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Operative versus conservative management in mid shaft clavicle fracture: A 2 year randomized controlled study

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Abstract

Background: Clavicle fractures are common injuries in active individuals, and it is becoming increasingly apparent that clavicular malunion is a distinct clinical entity with radiographic, orthopedic, neurologic, and cosmetic features.

Aims: To analyze the outcome of managements of nonoperative and operative procedures in fracture clavicle.

Materials and Methods: This two year randomized controlled trial was conducted in the Department of Orthopaedics of Shri B M Patil medical college from January 2014 to December 2015. After taking institutional ethical clearance and informed consent of the patients. Injuries were classified according to the robinson classification scheme. Patients were treated either conservatively or operatively and followed-up at 6 weeks and 3, 6, and 12 months.

Results: The mean time for fracture healing was significantly shorter in the operative group (14.6 ± 0.70 weeks) than nonoperative group (22.47 ± 0.74 weeks). The difference is statistically highly significant ($P < 0.000$). DASH score and Constant Moore Score were significantly better in the operative group. Constant Moore Score was 94.21 in O (OP & ON) and NO was 78.6 and CM SCORE in OP was 96.8 and ON was 91.62

Conclusion: Operative fixation of the clavicle fracture results in improved functional outcome, shorter time for union compared with nonoperative treatment at 2 year of follow-up and primary operative intervention in clavicle fracture in active adults may be of immense importance.

Keywords: Clavicle fracture, operative versus conservative management, outcome

1. Introduction

The clavicle or collarbone is the only long bone in the body that lies horizontally. Clavicle fractures are common injuries in active individuals, which account for approximately 2.6% of total body fractures and 34–45% of shoulder girdle injuries in adults, are among the most common bone injuries in the body^[1, 2]. Approximately 69-81% of clavicle fractures are in the middle one-third of the clavicle, which is the thinnest part and contains the smallest amount of soft tissue; 17% of clavicle fractures are in the lateral one-third, and 2% are in the medial one-third^[3]. Conventionally, most acute displaced midshaft clavicles fractures are treated non-operatively with the expectations of a high probability of fracture union, good functional outcomes and a high level of patient satisfaction^[4].

However, the outcome of nonoperative treatment are not as favorable as once thought, and the trend to surgically treat these fractures has grown^[5]. Whether surgical treatment is associated with improved outcome remains unknown.

2. Methodology

This two year randomized controlled trial was conducted in the Department of Orthopaedic in Shri B M Patil medical college from January 2014 to December 2015. Prior to the commencement of the study, ethical clearance was obtained from Human Ethics Committee. As the effect size was not available, the sample size was taken as 100, with 50 each in operative and non-operative group. In operative group, 25 patients treated with open reduction and anatomical locking plate and 25 patients treated with intramedullary nailing. General anaesthesia was used for all patients with or without supplementary interscalene blockade.

Correspondence

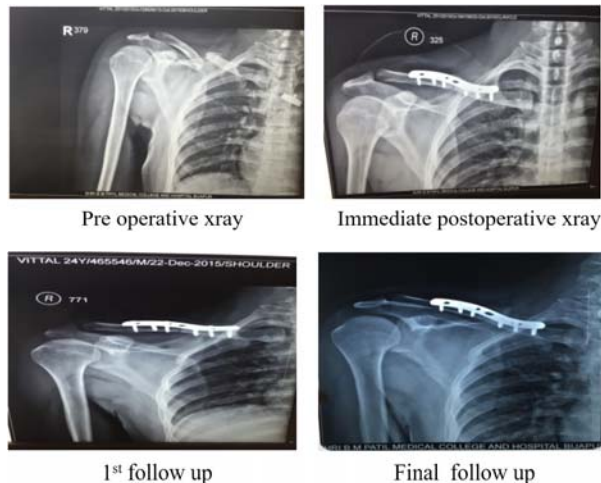
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Surgical procedures were performed by one of the orthopaedic consultants. The fracture was exposed through a curvilinear incision. Clavicle locking plate was applied to the superior surface of the bone and intramedullary nailing. In non-operative group, the arm on the fractured side was immobilized in a sling at the side in internal rotation for six weeks or until clinical or radiological union. Pendulum and elbow exercises were allowed the first day presenting in fracture clinic. Active mobilization above the horizontal and cross-arm adduction was commenced after six weeks. For all subjects, radiographs were performed at the second, six weeks, third and six month follow-up.

3. Results

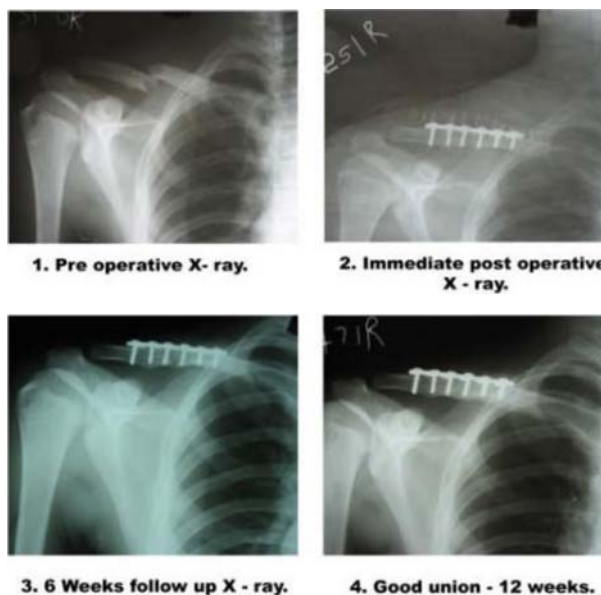
In group O, the male to female ratio was 4:1 while in group NO, it was 1.5:1. IN Operative group 50% patients in which 25% of patients in group OP (Operative Plate) and 25% of patients ON (Operative Nailing) and 50% of patients in group NO were aged ≤ 30 years. The mean age in group O and NO was comparable (37.2 ± 11.24 vs 38.4 ± 16.61 years; $p=0.301$) 50% of patients each in Group O (OP & ON) had road traffic accident and fall from height while in group NO 60% of patients had road traffic accident and 40% had fall from height ($p=0.525$). The history of associated injury was present in 25% of patients in group O compared to 15% in group NO ($p=0.429$). 45% of patients in group O (OP & ON) had B2.1 type fracture compared to 55% of patients in group NO with B1.1 type of fracture ($p=0.136$). No case of non-union was reported in operative group compared to 5 in non-operative group. 1 patient was reported in plate breakage and 2 patients had plate losing in operative plating group and 2 patients had nail impingement in operative nailing group. The mean time for fracture healing was significantly shorter in the operative group (14.6 ± 0.70 weeks) than no operative group (22.47 ± 0.74 weeks). DASH score and Constant Moore Score were significantly better in the operative group. Constant Moore Score was 94.21 in O (OP & ON) and NO was 78.6 and CM SCORE in OP was 96.8 and ON was 91.62. The mean follow-up of both groups were 12.56 months. The mean follow-up of patients in the operative group was 14.20 months. The mean follow-up of patients in the operative group was 12 months. There was no statistically significant difference between two groups with respect to flexion, extension, abduction, internal rotation and external rotation movements with $P = 0.532, 1.00, 0.344, 0.052$ and 0.056 respectively. Patients in the operative group had better range of Shoulder adduction movement than nonoperative group ($P = 0.015$).

Case 1



Range of Movements: Flexion, Extension, Abduction, Adduction, Internal Rotation, External Rotation

Case 2



Case 3



1. Pre operative X - ray.

2. Immediate post operative X - ray.



3. 6 Weeks follow up X - ray.

4. Good union - 10 weeks.



4. Discussion

A total of 100 cases with clavicle fractures were selected for the study. Of these 50 patients were managed by nonoperative methods and another 50 patients by operative methods. In operative group again 25 patients operated with plating and 25 patients operated with nailing.

The concept in the 1960's, as per the papers by Drs. Neer and Rowe, was that open reduction and internal fixation of displaced midshaft clavicle fracture should be avoided because of the high rate of union with non-operative treatment, high rate of failure with operative treatment and high risk of neurovascular complications due to the close proximity of the underlying subclavian artery, vein, brachial plexus, and pleura.^{10,11} But the treatment of displaced midshaft clavicle fractures has evolved over the past several years based on recent clinical studies demonstrating complications like persistent pain, persistent displaced fracture fragments, malunion and non-union¹².

According to Robinson CM, open reduction and plate fixation of acute displaced midshaft clavicular fractures, as compared

to conservatively treated fractures, decreases the rate of nonunion and leads to better functional outcomes¹³. One of the complication of surgery is plate prominence which can be reduced by the use of precontoured plating¹⁴. According to a survey conducted on 177 orthopaedic surgeons, operative treatment is preferred by most trauma and shoulder specialists for displaced mid-shaft clavicle fractures¹⁵. Moreover, early surgery is required in cases where perfect shoulder movements are needed¹⁶. Surgical management of displaced clavicle fractures results in early return to work and patient satisfaction¹⁷. Even in children, open reduction and internal fixation of displaced clavicle shaft fractures can be performed safely with good results¹⁸.

In Pearson *et al.* have reported the average age of patients sustaining a clavicular fracture is 33 years.¹⁹ Postacchini *et al.* reported that most patients were men (68%).²⁰ Zlowodzki *et al.* and McKee *et al.* described a fall or a blow to the shoulder, giving an axial compressive force on the clavicle, is the most common trauma mechanism of injury for any clavicular fracture^{21, 22}.

Postacchini *et al.* also described that the left side was involved in 61% of cases. Associated injuries commonly noted in this study were rib fractures (13.33%), abrasions (13.33%), fracture both bone leg (6.66%), and scaphoid fracture (3.33%), glenoid neck fracture (3.33%) and tibial plateau fracture (3.33%)²⁰. associated injuries have been reported in different studies. Thyagarajan *et al.* reported less satisfaction among patients. 23.5% (4/17) of the patients initially treated conservatively required operative treatment. As many as 41% of the patients in the conservative group had pain during daily activities. The mean time for fracture healing (radiological union) was shorter in the operative group (15.73 weeks) than no operative group (27.46 weeks)²³.

McKee *et al.* described the mean time for fracture healing were 14-16 weeks for operated patients and 24-28 weeks for nonoperated patients. The complications were more in the nonoperative group like symptomatic malunion 7 cases (46.66%), shortening 3 cases (20%), muscle wasting 4 cases (26.66%), pressure necrosis 1 case (6.66%) and complex regional pain syndrome 1 cases (6.66%). The complications noted in the operative group were incisional numbness 1 case (6.66%) and hardware irritation 1 case (6.66%). Second surgery was done to remove irritating hardware. None of the operated patients had nonunion or malunion. Range of movements of the involved side shoulder Group Mean±SD Student's t-test Flexion A 84.67±6.40 t (28)=0.632 B 86.00±5.07 P=0.532 Extension A 39.67±6.40 t (28)=0.00 B 39.67±5.50 P=1.00 Abduction A 166.67±6.17 t (28)=0.963 B 168.67±5.16 P=0.344 Adduction A 28.67±3.52 t (28)=2.603 B 32.33±4.17 P=0.015 Internal rotation A 70.67±7.99 t (28)=2.027 B 76.00±6.32 P=0.052 External rotation A 71.33±7.43 t (28)=1.991 B 76.67±7.24 P=0.056 SD=Standard deviation. Complications Complication Conservatively managed group (%) Operated group (%) Symptomatic malunion 7 (46.66) - Muscle wasting 4 (26.66) - Shortening 3 (20) - Droopy shoulder 2 (13.33) - Pressure necrosis 1 (6.66) - Complex regional pain syndrome 1 (6.66) - Incisional numbness - 1 (6.66) Hard ware irritation - 1 (6.66) No infection was seen in the operative group. All surgical wounds healed between 8 and 12 postoperative days. Refracture and nonunion were seen in neither of the groups²². McKee *et al.* reported the rate of nonunion in the nonoperated patients 14-24%, and 3.2% in the operated group. Iatrogenic neurovascular vascular injury is an imminent complication if proper operative techniques are not followed. Because major

neurovascular structures like subclavian vein, subclavian artery and brachial plexus are near to the surgical field [22, 24, 25, 26, 27].

However, in this study, none of our operated patients developed any neurovascular injury. None of the patients in this study had pulmonary injury either following primary injury or iatrogenically. Disability of the Arm, Shoulder and Hand scores in the operative group were superior (i.e. lower values) than in the nonoperative group at all time-points till final follow-up. The mean DASH score was 13.04. Constant Moore Score was 94.21 in O (OP & ON) and NO was 78.6. The mean follow-up of both groups were 12.56 months. The mean follow-up of patients in the operative group was 14.20 months. The mean follow-up of patients in the operative group was 12 months.

5. Conclusion

Operative fixation of the clavicle fracture results in improved functional outcome, shorter time for union compared with nonoperative treatment at 2 year of follow-up and primary operative intervention in clavicle fracture in active adults may be of immense importance. In intraoperative group comparison showing that anatomical locking plate is better function outcome and early union and less complication than intramedullary nailing.

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