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Dr. Anand SR
Assistant Professor, Department of Orthopedics, Mysore Medical College and Research Institute, Mysore, Karnataka, India

Dr. Paramesha KC
Associate Professor and Unit Chief, Department of Orthopaedic, Mysore Medical College and Research Institute, Mysore, Karnataka, India

Dr. Hariprasad KA
Post-Graduate Student, Department of Orthopaedics, Mysore Medical College and Research Institute, Mysore, Karnataka, India

Corresponding Author:
Dr. Hariprasad KA
Post-Graduate Student, Department of Orthopaedics, Mysore Medical College and Research Institute, Mysore, Karnataka, India

Comparative study of surgical management with plating versus non-operative management of displaced fracture of middle one-third of the clavicle

Dr. Anand SR, Dr. Paramesha KC and Dr. Hariprasad KA

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Abstract
Clavicle is subcutaneously located and is relatively anterior in location, these peculiarities makes clavicle fracture as one of the commonest injury. Among clavicle fracture mid shaft fracures are the most common type. Both non operative and surgical management are the standard method of choice for midshaft clavicle fractures, however there are lots of debate in literature regarding which gives better results, hence the present study is undertaken to compare surgical management with plating and conservative management interms of functional outcome, the rates of malunion, delayed union and nonunion and related complications.

Aims and Objectives:

1. To analyse the functional and radiological outcome of fracture of middle third of the clavicle treated surgically with plating versus non operative management.
2. To evaluate the complications associated with the operative and the non-operative management of the fracture of middle-third of clavicle.

Method: 40 cases of mid shaft clavicular fracture were recruited for the study. They were divided into 2 groups each having 20 patients. Patients in group 1 were managed conservatively and patients in group 2 were managed surgically. Follow up was done at 6 weeks, 3 month and 6 months to assess functional and radiological outcomes.

Result: Radiographic and clinical union was faster in the operative group, Constant and murley scores showed more improvement in the operative group when compared to non operative group. The average Constant murley score at the end of 6 months in group 1 was 73.8 and group 2 was 80 with significant mean difference of 6.20. Out of 20 cases operated 3 had surgical site infection (15%) and out of 20 conservatively managed cases three had non-union (15%) and two had delayed union (10%).

Conclusion: The current study showa that union rate was faster, incidence of malunion and non-union were lesser and fuctional outcome assessed using Constant murley scores were significantly higher in the surgical group, this asserts that for displaced and communited mid shaft clavicle fractures operative intervention provides better results and early recovery of function.

Keywords: Clavicle, plating versus, displaced fracture, surgical management

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.

Clavicle fracture is one of the most common injuries around the shoulder girdle [1]. It accounts for approximately 2.6% of all fractures [2]. The incidence in males usually peaks in second and third decade which later decreases with age [3]. The fracture clavicle has a bimodal distribution in females, with peak incidence in young and elderly [4]. The clavicle fractures were classified into three groups by Allman [5] based on their location along the bone. The most common among them is the middle-third fractures which accounts for approximately 80–85% of all clavicular fractures [6]. The narrow cross section of the bone in the middle shaft along with the typical muscle forces acting over it predispose to fracture the bone in this site.

Further, Allman classification was modified by Robinson based on the degree of displacement and comminution [3]. Majority of the mid-shaft clavicle fractures generally unite with any method of immobilization. Therefore, non-operative treatment was the established and accepted modality of these fractures. This was supported by extremely low nonunion rates shown by prior studies [7, 8]. However, when displaced fractures are managed conservatively suboptimal outcomes and a very high nonunion rates has been found by some studies [9, 10]. The drawbacks of non-operative treatment included functional impairment of the shoulder and a non-cosmetic bump at the base of the neck due to shortening of the clavicle and callus formation [9]. These shortcomings of the conservative management can be prevented by restoration of normal length and alignment by surgical methods. Though good outcome with high union rates and low complication rates has been reported with various surgical modalities, it has also got its own limitations such as surgical site infection, hardware prominence, hypertrophic scar, and a repeat surgery for implant removal at times. Clinical trials comparing the various therapeutic options for middle-third clavicle fractures are rare since mid-shaft clavicular fractures generally unite with most of the treatment modalities. In addition, there is no uniform consensus yet on the definite choice of treatment for displaced middle-third clavicular fractures. Hence, in this study was conducted to select the better approach for the management of mid-shaft clavicular fractures. The aim of this is to evaluate the functional outcome of "open reduction and internal fixation with locking compression plate" and "conservative management with figure of eight clavicle brace" in treating displaced middle third clavicular fracture as measured by Constant & Murley score. It was also intended to study the rate of nonunion, malunion and overall local complications up to 6 months after treatment.

Materials and Methods

A comparative study of management of the mid-shaft clavicle fractures was carried out at a tertiary care teaching hospital between November 2019 and November 2021. Study population included patients in age group of 18 to 60 years with displaced fracture of the middle third clavicle. Patients with open fracture of clavicle, undisplaced fractures, age <18 years and >60 years, patients medically unfit for surgery, patient not willing for surgery and patients with neurovascular deficit were excluded. It is a prospective observational study, consisting of 40 patients with middle third clavicular fractures. Patients were randomly allotted into 2 groups, group 1 consisted 20 patients who were managed conservatively and group 2 had 20 patients who were treated surgically. In the outpatient department of the hospital, the orthopedic resident identified the patients eligible for the study and the study protocol was instituted. Patients were informed in detail by the treating surgeon regarding the advantages and disadvantages of both operative and nonoperative care. The nature of the study was explained to all the patients in their own language that they understand and written informed consent was obtained after the patients gave their willingness to participate in the study. Group 1 patients were managed conservatively, with figure of eight clavicle brace and arm pouch/sling, whereas patients of group 2 were treated surgically with precontoured locking compression plate and screws. Patients who underwent conservative management were given figure of eight clavicle brace. To support the ipsilateral upper limb, an arm pouch/sling was also given. Patient was discharged either on the same day or the next day based on the general condition of patient. Patient was reviewed every 3rd week. Radiographs was taken during immediate post bracing period, 6th week, 3rd month, 6th month.

Patients allocated to plate fixation group underwent the operation as early as possible once the general condition of the patient improved and fit for surgery as assessed by the physician. With precontoured locking compression plate and screws. Patient positioned in modified beach chair position with one towel in the interscapular area. Entire upper limb from base of neck to hand is drapped and painted. Incision of around 7 to 9cms was made in the anterior aspect of clavicle, centering over the fracture site. The incision is deepened and skin, subcutaneous tissue and platysma were divided. The overlying fascia and periosteum were divided next. The fractured ends were made free from surrounding tissue. Minimal soft tissue and periosteum dissection was done. Fracture is then reduced and plate was placed over the superior aspect of the clavicle. At the junction of the medial and middle third of the clavicle, the inferior surface of clavicle is exposed in order to keep a protective instrument, while drilling to prevent injury to neurovascular structure underneath it. The precontoured locking compression plate was fixed to the medial and lateral fragment with locking screws/cortical screws and atleast three screws in medial and lateral fragment were applied. After achieving adequate hemostasis, wound was then closed in layers and sterile dressing was done. 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 2nd and 4th postoperative day. Suture removal was done on 12th postoperative day. Patients were discharged with the arm pouch.

A rehabilitation protocol was started after 3 wks in group 1 and immediately after plate fixation in group 2. Gentle pendulum exercises of the shoulder in the sling/arm pouch were allowed as per pain tolerance immediately after surgery in surgical treated group and after 3 weeks in conservative group. At 3 weeks, gentle active range of motion of the shoulder was allowed with abduction limiting to 90. Subsequently, active range of motion exercises that are to be performed at home is advised. At four to 6 weeks, active to active assisted range of motion in all planes was allowed. At eight to 12 weeks, isometric and isotonic exercises were prescribed to the shoulder girdle muscles with a return to full activities (including sports) at 3 months.

Regular follow up every week for first two weeks followed by once in the 6th week, 3rd month, 6th month. Affected clavicle was assessed for tenderness, instability, deformity and shoulder movements. Radiographs were taken at 6th week, 3rdmonth, 6th months and to know about progressive fracture union. Rehabilitation of the affected extremity were done according to the stage of fracture union and time duration from day of surgery. The functional outcomes were assessed by constant and murley's score at 6th week, 3rd month, 6th month.

Statistics

For the statistical analysis, descriptive statistics were calculated with the objective of summarizing the set of data analyzed. Thus, the quantitative variables of the study were characterized by calculating mean, standard deviation, frequency, minimums and maximums. The categorical variables were summarized by means of frequency tables. To investigate the association between the variables, Inferential statistical analysis like pearson Chi-Square test, fishers exact test were used to study the significance of difference between frequencies.

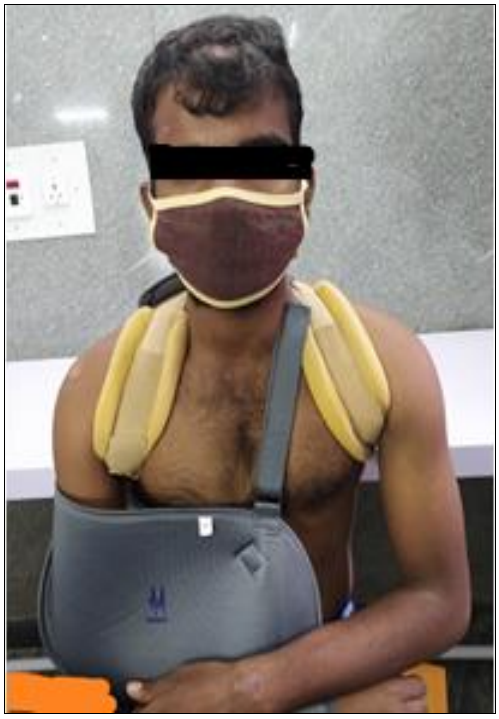


Fig 1: Clavicular brace with arm pouch

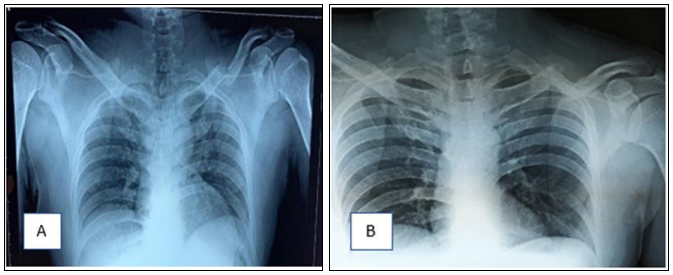


Fig 2: Patient treated conservatively A] Initial radiograph of the fracture at presentation B] Fracture union after 6 months of conservative management

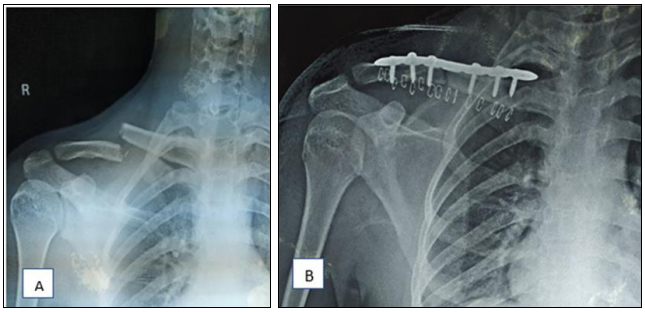


Fig 3: Patient treated surgically A] Initial radiograph of the fracture at presentation B] Radiograph in immediate post operative period

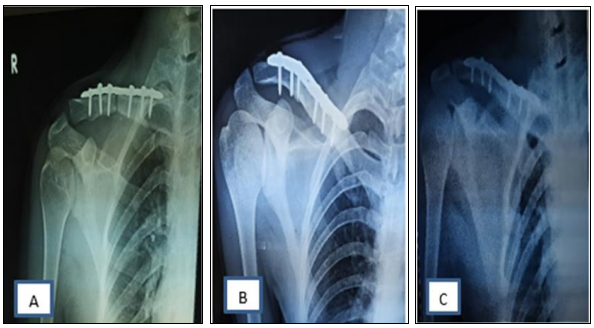


Fig 4: Radiograph of patient treated surgically A] at 6 weeks, B] at 3 months, C] at 6 months

Fig 5: A] Exposure of fracture site B] Fracture reduction C] Fixation with precontoured locking compression plate

Results

There was no statistically significant difference between the group 1 and group 2 with regard to demographic parameters such as age and sex of patients, side affected, mode of injury, presence of associated injuries(table 1). The mean Constant and Murley score was higher in the surgically treated group in comparison with conservatively managed group at the end of 6 months, and it was statistically significant (table 2, table 3). Ten patients (50%) in group 1 had various complications such as shoulder stiffness, non union, delayed union, as compared to 7 patients (35%) in group 2 who had implant failure, shoulder stiffness, infection(table 4). Delayed union and nonunion rates were higher in conservative group in comparison with the surgical group (table 5). However, complications of surgical group were generally related to surgical technique and the implant. Overall, the complication rate in the conservative group was relatively higher.

Table 1: Patient demographics

Demographic parameters	Group 1	Group 2	Chi-Square Tests (Asymp. Sig. 2 sided)
Age(mean)	37.15	32.35	0.349
Sex			
Male	11(55.0%)	13(65.0%)	0.519
Female	9(45.0%)	7(35%)	
Side affected			
Right	10(50.0%)	13(65.0%)	0.337
Left	10(50.0%)	7(35%)	
Mode of Injury			
RTA	14(70.0%)	14(70.0%)	1.000
Fall from height	6(30.0%)	6(30.0%)	
Associated injuries	3(15.0%)	6(30%)	0.655

Table 2: Constant and Murley scores-Group Statistics

C M score	group	N	Mean	Std. Deviation	Std. Error Mean
cms_6w	cons	20	44.9000	4.17889	.93443
	surg	20	56.3000	5.77745	1.29188
cms_3m	cons	20	67.9000	4.02492	.90000
	surg	20	70.7000	6.75200	1.50979
cms_6mon	cons	20	73.8000	4.93750	1.10406
	surg	20	80.0000	8.10458	1.81224

Table 3: Independent Samples Test

	t-test for Equality of Means			
	t	df	Sig. (2-tailed)	Mean Difference
cms_6w	-7.150	38	.000	-11.40000
cms_3m	-1.593	38	.119	-2.80000
cms_6mon	-2.922	38	.006	-6.20000

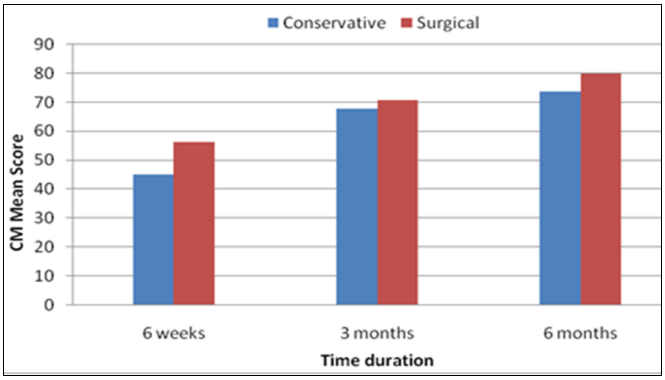
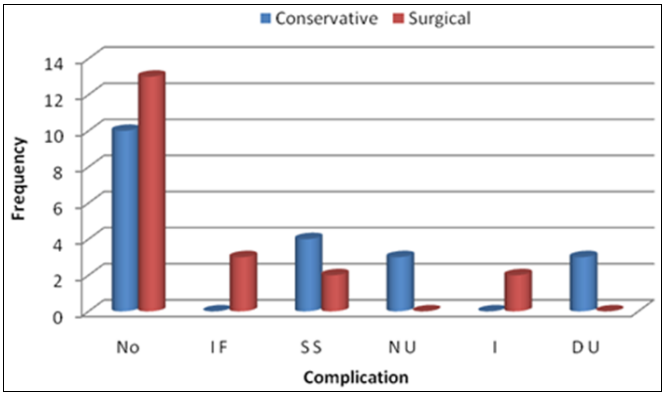


Table 4: Complications

			Group		Total
			Cons	Surg	
Complications	No	Count	10	13	23
		% within group	50.0%	65.0%	57.5%
	Implant failure	Count	0	3	3
		% within group	0.0%	15.0%	7.5%
	Shoulder stiffness	Count	4	2	6
		% within group	20.0%	10.0%	15.0%
	non union	Count	3	0	3
		% within group	15.0%	0.0%	7.5%
	infection	Count	0	2	2
		% within group	0.0%	10.0%	5.0%
	Delayed union	Count	3	0	3
		% within group	15.0%	0.0%	7.5%
Total		Count	20	20	40
		% within group	100.0%	100.0%	100.0%

Table 5: Chi-square test

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	12.058	5	.034



Discussion

In the past, conservative management was the mainstay of treatment for all clavicle fractures in middle third irrespective of displacement and comminution as clavicle has great power of remodeling. Conservative treatment with figure-of-8 bandage aligns the displaced fragments in an acceptable manner and results in a good functional outcome. However, a recent meta-analysis revealed higher nonunion rates for displaced fractures treated non-operatively (15%) than operatively (2.2%) with modern internal fixation techniques [10]. Multiple recent trials have also shown higher incidence of nonunion, malunion, shoulder weakness, residual pain, decreased shoulder endurance and lower overall satisfaction after non-operative management of mid-shaft clavicle fractures [11, 12]. The operative management with plating was reserved only for those with open fractures or highly displaced fractures.

The existing literature reports two sets of incidence of clavicle fractures: The first is associated with young active population (sports, motor vehicle accidents), whereas the second is associated with elderly individuals (osteoporotic fractures with simple falls) [4]. The most common mechanism of injury that produces a mid-shaft fracture of the clavicle is direct blow to the shoulder. As the shoulder is subjected to a high compression force from lateral side, the clavicle and its articulations are the main areas to get affected as they resist these forces. Most (85%) clavicle fractures occur in the mid-shaft as the bone is narrowest and surrounding soft tissue structures (which may help dissipate injury force) are most scarce [13]. In our study, the age group was 18–55 years. The mean age was 37.15 years in group 1 and 32.35 years in group 2. The right side was affected in 23 cases (65%) out of 40 subjects, whereas remaining 17 cases (35%) had fracture on the left side which is similar to the incidence reported in the literature [14, 15]. A careful clinico-radiologic assessment is absolutely necessary to exclude associated chest injuries, such as pneumothorax or haemothorax, which are reported in the literature to occur at rates of up to 3% [8]. In the present study, nine patients (22.5%) had associated injuries. However, none of these patients had pneumothorax or haemothorax or neurovascular injury. Generally, the clavicle fractures undergo operative fixation within first 10–14 days from the time of injury. However, various studies report increased number of complications, if the primary fixation is delayed for more than 2 weeks [16]. All patients underwent surgery within first 5 days in our study which might have contributed to higher rates of bony union. The advantages of plate fixation include immediate rigid stabilization and pain relief and it also facilitates early mobilization. The rehabilitation was instituted in both the treatment groups. The early mobilization in the surgical group helped the patients to maintain their shoulder strength and early shoulder function, whereas conservatively treated patients had their shoulder immobilized for 3 weeks, which might have resulted in shoulder weakness and delayed shoulder function. Hence, the functional outcome as measured by Constant and murleys score was higher in surgically treated patients at the end 6 months in comparison with conservatively managed group. Moreover, the earlier rehabilitation might have contributed to higher rates of bony union and early functional recovery as evident from our results.

A multicenter trial reported better functional outcomes, lower malunion and nonunion rates in operatively treated clavicle fractures after plate fixation [12]. In our study, the mean Constant and murley score for group 1 was 44.9, 67.9 and 73.8 at 6 weeks, 3 and 6 months, respectively. However, for group 2, it was 56.3, 70.7 and 80.00 at 6 weeks, 3 and 6 months, respectively. There was a statistically significant difference between the two groups with surgically managed patients achieving higher when compared to patients treated conservatively at the end of six months.

Earlier trials have studied the risk of shoulder dysfunction after conservative treatment, which generally was attributed to shortening of the bone segment, residual bone deformity, loss of force and persistent pain [17]. Some studies have observed lesser

number of consolidation defects after surgical fixation as compared to conservative treatment, whereas others have demonstrated a 37% risk of adverse events after a surgical procedure possibly due to invasion of the periosteal structures that can lead to blood loss, post-traumatic hematoma, nerve damage which can delay fracture healing [15].

In our study, we had a total of 23 patients (57.5%) out of 40 with complications across both groups. Out of 23 patients with complications, 10 patients belonged to non-surgical group and 7 patients belonged to surgical group. There was a significant difference between the group with conservative group showing greater complications when compared with the surgical group. There were surgical site infection in two patients (10%), implant failure in 3 patients (15%), shoulder stiffness in two patients (10%) within the surgically managed group. The study results are in line with more dated reports of outcomes of operative treatment of displaced mid-shaft clavicular fractures that show a complication rate of 23% and more. Some trials indicate that although clavicular deformities are complex and hard to analyze, shortening by 1.5–2 cm may result in an increased incidence of clinical symptoms.

Several recent studies have shown high union rates with surgical management using a variety of internal fixation devices, including plating and IM pin or rod fixation [11]. In addition, there is also strong evidence that the nonunion rate after conservative treatment may be higher than previously reported, particularly in certain patients and fracture types. In this study, we had 3 nonunions (15%) out of 20 patients in conservative group as compared to none in surgical group. Our results with regard to various complications compare well with the existing literature and the published studies on the subject.

From our study, we have noticed that in the surgical group, there is 100% union rates. The Constant and murley scores were also significantly higher at the end of 6 months. The numbers of complications were lesser and many of them were implant related and surgical technique related. On the other side, patients treated conservatively had more number of delayed unions and nonunions. Constant and murley scores were also lower at the end of 6 months. Hence, in a young, active patient, surgical fixation of displaced mid-shaft clavicle fracture in the form of plating appears to result in improved outcome. Plate fixation in these individuals is a reasonable option to maintain anatomic reduction and achieve union with restoration of maximal shoulder function.

In conclusion, anatomic reduction with plate fixation and early mobilization of displaced clavicle fractures is a viable treatment option, especially in young active adults with good outcomes and no major complications. There is also a need for further large multicenter prospective randomized controlled trials in order to generalize this preference of operative fixation over non-operative management in acute displaced mid-shaft clavicular fractures for all patients.

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Ethical approval: Considered and taken

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