0.09 NS). Male constituted 75.3 % of overall patients and no differences were observed in the distribution by sex. The demographic characteristics of the groups are compared in Table 1.

Most common presentation in group A was typical angina (58.7%) followed by atypical chest pain (38.7%) and

dyspnea (32.0%), In group B the commonest presentations were atypical chest pain (45.7%) then typical angina (33.3%) and dypnea (27.2%). In group C the commonest presenting feature was typical angina (42.8%). On comparing the groups with reference to presence of cardiovascular comorbidities like hypertension, diabetes and smoking no significant statistical difference between the two groups.

12.3% of the cases from group A, 9% group B and 10.7 % of the patients from group C had normal coronaries and showed no statistical differences between the three groups. Non - obstructive CAD was seen in 4.9 %, 7.1% and 3.5 % of cases in group A, B and C respectively with no statistical difference between the groups. There were also no signficant statistical difference between the groups on the basis of overall obstructive CAD (p>.05).

However presence of single vessel disease was significantly more common in Group C than in Group A and B with a p value of 0.04. The results of the angiographic findings and EST between the groups have been shown in Table 2. LAD, LCX and RCA are left anterior descending artery, left circumflex artery and right coronary artery respectively.

Table 1: Comparison of demographic characteristics of the groups

Parameters	Group A (N = 81)	Group B (N=33)	Group C (N=28)	P value
Age (years)	54.60	56.18	58.53	0.09
Sex (M / F)	62/19	27/6	18/8	0.74
Atypical chest pain	31 (38.7%)	15 (45.4%)	11(39.2%)	0.54
Angina	42 (51.8%)	11 (33.3%)	12(42.8%)	0.07
Dyspnea	26 (32.0%)	09 (27.2%)	11(39.2%)	0.92
Hypertension	68 (83.9%)	21 (75.0%)	18(64.2%)	0.74
Diabetes Mellitus	31 (38.2%)	13(39.3%)	14(50.0%)	0.56
Smoking	39 (48.1%)	10 (30.3%)	09(32.1%)	0.77

3dOur study shows that patients with ST changes in recovery only are more likely to have single vessel disease (SVD). However, patients with ST changes in recovery only stage were not more likely to have double vessel (DVD) or triple vessel disease(TVD) when compared to those patients with prominent ST depression in exercise or those with ST depression in exercise but prominent in recovery.

DISCUSSION

The diagnostic value of ST segment depression is well studied in many group of patients worldwide[8,9]. However, the clinical usefulness of ST segment depression limited to recovery phase of exercise stress test is poorly understood. There are no international consensus as to how these findings should be appreciated.

The prevalence of ST segment depression limited to the recovery phase of exercise test ranges widely among the few studies published in the literature. The variability can probably be explained mainly by differences in the characteristics of the study cohorts and methods applied for positivity of ST segment depression[4-7]. Among positive exercise tests, quite high proportions of recovery-only ST segment depression have been reported in two studies of asymptomatic, apparently healthy patients,young male aircrew (36%) in one study[5] and volunteers of both sexes, with a broad age range (29%), in the other(10%). In contrast, in stable patients with a history of MI (> 1 year), a lower prevalence of recovery-only ST segment depression were found in two previous studies 6% and 4.6% [4,5] respectively.

In the present study we observed recovery-only ST segment depression in 15.4% of patients with a positive exercise test,

Table 2: Showing angiographic and EST characteristics between the groups

Parameters	Group A (n = 81) ST - d in exercise	Group B (n=33) ST- d in exercise but prominent in recovery	Group C(n=28) ST-d in recovery only	P value
Normal Coronaries	10 (12.3 %)	03 (9.1 %)	03 (10.7 %)	0.57
Non-Obstrustive CAD	04 (4.9 %)	02 (7.1 %)	01 (3.5 %)	0.90
Obstructive CAD	68 (83.9 %)	28 (84.8 %)	22 (78.5 %)	0.10
SVD	26 (38.2 %)	09 (32.1. %)	12(54.5 %)	0.04
LAD	13 (50.0 %)	04 (44.4 %)	07(58.3 %)	
LCX	05 (19.2 %)	03 (33.3 %)	02(16.6 %)	
RCA	08 (30.8 %)	02 (22.2 %)	03(25.0 %)	
DVD	31 (45.5 %)	12 (42.8 %)	07 (31.81%)	0.10
LAD +RCA	13	04	03	
LAD+LCX	08	03	02	
RCA+LCX	10	05	03	
TVD	11 (16.1 %)	07 (25.0%)	03 (13.6 %)	0.10
Left Main Disease	06	03	02	0.12
> 90 % STENOSIS	29	08	09	0.24
Type A lesion	28	11	08	
Type B lesion	23	10	07	
Type C lesion	17	07	07	

a prevalence comparable with that found in two previous studies (15.5% and 16%) of populations of patients similar to ours—that is, with suspected or documented CAD and clinical indications for an exercise test[4].

The reasons for the appearance of ST depression in the recovery phase, rather than during exercise, are unclear. However, consistently with all previous studies, it cannot be predicted by the clinical characteristics of patients. The relatively frequent occurrence of recovery-only ST segment depression, however, highlights the importance of having an appropriate recovery phase, which should be prolonged to atleast five minutes.

ST segment is part of ECG tracing immediately succeeding QRS complex and its depression is considered significant, if it is depressed more than 1 mm at 0.08 second from J-point and is either downsloping or horizontal[1-6]. Screening with ECG and ETT could potentially reduce CHD events either by detecting people at high-risk for CHD events who could benefit from more aggressive risk factor modification, or by detecting people with existing severe CAD whose life could be prolonged by coronary artery bypass graft (CABG) surgery or PCI. However, the current evidence is inadequate to determine the extent to which people detected through screening in either situation would benefit from either type of intervention.

Whether ST segment depression in recovery phase alone adds to positive predictive value of ETT was not proved to be true as the data suggest that the diagnostic value of ST segment depression only in recovery phase of exercise stress test is almost similar to ST segment depression occurring during exercise phase of TMT.

Although, it increased the sensitivity but positive predictive value was same. The reason for appearance of ST segment depression in the recovery phase rather than exercise is unclear. So as in previous studies, it could not be predicted clinically. This also highlights that recovery only ST segment depression has frequent occurrence. So if patients develop ST segment depression during recovery phase of ETT, this should also be carefully assessed in patients of suspected or documented CAD and should be prolonged to at least 5 minutes and more, if needed.

Fewer studies have demonstrated the reliability and clinical importance of the data provided by EST for diagnosis, prognosis, risk stratification, and treatment of patients with suspected or documented CAD[2-3]. The diagnostic accuracy of CAD and the prognostic value of cardiac sudden death, particularly in hypertensive patients, smokers, and patients with dyslipidemia of significant ST-d that is only present in the recovery phase of EST, have been proved in previous works[5-7]. It has also been pointed out that the ST-d is a sign of acute subendocardial ischemia and of extensive and severe CAD, which is significant when the EST effort phase is over, but it increases even more during the first minutes of the recovery phase.[10]

The results of our study confirm the clinical value of the presence of ST-d, which occurs only in the EST recovery phase; these results show the importance of the ST-d diagnosis, which is at equivalent risk of obstructive CAD. Our study shows that patients with ST changes in recovery only are more likely to have single vessel disease. However, patients with ST changes in recovery only were not more likely to have double vessel or triple vessel disease when compared to those patients with prominent ST depression in exercise or those with ST depression in exercise but prominent in recovery. Although what causes the ischemic ST-d which occurs only during the EST recovery phase have not been defined yet, Dimsdale *et al*[11] consider that during the post-effort phase some patients maintain high levels of plasma catecholamines, which increase the myocardial demand of oxygen because they increase the myocardial contractility and the risk of acute ischemia, since it produces an imbalance between supply and demand in the coronary arteries with significant obstruction.

The correlation between the EST result and the analysis of the coronary angiography showed no statistical differences in the percentage of patients with significant CAD in each group. However, when considering the number of coronary vessels with significant obstructive lesion in patients from each group, we observed that group C patients had the higher prevalence of single vessel disease as well as statistically significant different from compared to group A and B ($p < 0.05$) but similar prevalence of double and triple vessel disease in all three groups and not statistical different among groups (p = NS)

The lesion in a coronary vessel was not significant different in all three groups in, which matches the results published by Rashid *et al*.[12] When comparing our results with those reported in previous works, we observe that the percentage of GA and GC patients with significant CAD was similar to the percentage referred by Lanza *et al*[13], and by Rashid *et al*[12] (Group A: 83.9% vs Lanza 85%, and Rashid 93%; Group C: 78.5% vs Lanza 78%, and Rashid 85%).

The consequences of false-positive tests may potentially outweigh the benefits of screening. False positive tests are common among asymptomatic adults, especially women, and may lead to unnecessary diagnostic testing, over treatment, and labeling. Because the sensitivity of these tests is limited, screening could also result in false-negative

results. A negative test does not rule out the presence of severe CAD or a future CHD event. Potential harms of screening asymptomatic patients for CHD include unnecessary invasive testing (for example, coronary angiography) and "labeling" of those who have had false-positive test results.

STUDY LIMITATIONS

Major limitation of this study is lack of follow-up in patients to prove the prognostic value of ST-d in the patients from each group. This study was an observational study, although it can measure association, they are not strong enough to prove causality.

CONCLUSIONS

The results of this study show that the presence of significant ST-d in an EST occurring only in the recovery phase, and the borderline ST-d during the exercise phase but then increasing and becoming positive in the recovery phase has a value and clinical importance similar to the significant ST-d present during the active phase of exercise. In our study, patients with ST changes in recovery only are more likely to have single vessel disease. However, patients with ST changes in recovery only were not more likely to have double vessel or triple vessel disease when compared to those patients with prominent ST depression in exercise or those with ST depression in exercise but prominent in recovery.

Thus careful evaluation of ST segment depression occurring only in recovery phase may add significantly to the clinical information derived from the results of TMT.

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How to cite this article: Kavi G. Diagnostic Value of St Depression in Both Exercise and Recovery Phase of Treadmill Test. Int J Sci Stud 2021;9(2):92-96.

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

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

Original Article

Assessing the Association of Zinc Level in Children with Simple Febrile Seizures

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Abstract

Introduction: Febrile convulsions are the most common type of seizure in children. A febrile seizure is an event in infancy and early childhood, usually occurring between 6 months and 5 years of age, associated with fever but without the evidence of intracranial infection or defined cause.

Aim: This study aims to study the association of zinc level with simple febrile seizures.

Materials and Methods: This observational study was conducted in the Department of Paediatrics, Government Headquarters Hospital, Dindigul, from January 2019 to June 2019 in 6 months to 5 years. Children were admitted to the pediatric intensive care unit with simple febrile seizures. Serum zinc level was estimated along with other investigations at the time of admission.

Results: In this study, 50 children from 6 to 60 months were included in the study. The mean weight of the children included in the study was 12.82 ± 3.11 kg. The mean zinc level of the children included in the study was 83.9 ± 14.44 mcg/dl. About 66.7% of children in the age group of 6–12 months and 73.1% of children in the age group of 13–60 having zinc levels between 60 and 90 mcg/dl.

Conclusion: The mean serum zinc level was significantly lower in children with simple febrile seizures.

Key words: Children, Febrile, Seizures, Zinc

INTRODUCTION

Febrile seizures are generally defined as seizures occurring in children typically 6 months–5 years of age in association with a fever >38°C (100.4°F), who do not have evidence of an intracranial cause (e.g., infection, head trauma, and epilepsy), another definable cause of seizure (e.g., electrolyte imbalance, hypoglycemia, drug use, or drug withdrawal), or a history of an afebrile seizure.[1-5] Febrile seizure is a significant challenge in pediatric practice because of its high incidence in young children and its tendency to recur. In recent years, there has been more awareness about the potential complications of febrile seizures and management of this condition.

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Month of Submission : 03-2021
Month of Peer Review : 04-2021
Month of Acceptance : 04-2021
Month of Publishing : 05-2021

The cause of febrile seizures is multifactorial. It is generally believed that febrile seizures result from a vulnerability of the developing central nervous system (CNS) to the effects of fever, in combination with an underlying genetic predisposition and environmental factors.[4] Febrile seizure is an age-dependent response of the immature brain to fever.[6]

A detailed description of the seizure event is essential for the evaluation of a possible febrile seizure patient. Historical information regarding the exact appearance and length of the event is vital. Information regarding the symptoms of a CNS infection, underlying structural abnormalities, personal history of neurologic problems, personal immunization history, and personal or family history of prior seizure is essential in deciding whether an event of concern constitutes a febrile seizure or rather constitutes a more severe illness presenting with a seizure.[7]

The role of trace elements such as selenium, magnesium, copper, and zinc has been described in association with febrile seizures. Trace elements appear to play a role in their ability to modulate neurotransmission by acting on

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ion channels and their coenzyme activity.[8] Zinc is an important element in growth, development, and normal brain function. It is also an important cofactor for different enzymes involved in cellular growth and differentiation, the enzymatic activity of different organs, proteins, and cellular metabolism.

Aim

This study aims to study the association of zinc level with simple febrile seizures.

MATERIALS AND METHODS

This observational study was conducted in the Department of Paediatrics, Government Headquarters Hospital, Dindigul, from January 2019 to June 2019 in 6 months to 5 years. Children were admitted to the pediatric intensive care unit with simple febrile seizures. Inclusion criteria: Six months–5 years children with simple febrile seizures were included in the study. Exclusion criteria: Children <6 months and more than 5 years, with congenital anomalies and known cases of seizure were excluded from the study. Informed consent was obtained from the parents. Sociodemographic data, seizure details, nature of the febrile illness, family history of epilepsy/febrile seizures, the temperature at admission, nutritional status, and vital signs, namely, heart rate, respiratory rate, and blood pressure, were measured. The axillary temperature was recorded in all children with mercury thermometers placed in axilla for three minutes followed by general examination and systemic examination in detail. Serum zinc level was estimated along with other investigations at the time of admission.

RESULTS

In this study, 50 children from 6 to 60 months were included in the study. The mean age of the children included in the study was 27.6 ± 19.34 years, 54% were male, and 46% were female. Children were divided into two groups with age, 48% were in 6–12 months age group and 52% were in 13–60 months age group [Figures 1 and 2]. The mean weight of the children included in the study was 12.82±3.11 kg. The mean zinc level of the children included in the study was 83.9 ± 14.44 mcg/dl. According to age group, the mean zinc level in the age group of 6–12 months was 84.41 ± 13.67 mcg/dl and in the age group 13–60 months was 83.42 ± 15.38 mcg/dl. Zinc level was classified into two groups, 60–90 mcg/dl and 90–120 mcg/dl. About 66.7% of children in the age group of 6–12 months and 73.1% of children in the age group of 13–60 having zinc levels between 60 and 90 mcg/dl [Figures 3 and 4]. About 33.3% of children in the age group of 6–12 months and 29.9% of children in the age group of 13–60 having zinc levels between 90 and 120 mcg/dl.

DISCUSSION

Zinc is an essential element in growth, development, and normal brain function. It is also an essential cofactor

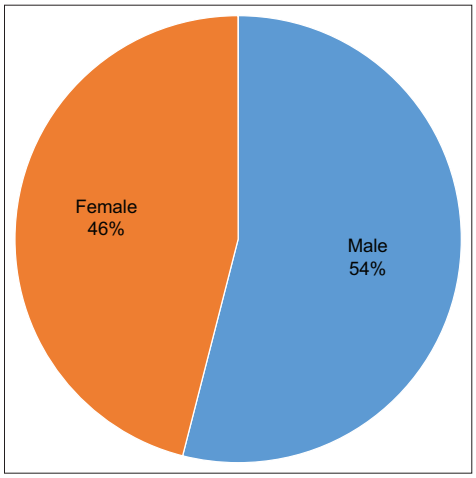

Figure 1: Gender distribution

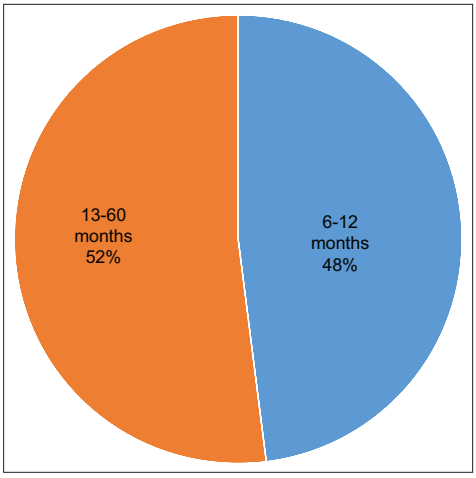

Figure 2: Age group distribution

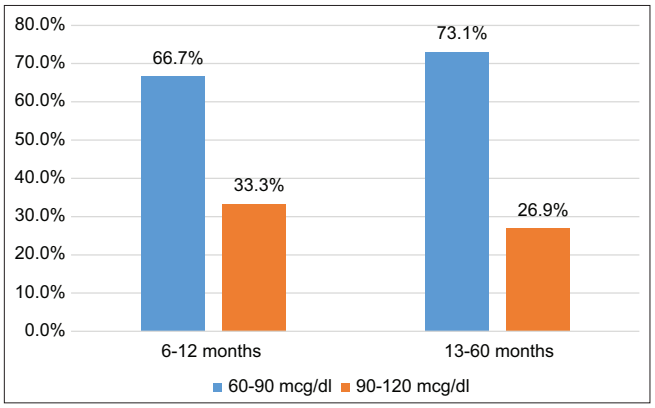

Figure 3: Comparison of age group with zinc level

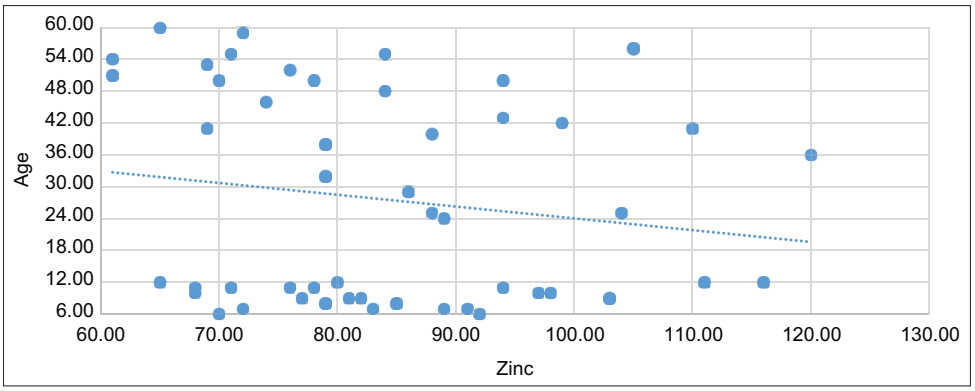

Figure 4: Correlation of zinc level with age group

for different enzymes involved in cellular growth and differentiation, the enzymatic activity of different organs, proteins, and cellular metabolism. In the brain, zinc is present in synaptic vesicles in a subgroup of glutaminergic neurons. In this form, it can be released by electrical stimulation and may serve to modulate responses at receptors for number of different neurotransmitters. These include excitatory and inhibiting receptors, particularly N-methyl-D aspartate and gamma-aminobutyric acid receptors.[9]

Zinc deficiency is implicated as a risk factor for febrile seizures. Several preliminary studies have shown that deficiencies in Vitamin B12, folic acid, selenium, calcium, and magnesium increase the risk of febrile seizures.[10] Other risk factors include a history of febrile seizure, febrile seizure in a first-degree relative, intrauterine growth retardation, staying in a neonatal nursery >28 days, neurodevelopmental delay, and daycare attendance.[11]

Heydarian *et al.* reported that the serum level of zinc was significantly lower in children with simple febrile seizures than febrile children without a seizure.[12] In Ehsanipour *et al.* study in Rasoul-e-Akram Hospital, serum zinc level was significantly lower in children with FC (cases group) than controls (children with non-convulsive fever and children with non-febrile convulsion).[13] Ganesh *et al.* from India reported that serum zinc levels are lower in children with febrile seizures than those with epileptic seizures and normal children.[14]

This study detected that serum zinc levels were significantly low in children who had simple febrile seizures compared to children who had fever without febrile seizures. Similar results were seen in other studies: Papierkowski *et al.* from Poland in 1999 who observed that serum and cerebrospinal fluid (CSF) zinc levels were significantly low in children with febrile seizures than healthy children in the control group.[15] Gündüz *et al.* from Turkey in 1996 observed that serum and CSF zinc levels decreased in children with infectious diseases. This decrease was more significant in patients with febrile convulsions.[16] Kumar *et al.*[17] in 2011, Amiri *et al.*[18] (2010), and Mahyar.[19] in 2013 found out that mean serum zinc levels were significantly lower in children with febrile seizures than controls. In this study, serum zinc levels were significantly low in children who had seizures of prolonged duration, which is similar to the study done by Margaretha and Masloman in 2009.[20]

CONCLUSION

In children with uncomplicated febrile seizures, mean serum zinc levels were lower. It's critical to figure out how zinc levels play a role in the pathophysiology of febrile seizures, as well as whether zinc supplementation can help avoid febrile seizures. When the children in the simple febrile seizure group were healthy, they should have received a follow-up serum zinc estimation to determine their baseline serum zinc level.

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How to cite this article: Thirunavukkarasu V. Assessing the Association of Zinc Level in Children with Simple Febrile Seizures. Int J Sci Stud 2021;9(2):97-100.

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