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## Comparative study of surgical management versus conservative management of displaced fractures of the clavicle

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### Abstract

**Back ground and objectives:** Clavicle fracture accounts for approximately 2.6% of all the skeletal fractures. These fractures are often associated with shoulder girdle injuries in approximately 44% of cases. Non operative treatment has been a mainstay of a modality of treatment, and irrespective of the type of fracture and amount of comminution, all these fractures were treated non-operatively.

Different surgical methods for clavicle midshaft fractures have been described and these are locking compression plate fixation, intramedullary K-wires, Steinmann pin fixation, and intramedullary nailing with TENS.

Therefore in this study we have compared the functional outcome of displaced clavicle fractures treated by non-surgical management with that of surgical management by TENS and by open reduction and internal fixation with clavicular locking compression plate.

**Methods:** 60 patients with clavicle fractures presenting to the Orthopaedic Department of R L Jalappa hospital from Nov. 2017 to April 2019 are included in the study after obtaining informed consent.

**Result:** Among 60 patients with clavicle fractures, majority of the injury occurred in male patients- 45 cases (75%), whereas a total of 15 cases (25%) were seen in females. The functional outcome at the end of 6 months in 30 conservatively managed cases showed, 4 cases (13.3%) with excellent outcome; 6 cases (20%) had good outcome. 16 cases (53.3%) had fair and 4 cases (13.3%) had poor outcome. While in surgically managed 30 cases, the functional outcome at the end of 6months showed a total of 23(76.6%) cases with excellent outcome, 4 cases (13.3%) had good outcome 2 cases (6.6%) had a fair, and 1 case (3.33%) had poor outcome. At the end of 6 months, functional outcome of both the groups were compared by applying chi square test, the p value was <0.001, showing the results, statistically significant. Thus, in our study operative group had fewer complications, early bony union and better functional outcome as compared to the conservative group.

**Conclusion:** This study concludes that irrespective of surgical modalities of management used, surgically treated cases have better functional outcome, fewer complications, early bony union and better overall patient satisfaction.

**Keywords:** Midshaft clavicle fracture, conservative management of clavicle fracture, Titanium elastic nailing system, intramedullary nailing, closed reduction, internal fixators, open reduction, clavicle LCP fixation.

### Introduction

The clavicle is the only long bone which lies horizontally and is subcutaneous in its whole extent<sup>[1]</sup>. Clavicle is present at the root of the neck and it helps to transfer the weight of upper limb to the axial skeleton. Clavicle also contributes to movements of shoulder girdle<sup>[1]</sup>.

Clavicle fractures are common injuries in young, active individuals, especially those who participate in activities or sports where high-speed falls (bicycling, motorcycles) or violent collisions (football, hockey) are frequent, and they account for approximately 2.6% of all fractures<sup>[4]</sup>. These fractures are often associated with shoulder girdle injuries in approximately 44% of cases<sup>[2]</sup>. Attributed to its S shape and thinner bone at the middle curvature, clavicle most commonly gets fractured at its middle third and hence is the most common site of fracture in approximately 70% to 80% of cases; while approximately 12% to 15% of fractures occur at lateral 1/3<sup>rd</sup> and 5% to 8% occur at medial third 1/3<sup>rd</sup> of clavicle<sup>[2]</sup>.

After non-operative treatment, particularly in displaced fractures with some amount of shortening, will have some degree of disability at shoulder girdle. Therefore there is increasing trend to operate all displaced clavicle fracture [2].

In this study we have compared the functional outcome of displaced midshaft clavicle fractures treated by non-surgical management with shoulder arm pouch and clavicular brace, to that of surgical management by closed or open reduction and internal fixation with TENS and by open reduction and internal fixation with clavicular locking compression plate.

### Aims and objectives

- To study functional outcome of midshaft clavicle fracture managed with conservative management and with surgical management using Constant scoring system.
- To study the complications, advantages and disadvantages of both treatment modalities.
- To study the duration of bony union following conservative management and surgical management.

### Methodology

#### a) Calculation of sample size

It is estimated based on the difference between functional outcome between the two methods of treatment in a similar comparative study with 5% of alpha error, a effect size of 62%(11.25), with 95% confidence interval, with 80% power, calculated sample size per group is 27. With 10% of dropout rate, final sample size per group was 30.

$$\text{Sample size (n)} = 2 \sigma^2 (Z_{1-\alpha} + Z_{1-\beta})^2 / d^2$$

$$\sigma = 1.4$$

$$Z_{1-\alpha} = 1.96 \text{ (95\% confidence interval)}$$

$$Z_{1-\beta} = 0.842 \text{ (80\% power)}$$

$$d = \text{effect size } 11.5\% \text{ difference in mean score}$$

#### b) Sampling method

With Sample size of 60, systematic random sampling method was used, and patients were randomized into 2 groups using block randomized technique, with block size of 4. Group A patients received non-operative treatment with arm pouch and clavicular brace (30 patients). Group B received surgical management (30 patients). All patients were evaluated by detailed history about the trauma and mode of injury, and detailed physical and radiological examination.

#### c) Method of collection of data

This study will be conducted on patients attending the orthopedic outpatient section and inpatient of R.L. Jalappa hospital and research centre Tamaka, Kolar. It is a prospective and comparative study of 60 cases of displaced diaphyseal fractures of the clavicle carried out from Nov. 2017 to April 2019. All the cases satisfying the inclusion and exclusion criteria were included in the study. Cases in the surgical group were managed either with intra medullary device like TENS or extramedullary device like plate and screw and cases in conservative group will be managed with shoulder arm pouch and clavicular brace. Functional outcome of both the methods

will be assessed using the objective and subjective parameters of the Constant and Murley score [67].

#### d) Inclusion Criteria

- Patients with displaced midshaft clavicle fracture aged

between 18 years to 65 years.

#### e) Exclusion Criteria

- Compound fractures of the clavicle.
- Severely comminuted fractures of the clavicle.
- Patients with neurovascular deficits

### 1. Conservative management

All selected patients were immobilized with help of clavicular brace and shoulder arm pouch for maximum three weeks. No method of reduction of fracture was used. Serial tightening of brace was done as tolerated by patient.

They were encouraged to discontinue the sling when they no longer felt it was necessary and to use the arm and shoulder within the limits of pain. No physiotherapy was instituted.



Fig 1: conservative management of Pateint

Patients with symptomatic radiological nonunion six months after the injury were offered surgical treatment, consisting of debridement, reaming of the medullary cavity, followed by fixation with clavicular LCP fixation. Bone graft was used from iliac crest if necessary.

### 2. Operative management

Selected cases were managed with either intramedullary device like TENS or extramedullary device like plate and screw.

No randomization was done in this group. First 15 patients were treated with open reduction and internal fixation with clavicular locking compression plate and screws and next 15 patients were treated with open reduction and internal fixation or closed reduction and internal fixation by TENS.

### Results and observations

In this series, 60 patients with mid shaft clavicle fracture were included. Out of total 60 cases; 30 were treated non-operatively and remaining 30 cases were treated with surgical management.

All 60 patients followed up for 6months from Nov. 2017 to April 2019. The observations are as given below:

Table 1: Distribution of cases according to sex

Sex	Number of cases	Percent
Female	15	25%
Male	45	75%
Total	60	100%

**Table 2:** Distribution of cases according to age group

Age group (in years)	Number of cases	Percentage
Up to 20	3	5.0%
21-30	21	35.0%
31-40	13	21.7%
41-50	9	15.0%
51-60	8	13.3%
>60	6	10.0%

**Table 3:** Distribution of cases according to Robinson classification

Robinson Classification	Frequency	Percentages
2B1	47	78.3%
2B2	13	21.6%

According to Robinson classification, there were 47 cases (78.3%) under 2B1 and 13 (21.6%) cases under 2B2.

**Table 4:** Comparison of time of union (in weeks) between group (n=56)

Time of Union (In Weeks)	Group		Chi square	P value
	Conservative (N=26)	Surgical (N=30)		
<8	1 (3.8%)	8 (26.6%)	17.7636	<0.001
9 To 16	9 (34.6%)	19 (63.3%)		
17 To 20	12 (46.15%)	2 (6.6%)		
21 To 24	4 (15.3%)	1 (3.3%)		

**Table 5:** Comparison of mean of union time in weeks between the groups

Parameter	Group	
	Conservative (Mean± SD)	Surgical (Mean± SD)
Union time in weeks(N=56)	16.61 ± 4.20	12.36 ± 4.05
Hospital stay in days(N=60)	8.2 ± 7.35	9.77 ± 5.63

The mean union time (in weeks) of conservative group was 16.61 ± 4.20 and it was 12.36 ± 4.05in surgical group. The mean hospital stay (in days) of conservative group was 8.2 ± 7.48and it was 9.77 ± 5.63 in surgical group.

**Table 6:** comparison of complication between group (n=60)

Complication	Group	
	Conservative (N=30)	Surgical (N=30)
Delayed Union	8 (26.6%)	2 (6.66%)
Distal Nail Migration	0 (0%)	1 (3.33%)
Hypertrophic Scar	0 (0%)	1 (3.33%)
Implant Failure	0 (0%)	1 (3.33%)
Implant Prominence	0 (0%)	2 (6.67%)
Malunion And Shortening	11 (36.6%)	0 (0%)
Non Union	4 (13.33%)	0 (0%)
Proximal Nail Migration	0 (0%)	1 (3.33%)
Shoulder Stiffness	1 (3.33%)	0 (0%)
Nil	7 (23.33%)	22 (73.33%)

**Table 7:** Comparison of complication between group (n=60)

Complication	Group		Chi square	P value
	Conservative (N=30)	Surgical (N=30)		
Yes	23 (86.66%)	8 (26.67%)	15.016	<0.001
No	7 (23.33%)	22 (73.33%)		

Among the patient with conservative group, 23 (76.67%) patient had complications. Among the patient with surgical group, 8 (26.67%) patient had complications. The difference in the proportion of complication between group was statistically significant (P value <0.001).

**Table 8:** Comparison of final outcome at 6 months between group (n=60)

Final Outcome At 6 Month	Group		Chi-square	P value
	Conservative (N=30)	Surgical (N=30)		
Excellent	4 (13.33%)	23 (76.66%)	24.45	<0.001
Good	6 (20%)	4 (13.33%)		
Fair	16 (53.33%)	2 (6.66%)		
Poor	4 (13.33%)	1 (3.33%)		

**Discussion**

Considering the excellent remodeling of clavicle, irrespective of displacement, amount of comminution, in the past, every fracture clavicle was treated non-operatively. The surgical treatment was only reserved for cases with neurological deficits, open fractures, clavicle fractures causing skin tenting. Many recent studies have showed increased incidence of nonunion, residual pain, malunion, decreased shoulder endurance, shoulder weakness, inferior patient and surgeon-oriented outcome scores, and lower overall patient satisfaction rate following conservative treatment [5].

In our study, we have calculated the functional outcome of all the 60 cases with Constant score [25]. The functional outcome at the end of 6 months in 30 conservatively managed cases, 4 cases (13.3%) showed excellent outcome; 6 cases (20%) showed good outcome. 16 cases (53.3%) showed fair outcome and 4 cases (13.3%) showed poor outcome. While in surgically managed 30 cases, showed a total of 23(76.6%) with excellent outcome, 4 cases (13.3%) had good outcome 2 cases (6.6%) had a fair outcome, and 1 case (3.33%) had poor outcome. Final outcome was compared by applying chi square test the p value was <0.001 showing the results statistically significant.

**Table 9:** Comparison of functional outcome

Study	Mean constant score in conservative group	Mean constant score in surgical group
Present study	80.23	94.3
C.M. Robinson, E.B. Goudie <i>et al.</i> [71]	87	92
B.M Naveen [77]	89.6	93
Shettar <i>et al.</i> [78]	55.63	71.16

**Conclusion**

Based on the results obtained during the study period and also considering the functional outcomes of both the groups of this prospective comparative study following conclusions were made.

The majority of complications in this study, were in conservative group. These complications were mainly attributed to the difficulty in maintaining fracture in anatomically aligned position. Presence of these many complications had a final effect on the functional outcome and majority of patients had good to fair outcome as compared to excellent outcome in the operative group. Non union rates were significantly high in the non-operative group as compared to operative group. All these complications lead finally to patient dissatisfaction to the treatment, prolonged period of absence from work, prolonged intake of analgesics and its subsequent complications.

Hence this study proves that, surgically managed displaced clavicle fractures have better functional outcome, fewer complications and early bony union when compared to non-operative treatment modality. But it is recommended that, treatment has to be individualized for every case and routine

use of operative procedure is not advisable especially in a rural set up like ours.

### Study limitations

- The conclusions drawn from this study cannot be generalized, because this study does not consider socioeconomic aspects of patients and also because of the small number of cases in both the groups.
- We have followed the patients in both the groups for 6 months, but whether the longer follow up period might affect the final outcome of the study or not remains unanswered.

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