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Functional and Radiological Outcome of Conservative and Surgical Management in Mid-Shaft Clavicle Fractures

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1. Abstract

1.1. Background: No uniform consensus exists on the management of clavicle fractures with conservative management being favored over operative treatment.

1.2. Study design: Prospective observational study.

1.3. Methods: A total of 40 patients with mid-shaft clavicle fractures were divided alternately into two groups and were treated conservatively and with internal fixation respectively. The evaluation methods were clinical examination, DASH (Disabilities of the Arm, Shoulder and Hand Score) score, VAS (Visual Analogue Scale Score) Score for pain and radiological assessment. Patients were followed up at 1, 3 & 6 months.

1.4. Results: Patients treated with ORIF (Open reduction & Internal Fixation) performed as good and even better than the conservative patients, at 6 months follow up with respect to disability scoring, pain perception and most importantly union. A 15% rate of non-union for conservative management cannot be ignored and stresses the importance of early surgical fixation.

1.5. Conclusions: Surgical fixation of the clavicle gives as good and if not better results compared to conservative means, and should be advocated in patients of younger age group with an active lifestyle. The complications arising from surgery are minimal and should not serve as a deterrent for early surgery.

2. Introduction

Clavicle fracture is often caused by a fall onto a shoulder, outstretched arm, or direct trauma. Clavicle fractures occur at 30–64

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cases per 100,000 a year and are responsible for 2.6–5.0% of all fractures [1]. Clavicle fractures most commonly occur in people under the age of 25 and above the age of 70. Males are most commonly affected than females. They constitute 5% of all fractures in adults and 13% of all fractures in children. The middle third of the clavicle is most often involved [2, 3].

The goals of treatment are to restore normal anatomy, limit pain and promote early return to function. Historically, even till recent times, clavicle fractures have been treated mostly non-operatively with immobilization in specifically designed bandages or immobilizers. This practice of treating clavicular fracture with non-operative methods has shown that pain and disability during the first three weeks is common. Nonunion after clavicular fracture is uncommon but with advents in better quality imaging, it's prevalence is discovered to be higher than reported.

Surgery for clavicle fractures is considered in cases of significant comminution, significant shortening, open fractures, associated neurovascular injury, displaced lateral third fractures, mal-unions & non-unions. Studies have shown that surgical treatment results in higher rates of fracture union and improved outcomes compared with conservative methods of treatment. Therefore, although conservative treatment is a viable option to treat displaced mid-shaft fractures surgery should be considered in patients with risk factors for nonunion, especially significant fracture displacement, comminution and shortening. Open reduction and internal fixation (ORIF) for displaced clavicular fracture has become popular because of high rates of union and lesser complications. Ahrens PM et al conducted a multicenter randomized controlled trial to compare effectiveness between non-operative management and ORIF for displaced mid-shaft clavicle fractures in adults. 154 participants (51%) were randomized to the surgery group and 147 (49%) to non-operative group [4]. There was no statistically significant difference in the nonunion rates between the operative and non-operative groups at 3 months however at 9 months, the proportion of patients with nonunion was 11% in the non-operative group compared with 0.8% in the operative group, which is significant. The DASH and Constant-Murley scores were significantly better in the operative group at 6 weeks and 3 months but at 9 months there was no significant difference between the operative and non-operative groups for either score. Patients with nonunion in the non-operative group had worse clinical scores at 9 months' even if they had subsequently undergone surgery. They concluded that ORIF is reliable with superior early functional outcomes and should be considered for patients with displaced mid-shaft clavicle fractures.

Ahmed FA et al conducted a meta-analysis to compare ORIF and nonsurgical treatment outcomes in displaced mid-shaft clavicle fractures. They concluded that ORIF is associated with favorable early functional outcomes and significant reduction in non-unions however, late functional outcomes, subsequent surgeries and pain scores in the ORIF group are similar to those treated conservatively [5]. Although patients treated with ORIF mainly had subsequent elective plate removals; non-surgically treated patients had more secondary surgical procedures for non-unions.

Dhakad RKS et al compared the outcomes of antero-superior plating with conservative treatment in 50 adults with closed mid-shaft fractures over a period of 1 year. Alternate patients were operated using a 3.5 mm antero-superior locking plate [6]. The functional outcome was evaluated by the Constant and Murley score at 3 months. The time taken for fracture union and associated complications was also compared. They concluded that early surgical fixation of comminuted & displaced mid-shaft clavicular fractures results in improved patient outcomes, earlier return to function and decreased rates of non-union and malunions.

From the above review of literature, it is seen that there remains inconsistent evidence regarding the best treatment for displaced mid-shaft clavicle fractures and there are unacceptable rates of non-unions with conservative management. Hence we have undertaken this study to evaluate the functional outcome of displaced mid shaft clavicle fractures treated conservatively and compared to a similar study group that is treated surgically by open reduction and internal fixation (ORIF).

3. Methods

Our study is a Single center based prospective observational study conducted over 18 months and reviewed by two independent observers (orthopedic surgeons).

3.1. Aims & Objectives

- To evaluate the effectiveness of conservative management versus ORIF of displaced mid-shaft clavicle fracture in adults.
- To conclude which of these two procedures will have better functional outcome.

3.2. Inclusion criteria

possible.

Patients in age group of 18-60 with displaced mid-shaft clavicular fracture

3.3. Exclusion Criteria: Open fractures & Un displaced fractures. Patients were enrolled consecutively, alternately to each arm i.e. conservative or surgical. There was no matching for age/gender or other parameters. Due to logistic difficulties blinding was not

3.4. Surgical Technique: An oblique 8-10cm incision was done just inferior to the clavicle centered over the fracture site. The platysma was incised transversely and tagged with sutures. After identifying and preserving the supraclavicular and supra-scapular nerves, the clavipectoral fascia was then incised. Proper exposure was done with careful dissection, and the broken bone fragments were exposed. Care was taken to maintain hemostasis, with careful dissection and use of electrocautery. Open reduction and internal fixation of the fracture fragments was done with locking compression plate (LCP), followed by closing the wound in layers (Figure 1). Post operatively the patients were encouraged to mobilize their shoulder both actively and passively from day 1. Following suture removal patients were put on active range of motion exercises for the shoulder with gradual increase in intensity. Patients were followed up at regular intervals of 1 month, 3 months and 6 months with clinical evaluation by DASH score, VAS for pain and radiological assessment for fracture union.



Figure 1: Surgical Technique

3.5. Statistical Analysis

Statistical evaluation was performed by statistical package for the social sciences (SPSS) version 17.0 (Chicago, IL). For continuous variables, mean \pm standard deviation was given, and if the data is skewed, then median was given. For statistical calculations Student's independent sample two-tailed t-test and chi square test was used. For variables including 3 comparison parameters, ANOVA test was used. A p value <0.05 was considered statistically significant.

4. Results

A total of 40 patients were selected, 20 underwent ORIF with LCP and 20 were treated conservatively with immobilization. For ease of further discussion, the groups shall be named as Group A for conservative management and Group B for surgical treatment. There was no statistically significant difference between the groups with respect to age, gender and mode of injury (P value>0.05). At the first follow up of 1 month the DASH Score was poor for both groups and the VAS scores were above 5 (Table 1). At the second follow up of 3 months there is no statistically significant difference between the two groups with respect to the DASH Score and VAS but more patients of the operative groups had satisfactory DASH scores (<41) and lesser pain compared to patients who were treated conservatively (Table 2). At final follow up, more patients of operative group had excellent DASH score (<21) and a lower pain score compared to the patients treated conservatively although it was not statistically significant (Table 3). Patients of both groups had a VAS pain score less than 8 at end of 6 months (Table 3). In both the groups, majority of patients achieved fracture union at 6months, but there were more non-unions in the conservative group compared to the surgical group (3 vs 1) although it was not statistically significant (Table 4). There were no complications reported in both the groups namely infection or deformity or skin necrosis. There was only 1 case of scar hypertrophy at the end of 6 months.

Table 1: DA	SH Score and	VAS at 1	month
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DASH Score	Group A	Group B	P value	
>60	20	20	p-not calculable	
<61	0	0		
VAS	Group A	Group B	P value	
>7	5	8	0.311	
7-May	15	12	0.311	
<5	0	0	p-not calculable	

Table 2: DASH Score and VAS at 3 months

DASH score	Group A	Group B	P value
>60	3	1	0.291
41-60	2	3	0.632
21-40	8	10	0.525
<21	7	6	0.735
VAS	Group A	Group B	P value
>7	1	0	p-not calculable
7-May	2	1	0.548
<5	17	19	0.291

Table 3: DASH Score and VAS at 6 months

DASH score	Group A	Group B	P value
>60	3	1	0.291
41-60	2	2	1
21-40	5	2	0.211
<21	10	15	0.102
VAS	Group A	Group B	P value
>7	0	0	p-not calculable
7-May	3	1	0.291
<5	17	19	0.291

 Table 4: Radiological Union

Union	Group A	Group B	P value	
Yes	17	19	0.201	
No	3	1	0.291	

5. Discussion

Majority of the patients were between the age group 30-50 years (52.5%). Majority of the patients were male (82.5%). 75% patients of the patients had suffered the fracture due to trauma most commonly RTA. Due to logistical difficulties randomization and blinding was not possible. Also due to the short number of cases, matching with respect to age and gender was not possible and every alternate patient was assigned to each group. In such a scenario there arises a question of case selection bias leading to statistical skewing of data to one group. However, on assessing the results there was no statistically significant difference between the groups with respect to age, gender and mode of injury. So despite blinding and matching not being done, the randomization was accurate and the results hold statistically valid.

On the first follow up at one month all patients in both the groups had a poor DASH score and a VAS score below 5 without any statistically significant difference between the two groups. This is because in the first follow up, there is significant amount of pain, leading to restriction of function at the joint giving poor scoring. This is due to the after effects of the tissue dissection, immobilization in general leading to stiffness, and inflammatory swelling at the site which takes some time to resolve slowly [5, 6].

At the second follow up of 3 months, there was no significant difference between the groups in the DASH score. However, people with ORIF had a greater proportion of a satisfactory DASH score (< 41) compared to conservative group. Also the VAS score of patients who underwent ORIF was better compared to the conservative group, although the difference was not statistically significant. This shows that difference between outcomes of the surgical group compared to the conservative group starts becoming evident from the second follow up or at the end of 3 months. Ahrens PM et al and Dhakad RKS et al Jones LD et al reported better outcomes in the surgical group compared to the nonsurgical group after the initial follow up, which was very well reciprocated in this study [4, 6, 7]. The success of surgery lies in the better approximation of the broken bone fragments to each other and earlier union of the bone leading to faster return of the bone to its normal strength prior to trauma, leading to improvement in the pain and disability scores at this follow up visit.

At the final follow up at 6 months, the group with ORIF had better DASH scores (<20) in 85% of the cases compared to the conservative group (75% cases), although the difference was not statistically significant. The VAS Score was better in the ORIF group compared to the conservative group although the difference was not statistically significant. This is similar to the findings of prior published studies [4-7].

In both the groups majority of the patients had radiological union at the end of six months but there were more non-union with the nonsurgical group (15%) compared to the ORIF group (only 5%). There were no complications reported in either the ORIF or the nonsurgical group either at initial post up or the scheduled follow ups. To sum up, surgical patients performed as good and even better than the conservative patients, at the later follow up months with respect to disability scoring, pain perception and most importantly union. A 15% rate of nonunion for conservative treatment should not be ignored.

6. Conclusion

In displaced mid-shaft clavicle fractures ORIF leads to faster recovery, early union, better pain scores, function and early return to activities than conservative treatment although in long term both groups show similar outcomes. Hence ORIF should be advocated in patients of younger age with an active lifestyle. The complications arising from surgery are minimal and should not serve as a deterrent for early surgery. The quality of life definitely improves after surgical fixation, and should be advocated to the patients while choosing the treatment modality for displaced mid-shaft clavicle fractures. Our study was limited by the small sample size and short duration of follow up. Longer follow ups with randomization of a large number of patients to either group would help in gaining more understanding about the preferred and optimal treatment.

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