

Functional Outcome of Biological Graft Versus Fiber Wire in Acromioclavicular Joint Dislocation: A Comparative Study

Dr. Vipin Kumar Raghuwanshi¹, Dr. Sandeep Bhide^{2*}, Dr. Shubham Nagdev³, Dr. Abhishek Dhoke⁴, Dr. Vinayak Mani Dwivedi⁵

Abstract

Introduction: Acromioclavicular (AC) joint dislocation is a common shoulder injury, particularly among athletes and individuals engaged in physical labor. The injury often requires surgical intervention to restore joint stability and function. Two popular surgical options are the use of biological grafts and synthetic materials such as Fiber Wire for AC joint reconstruction. This comparative study aims to evaluate the efficacy, safety, and functional outcomes of biological grafts versus fiber wire in the treatment of AC joint dislocations.

Materials and Methods: This study included a sample of 32 patients diagnosed with AC joint dislocation, divided into two groups: those treated with biological grafts and those treated with fiber wire. Patients were randomly assigned to each group and followed for a period of 12 months post-surgery. Clinical evaluations were performed using the Constant-Murley Score. Radiographic assessments were conducted to measure joint stability and alignment. Complications, such as infections and redislocations, were recorded.

Results: The study found that patients treated with biological grafts demonstrated slightly better joint stability and fewer complications compared to those treated with fiber wire. The Constant Murley indicated that the biological graft group achieved superior functional outcomes, with statistically significant differences ($p < 0.05$).

Conclusion: Both biological grafts and fiber wire provide viable options for AC joint dislocation repair, each with distinct advantages. Biological grafts offer better long-term stability and functional outcomes, making them preferable for patients prioritizing joint integrity and performance. Further research with larger sample sizes and longer follow-up periods is necessary to substantiate these findings and optimize treatment protocols.

Keywords: Acromioclavicular joint (AC joint); Biological graft; Fiber wire; Athletes; Constant-Murley Score; Shoulder

Introduction

The acromioclavicular (AC) joint, a vital articulation between the clavicle (collarbone) and the acromion process (scapular projection), plays a crucial role in shoulder girdle stability and function. Disruption of this joint, known as acromioclavicular joint dislocation, represents a prevalent injury within the spectrum of shoulder girdle trauma, accounting for 9% to 12% of all such occurrences [1]. The most common etiology is direct trauma to the AC joint or lateral trauma providing an axial load on the joint space. AC dislocations

Affiliation:

¹Senior Resident, Department of Orthopaedics, Dr. Laxminarayan Panday, Govt Medical College, Ratlam, Madhya Pradesh, India

²Associate Professor, Department of Orthopaedics, RD. Gardi Medical College, Ujjain, Madhya Pradesh, India

³Senior Resident, Department of Orthopaedics, RD. Gardi Medical College, Ujjain, Madhya Pradesh, India

⁴Senior Resident, Department of Orthopaedics, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

⁵Senior Resident, Department of Orthopaedics, MGM Medical College, Indore, Madhya Pradesh, India

*Corresponding Author:

Dr. Sandeep Bhide, Associate Professor, Department of Orthopaedics, RD Gardi Medical College, Ujjain, Surasa, Madhya Pradesh, India.

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are distinct from "shoulder dislocations," which refer to glenohumeral joint dislocations [2]. These dislocations typically arise from direct blows to the shoulder or falls onto an outstretched arm with the arm positioned inwards (adducted) [3]. AC joint dislocations are more prevalent in men than women, and they can affect individuals of any age and activity level [4]. AC joints are especially prevalent in the younger population participating in contact sports, representing 15%, 20%, and 41% of shoulder injuries in hockey, skiing, and American football, respectively [5].

The cornerstone of effective treatment hinges on accurately classifying the injury severity. The widely employed Rockwood classification system categorizes acromioclavicular dislocations into six distinct types (I-VI) based on the degree of ligamentous disruption [6]. Rockwood types I and II, characterized by minimal ligamentous damage, are managed conservatively through conservative techniques like using an ice pack, immobilization with a sling for several weeks, and physical therapy, taking anti-inflammatory over-the-counter drugs. Whereas in the Rockwood types III to VI, encompassing more severe ligamentous injuries with significant joint instability, often necessitate surgical intervention [7].

Surgical management for acromioclavicular joint dislocations encompasses a diverse array of techniques, broadly classified into four categories: Fixation with Hardware—This approach involves utilizing screws, Kirschner wires (K-wires), or a combination of both to directly secure the AC and/or coracoclavicular (CC) ligaments [8], or suture button or anchor fixation [9]. Also, in cases involving substantial ligamentous avulsion, reconstruction may be performed using autografts (tissue harvested from the patient) or allografts (donor tissue) to recreate the disrupted ligaments [10].

Evaluating the success of any treatment strategy for acromioclavicular joint dislocations necessitates using validated outcome measures. The Constant-Murley score (CMS) is a widely utilized and reliable tool for comprehensively assessing patient function and recovery following this injury. This study employed the CMS score as the primary outcome measure to assess patient function and recovery following each surgical approach. It evaluates four domains: pain, activities of daily living, range of motion, and strength.

Despite the existence of various surgical techniques, the optimal approach for managing acromioclavicular joint dislocations, particularly for Rockwood type III injuries, remains a subject of ongoing debate. While some surgeons advocate for conservative management for this type, others favor a surgical approach to achieve enhanced stability and potentially improve long-term outcomes [13].

This study aimed to contribute to the ongoing debate regarding the optimal surgical management of Rockwood type III acromioclavicular joint dislocations by comparing two prevalent surgical techniques: biological graft fixation and suture button fixation. By comparing the CMS scores between these two groups, the study sought to determine which technique yields superior patient outcomes regarding pain reduction, daily living function, range of motion, and strength. Secondary outcome measures were also evaluated, including radiographic assessment of joint stability, patient satisfaction scores, and complication rates associated with each surgical method. This study offered high-quality data to discuss the most effective surgical approach for managing Rockwood type III acromioclavicular joint dislocations.

Methods and Materials

The proposed study was conducted after approval by the research guide and institutional ethics committee and is anticipated to be completed within one year. The study was conducted at the Department of Orthopaedics at R D Gardi Medical College, Ujjain.

Selection Criteria:

a. Inclusion Criteria

- Adult patients with Rockwood types III, IV, V, and VI of acromioclavicular joint dislocation.
- Age >18 years and <65 years.
- Patients who have given consent
- Acromioclavicular joint dislocation duration: <3 months.

b. Exclusion Criteria

- Patients with Rockwood type I or II acromioclavicular joint dislocation
- Age <18 years and >65 years.
- Patients with comorbidities.
- Patient who refuses surgical treatment.
- Acromioclavicular joint dislocation duration >3 months.

Methodology:

The study was conducted at R D Gardi Medical College, Ujjain, upon approval by the ethical committee within the Department of Orthopaedics on patients with complaints of pain in the shoulder region by using a self-administered knowledge questionnaire after obtaining permission from concerned authorities in the department to conduct the main study.

Sample size calculation

All statistical analyses were conducted using suitable statistical software. Quantitative data was analyzed using

frequency distribution, measures of central tendency and dispersion, and graphical representation. Qualitative data was analyzed using frequency distribution, percentage calculations, and diagrammatic representations. A comparison of quantitative variables was done using both parametric and non-parametric tests.

Surgical technique

Surgery was performed under general anesthesia.

Position: Beech Chair Position (Figure 1-6)

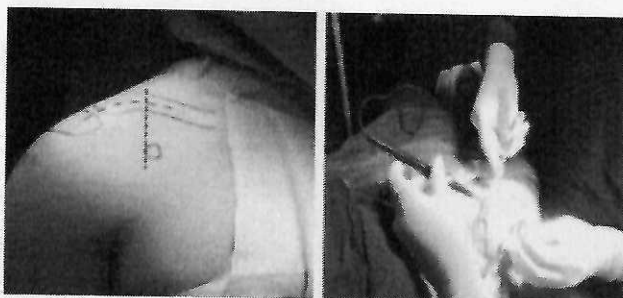


Figure 1: A vertical incision measuring 5 centimeters made from the tip of Coracoid process to lateral end of clavicle.

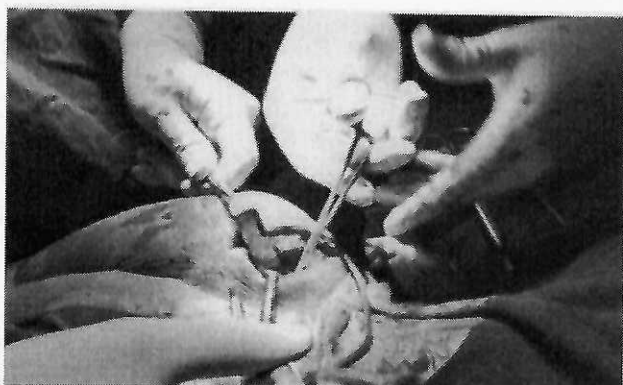


Figure 2: Skin and subcutaneous tissue incised and retracted.



Figure 3: Exposure of the clavicle achieved by detaching the trapezius and deltoid muscles from their attachments.

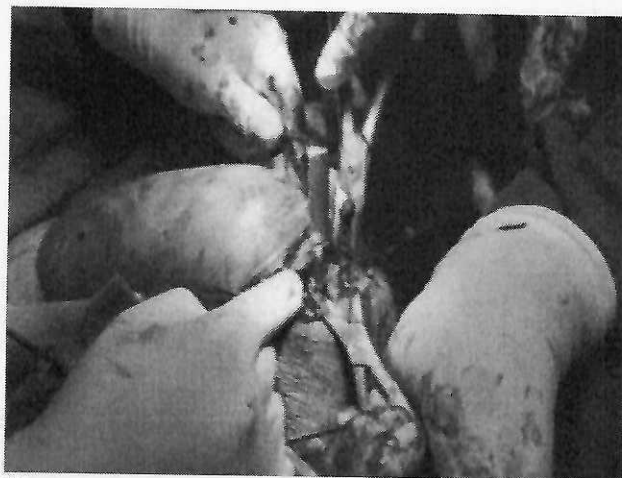


Figure 4: Clavicular tunnels: Conoid tunnel: 45mm medial to lateral end of clavicle (posteromedial). Trapezoid tunnel: 30 mm medial to lateral end of clavicle (anteriolateral). 1cm of lateral end clavicle osteotomy done.



Figure 5: A longitudinal split is made to access the coracoid process. Subsequently, a fibre wire is passed around the coracoid process and shuttled through pre-drilled tunnels in the clavicle.

Wound closure and cleaning and dressing done.

Surgical procedure is same in reconstruction with biological graft. In it tendon graft is used in place of fiber wire to reconstruct acromioclavicular joint.

Steps for graft harvest and preparation:

1. Graft Harvest – A small incision is made near hamstring insertion (Figure 7,8).

Tendon is taken with the help of tendon stripper.

A case of biological reconstruction (Figure 9-13):

A case of fiber wire reconstruction (Figure 14-18):

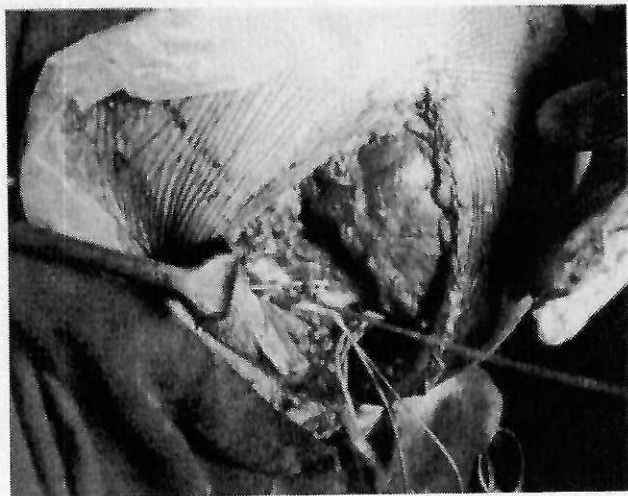


Figure 6: Reduction tried and secured with endobutton.



Figure 7: Tendon is taken with the help of tendon stripper.

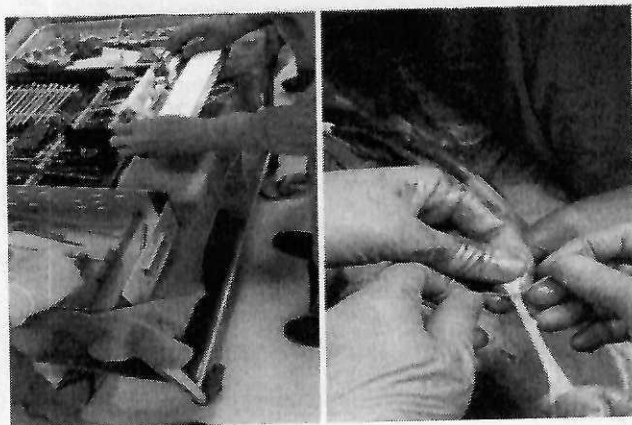


Figure 8: Graft preparation.

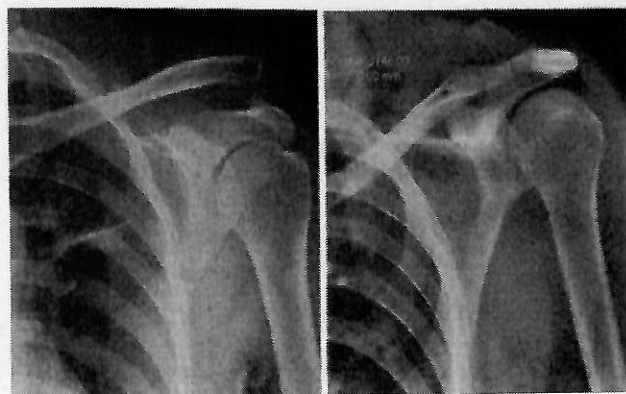


Figure 9: Pre op X-ray Post op X-ray.

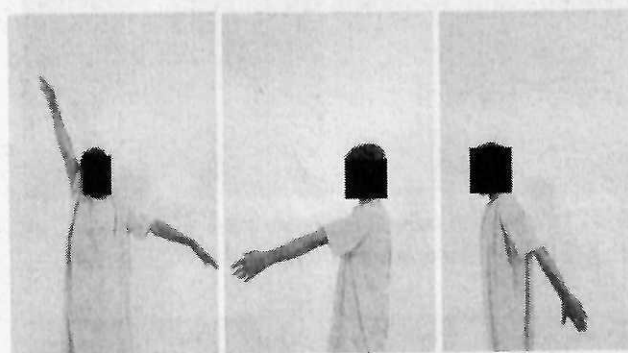


Figure 10: Pre-op range of motion: Abduction, flexion and extension respectively.

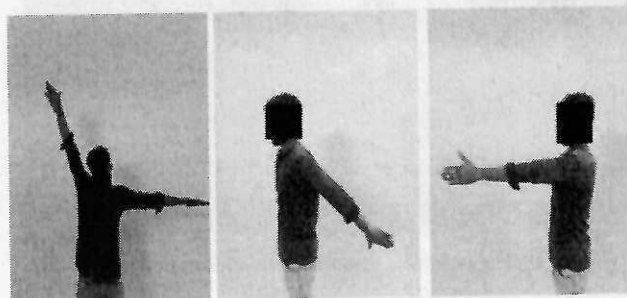


Figure 11: Post-op range of motion (6 weeks): Abduction, extension and flexion respectively.



Figure 12: Post-op range of motion (6 months): Extension, flexion and abduction respectively.

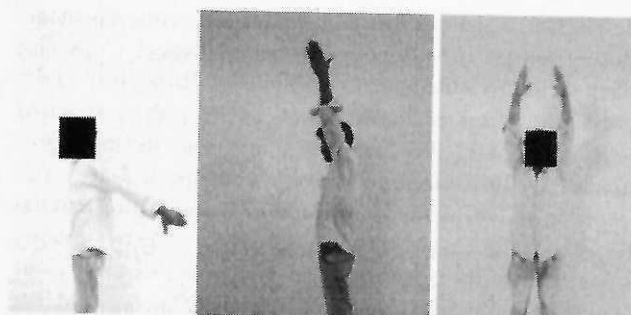


Figure 13: Post-op range of motion (12 months): Extension, flexion and abduction respectively.

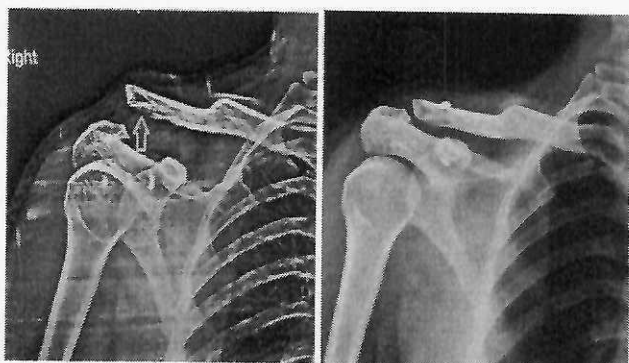


Figure 14: Pre-op x-ray Post-op x-ray.

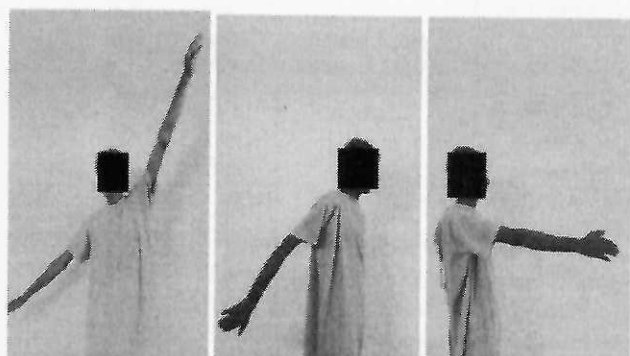


Figure 15: Pre-op range of motion: Abduction, flexion and extension respectively.

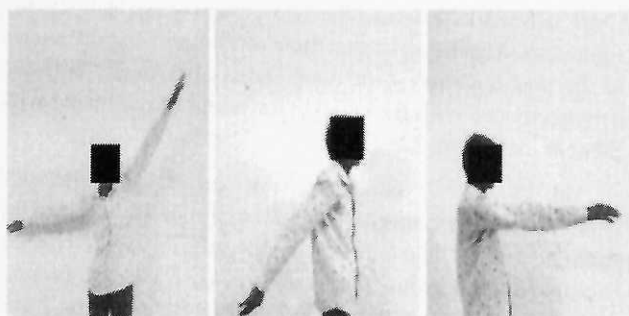


Figure 16: Post-op range of motion (6 weeks): Abduction, extension and flexion respectively.

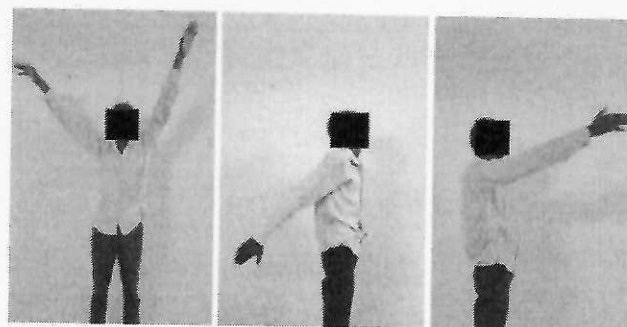


Figure 17: Post-op range of motion (6 months): Abduction, extension and flexion respectively.



Figure 18: Post-op range of motion (12 months): Abduction, extension and flexion respectively

Results

Present study, most frequently occurring age is 25 years. The standard deviation of 7.749 years reflects moderate variability in the ages within the sample. The ages range from a minimum of 21 years to a maximum of 48 years (Table 1-4; Figure 19 and 20).

Table 1: Age distribution of the cases.

Age group	N	%
<=30 years	15	46.9%
31 - 40 years	10	31.3%
>41 years	7	21.9%
Total	32	100.0%

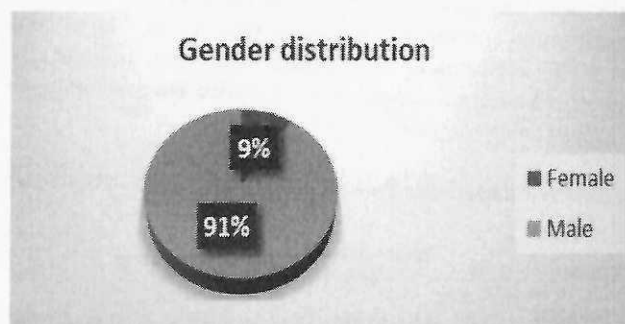


Figure 19: Gender distribution of the cases.

Table 2: Side affected of the cases.

Side affected	N	%
Left	12	37.5%
Right	20	62.5%
Total	32	100.0%

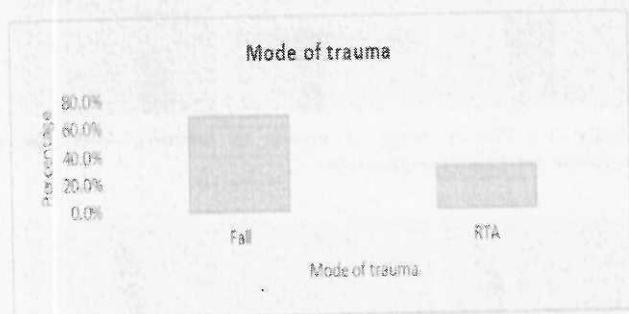


Figure 20: Mode of trauma.

Table 3: Complications.

Complications	N	%
None	29	90.6%
Subluxation	2	6.3%
superficial infection	1	3.1%
Total	32	100.0%

Table 4: Cross tabulation between complication and study group.

		Group				p
		Biological graft		Fibre wire		
Complications	None	14	87.5%	15	93.8%	0.596
	Subluxation	1	6.3%	1	6.3%	
	superficial infection	1	6.3%	0	0.0%	

The data compares the occurrence of complications between the Biological Graft and Fiber Wire treatment groups. Among those with no complications, 87.5% received Biological Graft and 93.8% received Fiber Wire. Subluxation occurred in 6.3% of cases in both groups. Superficial infection was reported in 6.3% of cases in the Biological Graft group and none in the Fibre Wire group. The p-value of 0.596 indicates no statistically significant difference in the distribution of complications between the two treatment groups (Table 5).

Table 5: Comparison of mean pre-operative CMS according to groups.

Group	N	Mean pre op CMS	Std. Deviation	t	p
Biological graft	16	35.56	5.416	-2.294	.0771
Fiber wire	16	36.13	5.402		

The Table 5 compares the mean pre-operative Constant-Murley Scores (CMS) between the Biological Graft and Fiber Wire treatment groups. For the Biological Graft group, the mean pre-op CMS is 35.56 with a standard deviation of 5.416. For the Fiber Wire group, the mean pre-op CMS is 36.13 with a standard deviation of 5.402. The t-value is -0.294, and the p-value is 0.771, indicating that the difference in the mean pre-op CMS between the two groups is not statistically significant. This suggests that there is no significant difference in the pre-operative functional status of patients between the Biological Graft and Fiber Wire groups (Table 6, Figure 21).

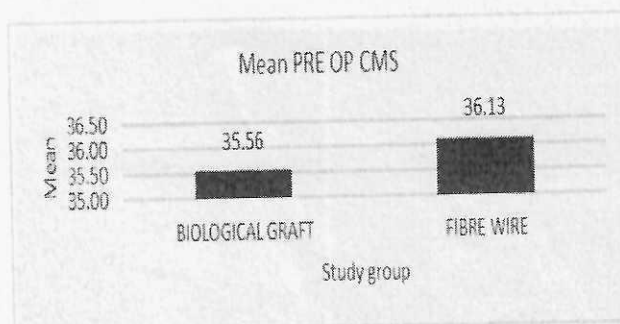


Figure 21: Mean PRE OP CMS.

Table 6: Comparison of mean post-operative CMS at 6 weeks according to groups.

Group	N	Mean post op CMS 6 weeks	Std. Deviation	t	p
Biological graft	16	63.00	4.412	.523	.605
Fiber wire	16	62.25	3.661		

The Table 6 compares the mean post-operative Constant-Murley Scores (CMS) at 6 weeks between the Biological Graft and Fiber Wire treatment groups. For the Biological Graft group, the mean post-op CMS at 6 weeks is 63.00 with a standard deviation of 4.412. For the Fiber Wire group, the mean post-op CMS at 6 weeks is 62.25 with a standard deviation of 3.661. The t-value is 0.523, and the p-value is 0.605, indicating that the difference in the mean post-op CMS at 6 weeks between the two groups is not statistically significant. This suggests that there is no significant difference in the post-operative functional status at 6 weeks between patients treated with Biological Grafts and those treated with Fiber Wire (Figure 22).

The Table 7 compares the mean post-operative Constant-Murley Scores (CMS)⁽¹⁴⁾ at 6 months between the Biological Graft and Fibre Wire treatment groups. For the Biological Graft group, the mean post-op CMS at 6 months is 91.06 with a standard deviation of 6.787. For the Fibre Wire group, the mean post-op CMS at 6 months is 85.94

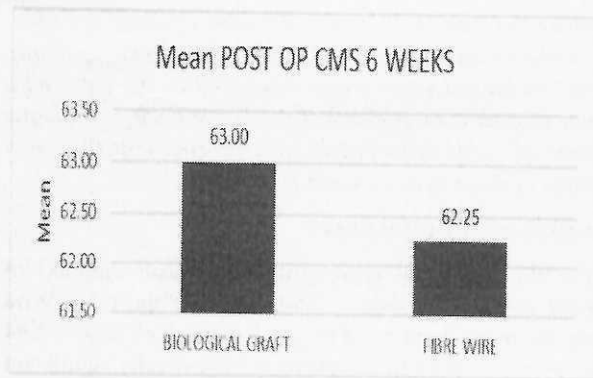


Figure 22: Mean Post OP CMS 6 weeks.

Table 7: Comparison of mean post-operative CMS 6 month according to groups.

Group	N	Mean post op CMS 6 months	Std. Deviation	t	p
Biological graft	16	91.06	6.787	2.107	.044
Fibre wire	16	85.94	6.971		

with a standard deviation of 6.971. The t-value is 2.107, and the p-value is 0.044, indicating that the difference in the mean post-op CMS at 6 months between the two groups is statistically significant. This suggests that patients treated with Biological Grafts have a significantly better functional status at 6 months post-operation compared to those treated with Fiber Wire (Figure 23).

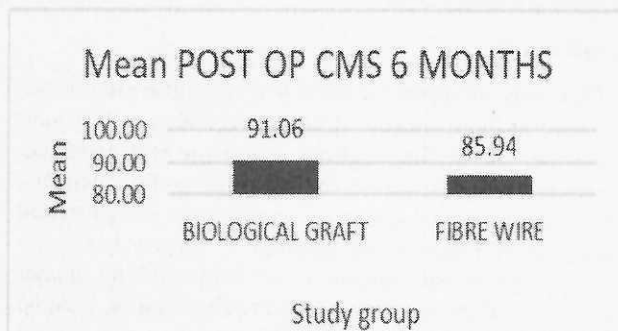


Figure 23: Mean Post OP CMS 6 months.

Table 8: Comparison of mean post-operative CMS 12 month according to groups.

Group	N	Mean POST OP CMS12 MONTHS	Std. Deviation	t	p
BIOLOGICAL GRAFT	16	95.25	2.543	3.258	.003
FIBRE WIRE	16	92.50	2.221		

The Table 8 compares the mean post-operative Constant-Murley Scores (CMS) at 12 months between the Biological Graft and Fiber Wire treatment groups. For the Biological Graft group, the mean post-op CMS at 12 months is 95.25 with a standard deviation of 2.543. For the Fiber Wire group, the mean post-op CMS at 12 months is 92.50 with a standard deviation of 2.221. The t-value is 3.258, and the p-value is 0.003, indicating that the difference in the mean post-op CMS at 12 months between the two groups is statistically significant. This suggests that patients treated with Biological Grafts have a significantly better functional status at 12 months post-operation compared to those treated with Fiber Wire.

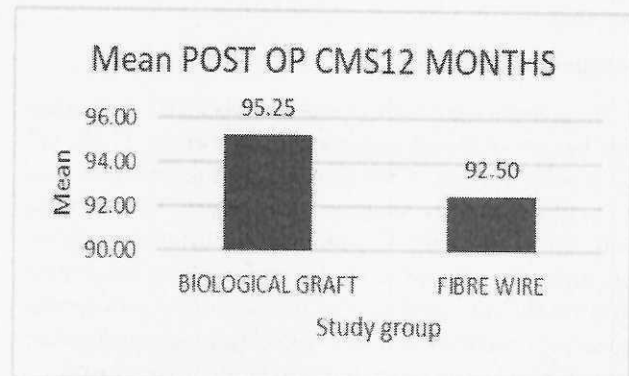


Figure 24: Mean Post OP CMS 12 months.

Discussion

Acromioclavicular (AC) dislocation involves the complete loss of articular contact. It is considered chronic when it occurs after conservative management or unsuccessful surgical treatment [11]. This study compares the use of biological graft and fiber wire in the treatment of acromioclavicular joint dislocation.

Age and Gender:

In our study, the mean age of the patients was 25 ± 7.749 years, ranging from 21 to 48 years. A significant proportion, 46.9% (15 cases), were ≤ 30 years old, 31.3% (10 cases) were aged 31-40 years, and 21.9% (7 cases) were ≥ 41 years. The sex distribution was predominantly male, constituting 90.6% (29 cases), while females accounted for 9.4% (3 cases). Similar to our study, **Jingwei et al.** evaluated the clinical outcomes of using suture anchors for acromioclavicular joint dislocation. They reported a mean participant age of 27.7 years (range: 19-55 years), with a predominance of male participants (24 males) compared to female patients (4 females) [15]. In their prospective study, **Fauci et al.** [11] reported a mean patient age of 35 ± 3.2 years, with a predominance of male patients (male-to-female ratio of 25 to 15). The analytical cross-sectional study conducted by **Mardani-Kivi et al.** reported that the participants' mean age was 32.6 ± 11.8 years, predominantly male participants

(35 males and 4 females). Our study's predominantly male cohort (90.6%) with a mean age of 25 ± 7.749 years aligns with similar findings from Jingwei et al., Fauci et al., and Mardani-Kivi et al., all of whom reported male predominance and comparable age ranges.

Among those 30 years or younger, 43.8% received biological grafts, while 50.0% received Fiber Wire. In the 31- to 40-year age group, 37.5% received biological grafts and 25.0% received Fiber Wire. For individuals over 41 years, 18.8% received biological grafts and 25.0% received fiber wire ($p=0.737$). Among females, 6.3% received biological grafts, while 12.5% received fiber wire. Among males, 93.8% received biological grafts, and 87.5% received fiber wire ($p=0.544$).

Occupation & Addiction:

The patients were 9.4% (3 cases) drivers, 28.1% (9 cases) were farmers, 6.3% (2 cases) were housewives, 37.5% (12 cases) were laborers, 6.3% (2 cases) had private jobs, and 12.5% (4 cases) were students. With respect to **addiction**, in our study, out of the 32 participants, most of the patients were primarily addicted to alcohol and smoking, accounting for 34.4% (11 cases) and 31.3% (10 cases) of the participants, respectively. Additionally, 15.6% (5 cases) had no addiction, while 18.8% (6 cases) were found to be chewing tobacco.

Side affected & Mode of trauma:

Regarding the affected side, 62.5% (20 cases) were on the right side, while 37.5% (12 cases) were on the left side. The data regarding the mode of trauma among the 32 cases shows that 68.8% (22 cases) were caused by falls, while 31.3% (10 cases) were due to road traffic accidents (RTA).

Grade of Dislocation:

The grade of dislocation data shows that Grade 4 and Grade 5 dislocations are the most common, each accounting for 34.4% of the cases. Grade 3 dislocations account for 12.5%, and Grade 6 dislocations make up 18.8% ($p\text{-value} = 0.98$).

Complications:

90.6% of the cases had no complications; among those with no complications, 87.5% received biological grafts and 93.8% received fiber wire. Subluxation occurred in 6.3% of cases in both groups. Superficial infection was reported in 6.3% of cases in the biological graft group and zero in the FiberWire group. $p\text{-value} = 0.446$ indicates no statistically significant difference in the distribution of complications between the two treatment groups.

Duration of Surgery:

For the biological graft group, the mean duration of surgery is $91.8 \text{ mins} \pm 19.2 \text{ mins}$. For the Fibre Wire group,

the mean duration is $78 \text{ mins} \pm 4.8 \text{ mins}$ ($p\text{-value} = 0.007$). Indicating the mean duration of surgery is significantly longer for the biological graft group compared to the FiberWire group. Jingwei et al. performed the suture anchor technique to treat AC joint dislocations and reported that the mean duration of surgery was $78 \text{ min} \pm 16.74$.

Duration of Hospital Stay:

For the biological graft group, the mean duration of hospital stay is 6.38 days $\pm$ 3.50 days. For the Fiber Wire group, the mean duration of hospital stay is 5.69 days $\pm$ 2.94 days ($p\text{-value} = 0.552$), indicating no statistically significant difference in the mean duration of hospital stay between the two treatment groups.

Pre- & post-operative CMS scores:

Preoperatively, the biological graft group had the mean pre-op CMS as 35.56 ± 5.416 , and the Fiber Wire group had the mean pre-op CMS as 36.13 ± 5.402 ($p\text{-value} = 0.771 \text{ NS}$). Post-operatively, the mean CMS at 6 weeks for biological graft was noted as 63.00 ± 4.412 . For the Fiber Wire group, the mean post-op CMS at 6 weeks was 62.25 ± 3.661 ($p\text{-value} = 0.605 \text{ NS}$). The mean CMS at 6 months for biological graft was 91.06 ± 6.787 . For the Fiber Wire group, the mean CMS at 6 months is 85.94 ± 6.971 ($p\text{-value} = 0.044$). The mean CMS at 12 months for biological graft was 95.25 ± 2.543 . For the Fiber Wire group, the mean CMS at 12 months is 92.50 ± 2.221 ($p\text{-value} = 0.003$). Jingwei et al. reported the average CMS score as 96.3 ± 1.73 , and out of a total of 26 patients, 8 patients showed full scores. Similarly, Mardani-Kivi et al. reported that the mean Constant score at 12 months was 91 ± 1 in the Ethibond suture group and 92 ± 1 in the semitendinosus autograft group ($p > 0.05$).

Conclusion

This study compares the efficacy of biological graft versus fiber wire in the treatment of acromioclavicular (AC) joint dislocation. Our findings indicate that while both treatment options are effective across different age groups, genders, and occupations, the biological graft group demonstrated a significantly longer mean duration of surgery but better long-term functional outcomes, as evidenced by higher postoperative CMS scores at six and twelve months. Despite the longer surgical time, the biological graft group showed better results in terms of shoulder function.

Additionally, the study highlighted that most patients in both treatment groups experienced no complications, with a minimal incidence of subluxation and superficial infections. The comparison of hospital stay duration between the two groups revealed no significant difference, further supporting the overall comparability of the two treatments in terms of patient recovery. Overall, while both biological graft and fiber wire are viable options for AC joint dislocation, the

biological graft may offer enhanced long-term functional outcomes, making it a preferable choice.

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Research Article

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Functional Outcome of Biological Graft Versus Fiber Wire in Acromioclavicular Joint Dislocation: A Comparative Study

Authors: Dr Vipin Kumar Raghuvanshi¹, Dr Sandeep Bhrinde², Dr Shubham Nagdev³, Dr Abhishek Dhoke⁴, Dr Vinayak Mani Dabwadi⁵

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Abstract

PDF

Dr Vipin Kumar Raghuvanshi¹, Dr Sandeep Bhrinde², Dr Shubham Nagdev³, Dr Abhishek Dhoke⁴, Dr Vinayak Mani Dabwadi⁵

¹Senior Resident, Department of Orthopaedics, Dr. Lakshminarayana Pandey, Govt Medical College, Raipur, Madhya Pradesh, India

²Associate Professor, Department of Orthopaedics, RD Girdi Medical College, Ujjain, Madhya Pradesh, India

³Senior Resident, Department of Orthopaedics, RD Girdi Medical College, Ujjain, Madhya Pradesh, India

⁴Senior Resident, Department of Orthopaedics, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

⁵Senior Resident, Department of Orthopaedics, MCM Medical College, Indore, Madhya Pradesh, India

^{*}Corresponding Author: Dr. Sandeep Bhrinde, Associate Professor, Department of Orthopaedics, RD Girdi Medical College, Ujjain, Suras, Madhya Pradesh, India

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Abstract

Introduction: Acromioclavicular (AC) joint dislocation is a common shoulder injury, particularly affecting athletes and individuals engaged in physical labor. The injury often requires surgical intervention to restore joint stability and function. Two popular surgical options are the use of biological grafts and synthetic materials such as Fiber Wire for AC joint reconstruction. This comparative study aims to evaluate the efficacy, safety, and functional outcomes of biological grafts versus fiber wire in the treatment of AC joint dislocations.

Materials and Methods: This study included a sample of 32 patients diagnosed with AC joint dislocation, divided into two groups: those treated with

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(Approved under rule 122DD Drugs and Cosmetics Rule 1945, Central Drug Standard Control Organization (CDSCO), India Registration number - ECR/1030/Inst/MP/2018/RR-21)

(Registered with Biomedical and Health research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research, India)

Name of the Ethics Committee: IEC-RDGMIC

IEC Ref. No- PG/ORTHOPAEDICS/50

Title of the Research Project Proposal: "Clinical and function outcome of philos plating in proximal humerus fracture"

Principal Investigator: Dr. Abhishek Dhoke

Department: Orthopaedics

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The following item ☒ have been received and reviewed in connection with the above study to be conducted by the above investigator.

☒ Patient Information Sheet

☒ Study Protocol / Synopsis

☐ Summary of Change Document (in case of a revision)

☒ Patient Information Consent Form

And have been ☒

☒ Approved (subjected to acceptance of conditions laid by the IEC-RDGMIC on Page no. 2)

☐ Rejected (identify item and specify reasons below or in accompanying letter)

Comments: Applicant is advised to communicate Ethics Committee about any amendment(s), if done, in the protocol & progress of work every 3 months or earlier as per the project duration.

Date of Approval: 16/08/2022

Secretary

Dr. Ashish Pathak

Institutional Ethics Committee
R D Gardi Medical College
Ujjain, Madhya Pradesh, India

Secretary

Institutional Ethics Committee

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Conditions for undertaking research in the R.D. Gardi Medical College, Ujjain

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2. Certificate of trial registry will be submitted before data collection to the institutional ethics committee in case of any clinical trial issued by appropriate authorities.
3. All the expenses incurred in the study including screening /diagnosis/treatment /any procedure/documentation will be responsibility of the researcher and study participants will not bear any expenses.
4. In case of funded research work, ethics committee will not be responsible for settling disputes between the researcher and the funding agency.
5. Principal investigator is whole sole responsible for the research work from planning to publication. All the legal disputes will be settled by the principal investigator, their guides and head of the department of the concerned department.
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9. If any incidental diagnosis or untoward effect of any procedure is identified by the researcher it will be reported within 24 hours to the IEC and appropriate care and or compensation will be provided to the study participants. The responsibility to provide care and or compensation lies jointly with the researchers and the institution.
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Name of Principal Investigator Dr. Abhishek Dhoke signature Adhoke date 30/8/22



A Comparative Study of Functional and Clinical Outcome of Proximal Humerus Fracture Treated with PHILOS Plate

Dr. Abhishek Dhoke¹, Dr. Sandeep Bhide^{2*}, Dr. Vinayak Mani Dwivedi³, Dr. Shubham Nagdev⁴, Dr. Vipin Kumar Raghuvanshi⁵

Abstract

Introduction: Proximal humerus fractures (PHFs) are the predominant form of humeral fractures, encompassing a spectrum of injuries affecting the articulating surface, greater tuberosity, lesser tuberosity, or the surgical neck of the humerus. PHFs account for approximately 10% of fractures in patients aged over 65 years. The third most prevalent type of osteoporotic fractures are PHFs, with a lifetime risk of 13% for women aged 50 years and above.

Materials and Methods: As per study criteria 40 patients with fracture of shoulder was included in this study. After admission of patients a detailed, careful history was taken to know the mechanism of injury. Patient was assessed clinically to evaluate general condition; vitals were recorded and examination of fracture site was done. Radiological assessment was done and fracture was classified and preoperative routine haematological investigation was done.

Result: According to NEER's classification of fractures, 14 (34.41%) cases had two-part fractures, 19 (46.3%) cases had three-part fractures and 8 (19.5%) cases had four-part fractures. Excellent results (score > 89) were noticed in 27 (65.85%) of the instances, good results (scoring 80-89) in 10 (24.39%) and fair results (score 70-79) in 4 (9.75%)

Discussion and Conclusion: After a mean follow up of 12 months, the mean Constant score was 88.90 ± 7.31 we recommend the use of the PHILOS plate as a surgical alternative in the management of displaced proximal humeral fractures.

Keywords: Proximal humerus fracture; PHILOS plating; Osteoporotic fractures; Arthroplasty; Osteonecrosis

Introduction

Proximal humerus fractures (PHFs) are the predominant form of humeral fractures, encompassing a spectrum of injuries affecting the articulating surface, greater tuberosity, lesser tuberosity, or the surgical neck of the humerus [1]. PHFs account for approximately 10% of fractures in patients aged over 65 years [2,3]. The third most prevalent type of osteoporotic fractures are PHFs, with a lifetime risk of 13% for women aged 50 years and above [4,5]. Many treatment methods are available for these types of fractures such as locking plates, arthroplasty, cabling, and nailing [6]. Elderly patients with osteoporotic bone mostly benefit from arthroplasty, whereas younger patients are mainly treated through closed reduction and internal fixation with intramedullary nailing or open reduction and plate osteosynthesis to achieve

Affiliation:

¹Senior Resident, Department of Orthopaedics, Shyam Shah Medical College, Rewa, Madhya Pradesh, India

²Associate Professor, Department of Orthopaedics, RD Gardi Medical College, Ujjain, Madhya Pradesh, India

³Senior Resident, Department of Orthopaedics, MGM Medical College, Indore, Madhya Pradesh, India

⁴Senior Resident, Department of Orthopaedics, RD Gardi Medical College, Ujjain, Madhya Pradesh, India

⁵Senior Resident, Department of Orthopaedics, Dr. Laxminarayan Panday, Govt Medical College, Ratlam, Madhya Pradesh, India

*Corresponding Author:

Dr. Sandeep Bhide, Associate Professor, Department of orthopaedics, R.D Gardi Medical College M.P. India.

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satisfactory function [7-11]. However, these modalities are associated with various complications such as implant failure, non or malunion, and osteonecrosis of the humeral head [6]. The PHILOS implant, with its anatomically analogous design, is the preferred choice for treating PHFs, as it facilitates angled stabilization and enhances the pull-out strength of osteoporotic bone, thereby improving its ability to withstand physiological loads [12]. This prospective study evaluated the effectiveness of the PHILOS plate in the surgical fixation of two, three- and four-part proximal humeral fractures.

Material and Method

Place and time of study: The study was conducted at the Department of Orthopaedics at R.D. Gardi Medical College, Ujjain. This study was completed within two years after receiving approval from the ethics committee.

Type of study: This is a prospective observational study.

Ethics: Approval from the institutional ethics committee was taken before start of the study. Written informed consent was obtained from all patients before enrolling them for the study.

Selection of patients

The patients admitted in the department of orthopaedics with displaced fracture of the proximal humerus were enrolled for this study as per the following exclusion and inclusion criteria.

Inclusion criteria

1. Displaced proximal humerus fracture by
2. Neer's classification.
3. Patients older than 18 years of age with proximal humerus fracture.
4. Patients willing for surgery.

Exclusion criteria

1. Non-displaced proximal humerus fracture.
2. Severely comminuted, open fractures and valgus impacted fractures.
3. A previous fracture to the proximal humerus, or patients presenting more than three weeks after the injury.
4. Pathological fracture from primary or metastatic tumours and skeletally immature patients.

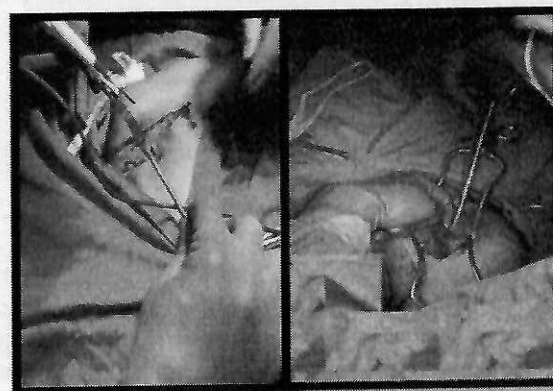
Method

As per study criteria, 40 patients with fracture of shoulder was included in this study. After admission of patients a detailed, careful history was taken to know the mechanism of injury. Patient was assessed clinically to evaluate general condition, vitals were recorded and examination of fracture site was done. Radiological assessment was done and fracture was classified and preoperative routine haematological investigation was done.

Surgical procedure

Deltopectoral approach used in all cases. Patient was placed in a supine position employing a deltopectoral approach. Locate the deltopectoral groove. "Initiate the incision just medial to the coracoid at the clavicle and extend it distally along the deltopectoral groove to the deltoid insertion, spanning approximately 15 cm. Develop skin flaps to expose the deep fascia. Use blunt scissors to open the fascia over the deltopectoral groove, ensuring to locate the cephalic vein. Bluntly develop the avascular interval between the deltoid and pectoralis major muscles. The vein can be ligated or retracted with the deltoid. For broader exposure, transecting the muscle origins from the coracoid can be considered. The osseous attachments of the rotator cuff are frequently displaced and require identification and retraction using sharp hook retractors. In cases of fracture-dislocation, reduction of the humeral head is achieved through closed manipulation without opening the joint capsule. K-wires were utilized for preliminary reduction, which was confirmed in both orthogonal views. The PHILOS plate was positioned 5-8 mm posterior to the bicipital groove and 2-4 mm distal to the greater tuberosity. Using the woodpecker technique, the plate was first fastened to the distal fragment, and screws were inserted into the head. An immediate check x-ray was obtained to evaluate the alignment of the bones and confirm that the reduction was ideal. Wound closure with drain beneath the deltoid muscle. Closure of anteromedial raphe, the subcutaneous tissues, and the skin. At the end of surgical procedure sterile dressings applied. No cast or splint was applied. Immediate post-operative x rays were taken in both AP and Lateral views. The patient was followed follow-up for 1 year after surgery and the constant score was used for functional assessment higher the score better was the outcome (Figure 1-9).

Intra OP Images



Incision

Deltopectoral groove

Figure 1: Shoulder Anterior (Deltopectoral) Approach.

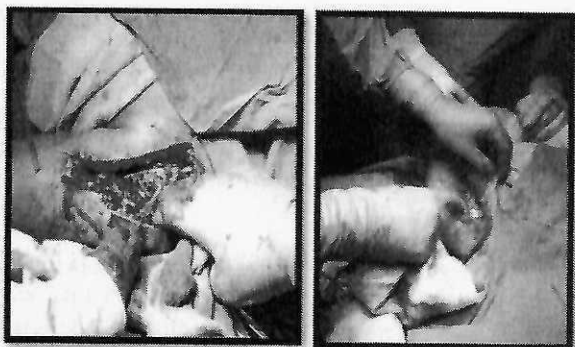


Figure 2: Philos plate fixation.



Figure 3: C- arm images.

Case 1:

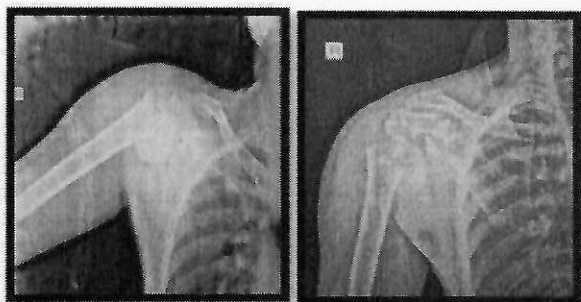


Figure 4: Pre OP x-ray.

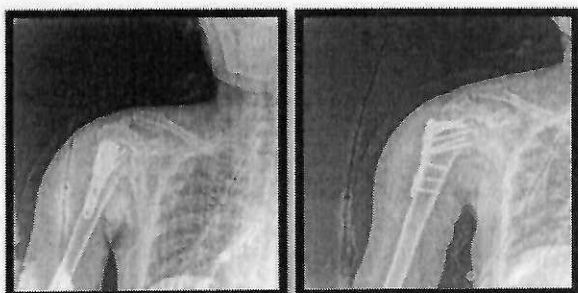


Figure 5: Post OP x-ray



Figure 6: Follow up after 12 months.

Case 2:

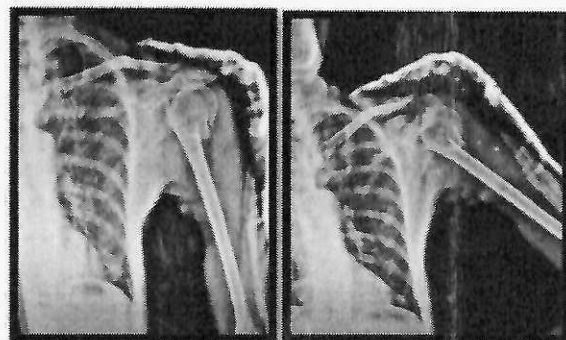


Figure 7: Pre OP x-ray

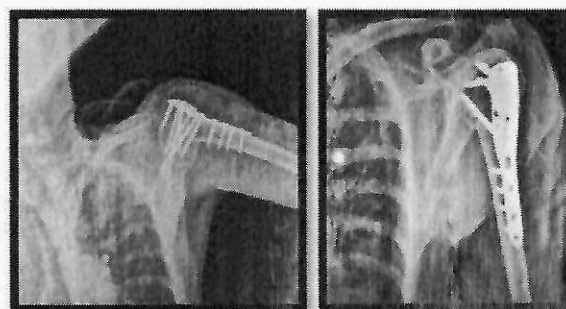


Figure 8: Post OP x-ray.

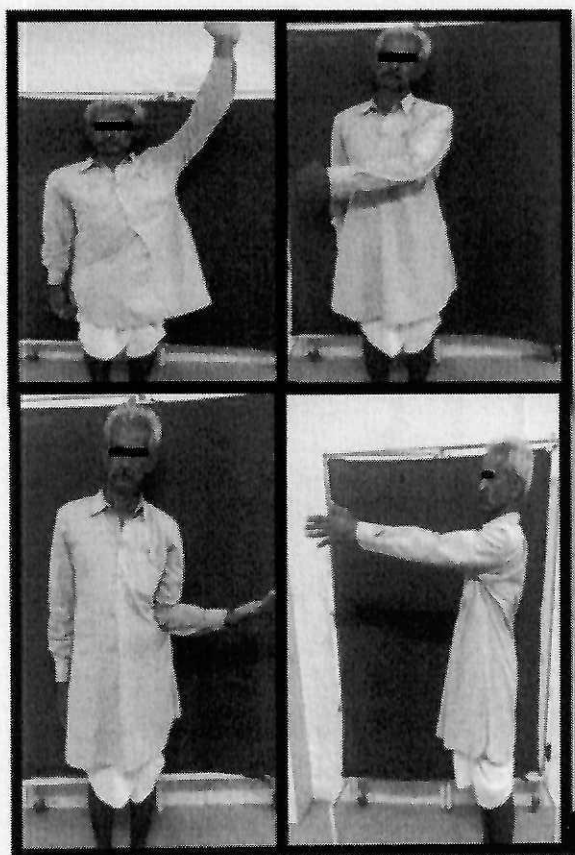


Figure 9: Follow up after 12 months.

Result

Table 1 represents the study subjects according to type of fracture, it was observed that a majority 46.3% study subjects had 3 part fracture followed by 34.1% having 2 part fracture and lastly only 19.5% had 4 part fracture.

Table 1: Distribution of study subjects according to Type of fracture.

Type of fracture	Number	Percentage
2 part	14	34.1
3 part	19	46.3
4 part	8	19.5
Total	41	100.0

Table 2 compares the overall CMS score among the study subjects at 3 months, 6 months and 12 months, it was observed that there was a significant difference in the overall CMS score at different time period. On comparing, pair wise it was observed that there was a significant increase in the CMS score from 3 months to 6 months, 3 months to 6 months as well as from 6 months to 12 months.

Table 2: Comparison of overall CMS Scores at 3, 6 and 12 months.

CMS score at	Mean	SD	Test statistic value	p-value*
months	74.66	3.94	59.663	<0.001(s)
months	84.2	5.52		
months	88.9	7.31		

Table 3 represents the study subjects according to months, outcome; it was observed that a majority 65.85% study subjects were in the excellent outcome closely followed by 24.39 % in good outcome lastly 9.75% in fair outcome.

Table 3: Distribution of study subjects according to outcome.

Outcome	Frequency	Percentage (%)
Excellent	27	65.85
Good	10	24.39
Fair	4	9.75
Total	41	100.00

Table 04 represents the study subject according to complication; it was observed that a majority 87.8% study subjects had no complications *Friedman's test however, 12.2% had some complication.

Table 4: Represents the study subjects according to complications,

Complications	No.	Percentage
Yes	5	12.2
No	36	87.8
Total	41	100.0

Discussion

In present study the mean age was 61.10 ± 8.01 at different time period. On comparing, pair wise, years. Of the total 41 cases of proximal humerus it was observed that there was a significant fractures. Out of 41 cases, 25(61.0%) were males increase in the CMS score from 3 months to 6 and 16(39.0%) were females. Patients suffering months, from 3 months to 12 months as well as from proximal humerus fractures arrived at our from 6 months to 12 months. Centres as they were part of motor vehicle injuries 27 (65.9%). this was followed by fall from height 14 (34.1%). According to NEER's classification of fractures, 14 (34.41%) cases had two-part fractures, 19 (46.3%) cases had three-part fractures and 8 (19.5%) cases had four-part fractures. Excellent results (score > 89) were noticed in 27 (65.85%) of the instances, good results (scoring 80-89) in 10 (24.39%) and fair results (score 70-79) in 4 (9.75%). After a mean follow up of 12 the mean Constant score was 88.90 ± 7.31 . In 86.8 % of cases, follow-up showed no complication, Shoulder stiffness was the most lastly 9.75% in fair outcome. frequent consequences, followed by

persistant pain, screw back out, wound dehiscence. results are comparable with those reported for the PHILOS plate. Ethiraj et al. [13] showed that mean forty patients was 46.8 (2070), with a female: male ratio of 1:2.3 [14].

In this study mean age of patients were 60.32 ± 9.34 years. There was female predominance [13]. The majority of patients were injured as a result of a traffic collision (70%), followed by a fall from a height (17.5%) and other reasons (12.5 %) [14]. Road traffic accident 26(65%) was a most common mode of injury, followed by fall from height 10 (25%) and trivial fall 4(10%) [15]. According to NEER's classification of fractures, 14 (56.33%) cases had two-part fractures, 19 (36.33%) cases had three-part fractures and 8 (19.5%) cases had four-part fractures [19]. According to NEER's classification of fractures, 46.88% (n=15) cases had two-part fractures, 37.49% (n=12) cases had three part fractures and 9.38% (n=3) cases had four-part fractures whereas 6.25% (n=2) cases. Frankhauser et al. [16] evaluated 29 proximal humeral fractures in 28 patients treated with the Locking Proximal Humerus Plate (LPHP). The mean Constant Murley score was 74.6 after 12 months [17]. In a series of 20 consecutive patients showed favourable early results with surgical treatment of proximal humeral fractures using the PHILOS plate. After a mean follow up of 16 months, the mean Constant score was 76.1. Hente et al. [18] studied 31 patients with displaced 3- and 4-part fractures of the proximal humerus treated with the PHILOS plate. After a mean follow-up of 18.5 months, the mean Constant score was 76 [14]. The constant score was excellent in 20 (50%) patients; it was good in 18(45%) patients and fair in 2(5%) patients. The mean of the constant score was 88.64 ± 8.42 , maximum value was 100 and minimum value was 72 [19]. According to NEER's classification of fractures, 6.25% of cases in our study showed fracture dislocation, whereas 46.88% of cases had two-part fractures, 37.49% had three-part fractures, and 9.38% had four-part fractures. The mean Constant-Murley score at the end of the follow-up period in this study was 85.8 [20]. Of 28 fractures, 20 (71.4%) healed in good anatomical position. At the end of the follow up period, the mean Constant Murley score was 57.9 ± 21.7 , and the mean adjusted Constant-Murley score was 67.5 ± 23.6 . The results were excellent or good in 16 patients (57.1%), moderate in one patient (3.6%), and poor in 11 patients (39.3%) [13]. The functional outcome was excellent in 2 patients (5%), good in 22 patients (55%), fair in 7 patients (17.5%), and poor in 9 patients (22.5%). The Constant mean score achieved was 68.75 ± 14.03 . Mootha et al. [2021] regarding complications of surgery, postoperative infection was found in 2(5%) patients, stiffness of the shoulder was present in 2(5%) patients, one patient developed malunion and Osteonecrosis was present in one patient. Egol et al. [21] studied a cohort of 51 patients treated with PHILOS® plates, reporting that 24% of patients

experienced postoperative complications. The most frequent complications observed were screw penetration (16%), osteonecrosis (3.9%), nonunion (3.9%), and infection (2.0%).

Conclusion

PHILOS plate offers the advantage of providing a high degree of angular and axial stability. The convergent and divergent arrangement of the locking screws engaging in the humeral head prevents pull out and failure of fixation. It facilitates early mobilization, yielding excellent radiographic and functional results that enable patients to regain good shoulder function and return to work sooner. Considering these factors, we recommend the use of the PHILOS plate as a surgical alternative in the management of displaced proximal humeral fractures.

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A Comparative Study of Functional and Clinical Outcome of Proximal Humerus Fracture Treated with PHILOS Plate

Authors: Dr. Abhishek Dhole, Dr. Sandeep Bhide, Dr. Vinayak Mani Dwivedi, Dr. Shubham Nagdev, Dr. Vipin Kumar Raghuwanshi

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Full Text

Abstract

Introduction: Proximal humerus fractures (PHFs) are the predominant form of humeral fractures, encompassing a spectrum of injuries affecting the articulating surface, greater tuberosity, lesser tuberosity, or the surgical neck of the humerus. PHFs account for approximately 10% of fractures in patients aged over 65 years. The third most prevalent type of osteoporotic fractures are PHFs, with a lifetime risk of 13% for women aged 50 years and above.

Materials and Methods: As per study criteria 40 patients with fracture of shoulder was included in this study. After admission of patients a detailed, careful history was taken to know the mechanism of injury. Patient was assessed clinically to evaluate general condition; vitals were recorded and examination of fracture site was done. Radiological assessment was done and fracture was classified and preoperative routine haematological investigation was done.

Result: According to NEER's classification of fractures, 14 (34.41%) cases had two-part fractures, 10 (46.3%) cases had three-part fractures and 8 (19.5%) cases had four-part fractures. Excellent results (score > 89) were noticed in 27 (65.85%) of the instances, good results (scoring 80-89) in 10 (24.39%) and fair results (score 70-79) in 4 (9.75%).

Discussion and Conclusion: After a mean follow up of 12 months, the mean Constant score was 88.90 ± 7.31 we recommend the use of the PHILOS plate as a surgical alternative in the management of displaced proximal humeral fractures.

Keywords

Proximal humerus fracture

PHILOS plating

Osteoporotic fractures

Arthroplasty

Osteonecrosis

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Name of the Ethics Committee: IEC-RDGMC

IEC Ref. No- PG/ORTHOPAEDICS/51

Title of the Research Project Proposal: "Cemented versus uncemented bipolar hemiarthroplasty for femoral neck fractures in the elderly"

Principal Investigator: Dr. Shubham Nagdev

Department: Orthopaedics

FOR OFFICIAL USE

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

[✓] Patient Information Sheet

[✓] Study Protocol / Synopsis

[x] Summary of Change Document (in case of a revision)

[✓] Patient Information Consent Form

And have been [✓]

[✓] Approved (subjected to acceptance of conditions laid by the IEC-RDGMC on Page no. 2)

[x] Rejected (identify item and specify reasons below or in accompanying letter)

Comments: Applicant is advised to communicate Ethics Committee about any amendment(s), if done, in the protocol & progress of work every 3 months or earlier as per the project duration.

Date of Approval: 16/08/2022


Dr. Ashish Pathak

Secretary

Institutional Ethics Committee

R D Gardi Medical College, Ujjain

Secretary
Institutional Ethics Committee
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5. Principal investigator is whole sole responsible for the research work from planning to publication. All the legal disputes will be settled by the principal investigator, their guides and head of the department of the concerned department.
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8. Approval by institutional Ethics committee (IEC) is mandatory before starting data collection. Researcher will maintain confidentiality of patient's identity and records.
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I Dr. SHUBHAM NAGDEV Department of ORTHOPAEDICS accept all the conditions Mentioned above and declare that If any plagiarism/copyright violation/violation of ethics committee's conditions is reported anytime during and or after the study, that will result in automatic cancellation of the ethical approval by the institutional ethics committee of R.D. Gardi Medical College, Ujjain.

Name of Principal Investigator SHUBHAM NAGDEV signature [Signature] date 29/8/22

[Faint circular stamp of the Institutional Ethics Committee, R.D. Gardi Medical College, Ujjain]



Cemented Versus Uncemented Bipolar Hemiarthroplasty For Femoral Neck Fractures In Elderly

Dr. Shubham Nagdev¹, Dr. Sandeep Bhide², Dr. Vipin Kumar Raghuwanshi³,
 Dr. Vivek Singh⁴, Dr. Abhishek Dhoke⁵

^{1,3,5}Senior Resident, ²Associate Professor, ⁴Professor & Head,
 Department of orthopaedics,

^{1,2,3,4}R.D Gardi Medical College, Ujjain, M.P., India

⁵Shyam Shah Medical college, Rewa, M.P., India

***Corresponding Author:**

Dr. Sandeep Bhide

Associate Professor, Department of Orthopaedics

R.D Gardi Medical College, Ujjain, M.P., India

Type of Publication: Original Research Paper

Conflicts of Interest: Nil

Abstract

Introduction: Femoral neck fracture in the elderly represent a significant clinical concern, often requiring surgical intervention to enhance mobility and manage pain. Bipolar hemiarthroplasty is a prevalent surgical approach for addressing these fractures, and it can be performed with either cemented or uncemented fixation methods. This study aims to assess and compare the clinical outcomes, functional recovery, and complication rate between cemented and uncemented bipolar hemiarthroplasties in elderly patients.

Material and methods: Prospective comparative review was conducted involving 44 elderly patients who had undergone Bipolar hemiarthroplasty for femoral neck fracture. the participants were categorized into two groups viz cemented or uncemented. 22 patients treated with cemented Bipolar hemiarthroplasty, while the remaining 22 underwent uncemented Bipolar hemiarthroplasty. Key metrics such as surgical duration, blood loss during surgery, intraoperative complication, mobilization, postoperative complications, and functional recovery (measured using the Harris Hip Score), were analyzed over a 6-month follow-up period.

Results: Both cemented and uncemented Bipolar hemiarthroplasties resulted in notable improvements in hip function and pain management. Cemented group had better results in term of hospital stay, early mobilization, and functional outcome as evaluated by Harris Hip Score. The uncemented group demonstrated advantages in terms of shorter surgical times and reduced intraoperative blood loss compared to cemented group. Rates of postoperative complication, including infections and dislocation, were similar across both groups.

Conclusion: Both cemented and uncemented Bipolar hemiarthroplasties are effective in treating femoral neck fracture in the elderly, offering substantial pain relief and functional improvement. The cemented approach showed a slight benefit in terms of operational efficiency. The selection of fixation technique should be guided by individual patients' factors, such as bone quality and surgical preferences.

Keywords:

Introduction

Femoral neck fractures are prevalent among elderly patients (aged 65 years and above). It presents significant challenges in the elderly population, including heightened mortality rates, diminished

mobility, and increased healthcare expenditure. 1.2 Proximal femoral fractures in younger individuals are primarily associated with high-energy trauma, disproportionately in the elderly often resulting from

low-energy falls. In elderly patients, factors such as advanced age, female gender, lower BMI, osteoporosis, longer thigh length, and reduced average circumference are risk factors.(1) Hemiarthroplasty, with or without bone cement, is a commonly utilized surgical

approach for treating femoral neck fractures in elderly patients. Unipolar hemiarthroplasty and bipolar hemiarthroplasty are the two options for surgical management(2). In clinical practice, bipolar hemiarthroplasty is often favored over unipolar hemiarthroplasty due to its ability to improve intra-articular mobility and reduce relative movement between the prosthesis and acetabular cartilage and subchondral bone, potentially leading to increased longevity of the prosthesis. Despite the benefits of bipolar hemiarthroplasty, debate persists regarding the optimal choice between cemented and uncemented techniques for elderly patients. (3)Cemented bipolar hemiarthroplasty offers enhanced implant fixation, reduced implant-related complications, and improved functional outcomes. Uncemented bipolar hemiarthroplasty offers several advantages over its cemented counterpart. Notably, it is associated with shorter operation durations and reduced blood loss, thereby avoiding bone cement implantation syndrome (BCIS)(8). The purpose of this study is to evaluate the clinical and functional outcomes of elderly patients affected by femoral neck fractures and treated with cemented and uncemented bipolar hemiarthroplasty.(4)

Materials And Method

This prospective comparative study includes patients admitted to the orthopedics department at RDGMC,

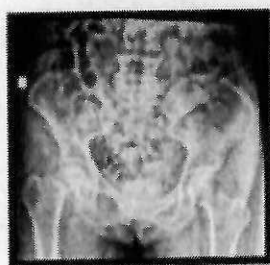
Ujjain, M.P., during the year July 2022-July 2024. In this study 44 cases of fractured neck femur were taken into account of those who underwent bipolar hemiarthroplasty and were divided into two groups, cemented and uncemented, based on fixation method. The aim of this study is to compare the effectiveness and safety of two surgical modalities (cemented and uncemented bipolar hemiarthroplasty) in the treatment of femoral neck fractures in elderly patients.

The primary objective of this study is to evaluate the clinical and functional outcomes between cemented and uncemented bipolar hemiarthroplasty in terms of improvement in ambulatory status of patients at variable periods, range of motion, and return to daily life activities.

Secondary objectives include identifying differences in outcomes between the two groups regarding blood loss, operative time, duration of hospital stay, dislocation rates, rate of reoperation, postoperative complications, and mortality rate. The outcome after surgery was assessed by the Harris Hip Score (HHS)(5).

Inclusion criteria were patients with fracture of the neck of the femur, elderly patients aged 65 years and above, patients with failed internal fixation, patients who were medically fit for surgery, and patients with both recent and old fractures. Exclusion criteria involve patients below 65 years of age; patients with arthritic changes involving the acetabulum; non-ambulatory patients prior to injury; patients with pre-existing joint pathologies like avascular necrosis of the femoral head, rheumatoid arthritis, and infection; and patients unwilling to undergo surgery.

A Case Of Cementer Bipolar Hemiarthroplasty



(A)



(B)



(C)



(D)

Results

The study included two groups, the cemented group and the uncemented group, each consisting of 22 patients, which accounted for 50% of the total population per group. In the cemented group, the mean age was 72.50 ± 6.70 years. In the uncemented group, the mean age was 73.96 ± 7.49 years. The gender distribution in the cemented group was 11 females (50%) and 11 males (50%), while in the uncemented group, there were 8 females (36.4%) and 14 males (63.6%), which was comparable.

In terms of intraoperative skin incision length, the cemented group had a mean of 11.77 ± 1.72 cm, while the uncemented group had a mean of 12.05 ± 1.56 cm.

Comparison of duration of surgery between the two groups. The mean duration of surgery in the cemented group was 1.81 ± 0.32 hours, while in the uncemented group, it was 1.23 ± 0.42 hours. The difference was found to be statistically significant ($P=0.001$). The mean duration of surgery was much longer in the cemented group compared to the uncemented group. The comparison of blood loss between the two groups. The mean blood loss in the cemented group was 122.73 ± 29.79 ml, while in the uncemented group, it

was 86.36 ± 44.14 ml. The difference was found to be statistically significant ($P=0.003$). Higher blood loss was seen in the cemented group compared to the uncemented group.

The comparison of intraoperative complications between the two groups. In the cemented group, bone cement implantation syndrome was seen in 1 (4.5%) patient. In the uncemented group, fracture of the proximal femur was seen in 1 (4.5%) patient.

The mean duration of hospital stay in the cemented group was 7.36 ± 2.01 days, while in the uncemented group, it was 9.68 ± 3.82 days. The difference was found to be statistically significant ($P=0.016$). The mean duration of hospital stay was significantly longer in the uncemented group compared to the cemented group.

The comparison of postoperative weight bearing started between the two groups. Postoperatively, weight bearing was started in the cemented group by 1.64 ± 1.05 days, while in the uncemented group, it was started on 7.55 ± 6.01 days. The difference was found to be statistically significant ($P=0.001$). The weight-bearing uncemented group was started late compared to the cemented group.

The above table shows the comparison of mean Harris Hip Score between the two groups at different time points.

Time point	Group-A (Cemented)	Group-B (Uncemented)	t value Df	P value
Preoperative	11.36 ± 5.49	11.82 ± 5.74	-0.268, df=42	0.790, NS
At 1 month	56.59 ± 3.35	47.55 ± 5.66	6.449, df=42	0.001*
At 3 months	79.64 ± 1.81	75.41 ± 7.97	2.425, df=42	0.020*
At 6 months	90.96 ± 1.81	86.09 ± 7.26	3.050, df=42	0.004*

Preoperative: The mean Harris Hip score in cemented group was 11.36 ± 5.49 and in uncemented group, it was 11.82 ± 5.74 .

At 1 month: The mean Harris Hip score in cemented group was 56.59 ± 3.35 and in uncemented group, it was 47.55 ± 5.66 . The difference was found to be statistically significant ($P=0.001$). The mean Harris Hip score was significantly higher in cemented group compared to uncemented group.

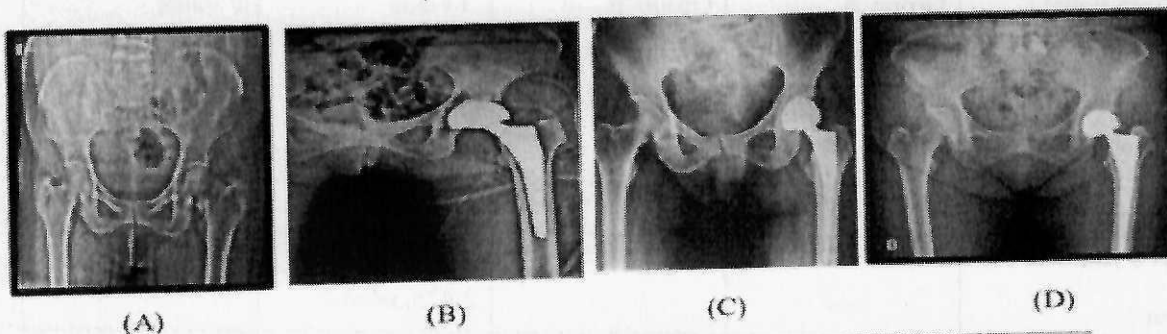
At 3 months: The mean Harris Hip score in cemented group was 79.64 ± 1.81 and in uncemented group, it was 75.41 ± 7.97 . The difference was found to be statistically significant ($P=0.020$). The mean Harris Hip score was significantly higher in cemented group compared to uncemented group.

At 6 months: The mean Harris Hip score in cemented group was 90.96 ± 1.81 and in uncemented group, it was 86.09 ± 7.26 . The difference was found to be statistically significant ($P=0.004$). The mean Harris Hip score was significantly higher in cemented group compared to uncemented group. At all the postoperative time points, the mean Harris Hip score was significantly higher in cemented group compared to uncemented group.

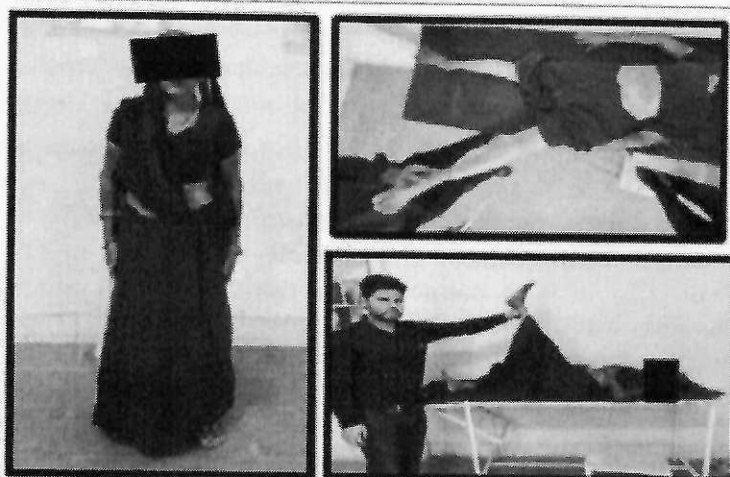
The postoperative complications between the two groups, **cemented group:** Foot drop was noted in 1 (4.5%) patient and superficial infection was seen in 1 (4.5%) patient

uncemented group: Aseptic implant loosening was seen in 1 (4.5%) patient and superficial infection was seen in 1 (4.5%) patient.

A CASE OF UNCEMENTED HEMIARTHROPLASTY



- (A) Preop x-ray PBH-AP view of left fracture neck of femur
 (B) Immediate Postop x-ray PBH-AP View showing prosthesis in situ.
 (C) Postop x-ray PBH-AP View 3 month,
 (D) 6 months follow up sequentially.



DISCUSSION

Our study involved 44 patients, equally divided into a cemented group and an uncemented group. In our study, the age distribution revealed that most patients fell within the 65 to 80-year age bracket, with similar mean ages observed in both groups (72.50 ± 6.70 years in the cemented group and 73.96 ± 7.49 years in the uncemented group, $P=0.501$). In a prospective study, Khorami et al.(6) (2016) ($n=51$) compared cemented versus uncemented hemiarthroplasty in patients with displaced femoral neck fractures and found insignificant differences in the ages of patients between the uncemented (mean age 71.7 years, range 65-76) and cemented groups (mean age 79 years, range 70-92) ($p = 0.45$). Pawar et al.(7)(2019) also reported the mean age of the patients was 75 (68-88) years in the cemented group ($n=55$) and 72.7 (65-78) years in the uncemented group ($n=35$). In a retrospective study, Choi et al. (8)(2016) reported the mean age of patients who underwent cemented hemiarthroplasty ($n = 115$) was 77 years, while for those who underwent uncemented hemiarthroplasty ($n = 65$), it was 76 years, with no significant difference between the two groups ($p = 0.51$). Similarly, a study conducted by Patil et al.(9) (2020) reported the mean age in the cemented group ($n=60$) was 69.8 ± 3.21 , and the uncemented group ($n=60$) was 69.6 ± 3.26 , and Çankaya et al.(10) (2013) reported a mean age of 78 ± 7.11 in the cemented group ($n=40$) and 76 ± 7.52 in the uncemented group ($n=46$). Our study aligns with those conducted by Khorami et al., Pawar et al., Choi et al., Patil et al., and Çankaya et al. Gender distribution in the cemented group was 11 females

(50%) and 11 males (50%), while in the uncemented group, there were 8 females (36.4%) and 14 males (63.6%), which was comparable ($P=0.361$). Movrin et al.(11)(2020) reported 33 males and 46 females in the cemented group.

($n=79$) and 31 males and 48 females in the uncemented group ($n=79$) ($P = 0.86$). Patil et al.(9) (2020) reported female preponderance: 27 males and 33 females in the cemented group ($n=60$) compared to 25 males and 35 females in the uncemented group ($n=60$) ($P = 0.713$). Similarly, Çankaya et al.(10) (2013) reported 10 males and 36 females in the cemented group ($n=40$) versus eight males and 32 females in the uncemented group ($n=46$) ($P = 0.843$). These results collectively exhibited insignificant gender distribution differences between the two groups across the studies.

In our study of the mode of injury in the cemented group, falling on the ground was reported by 14 (63.6%) patients, and road traffic accidents by 8 (36.4%) patients. In the uncemented group, falling on the ground was reported by 13 (59.1%) patients, and road traffic accidents by 9 (40.9%) patients. There was no statistically significant association between mode of injury and the groups ($P=0.757$). Similarly, Raj et al.(12) (2022) reported that accidental falls were the most common mechanism of injury in the cemented group ($n=20$), involving 65% of patients, while in the uncemented group ($n=20$), road traffic accidents (RTA) were the most common mechanism, involving 55% of patients, with no significant difference between the two groups. Mohabey et al.(13) (2017)

(cemented group, $n=20$, and uncemented group, $n=20$) reported that 97.5% of femoral neck fractures were due to minimal trauma, typically from slipping and falling on flat ground or in the bathroom, while only one case resulted from a road traffic accident.

The cemented group had a mean duration of surgery of 1.81 ± 0.32 hours, and the uncemented group had a mean duration of surgery of 1.23 ± 0.42 hours, indicating that the surgery duration was longer in the cemented group compared to the uncemented group ($P=0.001$). In a systematic review and meta-analysis, Li *et al.*(14) (2020) (782 uncemented and 795 cemented) found that cemented hemiarthroplasty had a significantly longer operation time compared to uncemented hemiarthroplasty across eight randomized controlled trials involving 1587 patients (OR = -7.30, 95% CI, -13.13, -1.46; $P = .01$). Santini *et al.*(15)(2005) ($n=53$, cemented and $n=53$, cementless) reported that the duration of operation was significantly less in the cementless group compared to the cemented group (56.98 ± 55.00 minutes vs. 75.00 ± 22.43 minutes, respectively; $p<0.001$). Also, Figved *et al.*(16) (2009) ($n=112$, cemented and $n=108$, cementless) demonstrated that the duration of surgery was significantly shorter in the uncemented group compared to the cemented group (70.2 minutes vs. 82.6 minutes, respectively; mean difference 12.4 minutes, 95% CI 7.2–17.6; $p<0.001$). In a prospective study, Khorami *et al.*9 (2016) ($n=51$) observed that the operative time was significantly shorter in the uncemented group compared to the cemented group (75 minutes vs. 95 minutes, respectively; $p = 0.001$). A meta-analysis of Lin *et al.*(17) (2019) showed shorter operation time in uncemented hemiarthroplasty than in cemented hemiarthroplasty (WMD = 8.22 min, 95% CI, 5.57–10.86 min; $P < .00001$). Our study corroborates previous findings, including those by Li *et al.*, Santini *et al.*, Figved *et al.*, Khorami *et al.*, and Lin *et al.*, showing shorter surgery durations in cementless compared to cemented procedures.

In our study, patients in the cemented group exhibited significantly higher blood loss, with a mean of 122.73 ± 29.79 ml, compared to the uncemented group, with a mean of 86.36 ± 44.14 ml ($P=0.003$). A follow-up study by Wang *et al.*(18) (2021) [cemented group ($n = 105$) and uncemented group ($n = 51$)] revealed that the uncemented group had significantly less intraoperative blood loss, with average intraoperative

blood loss reported as 299.0 ± 133.2 mL in the uncemented group compared with 370.1 ± 171.2 mL in the cemented group ($p = 0.01$).

In a meta-analysis, Elmenshawy *et al.*(2021) reported that among thirteen studies comprising 1561 bipolar hemiarthroplasties (770 cemented and 791 uncemented), uncemented hemiarthroplasty (288 ml) was associated with significantly lower blood loss compared to cemented hemiarthroplasty (362 ml) ($p < 0.0001$). In another meta-analysis, Fu *et al.*²² (2023) ($n=33,127$) demonstrated that intraoperative blood loss was significantly lower in the uncemented bipolar hemiarthroplasty group compared to the cemented group, with a weighted mean difference (WMD) of 80.57 ml (95% CI: 61.14-99.99, $P < 0.00001$) and no evidence of heterogeneity ($I^2 = 0\%$, $P = 0.89$). In conclusion, the blood loss in cemented was significantly higher compared to the uncemented bipolar hemiarthroplasty. In a systematic review, Ahn *et al.*(19)(2008) reported a significantly higher weighted average blood loss of 476 mL in the cemented group ($n=1632$) compared to 338 mL in the uncemented group ($n=981$) ($p<0.001$).

In terms of intraoperative complications, one complication was observed in both the cemented and uncemented groups. There was an insignificant association between the complications and the groups ($P=0.368$), indicating comparable intraoperative complications between the groups. Fu *et al.*(22) (2023) reported elderly patients over 60 years old with femoral neck fractures ($n = 33,127$) who underwent cemented bipolar hemiarthroplasty showed a lower incidence of intraoperative fractures. Also, Elmenshawy *et al.*(2021) reported that among thirteen studies comprising 1561 bipolar hemiarthroplasties (770 cemented and 791 uncemented), uncemented hemiarthroplasty was associated with significantly less infection ($p = 0.03$) and lower risk of heterotopic ossification ($p = 0.007$). Our study correlates with other studies and indicates no significant differences in the intraoperative complications.

In our study, the duration of hospital stay was also compared. The cemented group had a mean duration of 7.36 ± 2.01 days, while the uncemented group had a mean duration of 9.68 ± 3.82 days. There was a significant difference ($P=0.016$), indicating a more extended hospital stay in the uncemented group compared to the cemented group. Conversely, there

are many studies that demonstrated no significant difference between the groups with respect to length of hospital stay. In a meta-analysis, Elmenshawy et al. (2021) reported the average hospital stay for the cemented group (n=770) was 16.27 days, and in the uncemented group (n=791), it was 16.17 days, which was an insignificant difference between the groups ($p = 0.27$). Figved et al.(16)(2009) observed no significant difference in hospital stay duration, with the cemented group (n=112) staying 7.8 ± 4.11 days and the uncemented group (n=108) staying

8.4 ± 9.02 days ($P = 0.52$). Chaurasia et al.(20) (2018) reported no significant difference in hospital stay duration between the cemented group (n=26) (12 ± 2.31 days) and the uncemented group (n=28) (13 ± 3.17 days), with a P value of 0.67. Khorami et al.(6) (2016) (n=51) found no significant difference in hospital stay duration between the cemented group (11 ± 3.46 days) and the uncemented group (10 ± 3.17 days), with a P value of 0.67. Çankaya et al.(10)(2013) reported no significant difference in hospital stay duration between the cemented group (n=40) (9.10 ± 2.34 days) and the uncemented group (n=46) (9.80 ± 2.45 days), with a P value of 0.195.

In our study of the cemented group, a 1.5 cm limb length discrepancy was seen in 2 (9.1%) patients. In the uncemented group, 1 to 2 cm limb length discrepancy was seen in 4 (18.2%) patients. There was no statistically significant association between the postoperative limb length discrepancy and the groups ($P=0.380$). Prashanth et al.(21) (2017) found no changes in limb lengths in both groups; however, two patients in the cemented group (n=24) and four patients in the uncemented group (n=28) exhibited shortening of 1.5 cm. Raj et al. (12)(2022) reported no statistically significant difference between the two groups regarding leg length deformity ($p=0.164$), with only two patients presenting with 0.5 cm and 1.0 cm leg length deformity, respectively.

In our study, postoperative weight-bearing was started in the cemented group by 1.64 ± 1.05 days, while in the uncemented group, it was started on 7.55 ± 6.01 days. The difference was found to be statistically significant ($P=0.001$). Similarly, Elhadi et al.(22) (2019) revealed that out of 60 patients who were treated with cemented bipolar hemiarthroplasty, 93.3% of patients started partial weight-bearing on the 1st postoperative day, indicating positive early

mobilization. In a prospective study, Rai et al. (12)(2017) demonstrated increased walking ability in the cemented group (n=24) as compared to the cementless group (n=24) in the early follow-up period. Similarly, Parker et al.(23) (2010) (n = 200 cemented and n = 200 uncemented) reported mobility was better regained in those treated with cemented bipolar hemiarthroplasty ($p = 0.005$) at six months post-operation.

In our study, we have used the Harris Hip Score (HHS) to evaluate functional outcomes. With mean HHS being statistically insignificant between the groups ($P=0.871$). Both groups showed comparable functional results. The Harris Hip Scores were preoperatively similar between the groups: cemented group = 11.36 ± 5.49 and uncemented = 11.82 ± 5.74 ($P = 0.790$). However, at postoperative time points (1 month, 3 months, and 6 months), the Harris Hip score was significantly higher in the cemented group (1 month: 56.59 ± 3.35 , 3 months: 79.64 ± 1.81 , and 6 months: 90.96 ± 1.81) compared to the uncemented group (1 month: 47.55 ± 5.66 , 3 months: 75.41 ± 7.97 , and 6 months: 86.09 ± 7.26) ($P=0.001$, $P=0.020$, $P=0.004$, respectively). Inngul et al.(24) (2015) reported significantly better mean HHS in the cemented group (n = 67) (78 ± 14) compared to the uncemented group (n = 74) (70.7 ± 14.6) at 4 months, but at 12 months, they found no statistically significant difference between the groups. Patil et al.(9) (2020) reported

Harris Hip scores showed no significant difference between cemented (n=60) and uncemented (n=60) hemiarthroplasty at 3 and 6 months, but at 12 months, cemented hemiarthroplasty had significantly higher scores ($p=0.033$). Another study, Prashanth et al.(21)(2017), compared cemented (n=24) and uncemented (n=24) hemiarthroplasty in terms of HHS at 3, 6, and 12 months and reported statistically insignificant differences. In our study, we observed a statistically significant improvement of HHS at every interval in a cemented group compared to the uncemented group.

In our study, postoperative complication rates were similar across the two groups and included slight rates of foot drop, superficial infection, limb length disparity, and aseptic prosthesis loosening. The cemented group had one incidence of foot drop (sciatic nerve neuropraxia) and one case of superficial

infection. The uncemented group experienced one instance of aseptic prosthesis loosening and one case of superficial infection. Both groups experienced 2 (9%) postoperative complications, indicating comparable postoperative complications between the groups. In contrast, Choi *et al.* (8) (2016) observed that the patients in the cemented group ($n=115$) had a significantly lower rate of complications (postoperative infection, $P=0.04$) compared to the cementless group patients ($n=65$). In a meta-analysis, Elmenshawy *et al.* (2021) reported patients with cemented hemiarthroplasty suffered significantly less postoperative thigh pain than those with cementless implantation ($p < 0.00001$). Azegami *et al.* (25) (2011) ($n=1169$) demonstrated supportive evidence that using cement during hemiarthroplasty can reduce residual hip pain and allow better restoration of function. Similarly, Li *et al.* (14) (2013) revealed that patients with cemented stems had better postoperative clinical outcomes. They had no difference in major postoperative complications compared with patients with cementless stems. Our study results align with previous studies' findings of Choi *et al.*, Elmenshawy *et al.*, Azegami *et al.*, and Li *et al.*, showing no significant association between the complications and the two groups.

Conclusion

This study compared cemented (Group A) and uncemented (Group B) bipolar hemiarthroplasty, revealing significant differences in surgical and functional outcomes. Patients in the cemented group demonstrated significantly better functional outcome, shorter hospital stays and earlier initiation of weight bearing compared to the uncemented group. While in patients in the uncemented group demonstrated significantly shorter surgery durations, and reduced intraoperative blood loss compared to the cemented group. Furthermore, patients in the cemented group achieved clinically significant improvement in the Harris Hip Scores at key postoperative intervals: 1 month ($P=0.001$), three months ($P=0.020$), and six months ($P=0.004$). These findings indicated superior functional recovery and better patient-reported outcomes over time compared to Uncemented group. However, demographic characteristics, comorbidities, modes of injury, and complication rates were comparable between the groups, preventing the study from bias outcomes. Thus, through this study we can conclude that the cemented bipolar hemiarthroplasty is

a better modality in terms of hospital stay, early mobilization and functional outcome when compared with uncemented bipolar hemiarthroplasty. However, Uncemented group had its own advantages like shorter operative time, less blood loss and no complications related to cement.

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No. IEC. 13

Date: 19-07-16

Institutional Ethics Committee (Human Studies)

CERTIFICATE

This is to certify that the project No.10 entitled " Comparative evaluation of propofol, Etomidate, and propofol etomidate admixture at induction characteristics during general anaesthesia ."submitted by *Dr. Sunita Alawa P.G. Student Anaesthesia Batch 2015* ., under guidance of *Dr. Awtar Singh Yadav Asso. Prof. Anaesthesia and Co-guide Dr. Subhashchandra Agrwal Assistant Prof Anaesthesia* has been approved by the Institute Ethics Committee/Sub- Committee (Human Studies). at its meeting held on 25-02-2016, under the following terms and conditions.

This approval is valid for three years or the duration of the project whichever less is.

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Institutional Ethical Committee
S.S. Medical College, Rewa (M.P.)

Member Secretary

Chairman
Institutional Ethical Committee
S.S. Medical College, Rewa (M.P.)

Chairman

Institute Ethics Committee (Human studies) SSMC, Rewa

A Comparative Study between Propofol and Etomidate for Induction During General Anaesthesia

¹Dr. Sunita Alawa, Assistant Professor, Department of Anaesthesiology, R.D Gardi Medical College Ujjain (M.P.)

²Dr. Sandeep Bhinde, Associate Professor, Department of Orthopedics, R.D. Gardi Medical, College, Ujjain (M.P.)

Corresponding Author: Dr. Sunita Alawa, Assistant Professor, Department of Anaesthesiology, R.D Gardi Medical College Ujjain (M.P.)

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Abstract

Background: Propofol and Etomidate are non-barbiturate inducing agents. These drugs have different induction characteristics and recovery profiles. Propofol causes pain at the injection site, and hypotension but has clear-headed recovery whereas Etomidate is cardio-stable but can cause myoclonus.

Objective: The purpose of this study is to compare Propofol and Etomidate on induction characteristics i.e. loss of eyelash reflex, pain at the injection site, myoclonus, hemodynamic parameters and recovery profile.

Methods: 60 patients of ASA grade I and II, age group 18-55 years scheduled for the elective surgical procedure under general anaesthesia were randomly divided into two groups of 30 patients each. Patients in the group -I was induced with inj. Propofol (3mg/kg) i.v and patient of the group -II were induced with inj. Etomidate (0.3 mg/kg) i.v.

Onset time i.e. time to the disappearance of eyelash reflex, pain at the injection site and myoclonus, were noted. Continuous hemodynamic monitoring i.e. HR, SBP, DBP, MAP and recovery profile was done. All the results were tabulated and statistically analysed.

Result: Patients in the etomidate group showed little change in mean arterial pressure (MAP) and heart rate (HR) compared to propofol ($p > 0.05$) from baseline value. Pain on injection was higher in the propofol group while myoclonus activity was higher in the etomidate group.

Conclusion: This study concludes that etomidate is a better agent for induction than propofol because of hemodynamic stability and less pain on injection.

Keywords: Propofol, Etomidate, Mean arterial pressure; Heart rate; Pain; myoclonus; loss of eyelash reflex; recovery profile.

Introduction

Since the introduction of general anaesthesia, no ideal induction agent has yet been discovered in terms of providing stable haemodynamics during endotracheal intubation. All methods used for induction of anaesthesia, it is aimed to preserve the haemodynamic balance and to provide optimal conditions for the patient by reducing side effects.⁽¹⁾

Traditionally anaesthesia was induced by inhalational anaesthetic agents i.e. Ether and chloroform, later some other inhalation agents were also introduced i.e. Halothane, Isoflurane and Sevoflurane. Inhalational

agents have slower onset and longer residual effects .

Some cause irritation to respiratory mucosa, coughing, bronchospasm and marked haemodynamic changes.⁽²⁾

These effects can be overcome by using intravenous anaesthetic agents. The introduction of intravenous anaesthetic agents in the 1930s caused a major shift in the concept of anaesthesia by replacing the inhalation anaesthetic agents with intravenous anaesthetic agents.⁽³⁾

The Thiopentone sodium developed and researched by John Lundy and was clinically introduced in 1934 by Ralph M. Water at the University of Wisconsin Medical School (Madison, USA) was the first licensed intravenous anaesthetic induction agent used for induction of anaesthesia.⁽⁴⁾

Thiopentone sodium was the leading inducing agent of choice for the next 50 years. It causes bronchospasm and apnea. For these reasons, Thiopental is less commonly used nowadays.

Gradually newer intravenous anaesthetic induction agents were introduced such as Ketamine, Propofol and Etomidate.⁽²⁾

Propofol and Etomidate are non-barbiturates and are the most popular, acting and smooth intravenous-inducing agents.⁽⁵⁾

Propofol (2,6-diisopropyl phenol) is the most commonly used induction agent in general anaesthesia, due to its rapid onset and short duration of action. Propofol decreases blood pressure, cardiac output and systemic vascular resistance due to inhibition of sympathetic vasoconstriction and impairment of baroreceptor reflex regulatory system. Hypotension and pain on injection are the major drawbacks.⁽⁶⁾

Etomidate is a carboxylated imidazole-containing compound characterized by haemodynamic stability, minimal respiratory depression and cerebral protective effects. Its lack of effect on the sympathetic nervous

system, baroreceptor reflex regulatory system and increase in coronary perfusion even in patients with moderate cardiac dysfunction makes it an induction agent of choice in cardiac patients.⁽⁷⁾

The most important side effect of Etomidate is myoclonus. Myoclonus is a serious problem in patients with open globe eye injury and nonfasting condition. One of the most important, but rare side effects of this drug is the suppression of steroid production by reversible inhibition of the 11-beta-hydroxylase enzyme.⁽⁸⁾

Various other studies have been done in the past to compare the different anaesthetic agents for induction of general anaesthesia. When Propofol is used alone causes pain at the injection site and hypotension. When Etomidate is used alone is haemodynamically stable but causes myoclonus. So in search of an ideal induction agent, we conducted the study to evaluate Propofol, and Etomidate for induction, haemodynamic stability and their side effects.⁽⁹⁾

Material and Method

The present study entitled "A comparative study between Propofol and Etomidate for induction during general anaesthesia" was carried out in the Department of Anaesthesiology, S.S. Medical College and associated Sanjay Gandhi and Gandhi Memorial Hospitals, Rewa (MP) from April 2016 to March 2018. After approval from the institutional ethical committee, the study was conducted on ninety patients of ASA grade I and II between 18 to 55 years of age of either sex posted for elective surgery under general anaesthesia.

Pre anaesthetic checkup of all patients was done. A thorough preoperative evaluation was done including history, general physical examination, systemic examination, airway assessment and relevant laboratory investigations of all patients.

Inclusion criteria: All the surgical patients of ASA grade I and II between 18 to 55 years of age of either sex posted for elective surgery under general anaesthesia.

Exclusion criteria: Patients with Mallampatti grade III-IV, known hypersensitivity to in. Propofol or Etomidate, Cardiovascular dysfunction, were excluded from the study.

Patients fulfilling the selection criteria were briefly explained about the nature of the study and anaesthetic procedure. A written informed consent was obtained from all the patients and was kept nil orally for at least 6 hrs before surgery.

Ninety patients were randomly divided into three groups of thirty patients each depending on the study drug given.

Group I (n-30) were given Inj. Propofol 2.5mg/kg body weight I.V.

Group II(n-30) were given Inj. Etomidate 0.3mg/kg body weight I.V.

The study drugs were prepared in coded syringes by another resident to make the study blind and unbiased.

After shifting the patients to the operation table, NIBP, ECG and pulse oximeter were attached. Baseline parameters were recorded. An IV line was secured with an 18G IV cannula for fluids and other drug administration.

All the patients were uniformly premedicated with inj Glycopyrrolate 0.01mg/kg body weight, Inj. Midazolam 0.3mg/kg body weight, Inj. Fentanyl 2mcg/kg body weight and injection ondansetron 0.08mg/kg body weight intravenously 15 min before induction.

Pre-oxygenation was done with 100% oxygen for three minutes. The study drugs were provided in coded syringes which were prepared by another resident. Patients were induced by the study drug according to the Group.

After giving the study drug, induction time (from the start of injection to the disappearance of eyelash reflex) was recorded. Pain at the injection site and myoclonus were noted in all the patients. After the loss of eyelash reflex in. Succinylcholine 1.5 mg/kg, was given to facilitate muscle relaxation 60 seconds after injection of succinylcholine endotracheal intubation was done using an appropriate size endotracheal tube Anaesthesia was maintained with O₂:N₂O (30:70), Sevoflurane 2% and Inj. Atracurium intermittently.

Induction time: The induction time was noted in seconds from the start of injection to the disappearance of the eyelash reflex.

Pain at injection site: Pain at the injection site was assessed in all the patient Groups. The score was noted immediately before the patient lost consciousness.

Myoclonus: The severity of the myoclonus was recorded.

Heart rate, and non-invasive blood pressure (systolic blood pressure, diastolic blood pressure and mean arterial pressure) were recorded at 1 min before induction and 1min after induction, just after intubation and at 2 min, 5min, 10min, 15min, 20min, 30min, 45min, 60min at end of surgery.

After surgery, patients were reversed with Inj. Glycopyrrolate 0.5mg and Inj. Neostigmine 2.5 mg and were extubated.

Recovery profile: To assess recovery characteristics after intubation in Propofol, Etomidate and admixture of Propofol-Etomidate Groups, we observed drowsiness, excitement, PONV and cough.

More than 20% fall in MAP below baseline was considered as hypotension and was treated by decreasing Sevoflurane and in. Mephentermine 6mg intravenously. More than a 30% rise in MAP above baseline was considered hypertension. A heart rate less than 60 bpm

was considered bradycardia and a heart rate less than 50 bpm was treated with inj. Atropine 0.6mg intravenously. Heart rate greater than 100 bpm was considered as tachycardia.

At the end of the study, the observation was decoded, tabulated and statistically analysed by using mean, standard deviation, p-value, ANOVA test Chi-square test and student t-test. For comparison, p value less than 0.05 was taken to be statistically significant and less than 0.0001 was taken to be highly significant.

Observation

Chart 1 - Patients Characteristics

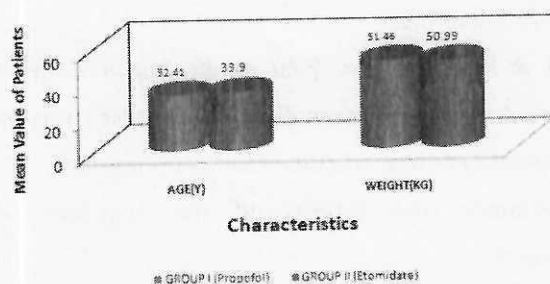


Chart 2 - Gender Distribution

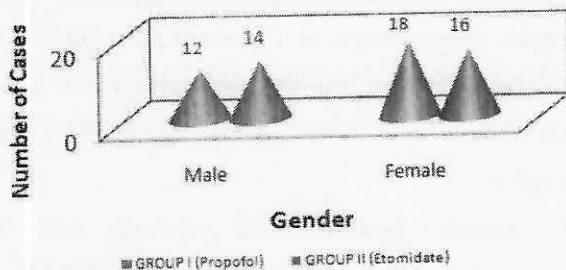


Chart 3: Comparison of induction time in different groups

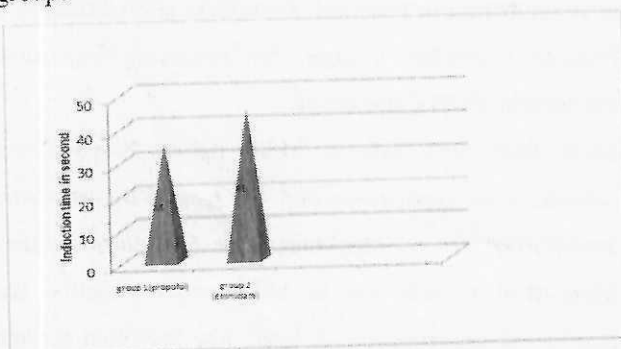


Chart 4 - Comparison Of Pain At Injection Site On Different Groups

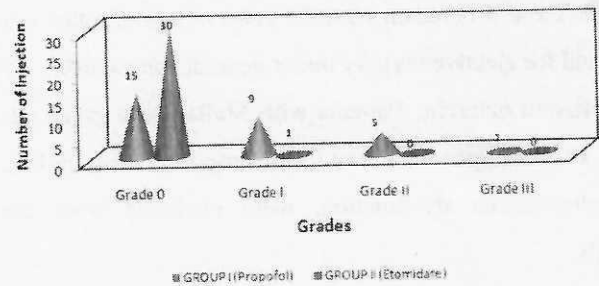


Chart 5 - Incidence of myoclonic movement in different groups

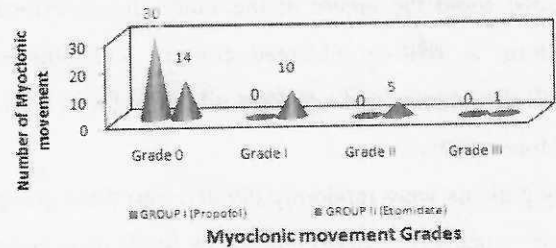


Chart 6 - Comparison of Mean heart rate at different time interval

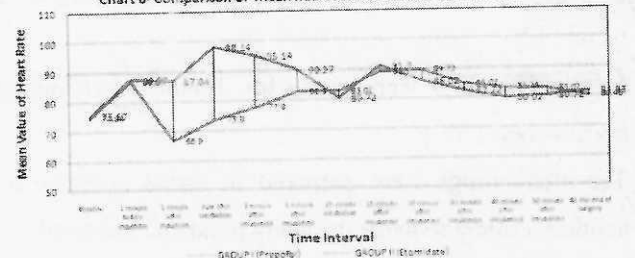


Table 1: Comparison of heart rate at different time interval

Time Interval	Group I (Propofol)	Group II (Etomidate)	p-value
Baseline	74.94 ± 5.78	75.57 ± 4.47	0.5867
1 minute before Induction	86.87 ± 5.74	87.57 ± 4.47	0.6004
1 minute after induction	66.9 ± 5.76	87.04 ± 4.40	0.0001
Just after intubation	73.9 ± 5.76	98.14 ± 4.20	0.0001
2 minute after intubation	77.9 ± 5.76	95.14 ± 4.20	0.0001
5 minute after intubation	82.9 ± 5.78	90.27 ± 4.21	0.0001
10 minute	83.02 ± 9.78	80.72 ± 7.92	0.062

intubation			
15 minute after intubation	89.3 ± 6.32	91.3 ± 3.07	0.124
20 minute after intubation	89.73 ± 9.70	86.02 ± 8.85	0.127
30 minute after intubation	85.02 ± 9.78	82.72 ± 7.92	0.062
45 minute after intubation	83.46 ± 9.78	80.02 ± 7.81	0.138
60 minute after intubation	83.02 ± 9.78	80.72 ± 7.92	0.062
End of surgery	80.46 ± 5.76	81.93 ± 5.81	0.329

Table 2: Comparison of Systolic Blood Pressure at Different Time Interval

Time Interval	Group I (Propofol)	Group II (Etomidate)	P-value
Baseline	120.3 ± 6.12	122.26 ± 4.48	0.1497
1 minute before induction	119.63 ± 5.33	121.86 ± 4.62	0.089
1 minute after induction	98.6 ± 6.12	119.26 ± 4.48	0.0001
Just after intubation	109.6 ± 6.13	135.26 ± 4.4	0.0001
2 minute after intubation	113.6 ± 6.123	131.26 ± 5.48	0.0001
5 minute after intubation	119.6 ± 6.14	127.26 ± 4.48	0.0001
10 minute intubation	124.7 ± 6.17	124.2 ± 4.52	0.722
15 minute after intubation	123.7 ± 6.57	123.2 ± 4.02	0.723
20 minute after intubation	124.8 ± 6.17	124.2 ± 6.52	0.716
30 minute after intubation	125.7 ± 6.09	125.2 ± 4.52	0.719
45 minute after intubation	125.8 ± 5.18	125.5 ± 5.57	0.813
60 minute after intubation	125.5 ± 6.09	124.6 ± 4.62	0.522
At the end of surgery	126.4 ± 6.22	125.2 ± 4.52	0.396

Table 3: Comparison of Diastolic Blood Pressure at Different Time Interval

Time Interval	Group I (Propofol)	Group II (Etomidate)	P-value
Baseline	77.45 ± 3.99	79.86 ± 5.38	0.052
1 minute before induction	75.51 ± 3.99	77.82 ± 5.32	0.062
1 minute after induction	62.2 ± 3.96	75.40 ± 7.08	0.0001
Just after intubation	65.63 ± 3.72	77.00 ± 4.29	0.0001
2 minute after intubation	67.37 ± 3.28	73.00 ± 3.83	0.0001
5 minute after intubation	72.46 ± 2.95	71.43 ± 2.27	0.305
10 minute intubation	72.13 ± 6.25	70.53 ± 5.25	0.287
15 minute after intubation	72.8 ± 5.93	70.73 ± 5.65	0.172
20 minute after intubation	72.06 ± 6.29	70.33 ± 5.99	0.261
30 minute after intubation	74.13 ± 6.25	72.53 ± 5.25	0.287
45 minute after intubation	76.33 ± 4.46	74.46 ± 6.43	0.196
60 minute after intubation	78.60 ± 6.11	76.54 ± 6.36	0.189
At the end of surgery	78.87 ± 5.82	78.16 ± 6.62	0.661

Chart 7: Comparison of Mean Arterial Pressure At Different Time Interval

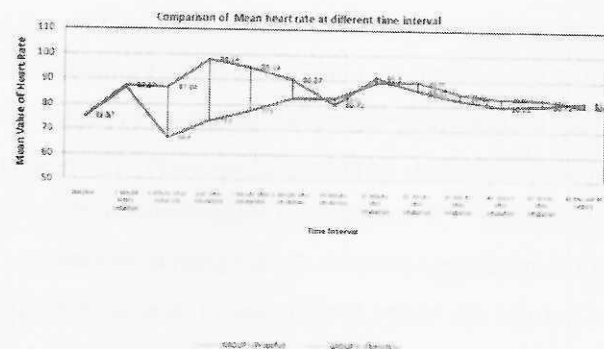
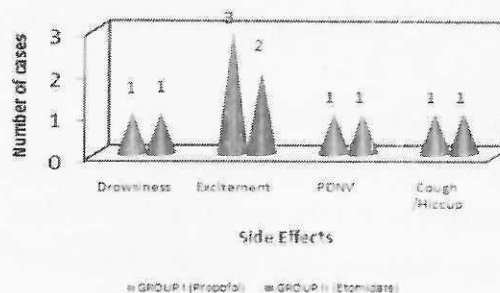


Table 4: Comparison of Mean Arterial Pressure at Different Time Interval

Time Interval	Group I (Propofol)	Group II (Etomidate)	P value(I vs. II)
Baseline	89.26 ± 4.71	88.2 ± 7.47	0.514
1 minute before induction	85.76 ± 4.72	85.2 ± 7.47	0.730
1 minute after induction	70.26 ± 4.12	83.7 ± 5.94	0.0001
Just after intubation	77.26 ± 4.71	89.36 ± 6.57	0.0001
2 minute after intubation	77.12 ± 4.89	87.86 ± 6.63	0.0001
5 minute after intubation	82 ± 4.89	86.36 ± 7.24	0.014
10 minute intubation	82.13 ± 6.25	80.53 ± 5.25	0.287
15 minute after intubation	84.45 ± 3.37	86.15 ± 5.13	0.135
20 minute after intubation	84.17 ± 5.47	87.62 ± 6.55	0.031
30 minute after intubation	85.73 ± 9.70	82.02 ± 8.55	0.127
45 minute after intubation	85.99 ± 7.51	85.42 ± 4.73	0.726
60 minute after intubation	85.60 ± 6.11	83.54 ± 6.56	0.189
At the end of surgery	85.60 ± 6.11	83.54 ± 6.56	0.159

Chart 08 : Recovery characteristics



Discussion

Induction is a critical step in general anaesthesia. All anaesthetic agents used for induction of anaesthesia aim to maintain stable haemodynamics. Various anaesthetic agents have been used in the past i.e. Inhalational agents,

Thiopantone sodium, Ketamine. Presently Propofol and Etomidate are popular non-barbiturate inducing agents. Due to rapid onset and short duration of action, they are a drug of choice for induction. In recent years combination of various anaesthetic agents has been used to reduce the dose and side effects of individual agents.(9) The present study entitled " A comparative study between Propofol and Etomidate for induction during general anaesthesia " was carried out in the Department of Anaesthesiology, S.S. Medical College and associated Sanjay Gandhi and Gandhi Memorial Hospitals, Rewa (MP) from 2016 to 2018. To find out a better-inducing agent for general anaesthesia. We compare Propofol and Etomidate to the induction characteristics, haemodynamic parameters and recovery profile.

After giving the study drug, induction time (from the start of Injection to the loss of eyelash reflex), pain at the Injection site, myoclonus, haemodynamic parameter and recovery profile were noted in all the patients.

Heart rate and non-invasive blood pressure (systolic blood pressure, diastolic blood pressure and mean arterial pressure) were recorded at regular intervals. All data were recorded, tabulated and statistically analysed using ANOVA, t-test and chi-square test whichever was applicable.

Induction characteristic

Induction time- In our study shows the mean induction time of Group I is 35 ± 10 second, and Group II 45 ± 9 second. The induction time is faster in Group I and Group II ($I > II$).

Pain at Injection site:-

The incidence of pain at the injection site was higher in Group I as compared to Group II and Group III. The difference in pain at the Injection site was clinically as well as statistically significant ($p < 0.0003$)

The incidence of myoclonus was more in Group II as compared to Group I.

Heart Rate

The baseline mean Heart Rate (HR) in Groups I & II, was 74.94 ± 5.78 , and 75.57 ± 4.47 respectively. The baseline heart rate of both Groups is almost equal and the difference in HR was statistically insignificant in all the two Groups. ($P > 0.05$)

After induction, the mean HR in Groups I. & II were 66.9 ± 5.76 , 87.04 ± 4.40 respectively. The HR was decreased in patients of both Groups from baseline value. The decrease in HR was more in Group I as compared to Group II. Inter-group comparison of mean HR shows significant differences among both Groups. ($P < 0.05$)

Just after intubation as well as after 2 min. of intubation, the mean HR was 73.9 ± 5.76 & 98.14 ± 4.20 and just after intubation and 77.9 ± 5.762 , & 95.14 ± 4.20 , 2 min after intubation in Group I, Group II, respectively. There was an increase in HR in both Groups from baseline value. However, this increase in HR was more in Group II as compared to Group I. The inter-group comparison shows the difference in the increase in HR was statistically significant in both Groups ($p < 0.05$).

After 5 min of intubation, the mean HR was 82.9 ± 5.78 , & 90.27 ± 4.21 in Group I, and Group II respectively. There was an increase in HR in both Groups from baseline value. The inter-group comparison shows the difference in increase in HR was statistically significant between Group I & II.

After 10 minutes of intubation and up to the end of surgery, the changes in mean HR were statistically insignificant ($p > 0.05$).

Systolic blood pressure

The baseline mean SBP was 120.3 ± 6.12 mmHg, & 122.26 ± 4.48 mmHg in Groups I, and II respectively. The baseline SBP of both Groups are almost equal and

the difference in SBP was statistically insignificant in both Groups. ($P > 0.05$).

After induction, the mean SBP was 98.6 ± 6.12 mmHg, & 119.26 ± 4.48 mmHg in Groups I, and II respectively. The SBP was decreased in patients of both Groups from baseline value. The decrease in SBP was more in Group I as compared to Group II. The inter-group comparison shows the difference of decrease in SBP was statistically significant between Group I & II ($p < 0.05$).

After intubation, the mean SBP was 109.6 ± 6.13 mmHg, & 135.26 ± 4.4 mmHg in Groups I, and II respectively. There was an increase in SBP in both Groups from baseline value. However, this increase in SBP was more in Group II as compared to Group I. The inter-group comparison shows the difference in increase in SBP was statistically significant in both Groups. ($p < 0.05$).

After 2 min as well as after 5 min of intubation, the mean SBP was 113.6 ± 6.12 mmHg, and 131.26 ± 5.48 mmHg at 2 min after intubation and

119.6 ± 6.14 , and 127.26 ± 4.48 mmHg, at 5 min after intubation in Group I, and Group II, respectively.

There was a slight increase in SBP in both Groups from baseline value. The inter-group comparison shows the difference in increase in SBP was statistically significant in Groups I & II.

After 10 min of intubation up to the end of surgery, the changes in mean SBP were statistically insignificant ($p > 0.05$).

Diastolic blood pressure

The baseline mean DBP was 77.45 ± 3.99 mmHg, and 79.86 ± 5.38 mmHg, in Groups I, and II respectively. The baseline DBP of both Groups are almost equal and the difference in DBP was statistically insignificant in both Groups. ($P > 0.05$).

After induction, the mean DBP was 62.2 ± 3.96 mmHg, and 75.46 ± 7.08 mmHg in Groups I, and II respectively.

The DBP was decreased in patients of both Groups from baseline value. The decrease in DBP was more in Group I as compared to Group II.

The inter-group comparison shows the difference of decrease in DBP was statistically significant between Group I & II ($p < 0.05$).

After intubation, the mean DBP was 65.63 ± 3.728 mmHg, and 77.00 ± 4.29 mmHg, respectively in Group I and II. There was an increase in DBP in both Groups from baseline value. But this increase in DBP was more in Group II as compared to Group I. In the inter-group comparison, the difference in increase in DBP was statistically significant in both Groups. ($p < 0.05$).

After 2 minutes of intubation, mean DBP was 67.37 ± 3.285 mmHg and 73.00 ± 3.833 in Group I, and Group II, respectively. There was a slight increase in DBP in both Groups from the baseline value. The inter-group comparison shows the difference of increase in DBP was statistically significant in Group I & II ($p < 0.05$).

After 5 minutes of intubation, mean DBP was 72.40 ± 2.95 mmHg, and 71.43 ± 2.27 mmHg in Group I, and Group II, respectively. There was a slight increase in DBP in both Groups from the baseline value. The inter-group comparison shows the difference of increase in DBP was insignificant between Group I & II and Group II ($p > 0.05$).

After 10 min of intubation up to the end of surgery, the changes in mean SBP were statistically insignificant in patients of both Groups. ($p > 0.05$).

Mean arterial pressure

The baseline mean MAP was 89.26 ± 4.71 , and 88.2 ± 7.47 , in Groups I and II respectively. The baseline MAP of both Groups are almost equal and the difference in MAP was statistically insignificant in both Groups. ($P > 0.05$).

After induction, the mean MAP was 70.26 ± 4.12 mmHg and 83.7 ± 5.94 mmHg in Groups I, and II respectively. The MAP was decreased in patients of both from baseline value. The decrease in MAP was more in Group I as compared to Group II. The inter-group comparison shows the difference of decrease in MAP was statistically significant between Group I & II ($p < 0.05$).

After intubation, the mean MAP was 77.26 ± 4.71 mmHg and 89.36 ± 6.57 mmHg, respectively in Group I, and II. There was an increase in MAP in both Groups from baseline value. However, this increase in MAP was more in Group II as compared to Group I. The inter-group comparison shows the difference in increase in MAP was statistically significant in both Groups. ($p < 0.05$).

After 2min as well as after 5 min of intubation, mean MAP was 77.12 ± 4.89 mmHg, 87.86 ± 6.63 , at 2min after intubation and 82 ± 4.89 mmHg, 86.36 ± 7.24 mmHg at 5 min after intubation in Group I, and Group II respectively. There was a slight increase in MAP in both Groups from baseline value. The inter-group comparison shows the difference in increase in MAP was statistically significant in Groups I & II ($p < 0.05$).

After 10 min of intubation up to the end of surgery, the changes in mean SBP were statistically insignificant in patients of both Groups. ($p > 0.05$).

Decreases in HR, SBP, DBP and MAP by Propofol are due to inhibition of the sympathetic nervous system and impairment of the baroreceptor reflex regulatory system. Minimal changes in HR, SBP, DBP and MAP by Etomidate are due to a lack of effect on the sympathetic nervous system and baroreceptor reflex regulatory system.

Recovery characteristics

In our study, we observed recovery characteristics after intubation. The incidence of drowsiness was found to be

equal (3%) in patients of both Groups i.e. Group I, and II respectively.

The incidence of excitement was found to be 3% and 6% in Groups I, and II respectively.

The incidence of PONV & cough/hiccups was found to be 3%, 3%, in Group I, II respectively.

Conclusion

This study concludes that etomidate is a better agent for induction than propofol because of hemodynamic stability and less pain on injection. The only drawback was a high incidence of myoclonus. Therefore we concluded that etomidate is a better drug in patients with hemodynamic fluctuation at Induction, like uncontrolled hypertension, severe illness, septic, and patients with heart disease.

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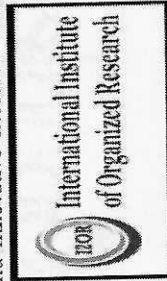
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