A Study of Operative versus Non Operative Treatment for Clavicle Fractures: A Randomized Control Trial

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Abstract: Clavicle fractures account for 2% of all the fractures in the body. Earlier the treatment of choice was conservative which led to high rates of mal-union and non-union. We conducted a randomized control trial to evaluate the efficacy of operative and non-operative management of clavicle mid-shaft fractures taking into account the patient satisfaction level and Quick DASH scores.

Keywords: Clavicle fractures, mid-shaft clavicle, conservative vs operative management, Allman classification.

I. Introduction

Approximately 2% to 5% of all fractures in adults and 10% to 15% in children involve the clavicle. The incidence of this type of fracture in the adolescent and adult population is reportedly 29 to 64 per 100,000 person’s annually. Fractures of the clavicle also show a bimodal age distribution. Young male patients who are aged less than 30 years and elderly patients aged over 70 years appear to be two distinct age groups at higher risk for clavicle fractures.

Clavicle fractures are almost always the result of trauma (often a direct blow to the shoulder) and occur most often in the young male population. Evaluation begins with a thorough history and physical examination and typically progresses to plain radiographs identifying the fracture site and pattern. These fractures have been classified by Allman into groups I (mid-shaft), II (lateral), and III (medial); this classification, along with fracture characteristics (displacement and comminution) helps in determining the strategy for management.

Traditionally, nonsurgical management has been favored as the initial treatment modality for most clavicle fractures because of the high nonunion rates reported after operative treatment. Recent evidence suggests that specific subsets of patients may be at high risk for nonunion, shoulder dysfunction, or residual pain after nonsurgical management. In this subset of patients, acute surgical intervention may minimize suboptimal outcomes. Also, surgical intervention may be required in cases of neurovascular compromise or significant fracture displacement. In children and adolescents, these injuries mostly consist of physeal separations, which have a large healing potential and can therefore be managed conservatively.

II. Methodology

This two year randomized controlled trial was conducted in the Department of Orthopaedics of KLE Dr. Prabhakar Kore Hospital and Medical Research Centre Belgaum from January 2013 to December 2014. 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, general anaesthesia was used for all patients with or without supplementary interscalene blockade. All procedures were performed in an orthopaedic theatre under antibiotic cover according to local microbiology protocol and 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. 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.
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**Figure 1**

**Pre op xray**

**Figure 2**

**Intra op images**

**Figure 3**

Post op X-ray
III. Results

In group O, the male to female ratio was 4:1 while in group NO, it was 1.5:1. 45% of patients in group O and 50% of patients in group NO were aged ≤ 30 years. The mean age in group O and NO was comparable (36.2 ± 12.26 vs 32.4 ± 16.61 years; p=0.301) 50% of patients each in Group O 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 had B2.1 type fracture compared to 55% of patients in group NO with B1.1 type of fracture (p=0.136).
I case of non-union was reported in operative group compared to 5 in non-operative group. Mean time of union was 22 weeks in non-operative group and 17 weeks in operative group. DASH score and patient satisfaction were significantly better in the operative group.

IV. Discussion

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. 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-union. 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 outcomes. One of the complication of surgery is plate prominence which can be reduced by the use of precontoured plating. According to a survey conducted on 177 orthopaedic surgeons, operative treatment is preferred by most trauma and shoulder specialists for displaced mid-shaft clavicular fractures. Moreover, early surgery is required in cases where perfect shoulder movements are needed. Surgical management of displaced clavicle fractures results in early return to work and patient’s satisfaction. Even in children, open reduction and internal fixation of displaced clavicle shaft fractures can be performed safely with good results. In our case series, those undergoing operative treatment achieved excellent clinical outcomes without any serious complications and therefore open reduction and internal fixation of displaced midshaft clavicle fractures is a safe procedure.

V. Conclusion

Based on the findings of this study it may be concluded that, operative method for treatment of acute fracture of middle third of clavicle results in excellent outcome based on functional assessment by CMDA and QuickDASH score with lower rate of complications compared to non-operative treatment.

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References