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#### A Novel Fixed Guiding Plane Prosthesis for Hemimandibulectomy Patient

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#### **Abstract**

Resection of tumors of the tongue, floor of the mouth, and mandible results in functional disability and cosmetic disfigurement which presents a major challenge to the rehabilitation team and the maxillofacial prosthodontics. The unilateral loss of mandibular continuity due to surgery or trauma results in mandibular deviation toward the defect side resulting in loss of occlusion on the unresected side. Mandibular resections also result in impaired speech articulation, difficulty in swallowing, mandibular deviation, poor control of salivary secretions, and severe facial disfigurement. A guiding flange guides the resected mandible into the correct position. Guiding flange made of acrylic polymers which lack the principles of removable partial denture design may affect the longevity of the remaining teeth. A guiding flange attached to a fixed partial denture was fabricated to be used as a long-term prosthesis restoring reasonable function and appearance.

Key words: Fixed guiding plane prosthesis, hemimandibulectomy, guiding plane prosthesis, and oral carcinoma

#### **INTRODUCTION**

Segmental resection of the mandible results in significant physiological and esthetic problems, especially if condylectomy has been performed. The most important difficulty encountered is mandibular deviation toward the defective side.<sup>[1]</sup>

The earlier the mandibular guidance therapy is initiated in the course of treatment, the more successful is the patient's definitive occlusal relationship and masticatory efficiency.

Any delays in the initiation of mandibular guidance appliance therapy, due to problems such as extensive tissue loss, radiation therapy, radical neck dissection, flap

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necrosis and other post-surgical morbidities, may result in an inability to achieve normal maxillomandibular relationships.<sup>[2,3]</sup>

#### CASE REPORT

A 49-year-old male patient was reported to the Department of Prosthodontics Crown and Bridge and Implantology, Rishiraj College of Dental Sciences and Research Center Bhopal, after surgical resection and radiation of squamous cell carcinoma involving left retromolar trigone.

The patient underwent surgical resection 5 years ago, with the chief complaint of inability to chew, impaired speech, difficulty in swallowing, and mandibular deviation on the left side (affected side).

#### **Examination**

Extraoral examination revealed an asymmetric ovoid face, facial paralysis on the left side due to facial nerve resection, and deviation of the mandible to the left side [Figure 1].

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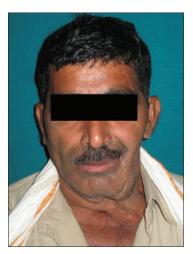


Figure 1: Pre-operative

On intraoral examination, there was a lack of proper contact between maxillary and mandibular teeth, a large mandibular defect on the left side, surgical scarring and fibrosis on the resected side [Figure 2], mouth opening and functional vestibular depth is reduced, and patient's maxillary arch was partially edentulous with missing 15,17,24,25,26, and 27.

#### **Investigations**

Orthopantomogram revealed resection of the mandible in the midline involving ramus, condyle, and coronoid process of the left side [Figure 3].

This represents Class III mandibular resection according to Cantor and Curtis classification, [1]

#### **Treatment Plan**

On the basis of examination and investigation, prosthetic rehabilitation was decided in two parts: the first one was to get an acceptable occlusion relationship and then the rehabilitation of the missing structure.

while selecting a treatment plan for acceptable occlusal function many types of the prosthesis was suggested to the patient which includes positioning prosthesis with palatal flange, widened maxillary occlusal table, acrylic splint Herbst, maxillary inclined plane prosthesis, mandibular lateral/oblique guide flange prosthesis, etc., [4] as the patient was not agreeing for removable prosthesis; thus, a fixed guiding flange was decided.

After extensively searching the literature for a fixed guiding prosthesis, it was found a fixed prosthesis which is proposed by Nelogi *et al.*, which is composed of a loop and a molar band. The only pre-condition of this appliance is that it would require opposing teeth; unfortunately, in the present case, the maxilla was partially edentulous.

Hence, it was decided to give a conventional fixed partial denture along with a guiding flange.



Figure 2: Surgical scarring and fibrosis



Figure 3: OPG showing left hemimandibulectomy

Here, in this case, a fixed prosthesis that would prevent scar contraction by keeping muscles in the stressed condition and at the same time provide corrective and masticatory functions.<sup>[6]</sup>

The first phase of treatment was the restoration of carious and conservative periodontal treatment and the second phase of treatment was to get the acceptable occlusion of the remaining teeth using a fixed guiding flange prosthesis.

#### **Procedure**

Tooth preparation was done with 14 and 17 to receive porcelain fused to the metal retainer and an elastomeric impression was made using (Xpress Putty and Light body 3M ESPE US) that cast was poured with type IV dental stone (Dentstone, Neelkanths healthcare products, India).

Assisted and unassisted interocclusal records [Figure 4] were made with silicone-based interocclusal record material (ExabiteII NDS GC US) with the use of these records articulation which was done on the Hanau wide vue semi-adjustable articulator [Figure 5].

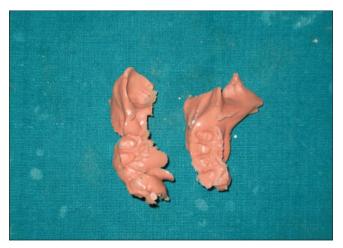


Figure 4: Assisted and unassisted interocclusal records



Figure 5: Mounting on hanau articulator using inter occlusal records

To test this concept of attaching a guide flange to a fixed bridge, it was decided to give a temporary restoration along with a fixed guide flange.

Auto-polymerized acrylic resin was added to the temporary restoration, when acrylic was in the dough stage mandible that is manipulated to achieve desired interocclusal relationship [Figure 6].

Cementation of the prosthesis was done with eugenolfree temporary luting cement. The patient was kept under observation for 1 month, gradual modification was done according to the patient's comfort level. The patient was quite satisfied with the final product.

A wax pattern was prepared and the guiding plane was attached to the pattern only [Figure 7], spruing and casting were done in a conventional manner.

Pontic was selected in such a way that there were selfcleansing areas so that the patient can maintain his oral hygiene using interdental brushes [Figure 8].



Figure 6: Temporary restoration with fixed guiding plane



Figure 7: Wax pattern with guide plane



Figure 8: Self-cleansing space

It was also decided to attach the guide flange on the occlusal 3<sup>rd</sup> so that there was a space between flange and cervical area for easy oral hygiene maintenance.

Finally, the metal coping try-in and shade selection was done.

It was also decided to add tissue-colored ceramic to the flange of the prosthesis, thus making it more esthetically acceptable [Figure 9].



Figure 9: Final prosthesis with gingival colored guide plane



Figure 10: Post-operative view of prosthesis

At last final occlusal correction was done and the prosthesis was cemented with type I glass ionomer cement (type I GIC GC US) [Figure 10]. After cementation, the patient is recalled every day for the next 1 week to evaluate any pain or strain in TMJ and muscle.

#### **DISCUSSION**

The proposed fixed guide flange is recommended for those patients with significant mandibular resection who have limited mouth opening ability resulting from tissue scarring and who lack the motor skill to manage a removable prosthesis.

The technique is proposed only when the remaining teeth are periodontally sound enough to bear the angular pull of muscles and masticatory forces. The fixed guide flange proposed is functional, esthetic, and comfortable.

After the placement of a fixed mandibular guide flange prosthesis, the patient must be evaluated for any strain or pain in the temporomandibular joints and muscles.

#### **CONCLUSION**

The proposed guide flange is a simple alternative to the removable mandibular guide flange prosthesis further research should focus on determining the influence of the fixed guide flange on the maxillary teeth and any long-term adverse effects of its use.

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## Acute Hepatitis: An Unusual Presentation of Adenovirus Infection

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#### **Abstract**

Adenovirus is a long known human infection presenting mostly in the form of upper and lower airway disease, pharyngitis, gastroenteritis, conjunctivitis, and hemorrhagic cystitis. However, adenovirus infection presenting in the form of hepatitis is an infrequent presentation, particularly in immunocompetent host. We hereby report a case of unexplained hepatitis with lower respiratory infection in a 6-year-old boy later confirmed on RTPCR to be adenovirus infection.

Key words: Adenovirus hepatitis, Quantitative RTPCR, Symptomatic management

#### INTRODUCTION

Adenovirus is well known infection in humans with presentation ranging from asymptomatic virus shredding to conjunctivitis to severe respiratory infections requiring mechanical ventilation. Hepatitis has been mentioned as an uncommon presentation. Nine cases of adenovirus hepatitis have been reported by CDC USA in April 2022 and issued an alert regarding the same. [1] Almost 300 similar cases of adenovirus hepatitis were reported in "The Lancet." [2] We hereby report a case of adenovirus infection presenting as unexplained hepatitis. The recent rise in number of cases of adenovirus hepatitis reported from around the globe makes our case worth reporting.

#### **CLINICAL DESCRIPTION**

A 6-year-old boy presented in pediatric OPD with complaints of cough (non-productive non-paroxysmal) for 5 days, fever (high grade, continuous, without chills) for 2 days. On evaluation, patients weight was 20 kg (weight for age at 24<sup>th</sup> centile), height was 124.8 cm (height for



Month of Submission : 05-2023 Month of Peer Review : 06-2023 Month of Acceptance : 06-2023 Month of Publishing : 07-2023 age 84th centile), and BMI 12.8 (1st centile) without any signs of nutritional deficiency. On examination, the child was awake conscious oriented with HR 102bpm, RR 32b pm, SpO<sub>2</sub> 98% under room air in the right upper limb, and BP - 100/70 mmHg (between 50 and 90th centile). On auscultation, chest was full of wheeze and occasional crepitations with mild respiratory distress. Abdomen was soft with mild tenderness in the right hypochondriac region. Rest of the systemic examination was non-contributory. Patient was admitted with provisional diagnosis of LRTI and started on nebulisation with levo-salbutamol, iv. PCM, oral chlorpheniramine plus phenylephrine, I/V fluids. Investigations revealed marginally raised TLC (12090) with DLC (P86.5% L9.7% M3.7% E0 B0.6%), positive CRP (2.1), normal LFT (SGOT 48 SGPT 50), normal KFT (Urea 30.7 S Creatinine 0.7), negative COVID RAT and RTPCR, and a negative typhi dot and widal. X-ray chest suggestive of increased bronchovascular markings in the right middle and lower zones. USG abdomen was done which was normal study except for minimal effusion in B/L lower lung fields. Diagnosis of bronchopneumonia was made and started on inj. Amoxycillin-clavulanic acid with amikacin. However, the patient did not respond in view of persistent fever and wheeze. Hence, oral oseltamivir was added on day 3 of admission and investigations were repeated which showed a normal TLC (4580) and DLC with mild thrombocytopenia (138000) along with a remarkably high SGOT (1227) SGPT (663) with normal values of bilirubin. PT/INR was normal. Proton pump inhibitors were added and the child was kept on IV fluids

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as oral intake was poor. Hepatitis viral panel (HbsAG HAV HCV HEV EBV HSV CMV Enterovirus) was sent which came to be entirely negative. Repeat CBC next day revealed leukopenia (TLC 2620) with further falling platelet count (119000). Patient developed conjunctival irritation with epiphora (without any congestion/discharge) on day 4 of admission. Ophthalmology reference was done and CMC and tobramycin eye drops were advised and improved next day. Fever was still persisting with B/L wheeze in chest for which antibiotics were upgraded to i/v Piperacillin Tazobactam with oral Azithromycin. IgM for Leptospira and rickettsia serology was negative. Dengue NS1 antigen and serology were negative. TB work up (Monteux/ CBNAAT for gastric aspirate) was negative. Blood culture was sterile. Respiratory viral panel was sent which showed negative H1N1 infection while confirmed Adenovirus infection instead. Repeat CBC showed TLC (2870) and platelet count (143,000) showed a modest increase while SGOT (654) SGPT (640) values were decreasing. Fever spikes were also improving with reduced chest wheeze. Patient was asymptomatic by 9th day of admission. Repeat investigations along with X-ray chest were entirely normal except for slightly raised SGPT and thrombocytosis (584000). Oral oseltamivir 5-day course was completed before the respiratory viral panel report was available. Rest all the antibiotics were discontinued as soon as the blood culture came sterile. Patient discharged after 12 days of hospital stay.

#### **DISCUSSION**

Adenoviruses are non-enveloped, icosahedral viruses of medium size (90-100 nm) that contain double-stranded DNA. Human infections can be caused by more than 100 immunologically different adenovirus types. Common disinfectants are unable to kill adenoviruses, although they can be found on surfaces such as doorknobs, items, and even the water of swimming pools.[3] Human adenovirus causes a variety of human clinical syndromes in both immunocompromised and immunocompetent hosts usually presenting in the form of severe conjunctivitis, upper and lower respiratory disease, pharyngitis, gastroenteritis, and hemorrhagic cystitis. While hepatitis, myocarditis, and meningoencephalitis are noted as less frequent presentations.[4] Polymerase chain reaction is described as a rapid, sensitive, and specific technique in establishing the diagnosis of adenovirus infection.<sup>[4]</sup> Although we did only qualitative RTPCR, quantitative PCR is considered superior as it can establish diagnosis and aids in assessing the response to treatment as well.

A notable finding in CBC was gradual increase in lymphocytes as the disease progressed starting from 9.7% to 54.2%, which was gradually reduced as the acute phase was over. Due to the increasing lymphocytes and no clinical improvement, atypical pneumonia was suspected and first oral oseltamivir and, later oral azithromycin was added. Transaminitis was associated with modest rise of serum bilirubin but remained subclinical throughout. PT/ INR and serum albumin levels were normal. Since the diagnosis was not established and clinically the patient was not improving, we were convinced to upgrade antibiotics to inj. Piperacillin with tazobactam; however, as soon as adenovirus was confirmed and culture came to be sterile inj. piperacillin with tazobactam was stopped. Oral oseltamivir was already given for 5 days. More than 100 serotypes have been identified so far with nearly 49 infecting human belonging to species A-G with replication defective HAdV-5-based vectors playing important role in gene transfer therapy. [5,6] Various serotypes have affinity for different tissues which correlates with the clinical presentation. We could not get the serotyping done but the previously reported cases state the serotype 41 to be most frequently associated. [3] The predominant serotypes circulating at a given time differ among countries or regions and change over time.

Transmission of novel strains between countries or across continents and replacement of dominant viruses by new strains may occur.

Although supportive care is the mainstay of management, cidofovir have been mentioned to be effective in vitro against adenovirus, with nephrotoxicity being an adverse effect to be watched for. There are mentions of other agents such as IVIG and adoptive immunotherapy involving infusion of HAdV specific T cells but experience is very limited and is yet not considered as standard therapy. Oral live vaccines are under routine use in US military and are effective against severe respiratory infections but not available for civilians.<sup>[7]</sup> In our case, the mainstay of management, that is, supportive care, was only provided and patient showed the signs of clinical improvement gradually and discharged.

#### **CONCLUSION**

Adenovirus should be considered as an important differential in cases of hepatitis without a known cause, particularly when associated with atypical symptoms such as kerato-conjunctivitis, pharyngitis, or pneumonia. Quantitative PCR should be done to establish the diagnosis and to assess the response to treatment. No antiviral agent is yet recommended hence making the supportive care as the mainstay of management.

Investigations	Admission day	Day 3	Day 5	Day 7	Day 9
Hb	10.8	10.7	10.3	9.3	11.6
TLC	12.09	4.58	2.62	2.87	8.29
DLC	P86.5 L9.7	P76.7 L21.4	P40 L54.2	P40.8 L50.5	P65.5 L21
	M3.7E0B0.6	M1.7E0B0.2	M5E0.4B0.4	M8.4E0.3B0.0	M11E2.3B0.2
Platelet	243	138	119	143	584
CRP	2.1	2.5	2.3	2.2	0.2
SGOT	50	1227	640	509	47
SGPT	48	663	654	357	182
S. bilirubin	0.39	1.36	1.00	0.76	0.65
Hepatitis viral panel	Negative				
(HBsAG, HCV, HAV, HEV, EBV, HSV, CMV, enterovirus)					
TB wokup	Negative				
Rickketsial serology	Negative				
Serology for leptospira	Negative				
Dengue NS1 and serology	Negative				
Typhidot and widal	Negative				
COVID-19 RAT and RTPCR	Negative				
Blood culture	Sterile				
Throat swab for H1N1	Negative				
RTPCR for EBV	Negative				
RTPCR for RSV	Negative				
RTPCR for CMV	Negative				
RTPCR for adenovirus	Positive				

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We confirm that this manuscript has not been published elsewhere and is not under consideration by another journal.

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#### **3D-Guided Implant Surgery: A Case Report**

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#### **Abstract**

Placing dental implants is much easier than it ever was thanks to advances in technology and increased use of computer-aided design and computer-assisted manufacturing (CAD/CAM). The location and angle of the neighboring teeth, laboratory simulations, computed tomography with CAD/CAM simulations, and surgical guides known as stents are used to determine the placement of implants. Every implant clinician must make the difficult decision of whether to use a surgical guide or to insert implants by hand. The use of surgical guides for implant placement can boost confidence and be predictable with proper technique. This case report provides an example of how 3D-guided technology was used in dental implant surgery for diagnosis, planning, and execution.

**Key words:** 3D planning, Computer-aided design and computer-assisted manufacturing, Dental implants, Flapless surgery, Surgical guides

#### INTRODUCTION

The advancement of computer-aided design and computerassisted manufacturing (CAD/CAM) technologies in recent years has greatly improved all aspects of routine dentistry, particularly in the area of oral implant surgery. [1] The two key components of oral implant surgery - planning the optimal prosthetic solution for the specific anatomic circumstance and using 3D data of the bone topography - have been reconciled as a result of the introduction of digital tools into diagnostic procedures. By overlaying either an intraoral surface scan in a fully digital workflow or a surface scan of a cast model to the radiography in a partially digital workflow, the virtual planning is translated into reality.<sup>[2]</sup> Guided implant surgery (GIS) has a number of benefits, including step-back planning and three-dimensional connection evaluation of the relationship between final reconstruction and local anatomy. Incorporating this virtual knowledge into reality could assist prevent implant misalignment or damage to important anatomical components.[2]



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This case report demonstrates how to use a 3D conebeam computed tomography (CBCT) for computerassisted diagnostics, do virtual implant planning, create a stereolithographic surgical template, and insert a dental implant using a surgical guide in a pre-planned location.

#### **CASE REPORT**

A 28-year-old female patient reported in the Department of Prosthodontics and Maxillofacial Prosthetics, Dr. HSRSM Dental College and Hospital, Hingoli, Maharashtra with a chief complaint of missing upper right back tooth. Intraoral examination revealed missing 14, 15, and 16; with a history of extraction with 14 and 16, 6 months back due to abutment failure. After considering several options, the patient decided on a screw-retained implant-supported crown and GIS to replace her missing tooth.

The case was then planned and executed according to guided surgery protocol as proposed by Osstem Guided implant surgery kit and protocol.

#### Step 1 – Treatment Planning

Photos of the patient's edentulous area inside the mouth, photos of the patient's right and left excursive movements during occlusion, and photos of each arch's occlusal surface were also taken [Figures 1-4]. Maxillary and mandibular

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Figure 1: (a) Patient's edentulous area inside the mouth. (b) Intraoral photograph with missing 14, 15, and 16 teeth



Figure 2: Occlusal photograph of mandible



Figure 3: Occlusal photograph of maxilla

diagnostic impressions were created using irreversible hydrocolloid impression materials [Figure 5]. After being poured into Type IV gypsum product, master casts were created [Figure 6]. CBCT, orthopantomograph, and radioautography were used to assess the condition of the residual dentition as well as the bone foundation above the implant site. It was done to evaluate the hard and soft tissues inside the mouth. Our proposal for guided flapless surgery using a stereolithographic surgical template for implant placement is supported by the existence of sufficient keratinized tissue and bone width of 0.5 mm.



Figure 4: Left lateral view introrally



Figure 5: Master casts made of type IV gypsum products



Figure 6: Impression made in elastomeric impression material

#### **Step 2 – Scan Prosthesis Fabrication**

Next, the cast was scanned using 3Shape Implant Studio Scanners to create a virtual model. The scan prosthesis was a radiopaque replica of the present clinical setting with the current arrangement of temporary teeth. The restoration of the prosthesis was planned on this virtual model. Once the alignment and design of the prosthesis were satisfactory, a soft copy STL file was created and saved for use in treatment planning with specialized 3D CBCT software.

#### Step 3 - CBCT Scanning

Soft copy images of the virtual prosthesis planned cast and 3D images of CBCT images were then merged together with the help of certain common reference points for definite planning of fixture length, diameter, and angulations.

#### Step 4 – Software-based Planning and Fabrication of the Surgical Template (Open System Approach)

After the evaluation of the edentulous site in CBCT with a virtual prosthesis, with tooth region 14 Osstem/TSIII/Regular/4.0 × 11.5; with tooth region 15 Osstem TSIII Regular 4.0 × 10.0; and with tooth region 16 Osstem/TSIII/Regular/4.5 × 8.5 implants were planned [Figure 7]. For planning the surgical guide, the sleeve system of Sirona-CEREC Guide drill keys was selected. After confirmation of implant and surgical guide planning, the fabrication of the surgical template was done [Figure 8].

#### $\label{eq:continuous} \textbf{Step 5-Surgery with OSSTEM-Guided Instruments and Guided Implant Insertion}$

After assuring the fit of the surgical template intraorally, the implant surgery was performed as per protocol with the guided instruments sets in the OSSTEM-Guided Surgery Cassette [Figure 6]. The surgical protocol provided, along with the surgical template recommended the sequence of instruments required to prepare each implant site. Under local anesthesia, the surgery was initiated with the mucosa punch (diameter 4.7 mm) at 15 rpm through the sleeves with a surgical template [Figure 7]. Mucosa punch allowed blade-free incision with minimum trauma. The next step was the use of a milling cutter to achieve a sufficient flat bone surface for the purpose of easy drilling in the following stage. The implant bed was then pre-drilled with the pilot drill (diameter 2.2 mm). Basic implant bed preparation was continued using the diameter 3 mm, 3.5 mm, and finally with 4.0 mm, 4.0 mm, and 4.5 mm in the tooth regions of 14, 15, and 16, respectively. This surgical guide assures correct osteotomy site preparation as pre-planned earlier.

After the completion of flapless implant bed preparation, OSSTEM implants with tooth region 14 Osstem/TSIII/Regular/ $4.0 \times 11.5$ ; with tooth region 15 Osstem TSIII Regular  $4.0 \times 10.0$ ; and with tooth region 16 Osstem/TSIII/Regular/ $4.5 \times 8.5$  were placed.

After that, a closure cap was put in place, eliminating the need to suture the soft tissues surrounding the implant site. A post-operative radiograph was taken to ensure that the

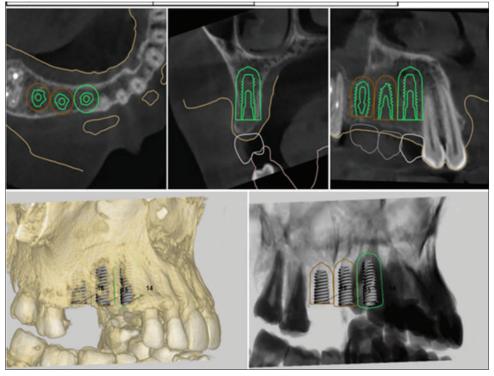


Figure 7: Digital planning of the implant placement

implant was placed according to design. The following day, the patient was contacted for follow-up. It was noted that there was no discomfort, bruising, or post-operative issues.

#### **Step 6 – Prosthetic Procedures**

The definite prosthetic procedure for this case was performed later after clinical and radiographic evidence of osseointegration. Screw retained crown with a solid abutment system was planned for this case.

Steps in the prosthetic phase included

- The splinting of the copings [Figure 9]
- Later, the assessment of the jig trial on the cast and sectioning of the pattern resin [Figure 10]
- Followed by the verification of the jig trial in the mouth [Figures 11 and 12]
- Verification of prosthesis on cast [Figure 13]
- Prosthesis loading in the mouth [Figure 14]
- Prosthesis evaluation in excursive and protrusive movements [Figures 15 and 16]
- Radiographic evaluation of the prosthesis [Figure 17].

#### **DISCUSSION**

Prosthetically driven implant surgery has been a subject of fundamental interest to the dental profession. Correct



Figure 8: Digitally fabricated surgical guide, placed on master cast



Figure 9: Sectioning of jig trail on casts

implant location provides clear benefits, including the potential to assure appropriate occlusion and implant loading, long-term stability of peri-implant hard and soft tissues as a result of straightforward oral hygiene,



Figure 10: Verification of copings on casts



Figure 11: Verification of jig trial in the mouth- lateral view



Figure 12: Verification of jig trial in the mouth - occlusal view

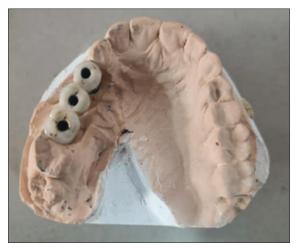


Figure 13: Verification of prosthesis on cast



Figure 14: Prosthesis loading in the mouth



Figure 15: Verification of prosthesis in mouth- left lateral view

and favorable esthetic and prosthetic outcomes.<sup>[3]</sup> Dental implant surgery has traditionally been done through raising flaps, until recently when flapless surgery was advocated.<sup>[4]</sup>



Figure 16: Verification of prosthesis in the mouth-right lateral view

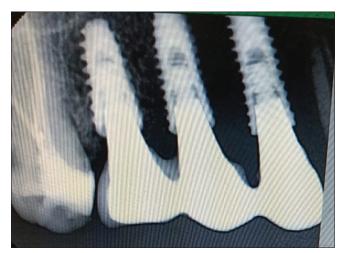


Figure 17: Radiographic evaluation of the prosthesis

A relatively new idea is GIS, which plans the final position of the implants before the procedure and the prosthetic work is done, utilizing 3D CBCT and a stereolithographic surgical template.<sup>[1]</sup> One 3D printing method, called stereolithography, uses a laser-cured resin model.<sup>[5]</sup> However, because this is a relatively new idea, it is critical to comprehend the technique and final positioning of implants inserted without the help of a surgical template. [2] Three-dimensional computer-assisted interactive implant planning software tools have sufficient accuracy and reliability required for predictable clinical use. Two methods for a computer-based transfer are available: Direct navigation and stereolithographic drill guides. [6] The fabrication of a surgical guide, used in implant treatment, is determined by the patient's anatomy and local references, such as the numbers and locations of teeth in the arch to be treated or in the opposing arch.[7]

To direct the surgical location of the drills and implants, the surgical template comprises guided sleeves that are positioned in accordance with the treatment plan.<sup>[8,9]</sup> Drill

keys are used throughout the drilling process to direct successive drills of various sizes in the right location and angulation by being placed into the sleeves within the guide. For some systems, the drill keys can be mounted on the drills.<sup>[10]</sup> The templates' stainless steel tubes perfectly direct the osteotomy drills, eliminating the requirement for pilot drills as specified in standard protocols.[11] They also stabilize the drilling procedure while the dental practitioner placing the implants performs the procedure by restricting the degrees of freedom of the drill trajectory and depth.<sup>[5]</sup> A trusted and well-known method for obtaining a fusion of anatomical data (CBCT) and prosthetic data (radiographic template) is the double scan technique. [12] This surgical protocol has the advantages of being minimally invasive, accurate implant placement, predictability, and a shorter recovery period.[13]

After overlaying a surface scan with CBCT to turn the virtual plan into reality, a higher level of surgical template accuracy is attained from a virtually designed and printed template. The accuracy may even increase if intraoral scans are employed in addition to surface scans of a cast model following impression production as the intraoral scan may lessen the sources of mistakes related to cast model preparation. [2] Planning prosthetically driven implants using a computer program is extremely effective and secure. This specialized program's three-dimensional view enables the selection of the ideal implant location, enhancement of the implant axis, and defining of the optimum surgical and prosthetic solution for the patient. Consequently, a protocol that combines a computer-guided technique with standard surgical techniques emerges as a viable choice.[14]

The creation of surgical guides (stereolithography) can be done immediately using the electronic data collected during the planning process. This method limits the need to raise a flap during the surgical installation of the implants.<sup>[14]</sup> Surgical drill guides may be placed on the remaining teeth or directly on the crest of the bone.<sup>[15]</sup>

Clinicians must be aware of potential variations that can happen while using a CAD/CAM surgical template to place implants to prevent anatomical hazards and prepare for the eventual prosthetic reconstruction. Numerous studies found comparable or superior clinical outcomes when comparing implants placed using CAD/CAM surgical templates with those placed using the traditional method.<sup>[2]</sup>

GIS, which evaluates the link between the final repair and local anatomy in three dimensions, has a number of benefits. By implementing this virtual knowledge in the actual world, it would be possible to prevent implant misalignment or damage to important anatomical structures.<sup>[2]</sup>

A quick surgical method and high implant precision help to minimize the impact on the patient and their morbidity. Patients' requests and preferences are met by reducing invasive surgical procedures, post-operative pain or swelling, and healing time.<sup>[14]</sup>

#### **CONCLUSION**

One of the solutions available on the dentistry market, smart fusion of conventional diagnostic data and computerized data superimposition combined with implant surgical guidelines, enables today's resolution of many challenging cases, formerly attainable only in expert hands. Improving a number of therapy procedures, especially in circumstances where treatment was previously impossible due to complicated anatomical restrictions.

In this case study, a dental implant-supported prosthesis was used to restore three lost maxillary teeth. The placement of dental implants was prosthetically planned using specialized implant planning software, 3D CBCT, and a virtual cast; the implant was then inserted flaplessly using a stereolithographic surgical template. The implant was successfully positioned in the intended location. The patient felt reduced discomfort and agony. The entire process took less time than the standard technique. In the upcoming evolutionary period, 3D GIS will be one of the standard practices for replacing lost teeth.

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# Comparative Evaluation of Ropivacaine (0.5%) and Levobupivacaine (0.5%) in Segmental Spinal Anesthesia for Patients Undergoing Laparoscopic Cholecystectomy: A Randomized and Clinical Trial

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#### **Abstract**

**Introduction:** Unadulterated S-enantiomers of bupivacaine include ropivacaine and levobupivacaine. These are the two amide local anesthetics that were just recently introduced and have a reduced likelihood of cardiotoxicity compared to racemic bupivacaine.

**Purpose:** The present study was conducted to compare equipotent doses of ropivacaine and levobupivacaine with the addition of fentanyl for the intraoperative characteristics and recovery profile of these drugs for patients undergoing elective laparoscopic cholecystectomy under segmental spinal anesthesia.

**Methods:** This randomized, prospective, double-blind, and single-center study comprised included 150 participants. They were allocated randomly into two Groups I and II receiving 0.5% hyperbaric Levobupivacaine and 0.5% hyperbaric Ropivacaine, respectively. Both the groups were compared with regard to characteristics of sensory block, motor block, hemodynamic parameters, and side effects.

**Results:** In our study, duration of sensory block and motor block is significantly more in Group I than Group II (P < 0.05), with mean duration of motor block in Group I was 194.12 min, while it was 98.33 min in Group II and mean duration of sensory block in Group I was 140 min, while it was 84 min in Group II was found to be highly significant (P < 0.0001). Both the sensory and motor blocks have a more rapid recovery with ropivacaine (0.5%) compared to levobupivacaine (0.5%). The study of hemodynamic parameters of the patients showed that the parameters such as heart rate, systolic, and mean arterial pressures were less variable in Group II during measurement at various intervals. Group II had more hemodynamic stability than Group I confirming the higher safety profile.

**Conclusion:** This study suggests that ropivacaine (0.5%) is suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage.

Key words: Bupivacaine, Cardiotoxicity, Fentanyl, Laparoscopic cholecystectomy levobupivacaine, Ropivacaine

#### INTRODUCTION

The standard method for doing a laparoscopic cholecystectomy (LC) using pneumoperitoneum is under general anesthesia. Several LCs have been



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successfully performed using spinal anesthesia techniques, in part because of the development of surgical and anesthetic techniques. [1-3] In comparison to general anesthesia, spinal anesthesia is less invasive and has lower rates of morbidity and mortality. Under spinal anesthesia, the individual undergoing surgery is awake, there are no airway devices, there is less postoperative pain, and nausea and vomiting are not present. [3] Uniform and complete muscular relaxation, a cognizant patient, cost-effectiveness, a relatively uncomplicated recovery, a pain-free early postoperative phase, and protection from potential general anesthesia

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problems are some of the benefits of spinal anesthesia over general anesthesia. [4,5]

Unadulterated S-enantiomers of bupivacaine include ropivacaine and levobupivacaine. These are the two amide local anesthetics that were just recently introduced and have a reduced likelihood of cardiotoxicity compared to racemic bupivacaine. The aforementioned drugs allow for a more rapid restoration of motor function due to their capacity to block sensory nerves more severely than motor nerves, which makes them potentially valuable anesthetic agents. <sup>[6,7]</sup>

With the potential to provide post-operative analgesia as well as better anesthesia quality, adjuvants such as opioids have been delivered concurrently with local anesthetics. Fentanyl has been found to considerably lengthen the duration of the sensory and motor block and improve VAS scores in brachial plexus blocks when used with local anesthetics.<sup>[8,9]</sup>

In this background, we designed a study to compare equipotent doses of ropivacaine and levobupivacaine with the addition of fentanyl for the intraoperative characteristics and recovery profile of these drugs for patients undergoing elective LC under segmental spinal anesthesia.

#### **MATERIALS AND METHODS**

This study was initiated after receiving approval from the institutional ethical review committee. Our study adhered to the principles mentioned in the Declaration of Helsinki. This randomized, prospective, double-blind, and single-center study comprised 150 American Society of Anesthesiologists (ASA) physical status I and II patients, aged 18-65 years, who had undergone elective LC under subarachnoid block at our institute during the time period of the study. Patients who were willing to participate and gave written informed consent, ASA 1 and 2 patients between 18 and 65 years old, with a BMI < 30 kg/m<sup>2</sup> and having normal coagulation status, were included in the study. Patients not giving written informed consent, of ASA Status 3 and 4, age <18 or >65 years, BMI >30 kg/m<sup>2</sup>, with evidence of severe cardiovascular, renal, hematologic, or hepatic disease, preexisting neurological or psychiatric illness, chronic pain syndrome, or a past history of alcohol or drug abuse, were excluded from the research study. After comprehensive pre-anesthetic check-up, patients were included in the study if they met the required inclusion criteria. All the relevant details of the participants were taken and noted down on a pre-designed, pre-structured proforma for the study. Participants were then allocated randomly into two groups (Group I and Group II) with the help of a computerized random number list. Depending on the group under which participants fell, the interventional modality was applied to the study participants. Participants falling under Group I received 2 mL (0.5% hyperbaric Levobupivacaine) and 25 μg (0.5 mL) fentanyl, while patients in Group II were given 2 mL (0.5% hyperbaric Ropivacaine) and 25 µg (0.5 mL) fentanyl. Patients who were included in the trial were kept fasting for 6 h (minimum 6 h) before surgery. Tablets of alprax 0.25 mg, pantoprazole 40 mg on the night before surgery, On the morning of the surgery, each patient received pre-loading with Ringer lactate (10–15 mL/kg over 30 min) and premedication (Ondansetron 0.1 mg/kg and Ranitidine Hydrochloride 150 mg intravenously). Then, the patients were shifted to the operating theater for all routine monitoring: Non-invasive blood pressure, pulse oximetry, end-tidal carbon dioxide, and electrocardiogram. Inj. Midazolam 0.03 mg/kg IV was given to the patient just before the start of the procedure to ease anxiety and apprehension. The sealed and coded envelopes containing details of the drug combinations to be used were kept in the operating room. Any one envelope was opened by a nursing assistant who was not a part of the study any further. Then, according to the random number list generated for randomization, respective drug combinations were prepared for each patient and marked with a coded label by the anesthesiologist who was not a part of the study, and it was handed over to the anesthesiologist performing the segmental spinal block in a blinded manner. Neither the principal anesthesiologist performing the block nor the patient were aware of the nature of the study solution.

Group I and Group II received 2 mL of 0.5% hyperbaric levobupivacaine and 2 mL of 0.5% hyperbaric ropivacaine added to 0.5 mL of 25 µg fentanyl, respectively.

In the sitting position, either of the drugs was aseptically administered through a 25G Quincke needle between T9-T10/T10-T11 interspace. As soon as the subarachnoid block was performed, patients were placed in a supine position.

Sensory block was graded according to the Gromley and Hill test using a pin protruding through a guard every 2 min until no sensation was achieved at T8 level. Motor block was graded according to the Modified Bromage Scale (0-3), where 0 = no motor block (full flexion of hip, knee, and ankle), 1 = ability to move knees and feet, inability to flex hip, 2 = ability to move feet only, inability to flex hip or knee, and 3 = full motor block, respectively.

The onset time of sensory block was assessed by referring to the interval between spinal puncture and the maximal pinprick score. The onset time of motor block was assessed by evaluating the time interval between puncture and the maximal definitive Bromage score. The offset time was considered a corresponding return to normal sensitivity and motility. The spread of anesthesia was referring to the upper dermatome with any grade of sensory impairment. Any side effects such as nausea, vomiting, pain, shivering, sedation, hypotension, bradycardia, and respiratory discomfort were noted and treated with the appropriate drug if required.

The surgical procedure was started within 30 min of the spinal puncture. The time interval for anesthesia parameters was checked every 2 min until 30 min to note the onset and maximum degree of block. Vital parameters were recorded at 5, 10, 15, 30, and 60 min, and then every 15 min till surgery ended, then every hour postoperatively until motility and sensitivity returned to basal condition.

Using a test for two proportions at a 95% confidence interval (CI) and 80% power, the sample size was estimated. In pilot research completed before the current investigation, the effectiveness of levobupivacaine was reported to be 90% and 60% in the ropivacaine group, respectively. Considering  $\alpha = 1\%$  at 95% CI and 95% power, p1 of 0.9 and p2 of 0.6, and a 1:1 ratio, we obtained a sample size of 71 in each group, amounting to a total minimum sample size of 141. Accounting for 5% lost to follow-up and rounding off to the nearest whole number, a final sample size of 150 was taken.

The statistical analysis was carried out utilizing IBM's Statistical Package for the Social Sciences version 23 (IBM, USA). The data were initially analyzed and coded using MS Excel Office version 2021. The Shapiro-Wilk and Kolmogorov–Smirnov tests were used to evaluate if the data were normally distributed. For categorical data, frequency and proportions were used in the descriptive analysis, whereas mean and standard deviation were used for continuous variables. The Fisher's exact test and the Chi-square test were applied when needed to evaluate if the categorical variables were showing any association. The Student's t test was used to see whether the continuous variable means differed significantly across the groups.

#### **RESULTS**

The mean  $\pm$  SD of mean age in Groups I and II was  $50.59 \pm 11.68$  and  $49.43 \pm 9.58$ , respectively. There was no significant difference between the two groups in terms of mean weight (t = 6.363, P = 0.750), although the mean age was higher in Group I. In Group I, 20 were male and 50 were female among the study participants. In Group II, males were 30 and females were 40 of the study population. The demographic data in both groups were comparable.

In our study, the onset of sensory block in the T10 segment was 3.5 min in Group I and 5 min in Group II (P = 0.989), which was insignificant. The median maximum sensory block at dermatome level is in Group I levobupivacaine T4 (T2-T8), in Group II ropivacaine T4 (T2-T10) with (P = 0.512), which is insignificant. The time to the maximum sensory block was reached in 25 min in Group I, 20 min in Group II (P = 0.241). Duration to T10 sensory block was set at 140 min in Group I and 84 min in Group II (P = 0.0135), which was found to be significant. The onset of sensory block regression was 265 min in Group I and 220 min in Group II (P = 0.0058), which was significant in both groups.

Bromage Scale 3 was seen in Group I in 67 patients (95.7%) and in Group II in 48 patients (68.5%) (P = 0.0053), which was significant in both groups. The time to max. motor block (min.) was 5 min in Group I and 10 min in Group II (P = 0.0484), which was significant in both groups. Motor block regression of 178 min in Group I and 90 min in Group II was found to be highly significant (P < 0.0001). The duration of motor blocks was 194.12 min in Group I and 98.33 min in Group II, which was found to be highly significant (P < 0.0001).

Per-abdominal pain was slightly higher in Group I, with 3 (4.29%) members experiencing it and 2 (2.86%) study participants in Group II. Post-operative shoulder tip pain was felt by 5 (7.14%) participants in Group I and 7 (10%) in Group II. Itching was seen in 2 (2.86%) members in Group I and 3 (4.29%) in Group II. Nausea and vomiting were seen in 2 (2.86%) members and 1 (1.43%) in Group II. A respiratory rate <12/min. was seen in only 1 (1.43%) member belonging to Group I. Hypotension was present in 22 (7.14%) in Group I and 29 (4.29%) in Group II.

The mean HR for Group I was  $131 \pm 4.07$  and  $133 \pm 2.10$  at 5-min interval. The fall in HR continued to increase throughout the follow-up until 30 min, when it reached its nadir at  $126 \pm 3.02$  bpm and  $128 \pm 2.10$  in Group II, thus showing a mean fall of 5 bpm. At 120 min, the mean HR was  $130 \pm 1.05$  in Group I and  $132 \pm 3.42$ , thus showing a mean change of only  $0.63 \pm 3.28$  bpm. Statistically, at all the time intervals except 120 min, the difference was significantly insignificant (P > 0.05).

At 5 min., mean arterial pressure (MAP) was 131  $\pm$  4.07 mmHg in Group II as compared to 133  $\pm$  2.01 mmHg in Group II. Statistically, this difference was insignificant (P > 0.05). At 60 min, the mean MAP was 130  $\pm$  1.05 mmHg in Group I and 132  $\pm$  3.42 mmHg in Group II. The decrease in MAP showed a declining trend to reach its nadir at 30 min, when the mean MAP was 126  $\pm$  3.02 in Group I, thus showing a mean decrease of 5 mmHg and 128  $\pm$  2.10 in Group II, thus showing a

Table 1: Demographic data in studied cases

	-		
Parameters	Group I (n)	Group II (n)	P-value
Mean age (in years)	50.59±11.68	49.43±9.58	0.850 (NS)
Sex			
Male	20	30	0.980 (NS)
Female	50	40	0.670 (NS)
ASA grade			
1	40	40	0.780 (NS)
II	30	30	0.900 (NS)
Mean weight (in kg.)	72.45±5.35	70.75±4.08	0.750 (NS)
Height (in cm.)	165±4.85	162±5.62	0.650 (NS)

Data presented as mean±standard deviation or Number: \*P<0.05 was considered significant

Table 2: Parameters for sensory block

Parameters	Group I	Group II	P-value
Onset to T10 (min.)	3.5 (2–14)	5 (2–10)	0.989(NS)
Median max. block (dermatome)	T4 (T2-T8)	T4 (T2-T10)	0.512(NS)
Time to maximum sensory block (min.)	25 (10–30)	20 (2–25)	0.241(NS)
Duration to T10 (min.)	140 (50-200)	84 (45-120)	0.0135(S)
Sensory block regression (min.)	265 (170–390)	220 (170–350)	0.0058(S)

Table 3: Parameters for motor block

Parameters	Group I	Group II	<i>P</i> -value
Bromage scale (grade 3)	67 (95.7%)	48 (68.5%)	0.0053(S)
Time to max. motor block (min.)	5 (2–20)	10 (5–20)	0.0484(S)
Motor block regression (min.)	178 (90–210)	90 (60–120)	<0.0001(S)
Duration of motor blocks (min.)	194.12 (120–250)	98.33 (70–150)	<0.0001(S)

Data presented as mean  $\pm$  standard deviation or Number: \*P<0.05 was considered significant

mean decrease of 5 mmHg. At 60 min, the mean MAP was  $130 \pm 1.05$ mmHg in Group I as compared to  $132 \pm 3.42$  mmHg in Group II. Statistically, the mean change in MAP was statistically insignificant at all the follow-up intervals (P > 0.05) [Figures 1-3] [Tables 1-6].

#### **DISCUSSION**

In our study, the onset of sensory block in the T10 segment was 3.5 min in Group I and 5 min in Group II (P = 0.989), the difference was statistically insignificant. Median maximum sensory block at dermatome level was observed in Group I with levobupivacaine T4 (T2-T8) and in Group II with ropivacaine T4 (T2-T10) (P = 0.512); here too, the statistical difference was insignificant. The time to the maximum sensory block was reached in 25 min in Group I and 20 min in Group II (P = 0.241). The duration to the T10 sensory block was set at 140 min in Group I and 84 min in Group II

**Table 4: Side effects** 

Side effects		oup I =70)	Group II ( <i>n</i> =70)	
	n	%	n	%
Per abdominal pain	3	4.29	2	2.86
Post-operative shoulder pain	5	7.14	7	10.00
Itching	2	2.86	3	4.29
Nausea/Vomiting	2	2.86	1	1.43
Respiratory Rate <12/min.	1	1.43	0	0.00
Hypotension	5	7.14	3	4.29

Table 5: Heart rate in study participants during surgery

Time interval	Groups (Mean±SD)		t-value	P-value
	Group I	Group II		
05 min	131±4.07	133±2.10	-3.573	0.189 (NS)
10 min	129±3.86	131±2.01	-1.750	0.270 (NS)
15 min	127±2.02	129±3.02	-2.44	0.267 (NS)
30 min	126±3.02	128±2.10	-4.185	0.190 (NS)
60 min	130±1.05	132±3.42	1.187	0.510 (NS)

Data presented as mean±standard deviation or Number: \*P<0.05 was considered significant

Table 6: Mean arterial pressure in study participants during surgery

Time interval	Groups (Mean±SD)		t-value	P-value
	Group I (n)	Group II (n)		
05 min	131±4.07	133±2.10	-3.573	0.986 (NS)
10 min	129±3.86	131±2.01	-1.750	0.810 (NS)
15 min	127±2.02	129±3.02	-2.44	0.252 (NS)
30 min	126±3.02	128±2.10	-4.185	0.451 (NS)
60 min	130±1.05	132±3.42	1.187	0.074 (NS)

Data presented as mean±standard deviation or Number: \*P<0.05 was considered significant

(P=0.0135), and the difference was found to be statistically significant. The onset of sensory block regression was 265 min in Group I and 220 min in Group II (P=0.0058), which was significant in both groups. Our study is in line with the results reported by Kopacz *et al.*<sup>[10]</sup>

In our study, the duration of sensory block and motor block was significantly greater in Group I than Group II (P < 0.05), with the mean duration of motor block in Group I being 194.12 min, while it was 98.33 min in Group II, and the mean duration of sensory block in Group I being 140 min, while it was 84 min in Group II, which was found to be highly significant (P < 0.0001). This could be explained by the greater vasoconstrictor property of levobupivacaine, as studied by Rachel and Foster. [11]

Breebaart *et al.* compared 10 mg levobupivacaine and 15 mg ropivacaine for our patients' knee arthroscopy and found the same results: the ropivacaine group moved

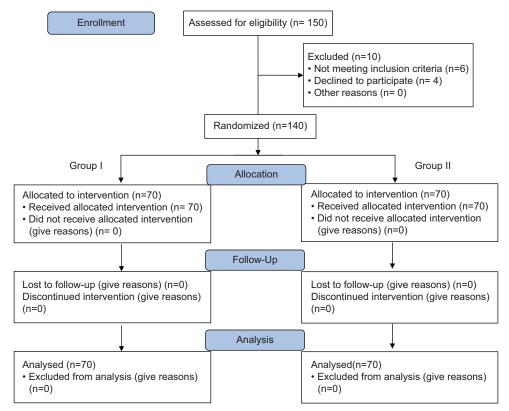


Figure 1: CONSORT flow diagram

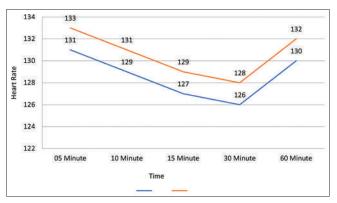


Figure 2: Heart rate in study participants during surgery

early and the need for post-operative analgesia was less in levobupivacaine, but they discharged home late. Ropivacaine presented a shorter duration of sensory and motor block than bupivacaine and levobupivacaine (P < 0.05). [12]

In our study, bromage scale 3 was seen in Group I in 67 patients (95.7%) and in Group II in 48 patients (68.5%) (P = 0.0053), which was significant in both groups. Time to maximum block (min.) was 5 min in Group I and 10 min in Group II (P = 0.0484). The motor block regression of 178 min and 90 min in Group II was found to be highly significant (P < 0.0001). The duration of motor blocks was 194.12 min in Group I and 98.33 min in Group II, which was found to be highly significant (P < 0.0001). Ropivacaine

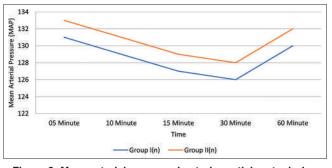


Figure 3: Mean arterial pressure in study participants during surgery

(Group II) had a shorter duration of motor block than levobupivacaine (Group I). Thus, the study suggests that levobupivacaine and ropivacaine provide satisfactory sensory anesthesia with minimal motor blockade at a concentration of 0.5%.

With regard to the side effects seen in our study, Jindal and Gupta, <sup>[13]</sup> Athar *et al.*, <sup>[14]</sup> Mehta *et al.*, <sup>[15]</sup> and Luck *et al.* <sup>[16]</sup> support our findings. While Jain *et al.* <sup>[17]</sup> found hypotension more frequently in the levobupivacaine group than the ropivacaine group, Singh *et al.* (2017) <sup>[18]</sup> found bradycardia more frequently in the ropivacaine group.

The study of differences in hemodynamic parameters among the patients showed that parameters such as heart rate, systolic, and MAP s were less variable in Group II during measurement at various intervals. Group II had more hemodynamic stability than Group I, confirming the higher safety profile and lower incidence of hypotension in Group II. These findings were similar to those of the studies conducted by Barişkaner *et al.*,<sup>[19]</sup> and Udelsmann *et al.*<sup>[20]</sup>

#### CONCLUSION

Segmental blockade provided by thoracic spinal anesthesia has the advantage of limiting sympathectomy to fewer segments with less vasodilatation than lumbar spinal anesthesia and thus fewer hemodynamic changes, which were achieved by both drugs.

Both groups showed minimal hemodynamic variability. This is considered an advantage of thoracic spinal anesthesia. Because of the proximity of the drug deposition site to the target site, thoracic spinal anesthesia requires a lower drug dose to achieve the desired effect.

Hyperbaric ropivacaine (0.5%) produces a segmental spinal block that has sensory block onset characteristics similar to those of equivalent doses of hyperbaric levobupivacaine (0.5%) but with a less intense motor block. Both the sensory and motor blocks are also subject to a more rapid recovery with ropivacaine (0.5%) compared with levobupivacaine (0.5%). This suggests that ropivacaine (0.5%) is suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage.

This study has provided preliminary evidence that segmental spinal anesthesia can be an effective anesthetic technique for routine laparoscopic surgery with minimal side effects.

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# A Retrospective Analysis of 2 Years of Faciomaxillary Injuries in Patients Treated at Various Regional Centers in Gujarat

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#### **Abstract**

**Introduction:** The incidence of faciomaxillary injuries is on the rise due to motor vehicle accidents and increased incidence of violence in recent times. The aim of this retrospective study was to determine the incidence, etiology, and the pattern of fractures in the faciomaxillary region.

**Materials and Methods:** After obtaining permission from the concerned authorities, a predesigned questionnaire was used to collect the necessary data from the department. A retrospective analysis of 1087 patients who suffered trauma and were managed in the Department of Burns and Plastic Surgery in three regional centers in Gujarat over a period of 2 years was carried out.

**Results:** Road traffic accident (RTA) was the common cause of faciomaxillary injuries. Men sustained more injuries as compared to women. Injuries were most commonly sustained in the age group of 11–40 years, constituting about 76% of all injuries, mandibular fractures were the most common.

Conclusion: RTAs were the most common cause for the faciomaxillary injuries.

Key words: Faciomaxillary fractures, Pre-designed questionnaire, Road traffic accidents

#### INTRODUCTION

Faciomaxillary trauma represents one of the greatest challenges to public health services worldwide, because of their high incidence and significant financial cost. The road traffic accidents (RTAs) are major public health hazard of primary magnitude became rapid increase in the automobile users. [1] They are often associated with morbidity and varying degrees of physical, functional, and esthetic damage. [2,3] Accidents are definitely on the increase in India. Our country has world's highest fatality rate in RTAs, 20 times that of developed countries. In India, mortality rate is 8% whereas, in developed countries

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such as UK, USA, and France; mortality rate is 0.1%. [4,5] Faciomaxillary injuries occur in significant number of trauma patients [6] and management includes treatment of facial bone fractures, dentoalveolar fractures, and soft-tissue injuries, as well as concomitant injuries. [7]

Epidemiological assessments of these injuries are essential to reaffirm patterns, identify new trends, plan, and evaluate preventive measures and health policies, and develop priority goals for research. Several studies of the incidence and etiology of faciomaxillary traumas have been carried out in countries such as Austria, [8] Germany, [9] New Zealand, [10] and United Arab Emirates. [11] Very less number studies from India are found in the literature. [12,13] There is lack of population based data on faciomaxillary injuries due to RTAs in this part of the country. This is an important research agenda; hence, the present study was taken up as an attempt to provide a retrospective analysis of patients treated for faciomaxillary injuries and to determine the factors responsible for facial fractures, the age and sex distribution, and the type of fracture.

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#### **MATERIALS AND METHODS**

A predesigned questionnaire was used to collect the data for the purpose of retrospective analysis a predesigned. After obtaining permission from the concerned hospital authorities, the hospital records of all the patients treated for faciomaxillary injuries in the department during the year 2017 and 2018 (January 2017–December 2018) were checked. The information pertaining to age and sex, distribution, etiology of fracture, type of fracture, and associated injuries was entered in the pro forma. The data were then computerized and subject to statistical analysis, using Statistical Package for the Social Sciences windows version 10.0.

#### **RESULTS**

A total of 1087 patients were treated for faciomaxillary injuries from January 2017 to December 2018. Men sustained significantly more faciomaxillary injuries as compared to females, with an overall ratio of 4.5:1 [Figure 1]. Majority of faciomaxillary injuries were seen in 2<sup>nd</sup>—4<sup>th</sup> decade of life constituting a major proportion (76.49%) of these faciomaxillary injuries [Figure 2]. Of the eight causes for sustaining faciomaxillary injuries, RTAs were the most common (74%) followed by interpersonal violence (15%) [Figure 3]. The fracture of the mandible was most common faciomaxillary injury (44.34%) followed by mid face fractures (18.42) [Figure 4]. Parasymphysis fracture was the most common (38%) lower third fractures [Figure 5] and zygomatic complex fractures were the most common of the middle third fracture (55.9%) [Figure 6].

#### **DISCUSSION**

In comparison to females, males have higher prevalence of faciomaxillary injuries in our study is well-documented in

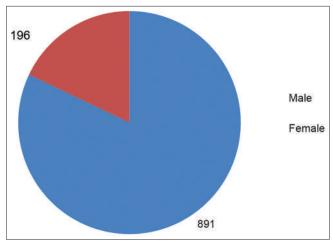


Figure 1: Sex distribution of faciomaxillary injuries

the literature.<sup>[3,14,15]</sup> Males are at greater risk because of their greater participation in activities such as driving vehicles, sports, working at height that involve physical contact, an active social life, and drug use, including alcohol.<sup>[16,17]</sup> However, over the past 4 decades, prevalence of trauma is increasing reported among females, mainly in the under-40

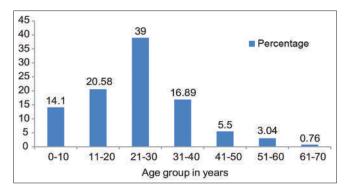


Figure 2: Age distribution of faciomaxillary injuries

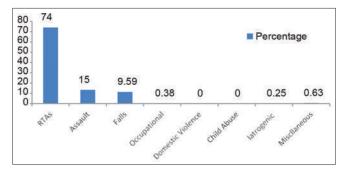


Figure 3: Etiology of faciomaxillary injuries

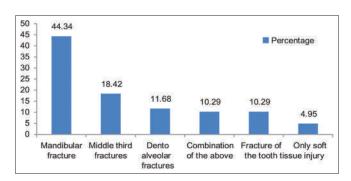


Figure 4: Type of faciomaxillary injuries

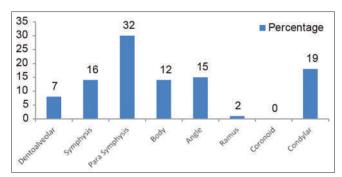


Figure 5: Distribution of mandibular fractures

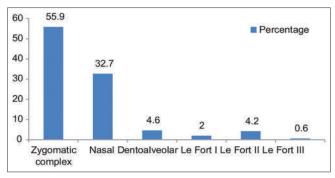


Figure 6: Distribution of middle third fractures

age group, probably due to change in women's social behavior, including their involvement in non-domestic work, a greater active social life, participation in vehicular traffic, and sports as a leisure and health activity.<sup>[17,18]</sup>

The fact that majority of the victims were in the 21–30 years age group (39%) is also in accordance with other studies. [2,7,13,19,20] This is possibly due to behavioral changes and socioeconomic and emotional conflicts to which these young adults are exposed. This age group is recognized as a phase of active age group with great personal independence, social excitement, intense mobility, careless driving on the roads, and exposure to urban violence. [10,13,21,22]

Children and individuals over 40 years are less involved in faciomaxillary injuries. [8,19,23,24] However, the considerable number of patients in the age group of 0–10 years (14%) underline the importance of the development and adoption of specific strategies for the prevention of trauma during the childhood, mainly the prevention of falls, traffic accidents, and domestic violence. [23,24]

RTAs were the main cause of faciomaxillary injuries (75%), corroborating other Indian and international studies. [2,3,12-16,18] The increasing number of RTAs in developing countries like India may be attributed to many factors like sharing of roadways by pedestrians and animals with vehicular traffic, low driving standards, large number of old and poorly maintained vehicles on road, large number of two wheelers, defective roads, and widespread disregard for traffic rules.<sup>[4]</sup> Drivers using mobile phones are 4 times more likely to be involved in crash. [25] The increasing use of mobile phones and drunken driving is becoming a growing concern for road safety. The disturbance caused by mobile phone usage can impair driving performance in number of ways such as longer reaction time, inability to keep correct lane. Safer roads, effective law enforcement, and public transport policies contributed to a significant decrease in the occurrence of traffic accidents in developed countries over the past 3 decades.[17,20] Vehicle accident statistics indicate that the best protection against injury includes

safety awareness courses, defensive riding skills, and a personal commitment to ride safely at all times.<sup>[25]</sup>

In the present study, assaults were the second most prevalent etiological factor (15%), which reinforces the need for the development of preventive programs, aiming to help individuals, organizations, and communities; and government agencies plan proactively for the successful mitigation of unexpected violence. Physical violence is another increasingly important etiological factor for faciomaxillary injuries. In countries such as United States, Finland, and Switzerland assaults have been reported as the main cause of faciomaxillary injuries. [10,26] The studies conducted by Veeresha and Shankararadhya, [3] Motamedi, [21] Ortakoglu et al., [27] and Qudah and Bataineh, [28] have also found mandibular fracture to be the most common faciomaxillary injury. The higher involvement of mandible may be attributed to its prominence and also to its exposed anatomical position on the face. Most of the victims of RTAs will try to avoid their head against injury at the time of accidents. Thus, in the process of avoiding their head, may receive maximum impact to the mandible. The force of the blow is transferred from the chin along the mandible to the condyle causing fractures in the neck, which is one of the weak anatomical locations within the mandible. As found in the studies by Veeresha and Shankararadhya, [3] Motamedi, [21] and Orkatoglu et al. [27] Parasymphysis was the most common site involved in our study. The long roots of canines, presence of third molars, and also the abrupt change in the direction between the large, strong body of the mandible, and the thin ascending ramus make the parasymphysis and the angle region, the other two weak anatomical sites susceptible for fractures

The observed high incidence of nasal and zygomatic complex in most of the middle third fractures is obviously related to the prominent position of these anatomic structures within the facial skeleton, and their greater exposure to external trauma. [10,20,22] However, few cases of nasal fractures are reported in faciomaxillary trauma studies as patients are usually referred to ear, nose, and throat (ENT) and plastic surgeons. [10,20,21] The studies by Al-Khateeb and Abdullah [29] have found zygomatic complex as the most common middle third fracture which is coinciding with the results of this study.

#### **CONCLUSION**

The findings of this study indicate the need for development of emergency protocols, effective educational and preventive strategies, and the implementation of policies aimed at preventing and reducing faciomaxillary injury and its effects.

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# Study of Histopathological Patterns of Endometrium in Abnormal Uterine Bleeding

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#### **Abstract**

**Background:** Abnormal uterine bleeding (AUB) is common gynecological condition and has a major impact on the quality of life. Endometrial sampling is done to evaluate various lesions and rule out malignancy.

Aims and Objectives: The aim of the study was to study the histomorphological pattern of endometrium in patients with AUB.

**Materials and Methods:** A prospective observational study done in 1-year duration among 432 women in reproductive and perimenopausal age group attending the gynecology outpatient department at Government Lalla Ded hospital Srinagar with complaints of AUB. A tissue sample was taken either by Pipelles biopsy or Dilatation and curettage, and was examined by pathologist.

**Results:** AUB was mostly seen in the women with age group of 36–45 years with the menorrhagia being the most common complaint. Multiparity was an important risk factor for the development of AUB. On histopathology, normal cyclical endometrium was the most common finding followed by hyperplasia.

**Conclusion:** Histopathological examination is the gold standard investigation for the patients presenting with AUB. Patients with AUB show a varying spectrum of endometrium pattern, ranging from normal cyclical endometrium to carcinomas.

Key words: Abnormal uterine bleeding, Endometrial biopsy, Menorrhagia

#### **INTRODUCTION**

Abnormal uterine bleeding (AUB) is a broad term that describes irregularities in the menstrual cycle involving frequency, regularity, duration, and volume of flow outside of pregnancy. Up to one-third of women will experience AUB in their life, with irregularities mostly occurring at menarche and perimenopause. A normal menstrual cycle has a frequency of 24–38 days, lasting 2–7 days, with 5–80 mL of blood loss and with regularity (shortest to longest cycle variation ≤7–9 days. Variation in any of these four parameters constitute AUB.<sup>[1]</sup>

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The cause of AUB varies with age; the first step is to exclude pregnancy in reproductive age group. After excluding pregnancy, a thorough investigations are done using the PALM-COEIN<sup>[2]</sup> classification proposed by The International Federation of Gynaecology and Obstetrics (FIGO) which focuses on causes by structural pathologies PALM (Polyps, Adenomyosis, Leiomyomas, and Malignancy or atypical endometrial hyperplasia) while the COEIN causes are non-structural and are diagnosed by a wider approach of clinical assessment, history, and investigations (Coagulopathies, Ovulatory disorders, Endometrial disorders, Iatrogenic and Not otherwise classified [COEIN]).

Various diagnostic techniques are available for the evaluation of AUB which includes laboratory tests (Complete Blood Count, platelet count and function, Prothrombin Time, activated Partial Thromboplastin Time, Human chorionic gonadotrophin, Thyroid profile, Follicle stimulating hormone, Luteinizing hormone, and Prolactin), imaging studies (pelvic ultrasonography and magnetic

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resonance imaging), and endometrial sampling (Dilatation and Curettage, Endometrial aspiration). Management of AUB is not complete without tissue diagnosis, especially in perimenopausal and postmenopausal women.

FIGO recommends endometrial tissue testing as a first-line management in women of perimenopausal age group who have AUB.[3]

#### Aim

The aim of the study was to study histopathological pattern of endometrium in patients presenting with AUB.

#### **MATERIALS AND METHODS**

This prospective study was done on the women attending the gynecology OPD at Government Lalla Ded Hospital with the complaints of AUB during the period of 1 year (January 2022–December 2022).

#### **Inclusion Criteria**

Women of reproductive and perimenopausal age group with complaints of heavy/prolonged/irregular/recurrent menstrual bleeding were included in the study.

#### **Exclusion Criteria**

Women with gestational cause, hemostatic disorders, and isolated cervical or vaginal pathology were excluded from the study. Women with polyps and fibroids were also excluded from the study.

The detailed history was taken which included demographic data, present history, past history, family history, drug history, and obstetric history. The detailed menstrual history was taken which included menarche, last menstrual period, duration of cycle, cycle length, number of pads per day, history of passage of clots, and any history of dysmenorrhea.

#### **Specimen Sampling and Laboratory Procedure**

Endometrial samples were obtained by Pipelles aspiration (out-patient department) and Dilatation and Curettage (operation theatre) and sent to the Histopathology Laboratory of Government Medical College Srinagar in 10% formalin.

In the laboratory, the samples were kept overnight in formalin for fixation. Next day morning, specimen was inspected, and a gross description was documented. Thereafter, the tissue was directly transferred into the cassette, lens paper was used for minute tissue bits to prevent loss of tissue during the processing. The baskets with tissue cassettes were put in automated

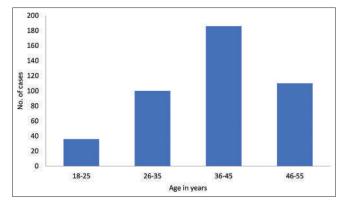


Figure 1: Age distribution in abnormal uterine bleeding

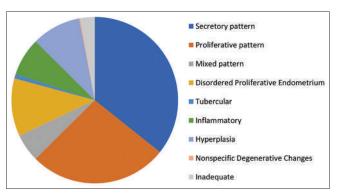


Figure 2: Histopathological findings in abnormal uterine bleeding

Table 1: Age Distribution in AUB			
Age (years)	Number of patients	Percentage	
18–25	36	8.40	
26-35	100	23.14	
36-45	186	43.04	
46-55	110	25.42	
Total	432	100.00	

Table 2: Histopathological findings in AUB

Histopathological findings	Number of patients	Percentage
Proliferative pattern	124	28.84
Secretory pattern	165	38.07
Mixed Pattern (proliferative+secretory)	25	5.70
Disordered proliferative endometrium	22	5
Tubercular	4	1.00
Inflammatory	34	7.98
Hyperplasia	44	10.17
Non-specific degenerative changes	1	0.24
Inadequate	13	3.00
Total	432	100.00

tissue processor. Next day morning, tissue embedding was done, paraffin blocks were made and submitted for microtomy, 4–5 microns thick sections were made and stained by Hematoxylin and Eosin stain in the Automated

Stainer. Histopathological microscopic examination and diagnosis were made on Haematoxylin and Eosin-stained slides.

Statistical method: Data were entered in a Microsoft excel spreadsheet and results were summarized as frequency and percentage. Graphically, the data were presented by bar and pie diagrams.

#### **RESULTS**

During 1-year period, a total of 432 endometrial samples with a clinical diagnosis of AUB were studied.

Patient's age ranged from 18 to 55 years and most of them were seen in the age group 36–45 years, followed by 46–55 years [Figure 1 and Table 1].

The AUB was most common in multiparous patients (204 patients, 47.3%).

The most common complaint was menorrhagia (220 patients, 51%).

Normal cyclical endometrium was found to be the most common pattern in histopathological examination of the samples with secretory endometrium in 165 patients (38.07%) and proliferative endometrium in 124 patients (28.84%). It was followed by disordered hormonal endometrium 5% (22), endometrial hyperplasia 10.17% (44), inflammatory endometrium 7.98% (52), and mixed pattern 5.7% (25) [Figure 2 and Table 2].

#### **DISCUSSION**

AUB is the commonest disease in gynecology accounting for 30–40% cases of outpatient department. AUB significantly affects the quality of life of otherwise healthy women. Endometrial sampling is a safe and easy procedure, even recommended by FIGO as first-line management in AUB.

In our study, AUB was mostly seen in age group of 36–45 years (43.04%) followed by 46–55 years (25.42%). In the studies done by Patne and Sirpurkar, Patil *et al.*, maximum number of patients were in the age group of 31–40 years, 33.8% and 45.26%, respectively.<sup>[4,5]</sup>

AUB was mostly seen in the multiparous females (47.3%) in this study which is consistent with the studies done by Patne and Sirpurkar, Behera *et al.*, 60.95% and 52.9%, respectively.<sup>[4,6]</sup>

Menorrhagia was the most common complaint (51%) among the females with AUB in our study. Patne and Sirpurkar, Behera *et al.* and Karim *et al.* also found that the maximum patients visit the outpatient department with the complaints of menorrhagia; 42.85%, 57.12%, and 42%, respectively.<sup>[4,6,7]</sup>

The most common histopathological pattern in our study was normal cyclical endometrium comprising of 38.07% secretory pattern and 28.84% proliferative pattern. This was followed by hyperplasia (10.17%), endometritis (7.98%), mixed proliferative and secretory pattern (5.7%), disordered proliferative endometrium (5%), tubercular pattern (1%), and non-specific degenerative changes (0.24%). Singh and Sonawane. also found that the patterns of normal cyclical endometrium were the most common (36.7%), followed by hyperplasia (21%).<sup>[8]</sup>

#### CONCLUSION

In this study, we found that 36–45 years age group is most susceptible to AUB. Multiparity increases the chances of AUB. Menorrhagia being the most common complaint among the females with AUB. Normal cyclical endometrium is the commonest histopathological finding followed by hyperplasia. Histopathological study is a safe and effective method not only for diagnosis but also for management of AUB. Histopathological examination also helps in detecting hyperplastic and disordered endometrial changes which are usually associated with carcinoma endometrium especially women of perimenopausal and postmenopausal age groups.

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# Awareness and Perception of Danta Bhagya Yojane among Patients and Accompanying Persons Visiting Outpatient Department of a Tertiary Dental Teaching Hospital in Bangalore City: An Exploratory Cross-sectional Survey

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#### **Abstract**

**Background:** The free prosthodontic services provided by Danta Bhagya Yojane (DBY) in Karnataka should be utilized to treat oral disabilities due to tooth loss.

Aim: Evaluation of the awareness and perception regarding DBY among patients visiting a dental college and hospital in Bangalore.

**Material and Methods:** An interviewer-administered, questionnaire-based cross-sectional survey of 400 adults was carried out in the outpatient department of a dental teaching hospital, to collect data regarding their perception and awareness about the DBY.

**Results:** Most respondents (n = 228, 57.0%) were below-poverty-line card holders. The majority (n = 260, 66.2%) of respondents were unaware of DBY. Among those (n = 133, 33.8%) who were aware, some (n = 19) had the wrong impression that fixed prosthesis such as implants, bridges, and crowns was included under DBY. Knowledge about DBY through television advertisements was reported by 15.3% (n = 61), while 6.5% (n = 26,) were aware through the Government-issued posters put up in the reception area. Few (n = 22, 5.5%) were aware that they could avail the DBY in private dental colleges, while a majority (n = 105, 26.3%) of them thought that they could avail the scheme only in Government dental college and hospitals.

Conclusion: There is a need to increase sensitization programs to improve awareness and utilization of DBY.

Key words: Awareness, Danta Bhagya Yojane, Free dentures, Perception, Public-funded prosthetic rehabilitation

#### INTRODUCTION

Edentulism, a worldwide public health problem, is a pathological condition characterized by missing teeth; it can be partial or total. Edentulism is exacerbated

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when masticatory function is not restored with dental prostheses.<sup>[1]</sup> Studies have concluded that individuals with impaired masticatory ability were at risk of malnutrition due to limitations in chewing food.<sup>[2-7]</sup>

A systematic review reported that 35% adult Indian population have complete or partial tooth mortality; the overall prevalence of complete tooth mortality (loss of 32 teeth) was 10.7% and partial tooth mortality (having one or more teeth) was 58.8%; rural adults showed twice that of urban adults. Significant risk association between edentulism and being poor has been reported in the literature. State With the anticipated 20% increase in

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the elderly population in India, by 2050, the challenges to provide for the oral health-care needs of the elderly must be considered in policy and action. Thirty percent of the elderly are below the poverty line (BPL) and only 28% of the elderly population is literate.<sup>[16]</sup>

Karnataka Health Department estimates that 16% of the state's population (25.92 lakh) are toothless and require dentures.<sup>[17]</sup> The potential benefits of Common Risk Factor Approach are far greater than isolated interventions.<sup>[18]</sup> On 7th of December 2014, the Ministry of Health and Karnataka State Government decided to provide free dentures to patients above 45 years of age with complete or partial tooth loss of three or more teeth and provided that they have the BPL ration cards and documents related to age proof, under the Danta Bhagya Yojane (DBY) scheme. [19] The scheme is operational in 7 District Hospitals, 2 Government Dental Colleges, and 43 Private Dental Colleges in Karnataka.<sup>[20]</sup> Although this scheme was launched in 2014 aiming to provide this service to 30,000 people from BPL families, it was reported that in 2015-2016, only 1600 people; in subsequent years, another 5,550 people; and in 5 years, only 17,000 people were benefitted.[21]

Karnataka State Government has incentivized the accredited social health activist (ASHA) workers to spread awareness about the scheme, and they will get Indian rupees 100 for every case they refer to the dental colleges. [22] The Health Department has been conducting camps to create awareness, screen, and provide dentures to the needy despite inadequate funds allocated. Furthermore, information-education-communication (IEC) strategy included publicity advertisements for the DBY through electronic mass media - television, radio, and cinema theaters and print media - pamphlets and posters. Yet, lack of awareness about the scheme and delay in disbursement of funds to dental colleges, apart from some technical glitches, are the main reasons for the slow progress of this initiative. [23]

The critical factor for the success of any health scheme is the awareness of beneficiaries about the scheme and its services. Lack of knowledge about health programs, especially those targeting vulnerable populations, is an impediment to the right to access health, a basic human right. [24] A positive association between beneficiaries' awareness and subsequent enrolment in the scheme was observed in the case of Rashtriya Swasthya Bima Yojana and Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (PM-JAY). [25] Yet, across settings and emerging schemes, limited scientific evidence is available on levels of awareness and their determinants. [25] Literature documenting the awareness levels about DBY among dental patients or the general public is scarce. [26]

Therefore, the present study was undertaken to assess the awareness and perception about the DBY among the adult patients and accompanying persons visiting the outpatient department of a dental teaching hospital which caters to a diverse patient population, including large numbers from surrounding villages of Bangalore South.

#### **MATERIALS AND METHODS**

An exploratory descriptive and cross-sectional survey was carried out after obtaining due informed consent and institutional ethical clearance (RRDCHET/04PHD/2020) over a period of 1 month, February 2020.

The study participants were selected based on consecutive sampling, in which every subject meeting the criteria of inclusion was selected until the required sample size was achieved. The sample size of 400 for the present study was estimated based on the following formula:

$$N = \frac{Z_{(1-\alpha)}^2 \times PQ}{\delta^2}$$

The study is first of its kind and witnessed no existence of the previous literature. It considered that probability of at least 50% (P = 0.50 and margin of error  $\delta = 0.05$ ) of the patients and their accompanying persons visiting the tertiary dental teaching hospital are aware of DBY.

The study also interviewed accompanying persons who were aware of the DBY and brought those unaware patients for enrolment into DBY; this enabled us to tap the intrinsic motivation similar to that of the patients seeking prosthodontic care and achieve homogenous sample with regard to awareness about DBY.

The study tool comprised of a structured closed-ended questionnaire with three separate sections comprising of sociodemographic details, perceptions and awareness of DBY, and perception about utility and benefit of DBY. The face validity was accomplished among 5 subject matter experts who scored "very good" face validity with a composite score of 3.5 out of 4, with minimal changes indicated toward the simplicity of the language. The content validity of the questionnaire was performed using Aiken's index for adequacy of the questions satisfying the objectives of the study and the Aiken's index score for all the 13 items ranged between 0.81 and 1.00. The reliability of the questionnaire was tested using the test-retest method which showed a Cronbach's alpha score of 0.86 indicating good internal consistency of the questionnaire. The study enrolled the participants based on the subjects who had the ability to understand and answer the questionnaire, and further, it used 04 standardized and calibrated interviewers who interviewed all research subjects using the simple questionnaire format, and hence, vernacularism was not a matter of concern. Anonymity and confidentiality were maintained by not recording the names of the respondents and assigning identification numbers instead.

A descriptive analysis comprising counts and percentage was performed for all the variables. Categorical variables were compared among the different groups using the Chi-square test. A P < 0.05 was considered statistically significant.

#### **RESULTS**

#### **Sociodemographic Information**

A total of 400 subjects took part in the survey; most (n = 225, 56%) of them were males. Nearly half (n = 194, 49%) of the respondents were aged above 40 years. More than half of the respondents (224, 56%) resided in urban areas whereas a lesser percentage (176, 44%) of them resided in the rural areas. More than a quarter of the respondents were found to be graduates (n = 105, 26.3%) and a little over a tenth (n = 44, 11%) of the respondents were found to be illiterates. A majority of the respondents, i.e. (n = 152, 38%) were found to have a monthly family income of <15,000 rupees and a small percentage of them (n = 29, 7.2%) were found to have a family income of >50,000 rupees.

#### **Perception and Awareness about the DBY**

About a quarter (n = 100, 25.0%) of the respondents were persons accompanying patients. Among the rest who were patients, about a fifth (n = 87, 21.8%) had visited the hospital to replace missing teeth and more than a tenth (n = 51, 12.8%) for removal/extraction of teeth. More than half of the respondents (228, 57.0%) were BPL card holders. Majority (n = 268, 67%) of the patients reported having up to two missing teeth, less than a quarter (n = 95, 23.8%) had three or more teeth missing; less than a tenth (n = 36.9%) had completely no teeth. A majority of the respondents (n = 260, 66.2%) had never heard about DBY; among those who had, only some (n = 67, 16.8%) were well informed about the treatment facilities covered under DBY, while less than 5% (n = 19) were under the wrong impression that fixed prosthodontic treatments such as implants, bridges, and crowns were also included under the scheme. A very less number of respondents (n = 22, 5.5%) were aware that they could avail the scheme in private dental colleges, while a majority of them (n = 105,26.3%) thought that they could avail the scheme only in Government dental college and hospitals [Table 1].

Most of the respondents (n = 61, 15.3%) were found to have the knowledge about the DBY through means of television advertisements; less than a tenth (n = 26, 6.5%) of the respondents knew about the scheme through the posters put up in the outpatient department of the college and a very small percentage (n = 2, 0.5%) of them were informed about the scheme by ASHA workers [Table 1]. About one-fifth (n = 28, 20.7%) of the respondents had availed the DBY. Most of the respondents who had heard about the scheme reported that they had informed others about it, while the rest of them (n = 66, 48.9%) have not shared the information of the scheme with anyone. On visiting the dental college, more than half of the respondents (n = 79, 58.5%) came to know about the DBY in the outpatient department of our college through advertisement posters and very few of them (n = 4, 3%) have heard about it through the public announcement system [Table 2].

#### Perception about Utility and Benefit of (DBY)

Nearly a fifth of the participants (n = 77, 19.3%) thought that the benefits to the patient under the scheme is cost-efficient. A little more than a tenth (n = 50, 12.5%) felt the scheme enables them to avail dentures at a lower cost; a few of them (n = 13, 3.3%) perceived that the scheme enables them to improve the speech and helps them to speak better. Finally, a third of participants (n = 14, 31.8%) faced a longer waiting period between appointments during or after availing the services under this scheme and a small percentage of the respondents complained of poor quality dentures being delivered to them under this scheme [Table 2].

#### **Distribution of Responses by Income and Gender**

Although it was not the objective of the study, the distribution of responses by income and gender revealed that a significant proportion of BPL card holders was aware of DBY (43.7%) as compared to APL card holders (21.1%) at P < 0.001. The majority of the BPL card holders (24.1%) knew about the scheme from the Electronic Mass Media as compared to other income groups (9.9%) at P = 0.004. Moreover, predominant proportion of BPL card holders (25.8%) has availed the service of this scheme for the replacement of missing teeth as compared to other income groups (7.9%) at P = 0.02. A significant proportion of 24.1% of the BPL card holders has perceived the various benefits of denture treatment under this scheme as compared to other income groups (12.8%) and the difference was statistically significant at P = 0.004.

However, no significant differences were observed in the subjects' responses to the study questionnaire the based on the gender distribution.

Table 1: Comparison of distribution of responses for study questions by participants using Chi-square goodness of fit test

Question	Response	n (%)	Chi-square	P-value
What is the reason for your hospital visit?	Routine checkup	27 (6.8)	97.280	<0.001*
• •	Replacement of missing teeth	87 (21.8)		
	Filling of decayed teeth	69 (17.3)		
	Correction of irregular teeth	16 (4.0)		
	Tooth removal	51 (12.8)		
	Painful tooth	50 (12.5)		
	Accompanying the patient	100 (25.0)		
Are you a BPL card holder?	Yes	228 (57.0)	7.840	0.005*
•	No	172 (43.0)		
Number of teeth missing	1–2 teeth	268 (67.2)	218.632	<0.001*
•	3 or more teeth	95 (23.8)		
	Completely no teeth	36 (9.0)		
Have you heard of DBY?	Yes	133 (33.8)	41.041	<0.001*
	No	260 (66.2)		
Treatment facilities covered under the scheme DBY as	Removable partial denture	17 (4.3)		
per your knowledge?	Complete denture	36 (9.0)		
	Both a and b	67 (16.8)		
	Fixed partial denture	8 (2.0)		
	Implant prosthesis/denture	11 (2.8)		
Where do you think the patients can avail DBY?	Government dental college and hospital	105 (26.3)		
·	Community health center	31 (7.8)		
	Private dental college	22 (5.5)		
How did you come to know about the scheme DBY?	Social media	12 (3.0)		
·	Television advertisement	61 (15.3)		
	Radio advertisement	11 (2.8)		
	Newspaper	18 (4.5)		
	Family and friends	15 (3.8)		
	ASHA worker	2 (0.5)		
	OPD	26 (6.5)		

DBY: Dantha Bhagya Yojane, BPL: Below poverty line, OPD: Outpatient department, ASHA: Accredited social health activist, \*Statistically highly significant

#### **DISCUSSION**

Studies have demonstrated that public-funded prosthetic oral rehabilitation programs lead to tangible improvements in oral health-related quality of life of older individuals.<sup>[27]</sup> Very few states in India have provisioned state Governmentfunded oral rehabilitation measures such as free removable partial dentures and complete dentures for the elderly. The Mandahasam scheme in Kerala<sup>[28]</sup> and the DBY in Karnataka are the notable initiatives in this direction. However, it remains to be known if there is adequate awareness among the general public about such initiatives which is essential for their utilization and intended benefit to the target population. This prompted the need to explore the impact of existing awareness measures about the Karnataka state-free denture scheme DBY among patients and accompanying persons visiting a tertiary care dental college and hospital in Bengaluru city.

In this study, out of 400 respondents, one-third of them were above the age of 50 years who are the target population for this scheme. Among the patients, the majority reported having missing teeth and had varying extent of edentulousness; nearly, a quarter (n = 95, 23.8%) of respondents were found to have 3 or more teeth missing

in their oral cavity and about a tenth (n = 36.9%) were found to be completely edentulous [Table 1] which is in line with the prevalence reported in other studies.<sup>[8,9]</sup> More than half of the respondents (n = 228, 57.0%) were BPL card holders. The lower income group people could perhaps not afford the treatment procedures that would have saved their questionable tooth and so might have opted for extraction. Less educated people are not much aware about oral health care. Socioeconomic parameters have been reported to have direct influence on the replacement of missing teeth.<sup>[9,29]</sup>

The majority (n = 260, 66.2%) of them had never heard about DBY. Even though the government has introduced the scheme, it has not put adequate effort in creating awareness about the same.<sup>[23]</sup> The same was reflected in the study. Of those who were aware of the scheme less than a fifth (n = 67, 16.8%) were well informed about the treatment facility; <5% (n = 19) were misinformed regarding the treatments covered under the scheme. This confusion among patients might be due to assumptions on their part that all types of tooth replacement prostheses are provided under DBY, and the lack of highlighting of the fact that fixed partial dentures and implant-supported prosthesis are not included in the DBY in the IEC

Table 2: Comparison of distribution of responses for study questions by participants using Chi-square goodness of fit test

Question	Response	n (%)	Chi-square	P-value
Have you availed the service of DBY for replacement of	Yes	28 (20.7)	46.230	<0.001*
your missing teeth?	No	107 (79.3)		
Have you informed about DBY to any of the following?	Family and relatives	35 (25.9)	91.481	<0.001*
	Friends	19 (14.1)		
	Domestic help	2 (1.5)		
	Other patients	13 (9.6)		
	None	66 (48.9)		
How did you come to know about DBY in this hospital?	Posters	79 (58.5)	135.333	<0.001*
·	Public announcement system	4 (3.0)		
	Reception staff	13 (9.6)		
	Word of mouth	27 (20.0)		
	Informed by the dentist	12 (8.9)		
What are the benefits to the patient under DBY?	Cost efficient	77 (19.3)		
	Ease of accessibility	12 (3.0)		
	Quality of work	6 (1.5)		
	Privilege of senior citizen	17 (4.3)		
	All of the above	42 (10.5)		
How does DBY help patients with missing teeth?	Improves ability to chew	42 (10.5)		
	Helps to look better	22 (5.5)		
	Helps to speak better	13 (3.3)		
	Saves expenses	50 (12.5)		
	All of the above	44 (11.0)		
What are the problems faced during or after availing the	Documentation	3 (6.8)	8.500	0.08
service?	Procedural issues	11 (25.0)		
	Poor quality prosthesis	6 (13.6)		
	Longer waiting between appointments	14 (31.8)		
	None	10 (22.7)		

DBY: Dantha Bhagya Yojane, \*Statistically highly significant

campaigns. Therefore, it is important to have a disclaimer in the mass media advertisements or a footnote in the IEC posters to make it clear that expensive treatments such as fixed partial dentures and implant-supported prosthesis are not provided under this scheme.

Furthermore, respondents were largely unaware regarding where to avail the scheme. Even though according to the English daily article, [23] the government tie-up with 45 private dental colleges under the DBY scheme had been announced, and very less patients (n = 22, 5.5%) were aware that they could avail the scheme in private dental colleges. To create more awareness about the same, the main patient waiting area of the dental college hospital, entrance and exit areas of the campus, and satellite centers of the colleges can display posters or huge signage about the DBY.

Television advertisements were reported as the source of information about DBY by most participants (n = 61, 15.3%), while the Government-provided posters displayed in the outpatient department of the college were able to create awareness among only a small number of (n = 26, 6.5%) of participants. Although out of those who were aware of the scheme, only a fifth (n = 28, 20.7%) had availed services under the Danta Bhagya Yojana. About a quarter of the participants had spread the awareness of Danta Bhagya Yojana to their family and relatives while most

of them (n = 66, 48.9%) have not shared the information about the scheme with anyone. This lack of "word of mouth" publicity could be one of the reasons as to why very less number of patients have availed the service under the scheme. This could be rectified by explaining to the patient how edentulism can result in adverse effects to the body so the patient understands and values the treatment under DBY and spreads a good word resulting in more awareness about the scheme. It was also found that very less percent (n = 2, 0.5%) were referred to the college for DBY scheme by the ASHA workers even though they get an incentive of INR 100/- for each patient referred. A similar pattern was observed in the evaluation of the DBY conducted in 2018 and reported delay in payments to ASHA workers as being the problem. [26] Timely payment of incentives would motivate the ASHA workers to create awareness about the scheme.

Our study revealed that less than a fifth of the participants (n = 77, 19.3%) thought that the benefits to the patient under the scheme of DBY are cost efficient. The possible explanation might be other out-of-pocket expenses involved, travel, time away from work, and lost income, obtaining referral letter for DBY from the Government facility in their area. A study conducted in 2018 also reported that difficulty and costs in transportation, and mobility of older adults was a limitation that impacted

utilization of DBY.[26] Being a teaching dental institution, the removable partial dentures and complete dentures are very nominally priced even for non-DBY patients as compared to that in private practice. Our institution has been a part of the rural camps conducted under DBY, wherein prosthodontic services have been made available at the campsite. However, the frail elders in the local communities have verbally shared their constraints with us about accessing the services as they are too old and dependent on others. Regular conduct of such DBY dental camps in the remote areas and satellite centers of the hospitals where patients are screened and encouraged for enrollment in the DBY scheme can serve to ensure better reach of the DBY. More than a tenth (n = 50, 12.5%) of participants thought that the benefits of the DBY scheme include saved expenses, helped them to avail dentures at a lower cost and a few of them felt that the scheme enables them to improve the speech (n = 13, 3.3%) and helps them to look (n = 22, 5.5%) better. Hence, awareness campaigns need to emphasize that along with less expense and good esthetics, dentures provided under DBY also improve one's ability to chew, thereby improving the general health of the patient. Evidence to support including this content in the IEC is available from a meta-analysis that showed that poor nutritional status was associated with lower number of pairs of teeth/functional teeth units.[7]

Some of the participants in this study (n = 14, 31.8%) complained of facing a longer waiting period between appointments during or after availing the services under this scheme and a small percentage of the respondents complained of poor quality dentures being delivered to them under this scheme. Delays in seeking dental care might have led to increased ridge resorption affecting denture fit. However, to reduce the waiting period between appointments, the DBY can support the institutions in creating a separate team of dentists and laboratory technicians dedicated to treat patients under the scheme.

Considering that this scheme continues to provide free RPDs and CDs in Karnataka, an effective IEC strategy like that utilized for the PM-JAY should be developed wherein eligible BPL card holders can be informed of the facilities that can be availed under DBY. Although this study was conducted in only one institution, it collected information from a good mix of rural and urban patients and provides valuable baseline data.

### CONCLUSION

This study points to a lack of awareness and utilization of this unique scheme DBY among potential beneficiaries. This study will be beneficial in planning sensitization programs and improving the ripple effect.

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## Evaluation of Quality of Anterior and Posterior Composite Resin Restorations Performed by Dentists of Union Territory of Jammu and Kashmir

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### **Abstract**

**Goal:** The goal of present study was to evaluate the effectiveness of composite resin restorations placed in the Union Territory of Jammu and Kashmir, both anteriorly and posteriorly.

**Material and Methods:** Among 161 patients who visited the Department of Conservative Dentistry and Endodontics at the Institute of Dental Sciences Sehora between March 2023 and May 2023, a total of 300 composite restorations were assessed. California Dental Association Quality Evaluation System was used to evaluate the quality of composite restorations.

Result: A total of 49% of all restorations were deemed good and satisfactory, while the remaining 51% were not.

**Conclusion:** Our results highlight the need to raise the standard of composite restorations given to the average patient in Jammu and Kashmir Union Territory.

Key words: Color mismatch, Composite resin restorations, Marginal defect, Overhang restoration

### INTRODUCTION

Resin composites are now thought to be appropriate for all kinds of direct restorations.<sup>[1]</sup> This material is adhesively bonded, strengthens teeth, seals teeth, and is more conservative because it does not need mechanical retention or precise preparation geometry and satisfies the patient's goal for a restoration that seems natural.<sup>[2-9]</sup> In addition, modern restorative composite resins are extremely sophisticated materials with high micro and nano filler content that optimizes excellent physical qualities and higher wear resistance, both of which are essential for long-lasting function.<sup>[10-13]</sup> The fact that in 2010, among dentists in the United States, the placement of composite resin restorations outpaced amalgam fillings by a ratio of

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Month of Submission: 05-2023 Month of Peer Review: 06-2023 Month of Acceptance: 06-2023 Month of Publishing: 07-2023 2:1 and that 1/3 of dentists reported not using amalgam at all is evidence of its present popularity. [14,15] Posterior resin composite restorations have been shown to be successful in controlled and clinical trials in Class I and II type restorations with annual failure rates of 0–9% over 5 years and beyond.[16-21] Furthermore, the minimal intervention dentistry concept's conceptual movement toward the preservation of tooth structure enhanced the indication of composites as adhesive materials. [22] It is anticipated that the clinical experience gained throughout that decade may have favored the clinical behavior of these restorations. Even after being deemed clinically insufficient, many restorations frequently functioned well for several more years before being replaced. Contrary to this observation, other restorations deemed adequate were occasionally replaced quickly after similar clinical evaluations were conducted. [23] According to a retrospective study by Mjor et al., [24] groups of clinicians with higher clinical expertise had longer-lasting restorations. Furthermore, it must be taken into account that throughout their dental school, these dentists did not obtain adequate training in installing resin composite restorations. The teaching of posterior composite restorative techniques began in the 1980s at

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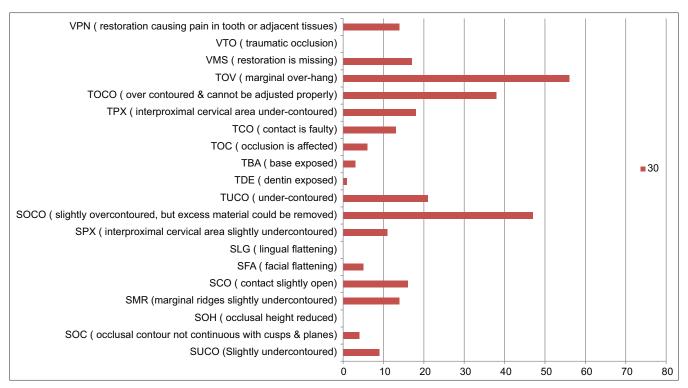


Figure 1: Anatomical form defects of the examined composite resin restoration

Nijmegen University's dental school in the Netherlands. [25] At present, Nijmegen students in the second to 5th years often place posterior composite restorations. The survival rate of resin composite restorations used in clinics however is rarely studied and is not supported by randomized, controlled, and clinical research. Despite the use of number of techniques including reciprocating pin-on-disc tribometers and tooth wear simulators, the ideal technique involves assessing long-term clinical performance. [26] Failure of a restoration can occur in a variety of ways and can be caused by serious flaws (such as fracture and loss of a significant amount of the supporting tooth or restoration) or it may result from tiny flaws such as staining, microleakage, or marginal deficiencies and after a repair has failed but does not result in tooth mass loss or restorative loss. It is unlikely that the failure would be observed by the patient unless there are symptoms or a noticeable esthetic issue.<sup>[27]</sup> Hence, the aim of study was to evaluate the quality of composite restorations placed by dentists of Jammu and Kashmir Union Territory both anteriorly and posteriorly.

### **MATERIALS AND METHODS**

Over a 3-month period, all patients with composite resin restorations who visited the Department of Conservative Dentistry and Endodontics at the Institute of Dental Sciences Sehora, Jammu between March 2023 and May 2023 were examined. The sample size for the present

study was 161 patients and a total of 300 composite restorations.

### **Inclusion Criteria**

All composite direct anterior and posterior restorations were included in the study.

### **Exclusion Criteria**

The following criteria were excluded from the study:

- 1. Composite indirect restorations
- 2. Amalgam and GIC restorations

With the exception of the assessment of the restoration shade, all clinical examinations were done in chair light. The restored teeth were first dried with an air-syringe before being isolated using cotton rolls. The number of teeth, G.V. Black classification of cavities, and restoration age were noted. The California Dental Association Quality Assessment System was used to assess the quality of the composite restorations. [28] The surface and color, anatomical form, and the marginal integrity of the restoration are the three main parameters taken into account in this examination. Restorations graded on a scale of excellent to completely undesirable (R, S, T, and V). The first two rates lie inside the acceptable range, whereas the latter two rates fall within the unacceptable range [Table 1]. As a result, a decision has been reached on the restoration deciding whether it should be kept or replaced either now or in the future. SPSS was used to examine the data. A 95% confidence level and a 5% level of significance were chosen for comparing the relationship between the categorical variables using the Chi-squire test. *P*-values under 0.05 were regarded as significant.

### **RESULTS**

A total of 300 direct composite restorations in 161 adult patients were examined. About 49% of all restorations were deemed acceptable when all three factors, including surface and color, anatomical shape, and marginal integrity were taken into account. Of all the restorations, 58% were anterior and 42% were posterior. Central incisor and molar were most frequently restored teeth in anterior and posterior group. Maxillary teeth were restored more in anteriors and premolars while mandibular teeth were restored more in molars [Table 2]. The distribution of the restorations according to cavity type (G.V. Black classification) showed that Class IV was the most frequent (30%), followed by Class III (23.3%), Class I (22.7%), and Class II (19.3%) while Class V was the least (4.7%). About 83.9% Class I restorations were found acceptable while 16.17% were non-acceptable. About 74.13% Class II restorations were acceptable while 25.9% were non-acceptable.

Table 1: Quality evaluation criteria according to the California Dental Association

Assessment	Rating scale	Criteria
Satisfactory	R "Romeo"	Excellent clinical quality or performance
	S "Sierra"	Acceptable clinical quality or performance
Non-satisfactoryT "Tango"		Clinical quality or performance, which must be repeated, replaced, repaired, or corrected to avoid future damage for the patient
	V "Victor"	Clinical quality or performance, which had to be repeated, replaced, repaired, or corrected immediately due to a damage occurring for the patient at that time

Table 2: Distribution of examined restorations

Tooth	Jaw	Frequency	Percentage
Central incisor	Upper	83	27.7
	Lower	3	1
Lateral incisor	Upper	51	17
	Lower	2	0.7
Canine	Upper	25	8.3
	Lower	10	3.3
Premolars	Upper	34	11.3
	Lower	23	7.7
Molars	Upper	30	10
	Lower	39	13
	Total	300	100

About 68.57% Class III and 68.88% Class IV restorations placed were acceptable while 31.43% and 31.12% were not accepted in Class III and Class IV. About 85.72% Class V restorations were acceptable while 14.28% were non acceptable [Table 3]. About 27.3% examined restorations were placed in <1 year from the data collection time while 4.7% were placed 4–5 years back from data collection time. Restoration placed between 4 and 5 years and above 5 years recorded highest percentage in unacceptable area in terms of anatomical form [Table 4].

### **DISCUSSION**

Esthetic dental restorations are definitely in demand, yet flawless direct restorations have long been elusive due to the defective optical characteristics of composite resins and partly due to incorrect clinical practice. One of most frequently discovered flaw (30.8%) was color mismatch within the spectrum of tooth shade. The composite material's color should be carefully matched to the natural tooth's color. Before the teeth are subjected to any prolonged drying, the shade of the teeth should be determined because dehydrated teeth become lighter

Table 3: Association between cavity class and marginal integrity quality (Quality Evaluation Criteria according to CDA)

Cavity	Acceptable	Non-acceptable	Total
Class I	57	11	68
	83.9% "R"	16.17% "T"	100%
Class II	43	15	58
	74.13% "R, S"	25.9% "V"	100%
Class III	48	22	70
	68.57% "R, S"	31.43% "V"	100%
Class IV	62	28	90
	68.88% "R, S"	31.12% "V"	100%
Class V	12	2	14
	85.72% "R, S"	14.28% "V"	100%
Total	222	78	300
	74%	26	100%

Table 4: Association between the anatomical form quality and the age of the restoration

Age	Acceptable (%)	Non-acceptable (%)	Total
0–1 year	58 (70.73)	24 (29.27)	82
1–2 years	56 (71.80)	22 (28.20)	78
2-3 years	60 (69.78)	26 (30.22)	86
3–4 years	14 (82.35)	3 (17.65)	17
4–5 years	4 (28.67)	10 (71.43)	14
Above 5 years	8 (34.78)	15 (65.22)	23
Total	198	102	300

P=0.001

in shade as a result of a decrease in translucency. [29] The tertiary amine accelerator's chemical reaction and surface deterioration are particularly important factors in how optical characteristics of resin composites evolve over time. [30] The results of this study's surface and color analysis are different from those obtained by Brukiene et al. in Lithuania (2004).[31] In the present study, 42.3% of the restorations were found to be anatomically undesirable, which is comparable to the result published by Brukiene et al.[31] in Lithuania (47.58%) and Ijaimi et al.[32] (44.3%) after evaluation of the anatomical form of the restorations. Rather than causing mechanical irritation, overhanging restorations are known to induce gingivitis or cause periodontal illnesses because to the nearby buildup of bacterial plaque. These iatrogenic variables and the etiology of local periodontal diseases have been shown to be closely associated in epidemiological and clinical experimental research.[33-35] In the present study, proximal overhang was detected in 19% of the restorations [Figure 1]. There was relevant correlation found between the age of the restoration and anatomical form of the restoration. Old done restorations showed highest unacceptability. A 4-5-year-old done restoration showed unacceptability of 71.43% while 5 and above years old restorations showed unacceptability of 65.2% [Table 4]. Reduced water resistance of composites may be linked to this problem. With resin composite materials, discoloration is still a significant clinical issue, and esthetic failure is one of the leading causes of restoration replacement.<sup>[36]</sup> In the present study, Class III and Class IV and Class II represented highest unacceptable marginal integrity percentage compared to other classes. There could be a moisture control issue, or there could be a lack of knowledge and experience with Class II composite applications. Only 2% of Sudanese practitioners employ the rubber dam for root canal therapy, according to Ahmed et al.[37] In addition to restoration techniques, the caries risk factor is crucial to the success of the restoration. In a recent study by Opdam et al., the results showed that both composite and amalgam restorations performed similarly in the high-risk patient group, with amalgam performing better on smaller restorations. The same study came to the conclusion that patients' caries risk significantly influences restoration survival. [38] Further research into the types of restorative materials utilized in relation to the caries risk factor is advised because the sample size for this study was rather small.

### **CONCLUSION**

Based on the evaluation of the composite restorations, it was decided within the constraints of the study that 48% of the composites were of poor quality and need to

be replaced. The biggest factor indicating the necessity for replacement (42.3%) was anatomic shape that was not acceptable. In this study's composite restorations color mismatch, surface roughness and overhang were the most typical flaws. Result of present study showed that 49% of total restorations were acceptable while remaining 51% were of unacceptable quality and had to be replaced.

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### **Laparoscopic Interval Appendectomy in Children** – is it Still Relevant?

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### **Abstract**

**Introduction:** Appendicitis is one of the most common conditions encountered by clinicians in pediatric population. Benefits of laparoscopic appendectomy in the acute setting have been largely advocated in the recent past due to significant post-operative complications seen with open appendectomy. However, gray areas remain as to when to go for laparoscopic interval appendectomy (LIA). In our study, we tried to identify a subset of pediatric patients who would benefit from LIA.

**Purpose:** The purpose of the study was to assess the role of Laparoscopy in Pediatric Interval Appendectomy at Department of General and Minimal Invasive Surgery, Government Medical College Srinagar.

**Materials and Methods:** A prospective and observational study involving 175 children who underwent management for acute appendicitis (AA) over a period of 2 years in our tertiary care institute.

**Results:** There were 175 children enrolled but only 51 were subjected to laparoscopy. Eight cases were excluded due to presence of additional intraoperative non-appendiceal findings. Rest 43 patients were included in the study and were subjected to LIA. All of them had previous history of an attack of AA. Age ranges from 2 to 14 years. There were 20 boys and 23 girls in the study group. Nineteen cases had some findings of AA at LIA and there were acceptable minor complications seen (three cases) during a mean follow-up period of 18 months.

**Conclusions:** LIA is safe and feasible surgical procedure which can be offered to patients where laparoscopy is not available in the emergency setting. LIA can be considered for as a day care procedure especially for the patients hailing from nearby places so as to decrease the in-patient hospital burden.

Key words: Appendicitis, Children, Laparoscopic interval appendectomy, Pediatric

### INTRODUCTION

Appendicitis in the pediatric population remains the most common surgical condition. <sup>[1,2]</sup> The lifetime risk of developing appendicitis is reported to be 6.7% in females and 8.7% in males. <sup>[3]</sup> Acute appendicitis (AA) in children can be treated by conservative method or Surgical intervention based on the stage of appendicitis. Surgical intervention



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can be accomplished as an emergency procedure or as an elective procedure post-conservative management. In both situations, surgical intervention can be approached by the open appendectomy (OA), or the laparoscopic appendectomy (LA). In tertiary care institutions where the expertise is available, it can be accomplished by minimal invasive methods or by Robotics. [4] Benefits of LA in the acute setting have been largely advocated due to significant post-operative (PO) complications seen with OA. [5,6] LA in children in the acute setting has gained popularity within the last decade but require laparoscopic infrastructure and expertise available in the emergency setting. However, gray areas remain as to when to go for laparoscopic interval appendectomy (LIA). In our study, we tried to identify a subset of pediatric patients who would benefit from LIA.

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### **REVIEW OF LITERATURE**

The first report on an operated case of appendix is described by Claudius Amyand (1681–1740).<sup>[7]</sup> In 1981, Semm performed the first LA.[8] Two German surgeons, Gotz et al. pursued Semm's purpose and established LA on a wide basis. Already in the early 90s, they had performed hundreds of appendectomies by this approach and perfected the technique. They even used it in patients with AA. [9] Kavic et al. concluded that in experienced hands, LA is a safe and efficient alternative to OA for the treatment of AA.[10] A systematic review of studies comparing laparoscopic and open appendectomies was performed by Sauerland et al. and published in 2002. The meta-analysis of 39 separate investigations concluded that wound infections were significantly reduced in LA (odds ratio 0.5), but abscess formation was significantly increased (odds ratio 2.8).[11] In the year 2011, Ching-Chung et al. retrospectively studied 177 children who underwent appendectomy from January 2000 to November 2004. The authors divided both groups of OA and LA into Simple appendicitis, perforated appendicitis, and appendicitis with abscess and found that the rate of complication was fewer in cases who underwent laparoscopic surgery among all stages but it took longer operating time (OT).[12] The British urologist Wickham was the first to use the term "minimally invasive surgery" and attracted significant attention when he published his visions about endoscopic procedures in 1987 in the British Journal of Urology. He predicted the paradigm shift in practical surgery that took place a little later: "Surgeons applaud large incisions and denigrate "keyhole surgery." Patients, in contrast, want the smallest wound possible, and we at Britain's first department of minimally invasive surgery are convinced that patients are right".[13]

### **MATERIALS AND METHODS**

This was a prospective and observational study conducted in the Department of General Surgery, Government Medical College, Srinagar, Union Territory of Jammu and Kashmir from July 1st, 2020, to June 30th, 2022, for a period of 2 years. All patients in the pediatric age group from 6 months up to 14 years presenting with clinical, biochemical, and radiological evidence of appendicitis managed conservatively and were subjected to interval appendectomy were included. This also included patients of diagnostic laparoscopy where no cause of non-specific pain lower abdomen was found intraoperatively and appendectomy was done. Exclusion criteria included diagnostic laparoscopy where alternative cause of non-specific pain lower abdomen was found other than appendix, Parents/Guardian refusing consent for laparoscopic surgery, and any other medical condition contraindicating laparoscopic intervention.

### **Aims and Objectives**

The aim of the study was to study the role of LIA in the management of pediatric appendicitis by studying parameters such as OT (minutes), total hospital stay (days), return to activity (usual playful), any additional intraoperative findings, requirement of PO analgesia, to determine early PO complications such as bleeding, infection, intra-abdominal abscesses, adhesion obstruction, and any other complication related to the procedure. All patients within the included age group were assessed by thorough history taking and clinical examination. The informant of the child was assessed for the reliability and was counseled properly. Clinical examination included general physical examination and per abdomen examination including inspection, palpation, percussion, and auscultation. Apart from base line investigations for general anesthesia such as complete blood count, kidney function tests with serum electrolytes, blood sugar, serology, electrocardiogram, and chest skiagram, patients were subjected to special investigation such as ultrasonogram abdomen (US), computerized tomography scan (CT), and magnetic resonance imaging whenever warranted. Parents/Guardian were counseled about the surgical intervention.

Pre-operative preparations for surgery included informed and written consent from the parents/guardian, patients were kept nil per oral 6 h before surgery, pre-anesthetic medication was given on the night before surgery, part preparation was done in the morning on the day of surgery, and single dose of IV Ceftriaxone was given at the time of induction. Surgical steps and technique of LA: The position of the patient, equipment and the surgical team: Supine Trendelenburg position (with his head down) sloping at 10°-15°, toward the operator. The operator and the assistant stood to the left of the patient, and the monitor was on the right of the patient. Procedures were performed under general anesthesia with Endotracheal Tube/Laryngeal mask airway. The bladder was emptied using a Foley catheter, which was removed immediately; older patients were advised to urinates immediately before the procedure. After making the umbilical incision, a pneumoperitoneum ranging from 6 mm Hg to 12 mm Hg depending on the age of the child was created with a Pediatric Veress needle. Classical 3 ports were placed as shown in the Figure 1a. Depending on the age of the child, one 5-mm/10-mm umbilical port was used for 5-mm/10-mm telescope, while the positions of the other ports vary according to the position of the appendix. Two working ports in triangulation, a 5 mm trocar in the upper right quadrant and a 5 mm trocar in the lower left quadrant were placed routinely or a supra-pubic trocar position, where a 5 mm trocar was placed in the lower right quadrant for the retrocecal positioned appendix.

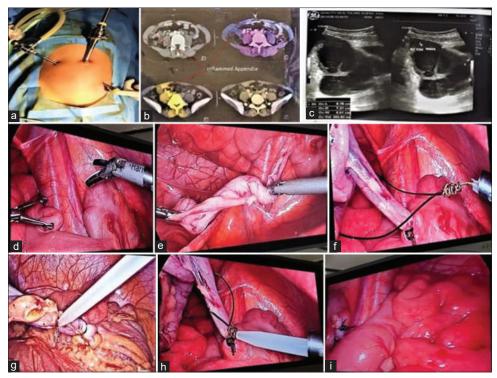


Figure 1: LIA picture (a) Port placements, (b) CECT abdomen, (c) USG abdomen, (d) localizing appendix, (e) taking down meso appendix, (f-h) securing endoloop, and (i) picture after appendent appendix (f-h) securing endoloop.

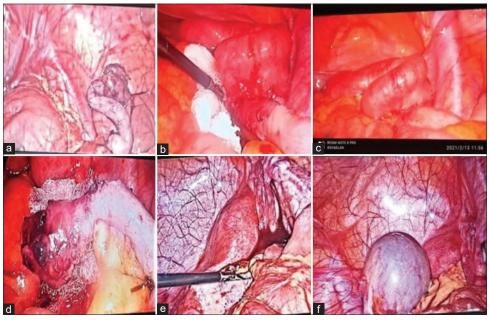


Figure 2: LIA with IO finding of AA or additional findings. (a-d) IO findings of acute appendicitis, (e) blood in pouch of Douglas, and (f) hemorrhagic ovarian cyst

Procedure: [Figure 1b-i and Figure 2a-d] the end of the appendix was seized by the grasper for the mesoappendix placed through the right lower abdominal 5 mm port. The mesoappendix was skeletonized from the top to the base using a 5 mm harmonic scalpel introduced through the left lower/supra-pubic trocar. After that, an endo-loop was introduced through the same trocar,

two endo-loops/extracorporeal Roeder's knot using preformed polyglactin 910/chromic catgut sized 2-0/3-0 were passed over the tip of the appendix whereby the base is secured. Another endo-loops/extracorporeal Roeder's knot using preformed polyglactin 910/chromic catgut sized 2-0/3-0 was passed and secured 1 cm from the 2<sup>nd</sup> knot. The appendix was resected using harmonic

scalpel, leaving two ligatures on the base. The appendix was removed by introducing a sterile drip set cover through 5 mm supra-pubic/left lower quadrant trocar. The resected specimen was sent for the histopathological examination. PO Management: Antibiotic treatment was continued for 1-day postoperatively routinely, 2-day postoperatively if intra-abdominal serous fluid was signaled as intraoperative findings or 7 days along with amikacin and metronidazole when the appendix was found to be necrotic or gangrenous. Antimicrobial agents were eventually changed on the basis of the antibiogram report. PO analgesia requirement was guided by FLACC/ Wong Baker pain scores. IV/IM analgesia was given till patient started taking orals. Oral analgesia was continued for as and when required; orals were started as the bowel movements returned; discharged once patient tolerated orals and wound was found to be healthy and healing well. Follow-up was done at week 1, week 3, and at 6-months PO. Stitch/clips were removed on week 1 follow-up. Check US was done at 3-week follow-up visit. Statistics: All the data were collected and analyzed for the parameters to be assessed and were compared with the global trends. The statistics were applied wherever indicated using Chisquare method and P value for statistical significance was calculated.

### **RESULTS AND OBSERVATIONS**

Age of the patients in this study ranged from 2 years to 14 years with mean age of 8.23 years (98 months). There was a total of 20 (46.5%) male patients and 23 (53.5%) female patients. The male to female ratio was 1: 1.15. All patients presented with a history of pain abdomen during the acute episode of appendicitis. Thirty-five (81.3%) presented as pain RIF, 7 (16.2%) had history of classical migratory pain abdomen, and 1 (2.5%) patient had diffuse abdominal pain. Anorexia was documented in 8 (18.6%), nausea and vomiting in 22 (51.1%). Fever was seen in 17 (40%) patients. On examination, all 43 cases had tenderness on palpating RIF whereas only 10 (23.2%) patients had rebound tenderness. Thirty-four (79%) patients had their counts raised.

Based on the findings during intraoperative abdominal surfing, it was revealed that: In 19 patients, there were intraoperative findings suggestive of AA like congestion, engorged appendix, perforation at tip, flimsy adhesions with parities/omentum, peri-appendiceal adhesions, fluid/pus collection in pelvis, and around appendix. In rest of the 24 cases, the appendix appeared normal, long, mostly retrocaecal in position and in five patients, it was pelvic in position. Fecolith was present in eight cases with IO findings of AA and only in one case with no AA.

 $(P=0.01 \, {\rm Significant})$ . The findings of AA were seen among younger children more than the older children. However, on applying statistics, it was found to be not significant (P=0.593). When statistics were applied with respect to gender associated with intraoperative findings, it was again found to be not significant.  $(P=0.275 \, {\rm for females})$  and 0.242 for males). Eight cases excluded from the study due to additional findings belonged to older age group, majority  $(5/8 \, {\rm cases})$  were females. All three male cases had an open DIR of 2–3 mm. Three cases in this group had history of pigtail drainage during acute attack.

The overall mean surgical operative time calculated was  $24.79 \pm 4.9 \text{ min (SD)}$ . Mean surgical operative time was  $27.10 \pm 5.6$  min (SD) for 19 patients having intraoperative findings of AA and 22.90 ± 4.58 min (SD) for cases with no such findings. Eight cases with additional findings who were excluded from the study had mean surgical operative timing of  $32.90 \pm 5.6$  min (SD). There was no statistically significant difference in the OT for patients with and without intraoperative acute features of appendicitis (P = 0.345) but when statistics were applied for OT in cases with additional findings, it was found to be significant (P = 0.01) as shown in Table 1. There was a total of three PO complications seen during immediate PO period and all belonged to the group with IO findings of AA which included transient fever in one patient, port site infection in one case (history of positive for Severe acute respiratory syndrome (SARS) COVId in recent past) and PO pain abdomen without distension in one case. There were no intraoperative and long-term PO complications. Among the cases with additional findings, there were three complications seen. Two cases had transient fever and one case had PO ileus. Higher complication rates were seen among this group and when compared to the AA group, it was found to be statistically significant (P = 0.044) as shown in Table 1.

The mean hospital stays for study group patients who underwent LIA was 1.23 days. There was slight longer hospital stay for patients with additional findings (exclusion group) which was 1.62 days (P = 0.001, Significant). Nineteen cases with IO finding of AA required 76 doses whereas 24 cases with no finding suggestive of AA required 76 doses. (P = 0.50, Not Significant). Majority of the patients 26/43 (60.4%) were started with and tolerated oral feeds and were ambulatory 24 h postoperatively. Seventeen (39.5%) patients returned to normal activities by 12 h PO. One patient (2.32) took 36 h for return to his usual activities. This patient belonged to the group having features of AA intraoperatively. PO early return to activity at 12 h when compared between cases with different IO findings, it was found to be statistically significant (P = 0.004, Significant) but at 24 h, it was found to be not significant (P = 1.0) as show in Table 1.

Table 1: Operative time, complications, hospital stay, return to activity, and PO analgesia requirement

	rval appendectomy excluded from the s		Intraoperative acute appendicitis	Intraoperative no acute appendicitis	Patients with additional findings
43			19	24	08
Mean operative time (Minutes)	24.79±4.9		27.10±5.6	22.90±4.58	32.90±5.6
Complications (Mean follow-up of	Intraoperative	Bleeding hematoma injury to bowel	Nil	Nil	Nil
18 months)	Immediate	Transient fever	1	Nil	2
	post-operative	Port site infection	1	Nil	Nil
		PO SAIO	Nil	Nil	1 (PO ileus)
	Late	PO Pain abdomen	1	Nil	` Nil
	post-operative	Port Site hernia	Nil	Nil	Nil
Total Complications	Study group-3 (6.97	7%)	3	0	3
Hospital Stay (Overs	, , ,	,	1.42 days	1.08 days	1.62 days
PO Analgesia requir	rement (3.53 doses/	patient)	4 doses/patient	3.1 doses/patient	4.1 doses/patient
Return to activity	` .	,	5%<12 h 95%<24 h	65%<12 h 100%<24 h	0%<12 h 38%<24 h

<sup>\*</sup>Statistics applied for additional findings w.r.t Operating Time (OT) was found to be significant (P=0.01), \*\*No statistically significant difference in OT for patients with and without intraoperative acute features of appendicitis (P=0.345), \*\*\*Statistically significant complication rates were seen in additional finding group. (P=0.044)

### DISCUSSION

AA in the pediatric population remains the most common surgical emergency<sup>[2]</sup> and the lifetime risk of developing appendicitis is reported to be 6%–8% among all ages and gender. The management varies from conservative, conservative followed by surgical and upfront surgical intervention which can be both by open or laparoscopic approach.<sup>[14]</sup> In this era of good antibiotics but non-availability of laparoscopy at peripheral health institutions patients with low Alvarado score can be offered LIA after conservative management of the acute episode.

### **OT**

Multiple previous studies compared the OT of OA with LA and found OT for LA to be slightly longer. Majority of these studies involved complicated appendicitis. The OT in these studies for LA ranged from 30 min to just over an hour.[15-17] All 43 cases underwent LIA. The OT in our study was much less than the global trend due to the fact that we performed LIA in early stages even if the findings indicated AA as only 1 case revealed perforated appendicitis without overt clinical, biochemical, and radiological features. The OT is markedly increased during LA for perforated complicated appendicitis. [15] Eight cases with additional findings who were excluded from the study had longer mean surgical operative timing. The very fact that presence of additional IO findings especially in females increased the OT by almost 15 min. There was no statistically significant difference in the OT for patients with and without intraoperative acute features of appendicitis but when statistics were applied for OT in cases with additional findings, it was found to be significant.

### **PO Complications**

There were a total of three complications seen during immediate PO period and all belonged to the group with

IO findings of AA as shown in Table 1. The complication rate in our study is comparable to the LA for acute complicated appendicitis from the previous studies. [18-20] Among the cases with additional findings, there were three complications seen. Two cases had transient fever and one case had PO ileus. As expected, higher complication rates were seen among this group and was comparable to the complication rates for LA in acute complicated appendicitis. [21] When compared to the LIA group, it was found to be statistically significant. Our study had one case of port site infection which required incision and drainage. The same girl child had history of SARS Covid infection 3 months earlier. Current literature support increased pulmonary and non-pulmonary complication rate among patients who had SARS COVID infection. [22]

### **Hospital Stay**

LA can be performed safely as an outpatient procedure in children with uncomplicated appendicitis. Complying with our institutional protocol all children undergoing operative intervention under general anesthesia were kept overnight for observation. In our study too, the mean hospital stays for study group patients who underwent LIA was 1.23 days. If we exclude 19 cases with IO findings of AA, it comes down to 1.08 days almost making it an out-patient procedure. There was statistically significant longer hospital stay for patients with additional findings (exclusion group) which was 1.62 days due to 2 days of hospital stay for such patients with PO minor complications which can be a factor for longer hospital stay as seen in few other studies.<sup>[23]</sup>

### **Requirement of PO Analgesia**

LA is a common emergency pediatric surgery procedure accompanied by substantial pain (pain scores >4 for >60% of the time) in 33% of these patients. [24] This can be tackled by a bundle of pain management interventions

including local anesthetic infiltration at the incision site, intravenous (IV) opioids by patient-controlled analgesia and scheduled doses of IV, and oral analgesics. Majority of the patients in our study required only 3–4 doses of initially IV and later oral analgesia till the next morning of the day of surgery. The dose requirement was more for cases with IO findings of AA but was not statistically significant. Cases with additional findings required maximum doses but were in the exclusion group. The difference in dose requirement was also not dependent of the age and acute presentation of the patient. <sup>[12]</sup> This may be due to evenly distribution of the cases with IO findings of AA among different age groups. Overall, 43 cases in the study group required a cumulative 152 doses (mean 3.53 doses per patient).

### **Return to Activity**

Return to activity was assessed based on the developmental milestones appropriate for the age. Acceptance of orals, joyful interactions with the parents and ambulation was considered as normal return to activity. Majority of the patients were started with and tolerated oral feeds and were ambulatory 24-h postoperatively. Many among them returned to normal activities by 12 h PO thus making us to think of considering LIA with no IO finding suggestive of AA a day care procedure as done by Akkoyun<sup>[25]</sup> One patient (2.32%) took 36 h for return to his usual activities. PO early return to activity at 12 h when compared between cases with different IO findings, it was found to be statistically significant (P = 0.004, Significant) but at 24-h, it was not significant (P = 1.0) and when compared among various age groups, it was again found to be statistically non-significant for children > 5 years of age. (P = 0.5). Since majority of our patients were having no IO evidence of AA the return to activity was much faster as compared to studies involving cases with AA.[12,23]

### **Clinical, Radiological and Intra-operative Findings**

It was added information gathered by this study to analyze the results of the clinical examination, US, and intraoperative findings Despite being a relatively common condition, the diagnosis of appendicitis in children can prove to be challenging in many cases. Presenting signs and symptoms, laboratory tests, and imaging studies such as US and CT abdomen form the diagnostic work-up of appendicitis. In spite of various composite measures based on multiple sources of diagnostic information, as well as the utility of clinical pathways as a means to streamline the diagnostic process the diagnosis still remains on the clinical judgment of the treating physician with respect to mode of treatment whether conservative of surgical. While CT is the most accurate mode of imaging in suspected appendicitis, the accompanying radiation is a concern. Ultrasound may help

in the diagnosis while decreasing the need for CT in certain circumstances. The Alvarado Score has good diagnostic utility at specific cut-off points. Laboratory markers have very limited diagnostic utility on their own but show promise when used in combination. Further studies are warranted for laboratory markers in combination and to validate potential novel markers. We did not routinely do CT owing to the risk of radiation exposure to small children and performed only in case of diagnostic dilemma. In a study Calprotectin, Serum Amyloid A, C-reactive protein, and total leucocyte counts were significantly elevated in patients with AA. However, none had cutoff points that could accurately discriminate between AA and other pathology in patients with suspected AA. In our study, we relied on modified Alvarado score supplanted by US abdomen for diagnosing AA and managed the cases as per the algorithm mentioned in materials and methods [Figure 3] and subjected 43 cases to LIA. The difference in detecting acute features was statistically significant between intraoperative findings and radiology/clinical findings (P = 0.01 and 0.0007, respectively) but not significant when clinical examination was compared with radiology. (P = 0.27). As per the study done by Karakas *et al.*, there is no statistical significance between the rates of diagnostic performance of US, CT, or their combination, nor between the negative appendectomy rates of each group, but the rate of perforation was significantly higher when CT was performed, alone or after US. Thus, CT should be done in cases with diagnostic dilemma or localized/diffuse peritonitis indicating perforation.<sup>[27]</sup> Cosmetic excellence: Laparoscopy scores significantly over scar formed after LIA in small children. Majority of the port site scars were found to be almost invisible at 12-week follow-up PO.

LA seems to be a more successful procedure for children, as long as their abdomens can physically support laparoscopic procedures. Another new area of potential benefit of laparoscopy is its ability to be diagnostic, especially with reference to gynecological conditions. A study looking at unnecessary appendectomies in women found that in situations where a healthy-looking appendix was found and a gynecological diagnosis existed. In a study by Sauerland R et al., non-appendiceal lesions were identified in 10% of patients.<sup>[28]</sup> In our study, we encountered additional findings in 19% of patients which included gynecological in females and open DIR in males. Conservative management of advanced complicated appendicitis in children is becoming more common. Mostly LIA is reserved for appendiceal mass or abscess in developed countries and metropolitan cities in developing countries.<sup>[29]</sup> Since India is at developing stage with respect to its health-care delivery system at peripheral health institutions and non-availability of laparoscopic infrastructure in emergency setting in such regions, LIA is

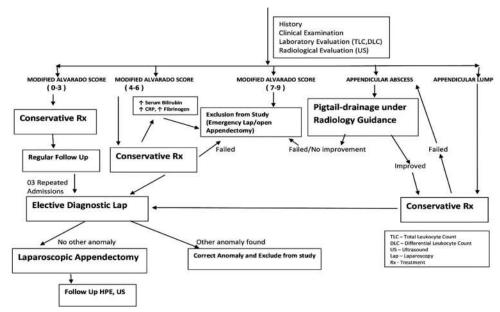


Figure 3: Highlighting management of pediatric appendicitis by Laparoscopic Interval Appendectomy (LIA)

a viable option available in the interest of the patient and health-care delivery where majority patients can be offered initial conservative methods to avoid all the complications of OA followed by LIA as seen in our study. Interval LA eliminates the risk of recurrent appendicitis too and serves to excise undiagnosed carcinoid tumors. In future, it may be possible to perform interval LA as a day-care procedure in selected patients.

### **CONCLUSION**

AA in the pediatric population remains the most common surgical emergency and is reported among all ages and gender. Modified Alvarado Score supplanted by US abdomen is a useful pre-operative diagnostic tool in the treatment of pediatric appendicitis and non-specific pain lower abdomen. LIA has very good cosmetic outcome, less PO pain, early return to activity, acceptable PO complications, comparable operative time, and negligible requirement of intra/PO blood products. LIA is safe and feasible surgical procedure which can be offered to patients where laparoscopy is not available in the emergency setting. LIA can be considered for as a day care procedure especially for the patients hailing from nearby places so as to decrease the in-patient hospital burden.

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# Comparative Evaluation of Prevalence and Distribution of Obesity in Various Districts of the Union Territory of Jammu and Kashmir in 2015–2016 and 2019–2020: An Observational Study

### Malvika Singh<sup>1</sup>, Manju Jamwal<sup>2</sup>

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### **Abstract**

**Background:** In recent times, obesity in India has become a major concern. It causes loss of health, environment and increases financial burden of an individual.

**Aims:** The aim of this study was to assess the prevalence and distribution of obesity intake among individuals of more than 15 years of age in union territory of Jammu and Kashmir, India.

**Materials and Methods:** District-wise data from National Health Survey-5 and 4, Ministry of Health, and Family welfare were collected, analyzed, and measured. Data collected were entered and statistically analyzed using the Statistical Package for the Social Sciences version 24.0 software (IBM, Armonk, NY, USA). Various districts were diagrammatically color coded and described as Figures 1 and 2.

**Results:** Out of all the districts in the union territory of J and K, prevalence of obesity among females was highest in Srinagar district and lowest in Kishtwar district in 2015–2016 whereas highest in Jammu district and lowest in Mirpur and Muzaffarabad district in 2019–2020.

**Conclusion:** Females should be made more aware about the ill effects of obesity. Although the Government of India started Program to control obesity in 2010, its reduction lies in our hands and same should be discussed with general masses by making them aware about the ill effects on mental and health of individual.

Key words: Distribution, Females, III effects, Jammu and Kashmir, Obesity, Obesity control

### INTRODUCTION

With world becoming more developed, obesity has emerged as a greater public health issue across the globe. The prevalence of people living with either overweight or obesity is increasing worldwide, and since 1975, this has almost tripled. Obesity is defined as abnormal or excessive fat accumulation that presents a risk to health. A body mass

index (BMI) over 25 is considered overweight and over 30 is obese. <sup>[2]</sup> Overweight and obesity have been found to be an important risk factor for various non-communicable diseases, and more recently, obesity has been recognized as a disease in itself. <sup>[3]</sup>

### ents a risk to health. A body mass MATERIALS AND METHODS

Data from National Family Health Survey-4 and 5, Ministry of Health, and Family welfare<sup>[4,5]</sup> were studied, analyzed, and measured for the prevalence and distribution of obesity in females aged 15 years and above in various districts of union territory of Jammu and Kashmir, India. Data collected were entered and statistically analyzed using the Statistical Package for the

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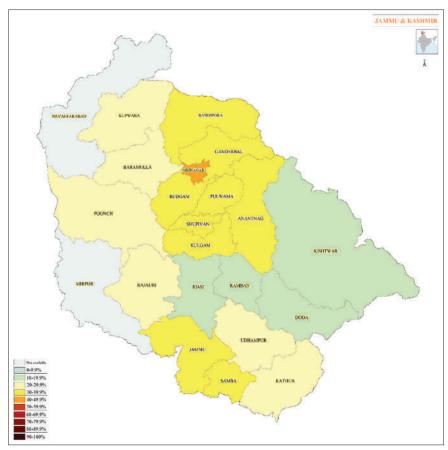


Figure 1: Distribution of obesity among females in various districts of the union territory of Jammu and Kashmir for year 2015–2016

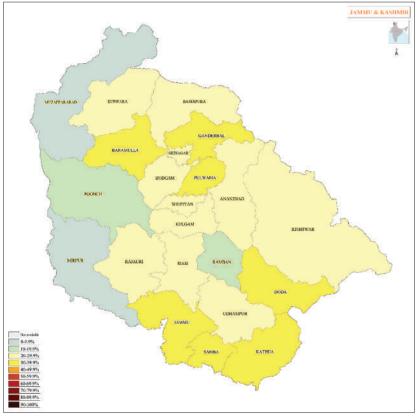


Figure 2: Distribution of obesity among females in various districts of the union territory of Jammu and Kashmir for year 2019–2020

Social Sciences version 24.0 software (IBM, Armonk, NY, USA). Various districts were diagrammatically color coded and described as Figures 1 and 2.

### **RESULTS**

It was found that highest percentage of females who were obese in 2015–2016 belonged to district Srinagar followed by Jammu and Samba. Respectively whereas least percentage was found in district Kishtwar, Reasi and Ramban respv [Table 1 and Figure 1]. While in year 2019–2020, the highest percentage of females who were obese in 2019 belonged to district Jammu followed by Kathua and Kishtwar respy and least percentage was found in district Muzzafarabad, Mirpur, and Ramban respv [Table 1 and Figure 2]. It is to be noted that that the many district showed positive and negative relative change in obesity among females during the course of 5 years. Positive relative change was seen in districts such as Kathua, Doda, and Kishtwar respv. which is alarming whereas the decline is seen in districts Srinagar, Badgam, and Badipora which is a positive news [Table 1 and Figure 3].<sup>[4,5]</sup>

### **DISCUSSION**

Overweight or obesity is not only a modifiable risk factor for various NCDs and premature mortality, but is also associated with increased COVID-19 mortality, which is an infectious disease, thereby broadening the spectrum of health conditions and leading to a unique intersection of communicable and non-communicable disorders. [6] Surprisingly, barring few districts, almost every district showed relative increase in percentage of obesity among females, which is a matter of concern. The previous studies have already affirmed that BMI increases with age in adult life, but starts declining or levels off in later years, due to decreases in energy intake due to illness, loss of appetite, or other factors. Obesity in all age groups poses grave risk for life and increases the probability of death in older adults.<sup>[7]</sup>

Obesity was also found to be higher among urban residents, similar to the findings of other studies. [8,9] This can be attributed to lifestyle and behavioral factors which markedly differ in urban and rural areas. Moreover, urbanization of villages, less space for recreational activities, and high

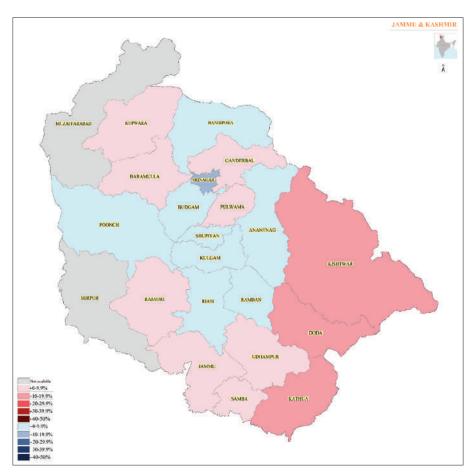


Figure 3: Change in distribution of obesity among females in various districts of the union territory of Jammu and Kashmir from year 2015–2016 to 2019–2020.

Table 1: Distribution of obesity among females in various districts of the union territory of Jammu and Kashmir for year 2015–2016 and 2019–2020

	Obesity In Females In Jammu and Kashmir (%)						
S. N	o.District	2015–2016 (%)	)2019–2020 (%)	Relative change (%)			
1	Anantnag	33.1	28.6	-4.5			
2	Badgam	31.4	25.3	-6.1			
3	Bandipora	34.0	28.2	-5.8			
4	Baramulla	24.5	31.1	+8.6			
5	Doda	18.7	31.3	+12.6			
6	Ganderbal	33.8	34.2	+0.4			
7	Jammu	36.9	38.3	+1.4			
8	Kathua	24.6	38.2	+13.6			
9	Kishtwar	14.5	24.9	+10.4			
10	Kulgam	31.4	25.9	-5.5			
11	Kupwara	20.5	21.3	+0.8			
12	Mirpur	NA	6.9	NA			
13	Muzaffarabad	NA	6.9	NA			
14	Pulwama	34.0	37.9	+3.0			
15	Punch	21.1	16.2	-4.9			
16	Rajauri	21.0	22.7	+1.7			
17	Ramban	17.8	15.8	-2			
18	Reasi	16.5	22.7	+6.2			
19	Samba	35.3	36.5	+1.2			
20	Shupiyan	31.3	27.6	-3.7			
21	Srinagar	40.8	27.8	-13			
22	Udhampur	20.3	29.3	+9			
	Total	27.08	28.19	+1.8			

substance use among urban residents are contributing factors to the obesity epidemic. However, this was different from findings of other studies. [10] The difference in obesity/overweight prevalence across different religions needs further exploration.

While health is a state subject, the central government supplements the activities and efforts of the states toward creation of awareness, health education, and health promotion. The Government of India in 2010 launched National program for prevention and control of cancer diabetes, cardiovascular diseases and stroke. The focus of the program is on awareness generation for behavior and life-style changes, early diagnosis of persons with high levels of risk factors, and their referral to higher facilities for appropriate management. The program is expended to cover more districts in 12th 5 Year Plan. From 2013 to 14, the program activities up to district level have been subsumed under national health mission. In the national monitoring framework and action plan for prevention and control of non-communicable diseases (2013–2020),

adopted by the Government of India, obesity has been identified as an area of intervention.<sup>[11]</sup>

### **CONCLUSION**

Prevalence of obesity was highest in Jammu District in from 2015 to 2019 which presents a matter of serious concern not only for health professionals and Government but also for the immediate society and environment associated with it. Although the Government is trying its best to reduce the same in any which way, its decline lies in our hands and we as responsible citizens of the country should stop taking excess sugar and encourage and motivate others who do the same so that we can live in clean and healthy environment which is not only safe for us but holds a true promise for coming generations too.

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### Comparative Evaluation of the Tensile Bond Strength between Polyvinyl Siloxane Impression Materials with Two Different Tray Materials using Three Different Tray Adhesives – An *In Vitro* Study

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### **Abstract**

**Introduction:** A dimensionally accurate impression is a prerequisite before any prosthesis can be manufactured. There is no chemical or mechanical bond between custom tray resin and elastomeric materials has been established. If the impression material gets separated from the impression tray while withdrawing from the oral cavity, it will affect its accuracy. Vinyl polysiloxane impression materials are the most frequently used non-aqueous elastomeric material by dental practitioners. The introduction of various tray adhesives has strengthened the bond between the resin and the impression materials.

**Purpose:** This study aims to evaluate and compare the tensile bond strength of three different tray adhesives used for polyvinyl siloxane impression materials with two different tray materials.

**Materials and Methods:** Medium-bodied elastomeric impression material (Coltene Affinis) and two different custom tray materials (DPI, Mumbai, India and Polytray) were used. For each tray material, three different tray adhesives were used (3M ESPE, Dentsply Caulk, and Coltene Affinis). Each of these specimens was then subjected to tensile load using Instron universal testing machine at a cross-head speed of 5 mm/min and the results were compared.

**Results:** Comparing the auto-polymerized tray resin with different adhesive groups, the 3M adhesive demonstrated a higher tensile bond strength, while Affinis demonstrated the lowest. Dentsply showed the highest tensile bond strength among the visible light cure (VLC) tray material group followed by 3M and Affinis. Dentsply outperformed both groups in terms of tensile bond strength, followed by 3M and Affinis.

**Conclusion:** The study showed that 3M tray adhesive has higher tensile bond strength with auto-polymerizing tray resin while Dentsply showed the highest tensile bond strength among VLC tray materials.

Key words: Impression, Polyvinyl siloxane impression material, Tensile bond strength, Tray adhesives

### **INTRODUCTION**

Fabrication of any prosthesis requires a dimensionally accurate impression.<sup>[1]</sup> The use of a custom impression tray

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Month of Submission: 05-2023 Month of Peer Review: 06-2023 Month of Acceptance: 06-2023 Month of Publishing: 07-2023 enhances the dimensional accuracy of the impression. Die results from a custom tray are more accurate than those from a stock tray.<sup>[2]</sup> There has been no established chemical bonding between custom tray resin and elastomeric materials, although stock trays often provide mechanical retention for impression materials. However, the accuracy of the impression material can be rendered absolutely useless if it detaches from the impression tray while withdrawing from the oral cavity.<sup>[3,4]</sup>

The most common non-aqueous elastomeric impression materials used in dentistry are vinyl polysiloxane (VPS)

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impression materials.<sup>[5]</sup> Various tray adhesives have been introduced to strengthen the bond between tray and impression materials to prevent the detachment of impression materials.<sup>[6]</sup>

The adhesives recommended for silicone impression materials are composed of poly (dimethylsiloxane) and ethyl silicate. Poly (dimethylsiloxane) adheres to the silicon material, whereas ethyl silicate forms hydrated silica that bonds with tray material physically, leading to an accurate and consistent impression.

Less attention has been paid to the attachment of impression materials to polymethyl methacrylate (PMMA) and visible light cure (VLC) trays. Switching adhesives for two VPS impression materials resulted in stronger bonds, according to one study. Another researcher discovered that switching adhesives between two additional silicon materials increased the bond between impression material and tray significantly.<sup>[7,8]</sup> Tray adhesive has usually been recommended to be applied on the custom resin tray, not only for the inside of the custom tray but also to the surface of the border molding materials of the tray borders, before placing the elastomeric impression material on to the tray.

The authors concluded that the material-adhesive combination provided by the manufacturer may not be the best. Drying times have been suggested ranging from 4 min to 72 h. Samman and Fletcher discovered that the ideal drying time for silicone material was 10 min. [9] Despite the commercial availability of universal adhesives, researchers have yet to reveal bond strength data for such products with VPS impression material and tray materials. Manufacturer-recommended tray adhesives as well as universal tray adhesives are now available. Since its introduction, many clinicians have begun to use universal tray adhesive, but studies on its efficacy are lacking. The objective of this study is to evaluate the tensile bond strength of three different tray adhesive, applied between VPS material and two tray materials.

### **MATERIALS AND METHODS**

One medium body elastomeric impression material (Affinis), two tray materials (autopolymerizing PMMA and VLC), and three tray adhesives (Affinis, Dentsply Caulk, 3M) were used.

Total 180 specimens were fabricated. Ninety were fabricated with auto polymerizing PMMA (DPI, Mumbai, India) and rest 90 were fabricated with visible light polymerizing acrylic resin (Polytray). The study was carried out in three steps:

### **Fabrication of Master Die**

A standard stainless steel cylindrical die of the dimension of  $20 \times 20$  mm was custom fabricated using milling technique and it was polished.

A cylindrical plastic die of the dimension of  $20 \times 20$  mm was custom fabricated using 20 mL dispovan syringe.

### **Preparation of Test Specimens**

- a. Ninety specimens of autopolymerizing PMMA (DPI, Mumbai, India) were fabricated using stainless steel die and after loading of PMMA excess material was flushed out using glass plates, then a stainless steel eye hook was submerged into one end of cylinder and these specimens were kept overnight for complete polymerization.
- b. Ninety visible light polymerizing acrylic resin (Polytray) were kept in curing unit (Eurolight UV chamber) with a stainless steel eyehook submerged on one end of cylinder for 10 min to polymerize into hard block.

The surface opposite to the eye hook attachment surface that is the testing surface 20 mm is hardened with 320 grid silicon carbide paper on a polishing machine (30,000 rpm) to standardize the surface roughness for the adhesion with tray adhesive.

An abbreviation for the specific brand of adhesive example "3M" for 3M adhesive, "A" for Coltene Affinis and "D" for Dentsply Caulk were written on the surface of PMMA specimen except testing surface for the future identification 20 mL Syringe (dispovan) cylinder of dimension 20 mm in diameter and 20 mm in length will be used to contain the impression material and multiple holes were made to retain impression material within the cylinder with the help of straight fissure bur (FG#58 SSWhite) of diameter 0.8 mm.

### **Fabrication of UTM attachment**

A metallic eye hook was submerged into each specimen (PMMA & VLC) opposite to the testing surface and served as a point of attachment for the upper arm of the UTM with the help of a stainless steel eye hook. Metal rod of diameter 2 mm was inserted across the syringe cylinder and was close to free end of cylinder for attachment of S-shaped eye hook and that was inserted to the lower end of UTM.

PMMA (90 specimens) and VLC (90 specimens) were divided into three sub-groups (30 in each group), as per the use of tray adhesive and were named accordingly, that is, 3M, Affinis and Dentsply Caulk. Each sample of tray material were coated on the testing surface with different tray adhesives, respectively, and left for 10 min for the solvent to evaporate according to the manufacturer's specifications. The perforated hollow cylinder was placed in

contact with the testing surface of specimen in the testing machine. The impression material was dispensed onto the testing surface through the other free end of cylinder until the cylinder fills completely and held in position until the material set completely.

### **Testing of Samples**

Each specimen is attached to the UTM with a stainless steel eye hook on one side and on the testing side a metal rod with a S-shaped hook is placed in its respective position. A crosshead speed of 5 mm/min, using a 2500-kg load cell set at full-scale load and gradually pulled apart until the impression material is separated from the specimen's testing surface. The values obtained will be divided by the area of adhesion of the cylinder with the specimen and the tensile bond strength will be calculated in megapascals (MPa) by the formula

$$\frac{\text{Tensile bond}}{\text{strength } \left(N \ / \ \text{mm}^{2}\right)} = \frac{\text{Maximum load } \left(N \ \right)}{\text{Section area of}}$$

$$\text{cylinder } \left(\text{mm}^{2}\right)$$

### **RESULTS**

The data obtained were subjected to statistical analysis using the Statistical Package for the Social Sciences (SPSS Version 23; Chicago Inc., IL, USA). Data comparison was done by applying specific statistical tests to find out the statistical significance of the comparisons.

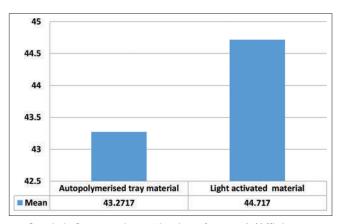
Kolmogorov–Smirnov and Shapiro–Wilk tests were performed to determine the normality of the data for the two major groups and their subgroups of adhesives to check for tensile bond strength. Both the tests showed no significant differences and hence confirmed that the data obtained were normally distributed.

Variables were compared using mean values and standard deviation. The mean for different readings for tensile between each group for autopolymerized tray material and light cured tray material was tested using independent "t"-test. Comparison between groups was done by applying one-way analysis of variance. P < 0.05 was considered to be statistically significant.

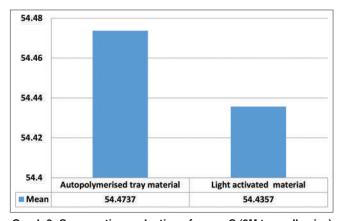
When Group A was analyzed between autopolymerized tray material and light-cured tray material for tensile bond strength, no significant difference was noted between them at P = 0.443, as shown in Table 1 and Graph 1.

Light-cured tray material in Group B adhesive type exhibited greater tensile bond strength than autopolymerized type which was significant at P = 0.000.

Group C samples showed no significant difference between tensile bond strength of autopolymerized tray material and light-cured tray material, at P = 0.982, as shown in Table 2 and Graph 2.



Graph 1: Comparative evaluation of group A (Affinis tray adhesive) between autopolymerized tray material and light-cured tray material



Graph 2: Comparative evaluation of group C (3M tray adhesive) between autopolymerized tray material and light-cured tray material

Table 1: Comparative evaluation of group A (Affinis tray adhesive) between autopolymerized tray material and light cured tray material

Groups	n	Mean	SD	Standard error mean	Mean difference
Autopolymerized tray material	30	43.2717	9.62026	1.75641	-1.44533
Light-cured material	30	44.7170	3.53399	0.64522	
"t" statistic				-0.772	
Df				58	
P-value				0.443 (NS)	

<sup>\*</sup>Significant; NS: Not significant

Table 2: Comparative evaluation of group C (3M tray adhesive) between autopolymerized tray material and light-cured tray material

Groups	n	Mean	SD	Standard error mean	Mean difference	
Autopolymerized tray material	30	54.4737	3.85440	0.70371	0.03800	
Light-cured tray material	30	54.4357	8.26184	1.50840		
"t" statistic		0.023				
df		58				
P-value		0.982 (NS)				

<sup>\*</sup>Significant; NS: Not significant

Table 3: Comparative assessment of autopolymerized tray material between groups

Groups	n	Mean	SD	Standard error
Affinis	30	43.2717	9.62026	1.75641
Dentsply	30	45.6543	7.28123	1.32936
3M Tray	30	54.4737	3.85440	0.70371
ANOVA/"F" statistic			19.537	
df			2	
P-value			0.000*	

<sup>\*</sup>Significant; NS: Not significant

Table 4: Post hoc/pairwise comparison for autopolymerized tray material between groups

Pairs	Mean difference	Standard error	<i>P</i> -value
Affinis versus Dentsply	-2.38267	1.88810	0.631 9NS)
Affinis versus 3M	-11.20200*	1.88810	0.000*
Dentsply versus 3M	-8.81933*	1.88810	0.000*

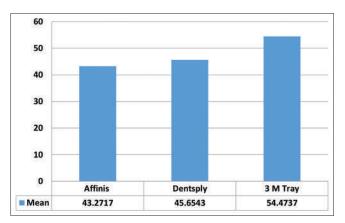
<sup>\*</sup>Significant; NS: Not significant

When evaluating for between different groups for autopolymerized adhesive, 3M adhesive demonstrated greater tensile bond strength with a mean of  $54.4737 \pm 3.85440$ , and the least was exhibited by Affinis, which was significant statistically at P = 0.000, as shown in Table 3 and Graph 3.

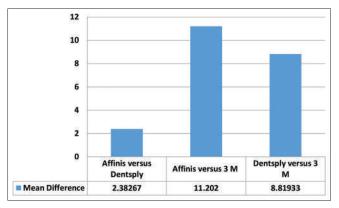
Between pair analysis reviewed that, the greatest mean difference was noted between Affinis versus 3M at 11.20200 significant at P = 0.000. Dentsply versus 3M also showed significant difference which was significant, as shown in Table 4 and Graph 4.

In case of light-cured tray material assessment between groups, Dentsply showed the greatest tensile bond strength at  $63.9267 \pm 9.68044$  followed by 3M and Affinis, which was significant at P = 0.000, as shown in Table 5 and Graph 5.

Turkeys *post hoc* analysis showed that the greatest mean difference in tensile bond strength was noticed between Affinis versus Dentsply at 19.20967, significant at P = 0.000. Affinis versus 3M and Dentsply versus 3M also showed significant differences, as shown in Table 6 and Graph 6.



Graph 3: Comparative assessment of autopolymerized tray material between groups



Graph 4: Post hoc/pairwise comparison for autopolymerized tray material between groups

On comparing the tensile bond strength between groups, Dentsply exhibited the greatest tensile bond strength with a mean of  $56.2810 \pm 12.33113$  followed by 3M and Affinis, which was statistically significant at P = 0.000, as shown in Table 7 and Graph 7.

Overall group comparison showed that Affinis versus Dentsply had the greatest mean difference at 12.28667 significant at P = 0.000. Affinis versus 3M was also significant at P = 0.000. Dentsply versus 3M was not significant at P = 0.810, as shown in Table 8 and Graph 8.

Table 5: Comparative assessment of light-cured tray material between groups

Groups	n	Mean	SD	Standard error
Affinis	30	44.7170	3.53399	0.64522
Dentsply	30	63.9267	9.68044	1.76740
3M Tray	30	54.9138	5.29882	1.08162
ANOVA/"F" statistic			60.237	
df			2	
P-value			0.000*	

<sup>\*</sup>Significant; NS: Not significant

Table 6: *Post hoc/*pairwise comparison for light-cured tray material between groups

Pairs	Mean difference	Standard error	<i>P</i> -value
Affinis versus Dentsply	-19.20967*	1.75109	0.000*
Affinis versus 3M	-10.19675*	1.85731	0.000*
Dentsply versus 3M	9.01292*	1.85731	0.000*

<sup>\*</sup>Significant; NS: Not significant

Table 7: Comparative assessment of tensile bond strength between groups (group A, B, and C) – including both autopolymerized and light-cured tray materials

Groups	n	Mean	SD	Standard error
Affinis	60	43.9943	7.22220	0.93238
Dentsply	60	56.2810	12.33113	1.59194
3M Tray	60	54.4547	6.39165	0.82516
ANOVA/"F" statistic			32.283	
df			2	
P-value			0.000*	

<sup>\*</sup>Significant; NS: Not significant

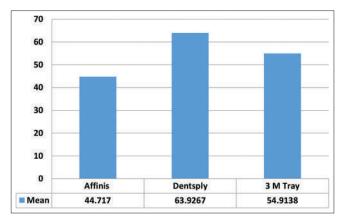
Table 8: *Post hoc*/pairwise comparison for tensile bond strength between groups (group A, B, and C) – including both autopolymerized and light-cured tray materials

Pairs	Mean difference	Standard error	P-value
Affinis versus Dentsply	-12.28667*	1.65015	0.000*
Affinis versus 3M	-10.46033*	1.65015	0.000*
Dentsply versus 3M	1.82633	1.65015	0.810 (NS)

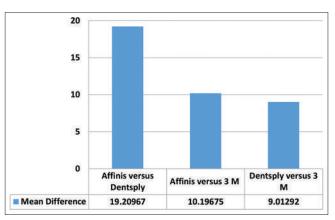
<sup>\*</sup>Significant; NS: Not significant

### **DISCUSSION**

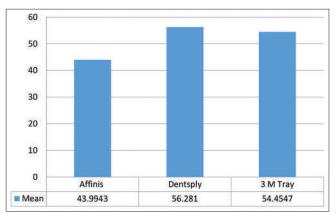
Impressions are an essential component of prosthodontics due to their superior properties, elastomeric impression materials are the preferred impression materials in dentistry including improved reproduction of surface detail VPS that is the most advanced impression material available in prosthodontics, but even these materials cannot provide an accurate reproduction of the tissues if the impression materials disengage from the tray, resulting in a distorted impression and poor final restorations made from such impressions.<sup>[10]</sup>



Graph 5: Comparative assessment of light-cured tray material between groups

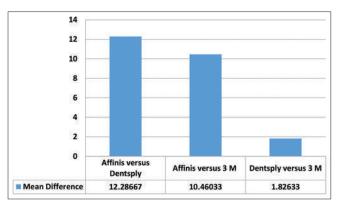


Graph 6: Post hoc/pairwise comparison for light-cured tray material between groups



Graph 7: Comparative assessment of tensile bond strength between groups (group A, B, and C) – including both autopolymerised and light-cured tray materials

The use of impression tray adhesive to keep the elastomeric impression material in place has definite advantages. Davis *et al.* looked into the bonding properties of elastomeric tray adhesive.<sup>[11,2]</sup> They concluded that because the bonding is insufficient and the material goes into the undercut, a significant amount of force is required to pull the material away. The surface preparation of the custom tray,



Graph 8: Post hoc/pairwise comparison for tensile bond strength between groups (Group A, B, and C) – including both autopolymerized and light-cured tray materials

particularly with silicone carbide paper, had a significant impact on retention by increasing the bond strength of the impression material with the adhesive.<sup>[3]</sup>

Applying a tray adhesive is a routine procedure because it controls the direction of polymerization shrinkage of the material toward the custom tray side. The impression adhesives used for silicone impression materials contain polydimethylsiloxane or a similar reactive silicone, as well as ethyl silicate. Polymethylsiloxane adhesive bonds to the silicone impression material, whereas ethylsilicate forms a hydrated silica that physically bonds to the impression tray material. The volatile solvent, ethyl acetate, reacts with the autopolymerizing tray material to form microporosites on the tray material, allowing the adhesive to physically and mechanically bond with it.<sup>[6]</sup>

The previous research suggested that the material adhesive combination supplied by the manufacturer might not be the best. Universal adhesives are now replacing the manufacturer's adhesive.<sup>[1]</sup> It has been discovered that paint-on adhesive on medium body VPS is effective.<sup>[12]</sup>

Considering this, the study is being conducted to compare the effectiveness of three different tray adhesives (3M ESPE, Coltene Affinis, and Dentsply Caulk) with the commonly available medium consistency VPS impression material (Affinis) with the three different tray adhesives using the custom autopolymerizing tray resin and VLC.

Other researchers have reported tensile strength values for VPS elastomeric impression materials ranging from 0.2 to 2.1 MPa depending on tray impression materials used.<sup>[13]</sup>

The adhesives were recommended for use in all trays, including those with perforations that aid in mechanical retention. Rapid removal of the impression from the mouth increased the retention between the tray and the impression materials. Furthermore, as the flexibility of the impression

materials increased, the retention between the tray and the impression material decreased. [12]

Several studies in the past have investigated the tensile bond strength of different tray materials to VPS impression material using different tray adhesives.

Tensile bond strength of auto polymerizing tray materials and VLC acrylic resin tray material to medium body addition silicone impression material after application of three different tray adhesives on tray materials is evaluated in this study.

Ashwini *et al.*,<sup>[14]</sup> three medium-body viscosity VPS (3M, Dentsply, and Affinis) treated with own adhesives and universal adhesives (Zhermack and GC) were used in this study to compare the tensile bond strength to the two tray materials (autopolymerizing resin and VLC resin).

- When compared to the adhesive that the manufacturer recommends, universal tray adhesives among group A (autopolymerizing resin tray material) showed greater strength
- 2. In comparison to the manufacturer-recommended adhesive and universal adhesive GC, universal tray adhesive (Zhermack) from group B (VLC resin tray material) demonstrated greater strength
- 3. Group B (VLC resin tray material) outperformed the other two groups in terms of bond strength when using the universal tray adhesive

Kumar *et al.*<sup>[15]</sup> stated no discernible variation in adhesive strength as a function of tray material was found within the constraints of the experimental conditions of this *in vitro* study. In comparison to the adhesives provided by the maker of the impression materials, GC revealed the highest tensile bond strength across all combinations. 3M showed the highest tensile strength out of the three impression materials tested. The 3M impression material with GC adhesive was found to be the most superior when different impression materials' effects on tensile strength were compared. Therefore, it is crucial for the success of the prosthodontic procedure and the end result in our clinical practice to understand the adhesive strength of different impression materials with specific adhesives.

Saha *et al.*<sup>[16]</sup> concluded that tray adhesives for silicone rubber impression material are effective for impression modeling plastics for border molding within the scope of the study to evaluate the tensile bond strength of autopolymerizing tray materials and medium body addition silicone impression material after the application of three different tray adhesives on tray materials. 3M had the highest tensile bond strength, followed by Dentsply and Coltene tray adhesive.

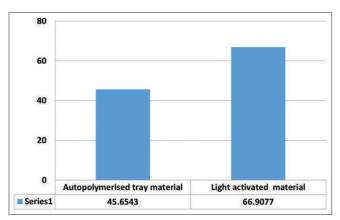
When Group A was analyzed between autopolymerized tray material and light-cured tray material for tensile bond strength, no significant difference was noted between them at P = 0.443, as shown in Table 1 and Graph 1.

Light-cured tray material in Group B adhesive type exhibited greater tensile bond strength than autopolymerized type which was significant at P = 0.000, as shown in Table 9 and Graph 9.

Group C samples showed no significant difference between tensile bond strength of autopolymerized tray material and light cured tray material, at P = 0.982, as shown in Table 2 and Graph 2.

When evaluating for between different groups for autopolymerized adhesive, 3M adhesive demonstrated greater tensile bond strength with a mean of  $54.4737 \pm 3.85440$  and the least was exhibited by Affinis, which was significant statistically at P = 0.000, as shown in Table 3 and Graph 3.

Between pair analysis reviewed that, the greatest mean difference was noted between Affinis versus 3M at 11.20200 significant at P = 0.000. Dentsply versus 3M also showed significant difference which was significant, as shown in Table 4 and Graph 4.



Graph 9: Comparative evaluation of group a (Affinis tray adhesive) between autopolymerized tray material and light-cured tray material

In case of light-cured tray material assessment between groups, Dentsply showed the greatest tensile bond strength at  $63.9267 \pm 9.68044$  followed by 3M and Affinis, which was significant at P=0.000, as shown in Table 5 and Graph 5.

Turkeys *post hoc* analysis showed that the greatest mean difference in tensile bond strength was noticed between Affinis versus Dentsply at 19.20967, significant at P = 0.000. Affinis versus 3M and Dentsply versus 3M also showed significant differences, as shown in Table 6 and Graph 6.

On comparing the tensile bond strength between groups, Dentsply exhibited the greatest tensile bond strength with a mean of  $56.2810 \pm 12.33113$  followed by 3M and Affinis, which was statistically significant at P = 0.000, as shown in Table 7 and Graph 7.

Overall group comparison showed that Affinis versus Dentsply had the greatest mean difference at 12.28667 significant at P = 0.000. Affinis versus 3M was also significant at P = 0.000. Dentsply versus 3M was not significant at P = 0.810, as shown in Table 8 and Graph 8.

The adhesives recommended for silicone impression materials are composed of poly (dimethylsiloxane) and ethyl silicate. Poly(dimethylsiloxane) adheres to the silicon material, whereas ethyl silicate forms hydrated silica that bonds with tray material physically leading to an accurate and consistent impression.

The molecular networks in polyvinyl siloxane react with the recently made adhesive's composition, which includes methyl acetate as a solvent and a joint monomer that bonds with both the impression material and the tray material. This allows the adhesive to chemically bond with both the elastomeric impression material and the acrylic tray material. It is claimed that these reactive adhesives can effectively retain the impression material without the need for mechanical retention. A more dependable method of retaining the impression material to the tray can be achieved if these adhesives offer better impression retention to the tray than conventional adhesives do.

Table 9: Comparative evaluation of group B (Dentsply tray adhesive) between autopolymerized tray material and light-cured tray material

Groups	n	Mean	SD	Standard error mean	Mean difference
Autopolymerized tray material	30	45.6543	7.28123	1.32936	-21.25333
Light-cured tray material	30	66.9077	4.76450	0.86987	
"t" statistic				-13.378	
Df				58	
P-value				0.000*	

<sup>\*</sup>Significant; NS: Not significant

### **CONCLUSION**

According to the study's findings, tray adhesives for silicone rubber impression materials are useful for molding impressions into plastics for border work, as long as the study's objectives are met, which were to assess the tensile bond strength between auto-polymerizing tray materials and VLC tray materials and medium-body silicone impression materials following the application of three different tray adhesives on tray materials.

Comparing the autopolymerized tray resin with different adhesive groups, the 3M adhesive demonstrated a higher tensile bond strength with a mean of  $54.4737 \pm 3.85440$ , while Affinis demonstrated the lowest, with a statistically significant difference of P = 0.000.

Dentsply showed the highest tensile bond strength among the visible light cure tray material groups at 63.9267  $\pm$  9.68044, followed by 3M and Affinis. At P=0.000, this outcome was significant.

With a mean of  $56.2810 \pm 12.33113$ , Dentsply outperformed both groups in terms of tensile bond strength, followed by 3M and Affinis. At P = 0.000, this outcome was statistically significant.

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## C-reactive Protein in Determining the Duration of Antibiotic Therapy in Neonatal Sepsis

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### **Abstract**

**Objectives:** The objectives of this study were to evaluate the role of C-reactive protein (CRP) to decide the duration of antibiotic use in cases of neonatal sepsis (NS).

Materials and Methods: The hospital-based observational study was performed in the Sick Neonatal Care Unit and Neonatal Intensive Care Unit of a Tertiary Care Hospital in West Bengal from January 2020 to July 2021. Forty neonate fulfilling the criteria of clinical sepsis with or without laboratory confirmations with serum CRP >10 mg/L were selected. All the patients were started on empirical antibiotics after drawing samples for blood cultures and CRP. Serum CRP was done every alternate day until a normal CRP was achieved. Antibiotics were discontinued when two consecutive CRP were normal provided that there was clinical improvement. Culture positive NS was followed up after a week of antibiotics with serum CRP and then repeated every 24 h.

**Results:** Eighteen neonates had a negative CRP on day 2 and none of them had positive blood culture report. Six had a positive CRP on day 2 which became negative on day 5 all of whom had positive blood cultures. Seven patients had a positive CRP on day 2 and 5 which became negative on day 7 among which 6 had positive blood culture. Seven patients had a positive CRP on days 2, 5, and 7 which became negative on day 14 among which 4 had positive blood culture. Two patients had a positive CRP report on day 2, 5, 7, and 14 among which both were culture positive. The negative predictive value of CRP in NS according to our study was thus 100%.

**Conclusion:** Thus, we can conclude that serial estimation of CRP can act as a diagnostic parameter to decide when antibiotics can be safely discontinued in cases of NS which decreases antibiotic associated morbidity and cost of healthcare significantly by shortening hospital stay.

Key words: Antibiotics in neonates, C-reactive protein, Neonatal sepsis

### INTRODUCTION

Any invasive bacterial infection occurring within the 1<sup>st</sup> month of life is defined as Neonatal Sepsis (NS), it is of early onset if it occurs within the 1<sup>st</sup> week of life and late onset if it occurs after the 1<sup>st</sup> week of 1 month.<sup>[1]</sup> NS is a very challenging scenario for neonatologists, because most of these neonates present with non-specific symptoms, and most of these mimic non-infectious causes with a lack of

specific laboratory criteria, making the exact and timely diagnosis very challenging.<sup>[2,3]</sup>

The prevalence rate of NS has been reported to be 10/1000-15/1000 live births in developed countries and 15/1000-25/1000 live births in South Asia. <sup>[2,4]</sup> In India, the prevalence of NS is 11-24.5/1000 live birth. <sup>[5]</sup> NS is responsible for 30 to 40% of total neonatal mortalities in developing countries. <sup>[6]</sup>

Current recommendations for the treatment of neonatal septicemia include endpoints of 48–72 h for clinically stable children with negative blood culture results and 7–14 days for blood culture positive or clinically probable infection.<sup>[7-9]</sup> However, the rationale and safety of these recommendations have never been formally evaluated. According to different studies, about 11–23% of neonates

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are treated wrongly for sepsis, but they are not having it. [10-12] This not only results in antibiotic resistance but it also has many other short-term complications (e.g., pain and infection) and some long-term complications (e.g., hearing disorder and necrotizing enterocolitis). [13,14]

In addition, different organisms causing NS have a different spectrum of infection. Hence, instead of following the strict protocols of antibiotic duration, the antibiotic duration should also be regionalized according to the causing organism.<sup>[15]</sup> Therefore, there is a need to look for rapid diagnostic evaluation tests for NS instead of culture sensitivity reports. Over the past decades, a variety of laboratory tests have been developed to enhance the early and accurate identification and treatment of infants with sepsis. Various tests include micro-ESR, band neutrophil ratio (B/N ratio), procalcitonin, interleukin (IL)-6, IL-8, tumor necrosis factor- $\alpha$ , and C-reactive protein (CRP). Among them, serum CRP levels have become the front runner for the early diagnosis and in the determination of the duration of antibiotic treatment through various studies.[16,17]

Serum CRP, an acute-phase reactant, is synthesized in the liver within 6–8 h in response to inflammatory cytokines and may raise 1000 folds during an acute phase response. CRP level falls quickly after efficient elimination of microbial stimulus due to its short half-life of 19 h.<sup>[15]</sup> Thus, CRP levels may sufficiently reflect the individual balance between the microbes and the immune system of the neonate for monitoring the effect of antibiotic treatment and for guiding the duration of antibiotic therapy.<sup>[18,19]</sup>

The objectives of the present study were to determine whether CRP can be used as a parameter to identify the time point when antibiotic treatment can safely be discontinued in a defined major subgroup of neonates treated for suspected bacterial infection and to shorten the duration of hospital stay.

### **MATERIALS AND METHODS**

The hospital-based observational study was performed in the Sick Neonatal Care Unit (SNCU) and Neonatal Intensive Care Unit (NICU) of a Tertiary Care Hospital in West Bengal from January 2020 to July 2021. Any neonate fulfilling the criteria of clinical sepsis with or without laboratory confirmations with serum CRP >10 mg/L were selected for the study. For clinical diagnosis of sepsis initial signs and symptoms of infection was considered. Forty neonates with clinically suspected septicemia were included in the study.

### **Inclusion Criteria**

Neonates (0–28 days of life) with clinical signs and symptoms of sepsis with or without positive sepsis screen were included in the study.

### **Exclusion Criteria**

The following criteria were excluded from the study:

- a. Neonates who were <1.5 kg in birth weight and <32 weeks of gestational age due to high occurrence of comorbidities
- Neonates who were diagnosed with meningitis (Lack of laboratory support to evaluate CRP in cerebrospinal fluid.)
- c. Neonates who had undergone surgery due to the risk of Wound Infection
- d. Neonates with congenital malformations predisposing to Infections
- e. Neonates with hypoglycemia, hypocalcemia, or other metabolic derangements at presentation
- f. Neonates with other comorbidities such as perinatal asphyxia, respiratory distress syndrome, bronchopulmonary dysplasia, meconium aspiration syndrome, hemolytic or hemorrhagic disease of newborn, acute kidney injury, congestive heart failure, and liver dysfunction.
- g. Neonates who had all their CRP results negative
- h. Parents who refused consent.

All patients included in the study were started on empirical antibiotics after drawing samples for blood cultures and CRP (as a part of sepsis screen). Strict aseptic measures were taken to rule out any systemic bias while taking blood cultures. A sample for serum CRP was taken every alternate day until a normal CRP level is achieved. CRP was read as negative when the level is ≤10 mg/L and positive when the level is >10 mg/L. Blood culture was followed for growth up to 7 days. The results of the CRP were verified by a laboratory technician of the microbiology department. The data collection tool was a pre-tested performa.

Suspected NS patients were started on empirical antibiotic therapy on admission after CRP and blood culture was sent for analysis. For NS without septicemia, serum CRP was monitored every 48 h. Antibiotics were discontinued when two consecutive CRP levels were within the normal range provided there is clinical improvement and with the senior consultant's permission. Culture positive NS was followed up after the 7<sup>th</sup> day of intravenous antibiotic with serum CRP and then every 24 h. With guidance from the visiting physician, antibiotics were discontinued when two consecutive results are normal. Single CRP value ≤10 mg/L was not considered as an endpoint. Neonates were kept up to 48 h after stopping the antibiotics to observe for recurrence of clinical features of septicemia.

For statistical analysis, data were entered into a Microsoft Excel Spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA). Data have been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Twosample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A Chi-square test (2 test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a Chi-square distribution when the null hypothesis is true. Without other qualification, "Chi-square test" often is used as a short for the Pearson's Chi-square test. Unpaired proportions were compared by Chi-square test or Fisher's exact test, as appropriate. Z-test (Standard Normal Deviate) was used to test the significant difference of proportions. Correlation was calculated by Pearson correlation analysis. The Pearson product-moment correlation coefficient was a measure of the linear dependence between two variables X and Y. Multivariate analysis was performed by logistic regression method for calculation of risk factors. Once a t-value is determined using a one-tailed or two-tailed test, P-value can be found using a table of values from Student's t-distribution. If the calculated P-value is above the threshold chosen for statistical significance, then the null hypothesis is rejected in favor of the alternate hypothesis.  $P \le 0.05$  was considered for statistically significant.

### **RESULTS**

In the study population, 12 (30%) neonates presented within 72 h of birth, 14 (35%) neonates presented between 72 h and 7 days of birth, 9 (22.5%) cases presented between 8 and 14 days while only 5 (12.5%) cases presented after 2 weeks of birth. The average age of presentation was 7.4  $\pm$  6.06 days. Twenty-two (55%) of the neonates were male while 18 (45%) were female. Thirty-three (82.5%) of the neonates included were born by vaginal delivery while 7 (17.5%) were born by cesarean section.

Twenty-seven (67.5%) of the neonates were preterm while 13 (32.5%) were term. Eighteen (45%) of the neonates were born with a birth weight of  $\geq$ 1.5–2 kg, 13 (32.5%) had a birth weight of  $\geq$ 2–2.5 kg, 6 (15%) had a birth weight of  $\geq$ 2.5–3 kg while only 3 (7.5%) had a birth weight  $\geq$ 3 kg. The study population had an average birth weight of 2.19  $\pm$  0.47 kg. A significant number of neonates admitted for NS were of low birth weight (P < 0.05). Fourteen (35%) of the neonates suffered from early-onset NS while 26 (65%) suffered from late-onset NS.

Among the study population, the most common risk factor for NS encountered was Vaginal delivery (82.5%), followed

by prematurity (32.5%) and maternal urinary tract infection (UTI) during 3<sup>rd</sup> trimester (30%). Maternal fever (10%) and prolonged rupture of membrane (15%) and meconium stained liquor (15%) were the lesser found risk factors. The most common clinical feature with which a neonate presented was refusal of feed (55%), followed by jaundice (45%), lethargy (37.5%), and poor cry (35%).

Among the 14 neonates with early-onset NS, 5 (35.71%) had a positive blood culture report. Among the 26 neonates with late-onset NS, 13 (50%) patients had a positive blood culture report. Patients with late-onset NS had a significantly greater number of positive blood culture reports (P = 0.013).

Among the 18 culture-positive patients, 13 (72.22%) grew Gram-negative organisms while 5 (27.78%) grew Gram-positive organisms. Among the Gram-negative organisms, *Klebsiella* (27.78%) was the most common followed by *Escherichia coli* (22.22%), *Pseudomonas* (22.22%), and *Acinetobacter* (5.56%). Among the Gram-positive organisms, *Staphylococcus aureus* (22.22%) was the most common.

Twenty-two (55%) had a raised CRP >10 mg/L on day 2, 16 (40%) had raised CRP on day 5, and 9 (22.5%) had raised CRP on day 7 while only 2 (5%) had a positive CRP on day 14.

Among the study population, 18 had a negative CRP on day 2 and none of them had positive blood culture report. Six patients had a positive CRP on day 2 which became negative on day 5 among which all of them had positive blood culture reports. Seven patients had a positive CRP on day 2 and 5 which became negative on day 7 among which 6 had positive blood culture reports. Seven patients had a positive CRP on days 2, 5, and 7 which became negative on day 14 among which 4 had positive blood culture reports. Two patients had a positive CRP report on day 2, 5, 7, and 14 among which both were culture positive. The negative predictive value (NPV) of CRP in NS according to our study was thus 100%.

Eighteen (45%) received antibiotic therapy for <3 days, 6 (15%) for 5 days, 7 (17.5%) for 7 days, 7 (17.5%) for 14 days, and 2 (5%) for >14 days. This was guided as per serum CRP levels and antibiotic was discontinued after consultation with senior pediatrician. None of the subjects required retreatment until 48 h post cessation of antibiotic therapy.

### **DISCUSSION**

The hospital-based observational study was conducted among 40 neonates presenting with clinical signs and

symptoms of sepsis with or without positive sepsis screen admitted at our SNCU and NICU wards were included in the study. This was in line with the incidence of NS in India which was 24/1000 as per epidemiological studies as on April 2019.<sup>[18]</sup>

In the present study, the average age of presentation in the study was  $7.4 \pm 6.06$  days. In a study by Hisamuddin *et al.*, mean age of the neonates was 5.72 days +3.86.9427 (67.5%) of the neonates included were preterm while 13 (32.5%) were term. There was significantly more risk of developing NS in preterm neonates as compared to term neonates (P = 0.027). [20] Similarly, in a meta-analysis performed by Belachew and Tewabe, it was revealed that NS was significantly associated with the gestational age of newborns with odds ratio (OR) 3.36 (95% CI: 2.50, 4.54), that is, preterm babies were 3.36 more likely to develop NS than term babies. [21] In a study by Mehar *et al.*, preterm were having 1.49 (CI [0.95, 2.35]) times risk of developing septicemia as compared to term neonates (P < 0.05). [22]

Our study had 18 (45%) of the neonates born with a birth weight of ≥1.5–2 kg, 13 (32.5%) had a birth weight of >2-2.5 kg, 6 (15%) had a birth weight of >2.5-3 kg while only 3 (7.5%) had a birth weight >3 kg. The study population had an average birth weight of  $2.19 \pm 0.47$  kg. A significant number of neonates admitted for NS were of low birth weight (P < 0.05). In a study by Hornik et al., data of over 108,000 very low birth weight (VLBW) infants were compared. Early-onset sepsis occurred in 1032 infants, and late-onset sepsis occurred in 12,204 infants. Early and late-onset sepsis was associated with increased risk of death controlling for other confounders (odds ratio 1.45 [95% confidence interval 1.21, 1.73], and OR 1.30 [95% CI 1.21, 1.40], respectively). They concluded that (VLBW, <1500 g birth weight) infants are at high risk for both early and late-onset sepsis.[23]

In our study, 14 (35%) of the neonates suffered from early-onset NS while 26 (65%) suffered from late-onset NS. A retrospective study from the Netherlands showed a decrease in the incidence of EONS from 4% between 1978 to 1982 to 1.2% from 2003 to 2006. The incidence of LONS in this study increased from 7.1% between 1978 to 1982 to 13.9% from 2003 to 2006.23 A review from the United States in 2012 reported that EONS occurs in 1.5–2% of VLBW infants and LONS in 21% of VLBW infants. [24] In a cohort study by Delhi Neonatal Infection Study Collaboration, nearly two-thirds of total episodes were early onset while the rest one-third were late. 27 In a study by Bangi *et al.* during 2003–2004, the incidence of EOS and LOS was 3.08% and 2.96%, respectively, while the same in 2013–2014 was 2.57% and 3.44%. [25]

The most common risk factor for NS in our study encountered was vaginal delivery (82.5%), followed by prematurity (32.5%) and maternal UTI during the 3<sup>rd</sup> trimester (30%). Maternal fever (10%) and premature rupture of membrane (15%) and meconium-stained liquor (15%) were the lesser found risk factors. In the study by Assa et al., the major infection risk factor was premature rupture membrane >24 h (14.9%), and minor infection risk factor was gestational age <37 weeks (78%), very low birth weight (44.6%), and asphyxia (41.1%).[26] Murthy et al., in their systemic review, found that male sex (OR: 1.3, 95% CI: 1.02, 1.68), outborn neonates (OR: 5.5, 95% CI: 2.39, 12.49), need for artificial ventilation (OR: 5.61; 95% CI: 8.21, 41.18), gestational age <37 weeks (OR: 2.05; 95% CI:1.40, 2.99), and premature rupture of membranes (OR:11.14, 95% CI: 5.54, 22.38) emerged as risk factors for NS.30 Leal et al. after logistic regression found that risk factors for sepsis included the following: low birth weight; prematurity; abnormal amniotic fluid; premature membrane rupture (PMR) for >24 h; respiratory complications; and the requirement of assisted ventilation, O2 Inspiration fraction (IF) >60%, or a surgical procedure. [27] Adatara et al., the neonatal risk factors associated with sepsis were birth weight ( $\chi^2 = 6.64$ , P = 0.036), neonatal age ( $\chi^2 = 38.31$ , P < 0.001), meconium passed ( $\chi^2 = 12.95$ , P < 0.001), the reason for CS ( $\chi^2 = 24.27$ , P < 0.001), and the duration of stay on admission ( $\chi^2 = 36.69$ , P < 0.001). [28] In a cross-sectional study by Bangi et al., highly significant risk factors were inadequate antenatal care, assisted vaginal delivery, and premature rupture of membranes, low birth weight, and associated complications. [25]

We observed the most common clinical features with which a neonate presented were refusal of feed (55%), followed by jaundice (45%), lethargy (37.5%), and poor cry (35%). In the study by Jajoo et al., lethargy/refusal to feed (77%), hypothermia (47.5%), and respiratory distress (44%) were common clinical presentations. [29] The most common clinical manifestations in a study by Hematyar et al. were respiratory distress in 49 (44.5%), jaundice in 28 (25.5%), vomiting in 26 (23.6%), and poor feeding in 23 (20.9%) of the infants. Other clinical manifestations were lethargy (weakness), decreased sucking reflex, fever, tremor, abdominal distention, and seizure, found in 12 (10.9%), 10 (9.1%), 4 (3.6%), 4 (3.6%), 3 (2.7%), and 2 (1.8%) neonates, respectively. Early-onset sepsis was considerably associated with respiratory distress (P < 0.001), while LOS in neonates was followed by jaundice (P < 0.001), seizure (P = 0.02), and fever (P < 0.001). [30] In a retrospective chart review of VLBW infants by Lim et al., apnea and/or bradycardia and/or cyanosis (65.8%), poor activity (48.7%), and increased respiratory effort (43.0%) were the most common presenting features of sepsis.[31]

Among the 14 neonates in the present study with early-onset NS, 5 (35.71%) had a positive blood culture while 9 (64.29%) had a negative blood culture report. Among the 26 neonates with late-onset NS, 13 (50%) patients each had positive and negative reports. Patients with late-onset NS had a significantly greater number of positive blood culture reports (P = 0.013). In a study by Kayange *et al.*, positive blood culture was found in 57 (47.1%) and 92 (51.4%) among neonates with early- and late-onset NS, respectively (P = 0.466).<sup>[32]</sup> Patel *et al.* found in his study found 276 positive blood culture reports in comparison to 546 negative blood culture reports in NS over a 4-year period.<sup>[33]</sup>

On the serial measurement of CRP, our study found that 22 (55%) had a raised CRP > 10 mg/L on day 2, 16 (40%) had raised CRP on day 5 and 9 (22.5%) had raised CRP on day 7 while only 2 (5%) had a positive CRP on day 14. 18 had a negative CRP on day 2 and none of them had positive blood culture report. Six patients had a positive CRP on day 2 which became negative on day 5 among which all of them had positive blood culture reports. Seven patients had a positive CRP on day 2 and 5 which became negative on day 7 among which 6 had positive blood culture reports. Seven patients had a positive CRP on days 2, 5, and 7 which became negative on day 14 among which 4 had positive blood culture reports. Two patients had a positive CRP report on day 2, 5, 7, and 14 among which both were culture positive. The NPV of CRP in NS according to our study was thus 100%. In a study by Hisamuddin et al., the sensitivity and specificity of CRP in the diagnosis of acute NS were determined as 76.92% and 53.49%, respectively. It had a positive predictive value (PPV) of 80% and a NPV of 48.94%. The overall diagnostic accuracy of CRP in the diagnosis of NS was 70.07%.[20] In a validation study by Ahmed et al., CRP results were positive in 85 (62.9%) neonates on first baseline measurement and were positive in 103 (76.29%) neonates after 72 h of admission. The sensitivity of CRP in diagnosing sepsis was found to be 98.03%, specificity was 91.0%, PPV was 97%, and NPV was 93.7%. [34] In a cross-sectional study by Bunduki et al., of the 228 neonates with suspected sepsis, 94 (41.2%) had a positive CRP. Among the 69 cases with positive blood culture, CRP identified 66 cases. The sensitivity, specificity, positive and NPVs of CRP were 95.7%, 82.4%, 70.2%, and 97.8%, respectively. The area under the curve for the CRP registrar of companies analysis was 0.948.[35]

In our study, 18 (45%) received antibiotic therapy for <3 days, 6 (15%) for 5 days, 7 (17.5%) for 7 days, 7 (17.5%) for 14 days, and 2 (5%) for >14 days. This was guided as per blood CRP levels and antibiotics were discontinued after consultation with a senior pediatrician. Ahmed *et al.* found that the mean duration of antibiotic treatment in the

CRP-guided group was 5.03 days versus 7.02 days in the standard treatment duration group (P < 0.001).<sup>[34]</sup> Bomela et al. found that repeat CRP estimation correctly identified 99 of 100 infants in the study as not requiring further antibiotic therapy (NPV, 99%; 95% confidence intervals, 95.6–99.97%). The one infant with a positive blood culture was premature with a gestational age of 31 weeks. Eight babies required repeat evaluation for suspected sepsis, four presented on days 3-4 and one of these babies died. Thus, they concluded that the use of serial CRP measurements to guide antibiotic therapy is a safe and practical approach in neonates with suspected sepsis in a developing country.<sup>[36]</sup> Gyllensvärd et al. carried out a study between 2 periods, period 1: 2016-2017 where a conventional antibiotic protocol was followed and then after the introduction of the new CRP guided protocol (period 2: 11 June 2018 to 30 Sept 2019). The median CRP was 52 mg/L (37–62) in period 1 and 42 mg/L (31-56) in period 2 in the group that met the criteria of the guidelines. The duration of antibiotic therapy (Median: 7 vs. 5 days, P < 0.001) and hospital stay (Median: 7 vs. 5 days, P < 0.001), as well as healthcare costs, was reduced in the group who met the criteria after the introduction of the guidelines.[37]

### **CONCLUSION**

Thus, it can be concluded that serial estimation of CRP can act as a diagnostic parameter to decide when antibiotics can be safely discontinued in cases of NS. The NPV of CRP in NS according to our study was thus 100%. This study has also shed light on the basic characteristics of NS by studying its risk factors and clinical features. It was observed that pre-term and low birth weight neonates had a significantly increased risk of NS. Serial estimation of CRP can, in turn, decrease antibiotic-associated morbidity and cost of healthcare significantly by shortening hospital stay for a neonate.

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## **Correlation between the Haematological Changes and CD4 Cells Counts in HIV Infected Patients**

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### **Abstract**

**Background:** The progression of HIV infection is studied through the haematological abnormalities correlating with CD4 cell counts.

**Methods:** The number of participated HIV infected patients were (n=120) in this study to evaluate the haematological abnormalities arises during the advancement of the disease. Also, 2–5 ml blood samples were collected to determine the CD4 count haematological parameters. The considered standard values of haematological parameters were followed to study Anemic condition for men Hb<13%, for non-pregnant women Hb<12 gm%), thrombocytopenia (platelets <1.5 lakh/mm³) leucopenia; white blood cells <4000/mm³.

Results: The current study deals with n=120 HIV infected patients. A common sign of AIDS disease is anaemia, approximately 46% of patients were affected followed by leukopenia 25% and rest 24% of thrombocytopenia patients with lowered CD4 counts was observed. The lowered value of CD4 count was observed <200 cells/ $\mu$ L in these patients, the incidence of anaemia, leukopenia and thrombocytopenia was 22/46(47.8%), 14/25(56%) and 13/24(54.1%) respectively, while the incidence of anaemia, leukopenia and thrombocytopenia was found in patients with CD4 count >500 cells/ $\mu$ L was least one i.e. 5/46 (10.8%), 1/25(4%) and 2/24(8.3%), respectively. The plate count decreases as the CD4 count (<500 cells/ $\mu$ L) decreases at (p=0.032) level and had a statistically significant relationship with CD4 counts.

**Conclusion:** HIV infection/AIDS disease progression could be measured by haematological changes and these abnormal changes indicate the disease severity. The anaemic condition being the most common abnormality had a significant correlation with CD4 counts followed by leukopenia and least one by thrombocytopenia, hence advanced stages of disease could be predicted as an anaemic condition approaches to become severe.

Key words: Anemia, CD4 count, Haematological, HIV, Leukopenia, Thrombocytopenia

### INTRODUCTION

Human immunodeficiency infection more suitable called AIDS, which is caused by a human deficiency virus (HIV), an RNA virus belongs to the retrovirus family. HIV attacks human immune system1 and ultimately destroy the defence system i.e. both innate and acquired immunity.<sup>[1,2]</sup> This attacking virus preferentially destroys the CD4 lymphocyte



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cells and reduces CD4 cells population day by day. It has been calculated that each day approx >109 CD4 cells were destroyed.<sup>[3,4]</sup> CD4 cell population decline is directly linked to the HIV viral load and measure the disease severity rate.<sup>[5]</sup> Previously, India becomes the third-largest country where the number of HIV-infected patient cases arises across the world after South Africa and Nigeria. In India, recent reports suggest the around 2.1 million individuals were infected with HIV/AIDS by the end of 2017 with an adult prevalence of 0.2% between the age group of 15-49 years. Haematological parameters were considered to assess diagnosis and measure its progression rate.<sup>[6]</sup>

Usually, the number of mature blood cells reduces known as cytopenias, identified in HIV positive patients.

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Cytopenias are a common cause of anaemia in HIV patients showed 60-80% haematological abnormalities arise in the later stage of HIV suffered patients. [7,8] Progression of Anemia, various factors are accountable in HIV suffered patients, including vitamin B-12, iron, folic acid, malabsorption insufficiencies, infiltration bone marrow and erythropoietin production rate decreases with HIV infection progress. [9]

HIV associated hematologic expressions seem to be dependent on the level of viral replication, as these abnormalities are severe in AIDS patients with high viraemia and decreased CD4 counts.<sup>[10]</sup>

Depending on the viral load, several haematological abnormalities arises associated with HIV infection, these abnormalities become severe in AIDS patients with decreased CD4 count and high viraemia. Few reports were studied associated with haematological changes and their correlation with CD4 count. The current study aimed to demonstrate the haematological changes associated with HIV infection and its correlation with CD4 count to check up the disease progression.

### **MATERIALS AND METHODS**

The present prospective study was conducted in the ART centre and the department of general Medicine, GR medical college, Gwalior on 120 HIV positive patients who were newly diagnosed. All the patients have undergone a detailed haematological evaluation. The data obtained was captured in a pre-defined proforma and data analysis was performed. Based on the data analysis following observation were obtained. All the participated patients had undergone a detailed clinical; haematological radiological investigations were done at the time of registration. Also, 2–5 ml quantity of blood samples was withdrawn carefully in a vacutainer tube to calculate the CD4 count and determines the haematological parameters. The minimum prescribed values were described to calculate the different haematological parameters such as Anemia: for men Hb <13%, for non-pregnant women Hb<12 gm%), thrombocytopenia (platelets <1.5 lakh/mm³) leucopenia; white blood cells <4000/mm<sup>3</sup>.

### **Statistical Analysis**

All the data analysis was performed using IBM SPSS ver. 20 software. Frequency distribution and cross-tabulation were used to prepare the tables. Categorical data were expressed as a percentage. PRISM and Microsoft office was used to prepare the graphs. The Chi-Square test was used to compare the categorical data. The P-value of <0.05 level was considered statistically significant.

### **RESULTS**

### **Demographic Study**

The current study dealed with 120 patients, 53.3% were males and 46.7% were females. Male patients were more involved in comparison to female patients. The age of the patients varied from <20 yrs to >50 yrs. The maximum numbers of patients (46.7%) participated in this study, were the age group of between 31-40 yrs. The mean age of the patients was  $40\pm31.99$  years.

### **Haematological Parameters**

In this study, the number of participated patients were (n=120) HIV infected patients, at the initial stages of HIV infection; several haematological abnormalities such as anaemia, leucopenia, and thrombocytopenia were frequently encountered. The most common symptoms are anaemia, approx. 46% of patients were affected, followed by leukopenia 25% and the rest are 24% of thrombocytopenia patients. Table 1 depicts the different mean value of haematological parameters in HIV infected patients. The CD4 marker system is employed to the efficacy of the immune system of HIV patients. The CD4 counts were further categorized into two groups: less than 500 cells/ $\mu$ L and more than or equal to 500 cells/ $\mu$ L. Initially, anaemia, leucopenia and thrombocytopenia were common symptoms of HIV-infected patients having lower CD4 counts. The lowered value of CD4 count was <200 cells/µL observed in these patients, the incidence of anaemia, leukopenia and thrombocytopenia was 22/46 (47.8%), 14/25 (56%) and 13/24 (54.1%), respectively, while the incidence of anaemia, leukopenia and thrombocytopenia was found in patients with CD4 count >500 cells/ $\mu$ L were least one i.e. 5/46(10.8%), 1/25(4%) and 2/24(8.3%), respectively.

In the present study, among 120 patients, male patients had lowered haemoglobin level of <13 gm% (93.7%) and rest 6.3% had a hemoglobin level of ≥13 gm%. Among females, the majority of the patients had haemoglobin level <12 gm% (87.5%) and 12.5% had haemoglobin level ≥12 gm%. From this data, the anaemic condition was graded according to the haemoglobin level. Females

Table 1: Comparing CD4 count with different haematological parameters

Parameters	CD4 coun	P-value	
	<500	≥500	
Hb (gm%)			
Normal	2 (2.1)	1 (3.8)	0.002
Abnormal	92 (97.9)	25 (96.2)	
Platelet count (lakh/mm³)			
<1.5	27 (28.7)	3 (11.5)	0.032
≥1.5	67 (71.3)	23 (88.5)	

were more prone to shift to severe anaemia than males as summarized in Figure 1.

Table 1 relates the severity of anaemia in case of patients with <500 CD4 counts 92(97.9) than the >500 CD4 count 25(96.2) respectively, which was statistically significant at p=0.002 level. The commonest type of anaemia was normocytic normochromic, which was accounted in 49.2% patients, while microcytic hypochromic anaemia was observed in 17.5% patients and the rest of the 25% of patients had macrocytic anaemia. Out of the 46 patients, 2 patients were undergone for thrombocytopenia, where plate count decreases as the CD4 count (<500 cells/μL) decreases at (p=0.032) level as shown in Table 2.

Rectic count (reticulocyte count) actually, reticulocyte count represents the formation and release of RBC by the bone marrow into the blood. The mean corpuscular volume (MCV) represents the average volume of RBC. Figure 2 showed the maximum MCV percentage of 38.3 in the range of 80-100 fl, it was noted that the infected HIV patients were prone to the anaemic condition as the disease progress. However, the p-value was found statistically significant as shown in Table 1 as < 500 cells/µL CD4 count appears in the blood and plate count number increased from 3–23 lakh/mm³ reflecting normal to an abnormal condition of patients.

In the present study, the highest value of rectic count was observed in 0.5-2% level i.e. 93.3% shows in Table 3 and there were 6.7% patients, who had the lowest value of retic count <0.5% level. None of the patients had retic count >2.

In the present study, majority of the patients had TLC between 4000–11000/cumm (94.2%) and there were 4.2% patients, who had TLC <4000/cumm and only 1.7% patients had TLC >11000/cumm shows in Table 4, as CD4 counts decreased, TLC values decreased.

Leukopenia was observed in 1/25(4%) of HIV positive patients. Leukopenia cases involve, agranulocytes and lymphocytes, although it was monocytopenia reported in HIV infected patients. Also, Neutropenia level was also decreased with decreased CD4 count, an early sign of HIV infection.

### **DISCUSSION**

Haematological abnormalities are considered as the most common reason for creating complication during HIV infections. These abnormalities involved in all the lineages of blood cells.<sup>[11]</sup> HIV associated haematological abnormalities appear to be dependent on the level of virus load, as these

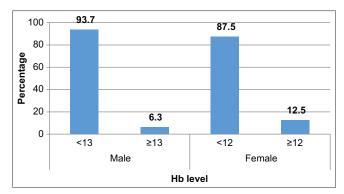


Figure 1: Distribution of patients according to Hemoglobin level

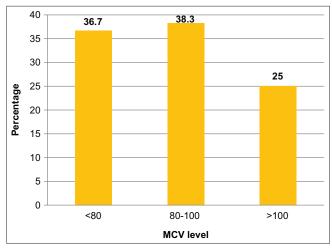


Figure 2: Distribution of patients according to MCV cut-offs

### Table 2: Patients distribution based on Platelet counts (expressed in lakh/cumm)

Platelet count	Frequency	Percentage (%)
<1.5 lakh/mm³	30	25.0
≥1.5 lakh/mm³	90	75.0
Total	120	100.0

Table 3: Distribution of patients according to Retic count cut-offs

Retic count	Frequency	Percentage (%)
<0.5%	8	6.7
0.5-2%	112	93.3
>2%	0	0
Total	120	100.0

Table 4: Distribution of patients according to TLC cut offs

TLC	Frequency	Percentage (%)
<4000/cumm	5	4.2
4000-11000/cumm	113	94.2
>11000/cumm	2	1.7
Total	120	100

abnormalities increased as the disease AIDS advances. The actual mechanism highlighting these abnormalities is still not known. [12] Anaemia is the most common cytopenia in HIV-infected patients, the initial occurrence of anaemia is approx. 10-20% of patients and it became more severe in 70-80% of patients as the disease progress. Hence, the incidence of anaemia is strongly significant with disease progression. The current study involved both male (53.3%) and female (46.7%). In this study, the male majority had a haemoglobin level of <13 (93.7%) and 6.3% had a haemoglobin level of  $\geq 13$ . Among females, the majority of the patients had haemoglobin level <12 (87.5%) and 12.5% had haemoglobin level ≥12. Cleeland et al.;[13] Saha et al.[14] study found the female distribution in HIV patients with anaemia in 57.33% females. Kusfa et al.[15] study, recorded the mean (±SD) values of the haematological parameters (at baseline and 6 months after initiation of ART) where: haemoglobin concentration (10.9±1.95 vs 11.8±1.83 g/dL at 95% CI-1.7713, -0.5030, P-value <0.001). (Ezeonwu et al.[16] study found the mean haematological levels of the patients were haemoglobin (Hb) (10.4±1.2 g/dl), neutrophil count (3.031±1.039 cells/mm³), and platelets count (294±78×109/L). Anaemia was the most common haematological abnormalities arises at the initial stage of the disease, about 77% of patients had haemoglobin below 13 g% and about 6% were having haemoglobin below 6 g%. Ferede and Wondimeneh<sup>[17]</sup> recorded an overall prevalence of anaemia in 138 (35%) patients. Female HAART naive HIV positive patients had significantly (at p<0.05) higher prevalence of anaemia than males (62% vs 38%). In the present study, the majority of the patients had platelet count ≥1.5 (75%) and there were 25% patients, who had platelet count <1.5. Shruthi et al.[18] recorded similar result, where the majority of the patients had platelet count  $\geq 1.5 60 (60\%)$ and there were 40 (40%) patients, who had platelet count <1.5. Shi et al.[19] concluded that in HIV infection, early stages may have decreased platelet count due to decreased survival and in late advanced disease due to marrow failure. (Kathuria et al.[20] and Carter et al.[21] also recorded majority of non-thrombocytopenia (platelet count>1.5 lakhs/mm³) 38(76%) and 12 (24%) patients had thrombocytopenia (platelet count<1.5 lakhs/mm<sup>3</sup>). Leukopenia abnormality arises in patients with the AIDS disease. Neutropenia of fewer than 1000 cells/µL was also reported in approximately 10% of patients with early, asymptomatic HIV infection and more than 50% of individuals with late stages of HIV infection.

### **CONCLUSIONS**

HIV infection/AIDS disease progression could be measured by haematological changes and these abnormal changes indicate the disease severity. The anaemic condition being the most common abnormality had a significant correlation with CD4 counts followed by leukopenia and least one by thrombocytopenia, hence advanced stages of disease diagnosis could be predicted by anaemic condition approaches to become more severe in HIV infected patients.

Therefore, it was important to investigate the reason of causing anaemia and need to find out the appropriate treatment of haematological abnormalities, thereby, reduce the illness and mortality of HIV positive patients. HIV infected patients suffer from haematological abnormalities therefore, abnormalities early diagnosis, exact causing agent finding retrieve the treatment therapy against these abnormalities, which reduces the morbidity and mortality rate of HIV positive patients.

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