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Original Research

Comparative analysis of the functional outcome between plating and conservative management of middle third clavicle fractures

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***ABSTRACT*:**
Background: The clavicle or collarbone is a long bone that serves as a strut between the shoulder blade and the sternum or breast bone. In the younger age group, apart from isolated clavicle fractures poly-traumatic injuries are also very common, and clavicular mid-shaft fracture remains a frequent entity. In such situations, the choice of treatment remains a constant dilemma for achieving maximum pre-fracture functional status. **Aim of the study:** To assess and compare the functional outcome between plating and conservative management of middle third clavicle fractures. **Materials and methods:** A prospective comparative study was conducted with 70 patients to analyse and compare the functional outcome of patients with midshaft clavicle fractures, treated with locking plate and conservatively. The patients were divided in the following two groups of 35 patients each: Group A patients were treated surgically and Group Bpatients were treated conservatively. **Results:** During 1month follow-up period, 29 (82.9%) and 5 (14.3%) patients in Group A and Group B respectively had excellent score while 2 (5.7%) and 7 (20%) patients respectively had good score. Moderate score was observed in 2 (5.7%) and 9 (25.7%) patients of Group A and Group B respectively whereas poor score was observed in 2 (5.7%) and 11 (31.4%) patients respectively. There was significant difference between the groups as per Chi-Square test ($p<0.05$). During 3 months follow-up period, 31 (88.6%) and 8 (22.9%) patients in Group A and Group B respectively had excellent score while 2 (5.7%) and 13 (37.1%) patients respectively had good score. **Conclusion**: Clavicle fractures are usually treated conservatively, but there are specific indications for which operative treatment is needed such as comminuted and displaced middle third clavicle fractures. It was observed that fresh middle third clavicle fractures provides a more rigid fixation and yielded better functional outcome and resulted in high union rates. As plate fixation provides rotational stability, there is no need of immobilization for long periods.
Keywords: Clavicle fracture, conservative treatment, plate fixation, fracture.

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INTRODUCTION:
The clavicle or collarbone is a long bone that serves as a strut between the shoulder blade and the sternum or breastbone.[1] There are two clavicles, one on the left and one on the right. The clavicle is the only long bone in the body that lies horizontally.[2] Together with the shoulder blade it makes up the shoulder girdle. Though not as large as other supporting structures in the body, clavicular attachments allow for significant function and range of motion of the upper extremity as well as protection of neurovascular structures posteriorly.[3] Each part of this long bone has a purpose in regards to its attachments that affects the overall physiology of the pectoral girdle. The clavicle happens to be one of the most commonly fractured bones in the human body; fracture can be as a result of direct contact or force transmission from falling onto an outstretched hand.[4] Depending on the level of displacement of the fracture, surgery may be indicated, and proper management is determined on an individual basis due to differentiating factors surrounding such injury. Clavicle fracture is a

common traumatic injury around shoulder girdle due to their subcutaneous position. It is caused by either low-energy or high-energy impact. Fracture of the clavicle accounts for approximately 5–10% of all fractures and up to 44% of injuries to the shoulder girdle. About 70–80% of these fractures are in the middle third of the bone and less often in the lateral third (12–15%) and medial third (5–8%).[5] Incidence in males is usually highest in second and third decade which decreases thereafter as per age.[6] In females, it is usually bimodal, with peak incidence in young and elderly.[7] Allman [8] classified clavicle fractures into three groups based on their location along the bone. The middle-third fractures are most common and account for approximately 80–85% all clavicular fractures.[9] The narrow cross section of the bone in the middle shaft combined with typical muscle forces acting over it predispose to fracture the bone in this locality. Fractures of the clavicle have been traditionally treated non-operatively. Although many methods of closed reduction have been described, it is recognised that reduction is practically impossible to maintain and a certain amount of deformity and disability is expected in adults.[5,10,11] In the past few years, several publications have described about poor outcomes like malunion and non-union (15%) after conservative treatment of severely displaced clavicular fractures.[12,13] In the younger age group, apart from isolated clavicle fractures poly-traumatic injuries are also very common, and clavicular mid-shaft fracture remains a frequent entity. In such situations, the choice of treatment remains a constant dilemma for achieving maximum pre-fracture functional status.

Recent studies in the adult literature have shown a higher prevalence of symptomatic malunion, non-union and poor functional outcome after non-operative treatment of comminuted mid shaft clavicle fractures. Hence the present study was done at our tertiary care center to assess and compare the functional outcome between plating and conservative management of middle third clavicle fractures.

MATERIALS AND METHODS:

A prospective comparative study was conducted with 70 patients to analyse and compare the functional outcome of patients with midshaft clavicle fractures, treated with locking plate and conservatively. The patients were divided in the following two groups of 35 patients each:

- **Group A:** 35 patients were treated surgically
- **Group B:** 35 patients were treated conservatively

The study was a hospital based prospective comparative study and was conducted for a year. All cases of midshaft clavical fractures classified with ROBINSON type2b fractures admitted to Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College, Kolhapur which fit into inclusion criteria were included for the study. Patient were informed about the study in all respects and written informed consent were obtained.

INCLUSION CRITERIA

- Patients in the age group of above 18 years.
- ROBINSON Type 2B Fractures.
- Closed fractures.
- Fractures reported within 9 days of injury.

EXCLUSION CRITERIA

- Other simultaneous upper limb fractures.
- Former surgery of the shoulder.
- Former chronic illness of the shoulder.
- Associated nerve or vessel damage of the affected arm.
- Compound fractures.

PRE-OPERATIVE EVALUATION AND CARE

The patients included in the study presented with pain, swelling and difficulty in using the involved limb following injury. Detailed clinical examination was done to rule out other associated injuries and documented. The associated injuries were also treated simultaneously. Antero-posterior radiograph of the shoulder joint with clavicle was taken with other relevant x-rays if needed, were ordered accordingly. Initially patients were supplemented with analgesics and the limb was immobilized with figure of 8 bandage. It was continued for patients who were not willing for surgery. They were included in conservatively treated group. The fractures were classified according to Robinson Classification. After completing the routine blood investigations ECG, chest X-ray and other relevant investigations and anesthetic fitness, the patients were taken up for surgery. Fracture fixation was done using plating. In our study plating was used for all patients with antero-superior plate placement.

CONSERVATIVE MANAGEMENT:

Patients not willing for surgery were invariably included in this group. All patients were applied with figure of 8 bandage. It was continued for 4 weeks with reinforcing of bandage at 2 weeks. At the end of 4 weeks bandage were removed and was started on with pendulum exercises. Radiological signs of union were noted, strengthening and resistive exercises of the rotator cuff, deltoid and trapezius were started. Follow-up was done at 1 month, 3 month and 6 months.

OPERATIVE TREATMENT:

- Preliminary treatment on admission- shoulder arm pouch, strapping, analgesics.
- Anaesthesia used – GA
- Approach used
- Type of table – Normal/ fracture table
- Size of plate and screws used
- Intra-operative complications
- Final inspection of the plate, screws and fracture reduction under ‘C’-ARM image intensifier.

POSTOPERATIVE CARE AND REHABILITATION:

- Intravenous antibiotics were continued for first three days.
- Check X-RAY on 1st post-operative day.
- Dressing were done on 2nd, 5th and 8th post-operative day.
- Sutures were removed on 12th post-operative day.
- The arm was maintained in a sling on a full-time basis for two weeks.
- Pendulum movements of shoulder started within two days with limb rested in arm sling.
- After two weeks, the wound status was assessed and use of the sling discontinued and active assisted range-of-motion exercises of the shoulder in the scapular plane were started.
- After four weeks, full active motion was initiated.
- When there is clinical and radiographic signs of union note (usually at six to eight weeks), strengthening and resistive exercises of the rotator cuff, deltoid and trapezius was started.
- After clinical and radiological union, most patients were allowed to participate in sports activities usually by three to four months.

Follow up - 1 month, 3 months, 6 months.

- At three months and 6 months follow up, patient's functional outcomes were assessed using DASH questionnaire.
- Radiological evaluation of the union was done by taking serial X-rays.
- Radiological union were assumed to be achieved when there is bridging
- trabeculations across the fracture site on three of four cortices at the fracture line.
- Any changes in the alignment, screw pullout or implant failure were also noted.
- Functional outcome is based on the Constant and Murley scoring system which included both subjective and objective variables and DASH score.

Comparison among the study groups is done with the help of unpaired t test as per results of normality test. Qualitative data is presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of Fisher test, student 't' test and Chi-Square test. 'p' value less than 0.05 is taken as significant**.**

RESULTS:

Table 1 shows the distribution of patients according to age. Majority of the patients (40%) in Group A were in the age group of 31-40 years followed by 31.4% in the age group of 21-30 years, 20% in the age group of 41-50 years and 8.6% in the age group of 51-60 years. The mean age of the patients was 34.63 ± 9.13 years. Majority of the patients (42.8%) in Group B were in the age group of 31-40 years followed by 34.2% in the age group of 21-30 years, 17.1% in the age group of 41-50 years and 5.9% in the age group of 51-60 years. The mean age of the patients was 33.94 ± 8.32 years. There was no significant association between the groups as per Student t-test ($p>0.05$). **Table 2** shows the distribution of patients according to sex. Majority of the patients in both groups were male. There were 85.7% and 82.9% male patients in Group A and Group B respectively whereas female patients constituted 14.3% and 17.1% of the study group respectively. There was no significant association between the groups as per Chi-Square test ($p>0.05$).**Table 3** shows the distribution of patients according to complications. 2 (5.7%) patients each in Group A had plate prominence and skin scar while 1 (2.9%) patient each had malunion and infection. 4 (11.4%) patients in Group B had malunion while 3 (8.6%) patients had restricted range of motion (ROM). 2 (5.7%) patients had non-union. There was no significant difference between the groups as per Chi-Square test ($p>0.05$). **Table 4** shows distribution of patients according to functional outcome. Functional outcome was evaluated by Constant-Murley Score. In Group A, the functional outcome was excellent in 24 (68.6%) patients while it was good and moderate in 2 (5.7%) and 5 (14.3%) patients respectively. 4 (11.4%) patients had poor functional outcome. In Group B, the functional outcome was excellent in 4 (11.4%) patients while it was good in 7 (20%) patients. 11 (31.4%) and 13 (37.1%) patients had moderate and poor functional outcome respectively. There was significant difference between the groups as per Chi-Square test (**$p<0.05$**).**Table 5** shows functional outcome of patients during follow-up period. During 1month follow-up period, 29 (82.9%) and 5 (14.3%) patients in Group A and Group B respectively had excellent score while 2 (5.7%) and 7 (20%) patients respectively had good score. Moderate score was observed in 2 (5.7%) and 9 (25.7%) patients of Group A and Group B respectively whereas poor score was observed in 2 (5.7%) and 11 (31.4%) patients respectively. There was significant difference between the groups as per Chi-Square test ($p<0.05$). During 3 months follow-up period, 31 (88.6%) and 8 (22.9%) patients in Group A and Group B respectively had excellent score while 2 (5.7%) and 13 (37.1%) patients respectively had good score. Moderate score was observed in 2 (5.7%) and 6 (17.1%) patients respectively of Group A and Group B while poor score was observed in 8 (22.8%) patients of Group B. During 6 months follow-up period, all patients in Group A had excellent score. 13 (37.1%) and 15 (42.9%) patients in Group B had excellent and good score respectively while 2 (5.7%) and 5 (14.3%) patients had moderate and poor score respectively. There was significant difference in functional outcome during follow-up period between the groups as per Chi-Square test ($p<0.05$).

Table 1: Distribution of patients according to Age

Age (years)	Group A		Group B		p Value
	N	%	N	%	
21-30 years	11	31.4%	12	34.2%	>0.05
31-40 years	14	40%	15	42.8%	
41-50 years	7	20%	6	17.1%	
51-60 years	3	8.6%	2	5.9%	
Total	35	100%	35	100%	
Mean ± SD	34.63 ± 9.13		33.94 ± 8.32		

Table 2: Distribution of patients according to Sex

Sex	Group A		Group B		p Value
	N	%	N	%	
Male	30	85.7%	29	82.9%	>0.05
Female	5	14.3%	6	17.1%	
Total	35	100%	35	100%	

Table 3: Distribution of patients according to Complications

Complications	Group A		Group B		p Value
	N	%	N	%	
Malunion	1	2.9%	4	11.4%	>0.05
Plate Prominence	2	5.7%	0	-	
Skin scar	2	5.7%	0	-	
Non-union	0	-	2	5.7%	
Infection	1	2.9%	0	-	
Restricted ROM	0	-	3	8.6%	

Table 4: Distribution of patients according to functional outcome

Functional Outcome	Group A		Group B		p Value
	N	%	N	%	
Excellent	24	68.6%	4	11.4%	**<0.05**
Good	2	5.7%	7	20%	
Moderate	5	14.3%	11	31.4%	
Poor	4	11.4%	13	37.1%	
Total	35	100%	35	100%	

Table 5: Functional Outcome of patients during Follow-up Period

Functional Outcome		Group A		Group B		p Value
		N	%	N	%	
Excellent	**At Discharge**	24	68.6%	4	11.4%	**<0.05**
	1 month	29	82.9%	5	14.3%	
	3 months	31	88.6%	8	22.9%	
	6 months	35	100	13	37.1%	
Good	**At Discharge**	2	5.7%	7	20%	**<0.05**
	1 month	2	5.7%	10	28.6%	
	3 months	2	5.7%	13	37.1%	
	6 months	0	-	15	42.9%	
Moderate	**At Discharge**	5	14.3%	11	31.4%	**<0.05**
	1 month	2	5.7%	9	25.7%	
	3 months	2	5.7%	6	17.1%	
	6 months	0	-	2	5.7%	
Poor	**At Discharge**	4	11.4%	13	37.1%	**<0.05**
	1 month	2	5.7%	11	31.4	
	3 months	0	-	8	22.8%	
	6 months	0	-	5	14.3%	

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 excellent 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[40]. Multiple recent trials have also revealed higher incidence of residual pain, nonunion, malunion, shoulder weakness, decreased shoulder endurance, inferior patient and surgeon-oriented outcome scores, and lower overall satisfaction after non-operative management of mid-shaft clavicle fractures.[14, 15] The operative management of these fractures with plating or nailing was reserved only for a subset of population with open fractures or highly displaced fractures. The existing literature reports two sets of incidence of these fractures: The first is the largest and is associated with young active population (sports, motor vehicle accidents), whereas the second is associated with elderly individuals (osteoporotic fractures with simple falls)[7]. A direct blow to the shoulder is the most common mechanism of injury that produces a mid-shaft fracture of the clavicle. 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 enveloping soft tissue structures (which may help dissipate injury force) are most scarce.[16]

In the present study, majority of the patients (40%) in Group A were in the age group of 31-40 years followed by 31.4% in the age group of 21-30 years, 20% in the age group of 41-50 years and 8.6% in the age group of 51-60 years. The mean age of the patients was 34.63 ± 9.13 years. Majority of the patients (42.8%) in Group B were in the age group of 31-40 years followed by 34.2% in the age group of 21-30 years, 17.1% in the age group of 41-50 years and 5.9% in the age group of 51-60 years. The mean age of the patients was 33.94 ± 8.32 years. There was no significant association between the groups as per Student t-test ($p>0.05$). In our study, majority of the patients in both groups were male. There were 85.7% and 82.9% male patients in Group A and Group B respectively whereas female patients constituted 14.3% and 17.1% of the study group respectively. There was no significant association between the groups as per Chi-Square test ($p>0.05$).This is similar to the studies of Dhakad RK et al[17], Naveen BM et al [18], Gyanendra KJ et al [19], Onta PR et al [20] and Ejagwulu FS et al.[21]

Dhakad RK et al[17] study comparing operative versus non-operative treatment of comminuted mid shaft clavicle fractures found a total of 21 patients (42%) were in the age group of 18–28 years. The youngest patient was 18 years and oldest patient was 56 years. The average patient age was 33 years. The majority were males, i.e. 45 patients (90%) and 5 patients were females (10%). Naveen BM et al[18] comparative study of management of mid-shaft clavicle fractures comparing conservative approach with primary internal plate fixation found age group was 20–50 years. The mean age was 35.2 years in group 1 and 32.4 years in group 2. Gyanendra KJ et al[19] single center, prospective clinical trial comparing the radiological and functional outcome with plating for displaced midshaft clavicle fractures found youngest patient was 17 years, and oldest patient was 59 years with the average age being 32.2 years. The majority of patients (55% of total cases) were below 30 years of age. Majority of cases (78.3%) were male, and 21.7% were female. Onta PR et al[20] study evaluating the clinical and radiological outcome, time for fracture union and complications in midshaft clavicle fracture found mean age of the patient was 37.19 (11.96) years. Ejagwulu FS et al[21] prospective study assessing the incidence of clavicle injuries, treatment modalities with their outcomes found total of 49 patients comprising 34 males (69.4%) and 15 females (30.6%). The age range was 2 weeks (0.6 years) to 62 years (mean- 32.1 years).

In the present study, 2 (5.7%) patients each in Group A had plate prominence and skin scar while 1 (2.9%) patient each had malunion and infection. 4 (11.4%) patients in Group B had malunion while 3 (8.6%) patients had restricted range of motion (ROM). 2 (5.7%) patients had non-union.There was no significant difference between the groups as per Chi-Square test ($p>0.05$). Dhakad RK et al [17], Naveen BM et al[18] and Gyanendra KJ et al[19] noted similar observations in their studies.

Dhakad RK et al[17] study comparing operative versus non-operative treatment of comminuted mid shaft clavicle fractures reported a complication requiring inpatient treatment and resulting in an additional morbidity of 2 months or more was regarded as a major complication. In the operated group, 2 patients (8%) had hypertrophic skin scar and in 2 patients (8%) plate prominence occurred. In 1 patient (4%), infection (superficial) occurred. In 1 patient (4%), plate loosening occurred. In 2 patients (8%), delayed union occurred which went for malunion and in 1 patient (4%) plate breakage occurred. In 25 patients treated with figure of 8 brace and sling, 4 patients (16%) had delayed union, 2 patients (8%) had malunion, 3 patients (12%) had non-union and 4 patients (16%) had restricted shoulder motion and pain. Naveen BM et al[18] comparative study of management of mid-shaft clavicle fractures comparing conservative approach with primary internal plate fixation reported nine patients (30%) in group 1 had various complications such as malunion with cosmetic deformity, non-union and restriction of shoulder movements, as compared to 6 patients (20%) in group 2 who had scar-related problems and hardware prominence along with the

one malunion. Malunion and nonunion rates were higher in conservative group in comparison with the surgical group. 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.

In our study, functional outcome was evaluated by Constant-Murley Score. In Group A, the functional outcome was excellent in 24 (68.6%) patients while it was good and moderate in 2 (5.7%) and 5 (14.3%) patients respectively. 4 (11.4%) patients had poor functional outcome. In Group B, the functional outcome was excellent in 4 (11.4%) patients while it was good in 7 (20%) patients. 11 (31.4%) and 13 (37.1%) patients had moderate and poor functional outcome respectively. There was significant difference between the groups as per Chi-Square test (**p<0.05**). This is similar to the studies of Dhakad RK et al[17], Ethiraj P et al[22] and Gyanendra KJ et al[19]. Dhakad RK et al study comparing operative versus non-operative treatment of comminuted mid shaft clavicle fractures reported functional outcome was assessed by Constant and Murley score. In the operative group, 19 patients (76%) had excellent functional outcome, 4 patients (16%) had good functional outcome and 2 patients (8%) had fair functional outcome. In the non-operative group, 7 patients (28%) had good functional outcome, 8 patients (32%) had fair functional outcome and 10 patients (40%) had poor functional outcome. Ethiraj P et al prospective study evaluating the functional outcome of surgically managed clavicle fractures with precontoured locking plate reported 93.4% excellent to good results, 5% fair results, 1.6% Poor results. Operative results were satisfactory in 93.4% cases, with good to excellent functional outcome. Gyanendra KJ et al[84] single center, prospective clinical trial comparing the radiological and functional outcome with plating for displaced midshaft clavicle fractures reported average value of Constant and Murley score in the conservative group was 94.47±7.514 and that in operative group was 96±7.909. The difference in Constant and Murley scoring of the two groups was not significant (p value=0.445).

In our study, during 1 month follow-up period, 29 (82.9%) and 5 (14.3%) patients in Group A and Group B respectively had excellent score while 2 (5.7%) and 7 (20%) patients respectively had good score. Moderate score was observed in 2 (5.7%) and 9 (25.7%) patients of Group A and Group B respectively whereas poor score was observed in 2 (5.7%) and 11 (31.4%) patients respectively. There was significant difference between the groups as per Chi-Square test (**p<0.05**). During 3 months follow-up period, 31 (88.6%) and 8 (22.9%) patients in Group A and Group B respectively had excellent score while 2 (5.7%) and 13 (37.1%) patients respectively had good score. Moderate score was observed in 2 (5.7%) and 6 (17.1%) patients respectively of Group A and Group B while poor score was observed in 8 (22.8%) patients of Group B. During 6 months follow-up period, all patients in Group A had excellent score. 13 (37.1%) and 15 (42.9%) patients in Group B had excellent and good score respectively while 2 (5.7%) and 5 (14.3%) patients had moderate and poor score respectively. There was significant difference in functional outcome during follow-up period between the groups as per Chi-Square test (**p<0.05**). This is comparable to the studies of Dhakad RK et al [17], Naveen BM et al[18] and Gyanendra KJ et al.[19]

Dhakad RK et al study reported early primary plate fixation of comminuted mid shaft clavicular fractures results in improved patient-oriented outcomes, improved surgeon-oriented outcomes, earlier return to function and decreased rates of non-union and malunion. Naveen BM et al[18] comparative study of management of mid-shaft clavicle fractures comparing conservative approach with primary internal plate fixation reported around 73% of patients were fully satisfied, with the treatment at the end of 6 months in group 1, as compared to 83% in group 2. Mean Constant score was higher in the surgically treated group in comparison with conservatively managed group at the end of 6 weeks, 3 and 6 months, and it was statistically significant. More patients were satisfied and subjective outcome was better. Gyanendra KJ et al single center, prospective clinical trial comparing the radiological and functional outcome with plating for displaced midshaft clavicle fractures reported patient satisfaction was found to be significantly higher in operative group compared to the conservative group at the end of six months. It was found that 93.3% patients were satisfied with results in operative group compared to 70% in conservative group.

CONCLUSION:

Clavicle fractures are usually treated conservatively, but there are specific indications for which operative treatment is needed such as comminuted and displaced middle third clavicle fractures. It was observed that fresh middle third clavicle fractures provides a more rigid fixation and yielded better functional outcome and resulted in high union rates. As plate fixation provides rotational stability, there is no need of immobilization for long periods.

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