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Original Article

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Comparative Study of Clinical and Functional Outcome of Displaced Fractures of the Middle-Third of the Clavicle Treated with Conservative Management and Surgical Fixation with Plating

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ABSTRACT

Introduction: Clavicle fracture account for approximately 2.6% of all fractures and for 44 % to 66% fractures about the shoulder. Middle third fractures account for 80% of all clavicle fractures whereas fractures of lateral and medial third of the clavicle account for 15% and 5 % respectively. Most minimally displaced clavicle fractures can be successfully treated non-operatively with some forms of immobilization.

Materials and methods: Plain radiograph of clavicle with shoulder in antero-posterior view was taken to assess the site of fracture and the fracture type (displacement and comminution). The fractures were classified according to Robinson's classification. Patients were then allotted randomly into two groups. Patients selected for conservative treatment with figure of eight Clavicle Brace and arm sling/pouch were treated with the brace immediately. Patients selected for surgery were operated as early as possible once the general condition of the patients were stable and the patients were fit for surgery as assessed by the physician. All patients were followed up every week for 2 weeks post treatment and thereafter every 6th week, 3rd month and 6th month.

Radiographs are taken at immediate post treatment period, 6 weeks, 3 months and 6 months. Features of healing and functional outcome were looked for with help of Constant and Murleys scoring system at the time of injury, 6 weeks, 3 months and 6 months. Also, evidence of implant breakage, non-union, infection was also looked for.

Result: The patient's functional outcome was measured using Constant and Murley scoring system and it was found that patient treated surgically had significantly better functional outcome at 6 weeks, 3 months and 6 months respectively when compared to conservative group. The complications we faced in surgical group were 2 cases of infection, 3 cases with implant failure and 1 case of non-union. In conservative group 4 cases of non-union, 3 cases of delayed union and 4 cases of shoulder stiffness. There was also two case of superficial skin infection in surgical group.

Conclusion: It was observed that patients who underwent surgical treatment had better functional outcome in terms of early ROM and so return to work was earlier compared to conservative group. According to present study, surgery can be recommended over conservative treatment in patients with displaced
mid-third fracture clavicle

Key Words: *Functional outcome, ROM, Conservative group, Plate and Screw fixation.*

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INTRODUCTION

Clavicle fracture constitutes approximately one third to two thirds of shoulder fractures, accounting for approximately 2.6% of all fractures [1]. The clavicle, an S-shaped bone, serves as a strut connecting the sternum and the glenohumeral joint, providing support to the shoulder girdle. The coracoclavicular ligament suspends the shoulder from the clavicle [1].

Among clavicle fractures, middle third fractures make up 80%, while fractures of the lateral and medial thirds account for 15% and 5%, respectively. The displacement of clavicle fractures is influenced by the muscular and ligamentous forces acting on the bone. Understanding the nature of displacement aids in determining the appropriate treatment and expected outcome [3].

Mid-clavicular fractures represent 3% to 5% of all fractures and 45% of shoulder injuries. Men have twice the incidence compared to women, with an overall incidence of approximately 64 per 100,000 population [3]. The peak incidence occurs during the third decade of life. Open clavicular fractures are rare, comprising about 0.5% of cases[4].

Conservative management was traditionally the preferred treatment for middle third clavicle fractures due to concerns regarding associated complications. However, with advancements in classification systems based on age and displacement, along with improved knowledge and investigations, the incidence of nonunion in displaced comminuted midshaft clavicular fractures in adults ranges from 10% to 15% [4]. Reducing this rate is essential for enhancing effective patient care.

Complications commonly observed with conservative management, in addition to nonunion or malunion, include prolonged pain and disability lasting 3 to 6 weeks or even lifelong. Displaced fragments may compress nerves such as the brachial plexus, leading to further complications. Persistent wide separation of fragments with interposed soft tissue can hinder closed reduction, resulting in a 15% nonunion rate in widely displaced fractures of the middle third of the clavicle treated without surgery [5].

Consequently, many surgeons now prefer operative management over conservative treatment. Recent studies support the use of primary open reduction and internal fixation for completely displaced midshaft clavicular fractures, as it achieves a high union rate with low complication rates [6]. Locking compression plates have been found to yield satisfactory outcomes in a significant number of complex clavicular fractures [7]. Treating displaced comminuted midshaft clavicular fractures with primary internal fixation leads to predictable and early restoration of function.

Surgical interventions for clavicle fractures include intramedullary K-wires, Steinmann pin fixation, tension band wiring, smooth or threaded pins, plate fixation, and external fixation. Plate fixation options include dynamic compression plates, Sherman plates, locking clavicle plates, and semi-tubular plates, which facilitate firm anatomical reduction in cases of severe displacement or comminuted fractures [8].

Conservative management involves immobilizing the middle third of the clavicle using braces such as the Bohler's brace, Parham support, Taylor's support, Velpeau wrap, Billington yoke, and commercial figure-of-eight brace. The commercial figure-of-eight brace is the most commonly utilized option.

AIMS AND OBJECTIVES

1. To evaluate the functional outcome of “open reduction and internal fixation with plating” and “conservative management with figure of eight clavicle brace” in treating displaced middle third clavicular fractures measured by Constant &Murley score.
2. To study the post treatment complications like nonunion, infection, shoulder stiffness as per Constant and Murley score, on treatment with “open reduction and internal fixation with Plating and “conservative management with figure of eight clavicle brace” and arm pouch/sling application.

MATERIALS AND METHODS

Study Design: This study was conducted as a prospective study.
Study Setting: The study took place in the Department of Orthopedics at Vijayanagar Institute of Medical Sciences.
Study Duration: The study was carried out from December 2020 to November 2022, with a treatment period of 24 months.
Study Population: The study included all patients between the ages of 18 and 50 years with displaced middle third clavicle fractures.

Inclusion Criteria:

Patients aged 18 years or older and below 50 years.
Patients with closed fractures of the middle third of the clavicle.

Exclusion Criteria:

Patients younger than 18 years or older than 50 years.
Patients with pathological fractures.
Patients with intra articular extension of fractures.
Patients medically unfit for surgery.
Open fractures.
Polytrauma.
Patients with brachial plexus and vascular injury.

Sample Size Calculation:
The sample size was calculated using the following formula:
N = (Z1 + Z2)^2 * (S^2) / D^2

Variable considered for calculation:

The average value of the Constant and Murley score in the conservative group was 94.47±7.514, and in the operative group, it was 96±7.90.

M1: Mean score - conservative group = 94.47 M2: Mean score - surgical group = 96.00 S1: Standard deviation of M1 = 7.51 S2: Standard deviation of M2 = 7.9 S: Pooled standard deviation = 7.70 1-α: Set level of confidence (usually 0.95) = 2 1-β: Set level of power of test (usually 0.8 or 0.9) = 0.99 Z1: Z value associated with alpha = 0.9 Z2: Z value associated with beta = 2.58 D: Absolute precision = 4.72

By using the above formula and the given values, the minimum total sample size was determined to be 36. Each group consisted of 18 participants.

Ethical Consideration:

Ethical clearance was obtained from the institutional Human Ethics Committee. All patients included in the study provided signed, written informed consent. Confidentiality and anonymity of the patients' information were maintained during and after the study.

Study Tools:

a. Informed consent b. Structured Performa

Study Procedure:

General information, including name, age, sex, in-patient number, and address, was collected for each patient. The history of the injury, including the mode of injury (road traffic accident, direct injury to the shoulder, fall from height, or fall on an outstretched hand), as well as the location of pain and any swelling, was recorded. Past medical illness, surgical history, and family history were also noted.

Local examination included assessing abnormal swelling in the middle third of the clavicle for fractures. The condition of the skin over the injury, such as abrasions, lacerations, discoloration, and contusion, was observed. Palpation was performed along the entire clavicle to check for tenderness, swelling, and abnormal mobility. Any crepitus was noted, and movements of the affected side were assessed for limitations due to pain. The distal neurovascular status of the affected upper limb was examined, and associated injuries were documented.

Investigations included plain radiographs of the clavicle in the antero-posterior view to assess the site and type of fracture. Fractures were classified according to Robinson's classification. Patients were then randomly assigned to two groups. Those selected for conservative treatment received a figure-of-eight Clavicle Brace and arm sling/pouch immediately. Patients selected for surgery underwent the procedure as soon as their general condition was stable and they were deemed fit for surgery by the physician. Patients were followed up weekly for 2 weeks post-treatment and then at 6-week intervals, including at 3 months, 6 months, and 1 year. Radiographs were taken immediately post-treatment, at 6 weeks, 3 months, 6 months, and 1 year. The outcome was assessed using the Constant and Murley scoring system, and healing and function features were noted at the time of injury and at the subsequent follow-up visits. The presence of complications, such as implant breakage, malunion, nonunion, and infection, was also recorded.

Additional investigations, including hemoglobin levels, total white blood cell count, differential white blood cell count, blood grouping and Rh typing, bleeding time and clotting time, random blood sugar, blood urea, serum creatinine, HIV I & HIV II, hepatitis B, ECG, plain X-ray, special investigations (such as CT chest), and COVID-19 rapid antigen test and RT-PCR, were conducted as necessary.

Data Analysis:

Data were collected using a structured proforma and entered into an MS Excel sheet. Statistical analysis was performed using SPSS version 24.0 from IBM USA. Qualitative data were expressed in terms of proportions, while quantitative data were expressed as mean and standard deviation. Association between two qualitative variables was assessed using the chi-square test or Fisher's exact test. Comparison of means and standard deviations within the same group was done using paired t-tests, while unpaired t-tests were used to compare means and standard deviations between the two groups. Descriptive statistics for each variable were presented as mean, standard deviation, and standard error of the mean. A p-value of <0.05 was considered statistically significant, and a p-value <0.001 was considered highly significant.

RESULTS AND OBSERVATIONS

The current study included 36 subjects divided into 2 groups. Each group includes 18 subjects. First group includes patients with fresh mid third clavicular fracture treated surgically with clavicular locking compression plate and screws. The second group includes patients with mid third clavicular fracture treated conservatively with figure of eight clavicle brace and armpouchorsling between December 2020 and November 2022. These subjects were followed up at regular intervals and results were analyzed both clinically and radiologically.

MODE OF INJURY:

Table-1: Mode of Injury

-Mode of Injury	**No. of Middle Third clavicle**	%
1.Roadtraffic Accident	25	69.4
2.FallfromHeight	11	30.6
Total	36	100

Out of the 36 patients that were included in the study, 26 patients (69.4%) sustained fracture as a part of a Road traffic accident. 10 patients sustained fracture due to direct fall from height (30.5%)

Age:

The distribution of age in surgical group ranges from 22 to 49 years. The mean age in the surgical group was 40.73 years and a SD of 7.48 years. The distribution of age in conservative group ranges from 19 to 50 years. The mean age in the conservative group was 38.28 years and aSD 10.24 of years.

Table2: Distribution of participants according to age

Age characteristics(years)	Surgical group(N=18)	Conservative group(N=18)
Minimum	22	19
Maximum	49	50
Mean	40.73	38.2
Standard deviation	7.48	10.2

Table3: Distribution of participants according to Gender

Gender	Surgical group		Conservative group	
	Frequency	Percentage	Frequency	Percentage
Male	13	38.9	9	50
Female	5	61.1	9	50
Total	18	100	18	100

Table4: Distribution of participants according to Side

Side	Surgical group		Conservative group	
	Frequency	Percentage	Frequency	Percentage
Left	8	38.9	7	44.4
Right	10	61.1	11	55.6
Total	18	100	18	100

Comparison of Constant & Murley score between surgical and conservative group

Constant & Murleys core at 6weeks, at 3 months, at 6 months were significantly higher in surgical group than conservative group. There was a statistically significant difference in Constant & Murley score at 6 weeks, at 3 months, at 6months between surgical group and conservative group.

Table5:Distribution of mean Constant & Murley score in surgical group

Constant & Murley score	**Surgical group**		**Conservative group**		**t value**	**p value**
	Mean	**SD**	**Mean**	**SD**		
Attime of injury	29.44	2.812	28.22	1.801	1.553	0.130
At6weeks	56.78	5.537	44.89	4.296	7.198	0.000***
At3 months	71.11	5.910	67.56	3.729	2.159	0.038*
At6 months	80.11	7.684	73.11	4.51	3.33	0.002**

Table6: Distribution of complications in the Participants

Complications	Surgical group		Conservative group	
	Frequency	Percentage	Frequency	Percentage
No complications	12	66.6	7	38.9
Implant failure	3	16.8	0	0
Infection	2	11	0	0
Shoulder stiffness	0	0	4	22.2
Delayed union	0	0	3	16.7
Non-union	1	5.6	4	22.2
Total	18	100	18	100

DISCUSSION

Clavicle fractures are commonly observed in young and active individuals, particularly those engaged in sports activities. The majority of clavicular fractures occur in the mid-shaft region, which is highly susceptible to fracture, especially with axial loading. The middle third of the clavicle lacks reinforcement by muscles or ligaments distal to the subclavius insertion, making it even more vulnerable. Displacement of the fracture results in superior displacement of the proximal fragment due to the pull of the sternocleidomastoid muscle, which attaches to the proximal portion of the clavicle. The distal fragment is displaced inferiorly under the weight of the arm and due to gravity. Additionally, shortening often occurs due to the pull of the subscapularis and pectoralis muscles, which internally rotate and pull the arm towards the chest. Undisplaced fractures are typically managed conservatively.

The results of our study on patients with middle third clavicle fractures were compared with findings from the existing literature. We specifically examined the studies conducted by Bostman et al. [9], which treated 103 patients with middle third clavicle fractures using early open reduction and internal fixation with plates and screws, and the study by Cesare Faldini et al. [10], which treated 100 patients with midshaft clavicle fractures using a figure-of-eight clavicle brace.

Middle third clavicle fractures are among the most common fractures in the body, accounting for approximately 4% of all fractures. These fractures often result in short-term disability and pain, and if inadequately treated, can lead to long-term deformity and disability [11]. Fractures predominantly occur in the middle third of the clavicle (76-82%), followed by the distal (12-21%) and medial (3-6%) thirds [12,13]. Traditionally, most of these fractures were managed with conservative measures such as slings or figure-of-eight harnesses, as it was believed that non-operative treatment yielded satisfactory results in more than 95% of cases in terms of union, cosmesis, and function. However, recent studies have shown poor outcomes with non-operative treatment of displaced mid-third clavicular fractures in adults, including higher rates of nonunion and cosmetic concerns, shoulder discomfort, and patient dissatisfaction, even when union occurs [12,14,15]. Earlier, malunion of the clavicle in displaced fractures was considered of radiographic interest only and did not require treatment. However, it is now recognized as a distinct clinical entity with implications for radiography, orthopedics, neurology, and cosmesis. A study by Nowak et al. [16] found that at ten years post-injury, 46% of adult patients with clavicular fractures still experienced symptoms, even though only 7% had nonunion. In young patients, compromised shoulder function due to malunion or nonunion severely affects employability. Patients today expect a rapid return to pain-free function following a fracture. Numerous recently published articles have documented the success of open reduction and internal fixation with low complication rates in treating nonunion of displaced clavicle fractures, with plate fixation being the preferred approach in many studies. In our study, we compared the outcomes of open reduction and plating with a locking compression plate and conservative treatment with a figure-of-eight clavicle brace for mid-third clavicle fractures.

Mechanism of injury:

In our study, out of 36 patients with mid-third clavicle fractures, 25 patients (69.45%) sustained fractures as a result of falls from bikes due to road traffic accidents, while 11 patients (30.6%) sustained fractures due to direct falls on the shoulder. All injuries were direct in nature (100%). In the study by Bostman et al. [9], the mechanisms of injury were falls from two-wheelers in 38 patients (36.8%), slipping and falling in 24 patients (23.3%), motor vehicle accidents in 19 patients (18.45%), and sports-related injuries in 22 patients (21.36%). Direct shoulder injury was found to be the most common cause of clavicle fractures. Cesare Faldini et al. [10] reported that all fractures in their study resulted from high-energy traumas, including road accidents in 48 cases (48%), sports accidents in 22 cases (22%), work-related accidents in 18 cases (18%), and domestic accidents in 12 cases (12%). All injuries were direct in nature (100%).

Age Incidence:

In our study, the average age of patients with mid-third clavicle fractures was found to be 45.11 years in the surgical group and 45.33 years in the conservative group. The youngest patient in the conservative group was 19 years old, while in the surgical group, the youngest patient was 22 years old. The oldest patient in the surgical group was 49 years old, while in the conservative group, it was 50 years old. In the study by Bostman et al. [9], the average age of

patients was 33.4 years, with the youngest patient being 19 years old and the oldest patient being 62 years old. Cesare Faldini et al. [10] reported an average age of 32 years, ranging from 18 to 67 years old. These studies indicate that mid-third clavicle fractures occur primarily in young and active individuals.

Sex Incidence:

In our study, out of 36 patients, 22 were male (61.2%) and 14 were female (38.9%). In the surgical group, there were 13 male patients and 9 female patients, while in the conservative group, there were 5 male patients and 9 female patients. Bostman et al. [9] reported that 76 patients (73.79%) were male and 27 patients (26.21%) were female. Cesare Faldini et al. [10] included 78 male patients and 22 female patients out of a total of 100 patients.

Fracture classification:

In our study, all fractures (36 patients, 100%) were classified as Robinson Type-2 B1 (displaced with a simple or butterfly fragment). Bostman et al. [9] also found Robinson Type-2 B1 to be the most common classification, occurring in 81 patients (78.64%), while Robinson Type-2 B2 occurred in only 22 patients (21.36%).

Time interval for treatment:

All patients in the operative group were operated on the immediate next day after presentation, while patients in the conservative group were provided with bracing on the day of presentation itself. Bostman et al. [9] operated on all patients within 3 days of injury, and Cesare Faldini et al. [10] provided all patients with a figure-of-eight clavicle brace on the day of examination.

Fracture union time:

In our study, the average time of union in patients in the surgical group was 6 weeks (range: 5-8 weeks), while in the conservative group, it was 10 weeks (range: 9-12 weeks). Cesare Faldini et al. [10] reported an average fracture healing time of 9 weeks (range: 8-12 weeks), with no statistically significant correlation between fracture type and healing time.

Complications:

Major Complications: Nonunion

In our study, none of the patients in the operative group experienced nonunion, while 4 patients (22.2%) in the conservative group developed nonunion. Among these patients, one underwent open reduction with clavicular plate and bone grafting for nonunion. Bostman et al. [9] did not report any cases of nonunion in their study. Hill et al. [17] reported a nonunion rate of 15% in non-operatively treated clavicle fractures, while Poigenfurts et al. [18] reported a nonunion rate of 2.2% in patients undergoing operative management.

Implant Breakage:

In our study, 3 patients in the surgical group (16.7%) experienced implant failure. One patient had a history of fall and implant failure (5.6%), one patient had implant failure associated with a road traffic accident (5.6%), and one patient had implant failure combined with nonunion (5.6%).

Minor Complication: Infection

In our study, two patients (11%) in the operative group experienced superficial skin infections, which were successfully treated with oral antibiotics for 5 days. Bostman et al. [9] reported an infection rate of 7.8% in their study.

These findings provide valuable insights into the management and outcomes of mid-third clavicle fractures, comparing operative and conservative treatment approaches.

Functional outcome:

The functional outcome was measured as per constant and murley score at the time of injury, at 6 weeks, at 3 months and 6 months. Constant and murley score at 6weeks, 3months and 6months were significantly better in surgical group than conservative group.

In a randomized control study by Canadian orthopaedic trauma society, it was found that Constant score and DASH Scores are significantly better in surgical group at 6 weeks, 12 and24 weeks than conservative group[17].

The main advantage of surgical treatment of mid-third fracture clavicle with plate is that it gives immediate pain relief, early shoulder movements, less chance of non-union and early return to work compared to conservative treatment.

CONCLUSION

This study aimed to compare the outcomes of two treatment options, namely open reduction and internal fixation with clavicular locking compression plate, and conservative treatment with a figure-of-eight clavicle brace and sling application for mid-third clavicle fractures. A total of 36 patients with mid-third clavicle fractures, presenting between

December 2020 and June 2022, were randomly assigned to either the surgical group or the conservative group, with 18 patients in each group. The patients were followed up for a period of 6 months at regular intervals.

The functional outcomes of the patients were assessed using the Constant and Murley scoring system. The results showed that patients who underwent surgical treatment had significantly better functional outcomes at 6 weeks, 3 months, 6 months, and 12 months compared to the conservative group. This indicates that surgical intervention led to improved functional recovery.

In terms of complications, the surgical group experienced two cases of infection and two cases of implant failure. These rates were consistent with those reported in standard literature. The conservative group had four cases of nonunion, which is also in line with the expected nonunion rates. Additionally, there were two cases of superficial skin infection in the surgical group.

It was observed that patients who underwent surgical treatment had better early range of motion (ROM), which facilitated earlier return to work compared to the conservative group.

Based on the findings of this study, surgery is recommended as the preferred treatment option for patients with displaced mid-third clavicle fractures, as it resulted in better functional outcomes compared to conservative treatment.

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