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Comparative prospective study between operative and conservative management of clavicular fractures

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Abstract

Background and objectives: Clavicle fracture is one of the most common bony injuries which accounts for 2.6% to 4% of adult fractures and 35% of injuries of shoulder girdle. The annual incidence of midclavicular fracture is 64 per 100 000 population. Breaks of the shaft form 70% to 80% of all clavicular fractures; lateral fractures contribute to 15% to 30% of the total and medial fractures accounts for 3% and are relatively rare. Open clavicular fracture is an absolute rarity, found in only 0.1% to 1% of cases. There are various methods for treating clavicular fractures such as intramedullary K-wire or Steinmann pins and plating.

We have taken up this study to gain deeper understanding of the results and problems associated with clavicular fractures and to evaluate the functional outcome after fixation of clavicular fracture with LCP and conservative management.

Materials and methods: The present study was conducted in Department of Orthopaedics at Sri Siddhartha medical college, hospital and Research Center Tumkur during the period from March 2015 and February 2017. In this prospective study, 60 patients between 18 and 60 years of age who had an acute displaced mid-shaft clavicular fracture were randomized to receive either primary open reduction and plate fixation (n = 30) or nonoperative treatment (n = 30). Functional assessment was conducted at 3 months, 6 months, and 1-year with the use of the constant scores. Union was evaluated clinically and radiographically. Complications were recorded and compared.

Results: The rate of nonunion was significantly reduced after nonoperative treatment (none nonunion) as compared with open reduction and plate fixation (two nonunion). Constant scores were significantly better after nonoperative treatment than after open reduction and plate fixation.

Conclusion: Our study shows that nonoperative treatment reduces the rate of nonunion after acute displaced clavicular fracture compared with Open reduction and plate fixation and is associated with better functional outcomes. Open reduction and plate fixation using precontoured locking plate have non union as complication (7% of cases).

Keywords: Precontoured clavicular locking plate, clavicle fracture, Conservative clavicular fracture

Introduction

The clavicle is an s-shaped bone that acts as a strut between sternum and glenohumeral joint. It also has a suspensory function of shoulder girdle. The shoulder hangs from clavicle by coracoclavicular ligament [1].

The annual incidence of mid clavicular fracture is 64 per 100 000 population. Breaks of the shaft form 70% to 80% of all clavicular fractures; lateral fractures contribute 15% to 30% and medial fractures which account 3% and are relatively rare. Open clavicular fracture is an absolute rarity, found in only 0.1% to 1% of cases [2].

There are various methods for treating clavicular fractures such as intramedullary K-wire or Steinmann pins and plating. We have taken up this study to gain deeper understanding of results and problems associated with fracture and are to evaluate the functional outcome after fixation of clavicular fracture with LCP and conservative management.

Methods

The present study was conducted in Department of Orthopaedics at Sri Siddhartha medical college, hospital and Research Center Tumkur during the period from March 2015 and February 2017.

In this prospective study, 60 patients between 18 and 60 years of age who had an acute displaced clavicular fracture were selected to receive either primary open reduction and plate fixation (Group A)(n = 30) or nonoperative treatment (Group B)(n = 30).

Functional assessment was conducted at 2 months, 3 months, 6 months with the use of the constant scores. Union was evaluated clinically and radiographically.

General information like name, age, sex, occupation and address were noted. Then a detailed history was elicited regarding mode of injury like fall on the shoulder, Road traffic accident, direct injury to shoulder and fall on outstretched hand. Enquiry is made to note site of pain and swelling over the affected clavicle. Past medical illness and family history were also recorded. General condition of the patients was examined for pallor, pulse rate and blood pressure. Respiratory and cardio vascular system and central nervous system were examined for any abnormalities.

Clinical examination (both local and systemic)

1. On inspection the following points were noted. Patients with fracture clavicle often support the flexed elbow of the injured side with the other hand. Abnormal swellings present in the middle third for middle third clavicle fracture and in the lateral third for lateral third clavicle fracture should be looked for. The condition of the skin over the clavicle was noted for any abrasion, laceration and contusion.
2. On palpation the following points were noted palpation of the entire length of the affected clavicle for tenderness in the medial middle third or in the lateral third fracture. The clavicle was also palpated for any abnormal mobility and crepitus.
3. Movements
The movements of the affected side shoulder was restricted due to pain. The distal neurovascular status of the affected upper limb was examined and also the associated injuries along with fractured clavicle were noted.

Radiological examination

Plain radiograph of clavicle with shoulder in anteroposterior view was taken to assess the site of fracture and the fracture type.

Routine investigation

Hb%, Total count, Differential count, RBS, Blood urea, Serum creatinine and ECG Were done. HIV, HBsAg, HCV, screening tests were done before surgery on all Subjects.

1. Fracture anatomy assessed with X-rays.
2. Diagnosis was done after clinical and radiological assessment.
3. Written informed consent was taken for surgical procedure after being explained about the pros and cons.
4. All patients were operated as early as possible once the patient was declared fit for the surgery by the physician.
5. Surgery – Open reduction and internal fixation with LCP.

Aims and objectives

Aim of the study

- To compare early and complete functional outcome between locking compression plate and conservative management in clavicular fractures.

Objectives

- To provide early and complete functional activity of the upper extremity.

- To study advantage and complication

Inclusion Criteria

Adult male and female patients above 18 years with clavicle fracture were included for this study after taking written consent from them.

Exclusion Criteria

1. Pathological fractures
2. Associated head injury
3. Associated with neurovascular injury
4. Established non-union from previous fracture
5. Associated acromioclavicular joint dislocation
6. Any medical contraindication to surgery or general anesthesia (heart diseases, renal failure or active chemotherapy)

Technique of conservative management

After reduction figure of eight bandage/ clavicular brace was applied and limb was supported by a triangular sling/arm pouch under the elbow and forearm.

Postreduction treatment

Treatment is maintained for 6 weeks. All patients were counseled that there will likely be some deformity to the shoulder girdle, but that function will typically be normal. Shoulder joint movements (pendulum range of motion exercises) were started afterward. Heavy tasks were forbidden; contact sports were restricted for 3 months after injury. Heavy laborers were allowed to return to light-duty of lifting 6 weeks after injury with a return to full duty by 12 weeks

Operative procedure

1. Under general anesthesia patient was put in supine position on OT table with a towel under the shoulder.
2. Entire upper limb from base of neck to hand was prepared and draped.
3. About 7-9 cms, incision was made in the anterior aspect centering of clavicle over the fracture site.
4. The skin subcutaneous tissue and platysma were divided without undermining the edges.
5. The overlying fascia and periosteum were next divided. The osseous ends were freed from surrounding tissue.
6. Minimal soft tissue and periosteum dissection was done.
7. Fracture fragments were reduced and precontoured locking compression plate was applied over the superior aspect of the clavicle.
8. At the junction of the medial and middle third of the clavicle, the inferior surface is exposed so that a protective instrument can be inserted during drilling(3.2mm drill bit was used for 4mm locking screws and 2.8mm drill bit was used for 3.5mm cortical screws)to prevent injury to neurovascular structure underneath it.
9. The precontoured locking compression plate was fixed to the medial and lateral fragment with 4.0 mm locking screw or 3.5mm cortical screw at least three screws in medial and lateral fragment were applied.
10. Wound was closed in layers after ensuring meticulous hemostasis and sterile dressing was applied.

After treatment

Patients were kept nil orally for 4 to 6 hours post-operatively. Intravenous fluids were given as needed.

Antibiotics were continued for 10 days.
 Analgesics and tranquilizers were given according to the needs of the patient.
 The operated upper limb was immobilized in an arm pouch.
 Check X- rays were taken to study the alignment of fracture fragments.
 The wound was inspected at 3or 4th postoperative day.
 Suture/staple removal was done on 10th postoperative day.
 Patients were discharged with the arm pouch.
 Rehabilitation of the affected arm was started at the end of 2 weeks.
 At 4 to 6 weeks gentle active range of motion of the shoulder was allowed but abduction was limited to 80 degrees. At 6 to 8 weeks active range of motion in all planes were allowed.

Follow-up

All the patients were followed up at 6, 12 and 24 weeks.
 Local examination of the affected clavicle for tenderness, instability deformity and shoulder movements were assessed.
 1. X-rays were taken at each follow up visits to know about progressive fracture union and implant position.
 2. Rehabilitation of the affected extremity was done according to the stage of fracture union and time duration from day of surgery.
 3. Patients were followed up for 6 months.
 4. The functional outcome was assessed by Constant and Murley score [3, 4, 5].

Criteria for functional results

Functional outcome was evaluated using the constant shoulder score, which is scored from 0 to 100, with a lower score representing a higher level of functional disability.

Statistical tests

Descriptive statistics such as mean, standard deviation and proportion were calculated. Statistical Methods: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean, SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance.

The following assumptions on data is made:

1. Dependent variables should be normally distributed,
2. Samples drawn from the population should be random, cases of the samples should be independent.

Student ‘t’ test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters.

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis.

Statistical software: Data collected was entered in Microsoft excel and analyzed in epiinfo 3.4.3, SAS 9.2, SPSS 15.0,

Stata 10.1, MedCalc 9.0.1, Systat 12.0 and Renvironment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc [6, 7, 8, 9].

Results

The present study included 60 patients, which were divided into two groups. The first group of twelve patients was treated by ORIF by precontoured clavicle locking plate and twenty patients of the second group were treated by conservative measures.

Age Distribution

In our study we had majority of cases (40%) in 51-60 age group with average of 46 years (19-58) years in Group A and Group B majority of cases (40%) were in 51-60 years with an average of 47.3 years (18-59) years. (Table 1)

Sex Distribution

In both the groups there was increased distribution of Males accounting for 73% and 67% respectively. (Table 2)

Side of Fracture

In Group A equal distribution of sides where as in group B right side was more involved with 53% (Table 3)

Mechanism of Injury

In group A RTA’s accounted for majority of cases (73%) and group B(76%)RTA and Fall has 8% and 7% each (Table 4)

Plate Size Used

In group A 6 hole and 7 hole plate was used in 12 cases each(40%) and 5 holed plate (3%) in 1 case, 8 holed plate (17%) in 5 cases (Table 6) All the 40 patients were followed up at 4-6 weeks, 11-14 weeks and 6 months for Functional and Radiological review.

In Group A the average follow up was 12.8 months range (6-20 months) Group B the average follow up was 13.1 months range (6-18 months)

Complications

In this study, complications were superficial infection of each case in each group and two non unions in group A (Table 6)

Duration of union

The fracture was considered to be united when clinically there was no tenderness, no appreciable inter-fragmentary movement, radio logically presence of bridging callus, and full unprotected function of the limb was possible 21 cases (70%) had union time within 4 month in both the groups however 2 cases (7%) were considered as non union in group A and all cases in group B united within time period.

Functional outcome

The functional outcome was assessed by Constant and Murley¹⁰ score [Table 8].

Table 1

Age Group(years)	Group A No of Cases	%	Group B No of Cases	%
<20	1	3	1	3
21-30	1	3	1	3
31-40	6	20	5	17
41-50	10	34	11	37
51-60	12	40	12	40
	30	100	30	100

Table 2

Sex	Group A No of Cases	%	Group B No of Cases	%
Male	22	73	20	67
Female	8	27	10	33
	30	100	30	100

Table 3

Side of fracture	Group A No of Cases	%	Group B No of Cases	%
Right	15	50	16	53
Left	15	50	14	47
	30	100	30	100

Table 4

Mechanism of injury	Group A No of Cases	%	Group B No of Cases	%
RTA	22	73	23	76
FALL	8	27	7	24
	30	100	30	100

Table 5

Plate size used	Group A No of bones	%	Group B No of bones	%
5 holed	1	3	-	-
6 holed	12	40	-	-
7 holed	12	40	-	-
8 holed	5	17	-	-
	30	100	-	-

Table 6

Complication	Group A No of Cases	%	Group B No of cases	%
Non union	2	6.7	1	3.3
Superficial infection	1	3.3	-	-
Implant failure (broken implant)	1	3.3	-	-
	4	13.3	1	3.3

Table 7: Duration of fracture union

Time of union	Group A No of Cases	%	Group B No of cases	%
< 4 months	21	70	21	70
4-6 months	6	20	7	23
6 months- 1 year	1	3	2	7
Non union	2	7	-	-
Total	30	100	30	100

Table 8: Results

Results	Group A No of Cases	%	Group B No of cases	%
Excellent	20	65	21	70
Good	6	21	9	30
Fair	2	7	-	-
Poor	2	7	-	-

**Photos
Group A**

Photographs showing radiological union (Pt. No.2)



Pre-op



Post-op



Non union in Group A case no. 9



Superficial infection in Group A

Group B



Case of clavicle x ray of patient 7 in group B



Union of patient 7 in group B



Non union of patient 9 in group B

Discussion

Clavicle fractures are usually treated conservatively. In a study conducted to analyze the results of conservative treatment by Hill *et al.* [11] in 1997, Nordqvist *et al.* [12] in 1998 and Robinson *et al.* [13] in 2004 found poor results following conservative treatment of displaced middle third clavicle fracture.

In Böstman *et al.* study [14]. of patients treated with semi tubular plate, 1.9% of the patients had implanted breakage and 6.8% had loosened. But however in our study there was no such complications in operative group. The reason for this seems to be due to two factors. First, less stress on our precontoured fixation device because of S-shape better suited for clavicle anatomy thus causing less stress in the overall construct. Second, greater strength of locking plate as

compared to the semi-tubular plate.

The functional outcome according to Constant and Murley [10] was found to be significantly higher in operative group. In this study, average constant score in the nonoperative group was found to be 90.7 and 86.9 in operative group. Canadian Orthopaedics Trauma Society [15] found an average constant score of 96.1 in operative group and 90.8 in the nonoperative group which is contradictory. Sample size being small, low prevalence complications could not be encountered in this study. Larger sample size will be a prerequisite for knowing the prevalence of nonunion and symptomatic malunion in operative group.

Conclusion

We conclude

In modern day world, Clavicle fractures are treated more surgically with plating techniques for rigid fixation, but there are specific indications for which operative treatment is needed such as comminuted and displaced, middle third clavicle fractures. It was observed that conservative management yielded better functional outcome and resulted in high union rates. All the fractures united, and there was no nonunion in conservative group. For clavicle fractures non operative management gave excellent result in 70% patients and rest cases gave good results with 30% and non fair or poor outcome. In a operative group, nonunion rate was found to be 7%, and the excellent outcome was found only in 65% patients with 7% fair and only 21% good outcome.

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Declarations

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