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A comparative study on management of mid-shaft clavicular fractures between conservative and operative treatment

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Abstract

Background: Mid-shaft clavicular fractures are very common and can be treated operatively or nonoperatively. Traditionally, conservative treatment has been practiced, with malunion occurring commonly as a complication. However, there is still no uniform consensus on to leave mid shaft clavicular fracture or to fix it surgically.

Aim: To compare the results of surgical management with established modality of conservative treatment, and comparison among operative group (TEN vs Plate).

Material and Methods: The prospective Cohort study, with consenting 110 patients (nonoperative and operative treatment, n = 30, loss to follow up 38 & 12, respectively), with mean age of 36.98±12.23 years, who had mid shaft clavicular fractures, was conducted at Level 1 trauma centre in D.Y. Patil Medical College, Kolhapur, between April 2010 to March 2013. Data was analysed using R software v 3.6.0. Functional outcome, union time and complication rate were assessed using, chi-square and independent t-test.

Results: Significantly, higher mean Constant and Murley score (CMS), less union time ($P<0.01$), and less complications ($P=0.014$), was noted among operative group. Among surgical group, nail vs. plate method used (n=16 vs. 14), excellent outcome (n=11 vs. 9), and CMS score (90.64 vs. 89.57), respectively.

Conclusion: Surgical management could be used in, severely displaced mid-shaft clavicular fractures. Further prospective trials are required to establish it.

Level of Evidence: Therapeutic Level III.

Keywords: Clavicular fracture, operative treatment, nail, plate, constant Murley score, robinson classification

Introduction

Clavicular fractures are common injuries, accounting for 2.6% of all fractures, and they occur most commonly in young active individuals [1]. Allman classified clavicle fractures into three groups based on their location along the bone [2]. The middle-third fractures are most common and account for approximately 80–85% all clavicular fractures [3]. The narrow cross section of the bone in middle shaft combined with typical muscle forces acting over it predispose to fracture the bone in this locality [4].

These fractures have traditionally been treated non operatively (as generally unite with any method of immobilization), and extremely low non-union rates were shown by previous studies [5, 6]. However, certain recent studies have shown suboptimal outcomes, and a very high nonunion rates when displaced fractures are managed conservatively [7]. Other shortcomings of non-operative treatment brought out were functional impairment of the shoulder and a non-cosmetic bump at the base of the neck possibly due to shortening of the clavicle and exuberant callus formation [8]. Restoration of normal length and alignment, by surgical methods can prevent these drawbacks of conservative treatment [9]. Hence, aim of the study was to compare the results of surgical management with traditional conservative treatment. An attempt was also made to analyze the outcomes of surgical management of patients using titanium elastic nail (TEN) and plate-screw technique to fix clavicle fractures with respect to functional

outcome and union time.

Material and Methods

Study Design, and Sample, Data collection

A prospective, cohort study was conducted, at Level 1 trauma centre in patients (classified according to Robinson's classification) [10], who were registered with department of Orthopaedics at D.Y. Patil Medical College, Kolhapur, between April 2010 to March 2013. Institutional ethical committee approval was taken prior to the study.

A total of 110 patients selected, belonging to both genders, ranging from 17 – 60 years, having middle third clavicle or fresh fracture, specifically displaced (having no cortical continuity between proximal and distal fragments), presented within 10 days of injury, and who gave consent, were included in the study. Patients with lateral third or medial end clavicle, bilateral or open, nonunion or pathological fracture, with a distal neuro-vascular deficit, and not fit for general anaesthesia, were excluded from the study.

Non-operative Group

Patients allocated to this group were given either a sling or a figure-of-eight brace which was applied for six weeks as described by Andersen K *et al.* [11]. The compliance, however, was variable. Patients started out of sling activities at three weeks, followed by active physical rehabilitation by six weeks, depending upon fracture healing status. Patients were allowed all activities except for sports at three months and by the end of six months, even contact sports were allowed.

Operative group (Elastic Nail, Plates and Screw) and rehabilitation protocol

Consisted of patient who opted for surgery. Type of surgery (elastic nails or with plates and screw) was decided by the surgeon. Surgery was conducted within a period of 7 days post trauma. In the elastic nail group, patient was operated as

per the procedure described by Liu P *et al.* [12], and in the plate group the procedure was conducted as described by Muralidhar BM *et al.* [13], Naveen BM *et al.* [14]. Rehabilitation protocol was undertaken within 3-4 days post procedure [13]

Assessment, functional outcome and complication

All the patients were followed up post treatment every 4 weeks for the first 3 months. After which follow up was done at 6, 12, 18 and 24 months, respectively. Local and X-ray (radiographic union¹ and implant position), examination was done at each visit.

Functional outcome was evaluated using the Constant and Murley score (CMS) [15], which is scored from 0 to 100, with a lower score representing a higher level of functional disability [13].

An adverse event or complication was defined as any event that necessitated another operative procedure or additional medical treatment [1]. Expected complications were non-union, malunion, infection and implant failure.

Statistical analysis

Statistical analysis was performed using R software v 3.6.0 and results were presented as frequency and percentages for non-categorical data. However, categorical data were represented as Mean±SD. Chi-square, odds ratio and independent t-test were used to find the association between variables.

Results

Patient recruitment and follow-up rates

Of the 110 participants, patients in each respective treatment modality were followed for 24 months (n=30) [Figure 1], with mean age of 36.98±12.23 years. A male predominance of 81.8% was seen. Final outcome was seen to be significantly associated with gender and age, ($P<0.05$).

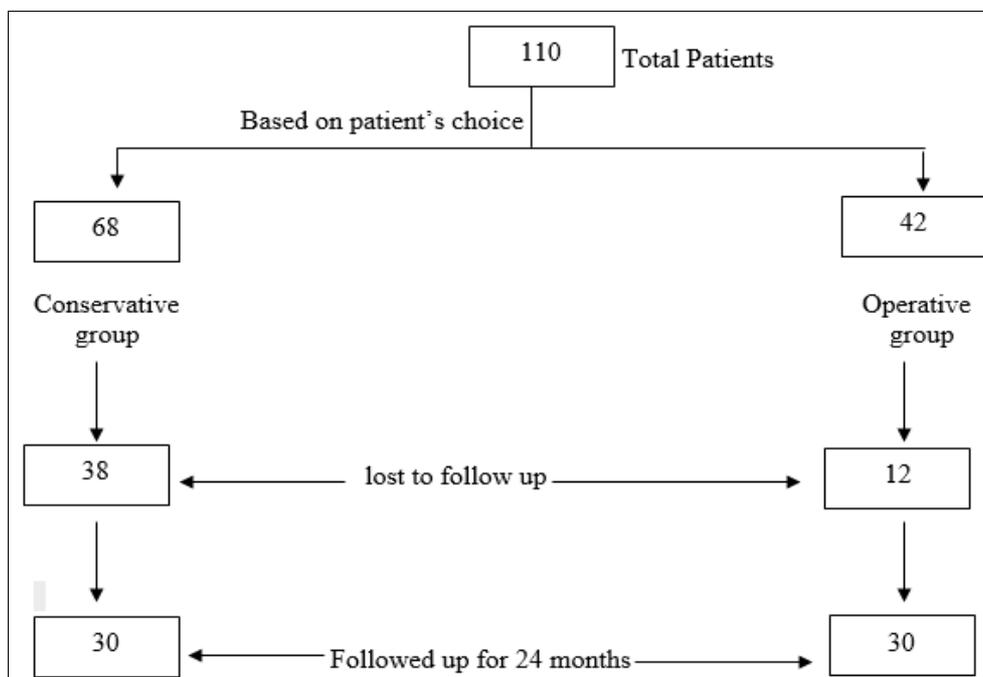


Fig 1: Flowchart representation of patient recruitment and the follow-up rates

Most of cases had right side fracture 51.67% (31; 27 males and 4 females). The common mode of injury was road traffic accident (RTA) (31; 51.67%) followed by direct injury (26; 43.33%). According to Robinson classification, majority of

patients were in B1 group (39; 65.0%). [Table 1] No significant association was observed between age, gender and treatment methods, ($p>0.05$).

Table 1: Demographics of the patients

| Parameters | Conservative | Operative |
|----------------------------------|--------------|------------|
| Types of fracture | | |
| Right side fracture | 15 (48.3) | 16 (51.61) |
| Left side fracture | 15 (51.72) | 14 (48.27) |
| Types of injury | | |
| Direct Injury | 14 (53.84) | 12 (46.15) |
| Road traffic accident | 14 (45.16) | 17 (54.83) |
| Outstretched Hand | 2 (66.67) | 1 (33.33) |
| Robinson's Classification | | |
| B1 | 16 (41.02) | 23 (58.97) |
| B2 | 1 (20.00) | 4 (80.00) |
| A1 | 4 (100.0) | 0 (0.0) |
| A2 | 9 (75.0) | 3 (25.0) |

Higher mean CMS score was noted among operative group, (90.13±4.58). Method of treatment was significantly associated with rehabilitation time, complications, functional outcomes ($P<0.05$), table 2. Immediate rehabilitation and less complications, was observed in operative as compared to conservative group, respectively, ($P<0.001$). Complications seen in both groups are given in table 3. Malunion was

significantly associated with treatment groups, ($P<0.05$), and was a common complication in conservative procedure group (48.48%).The presence of a complication did not affect the outcome ($P=0.8536$). Excellent functional outcome seen in majority of patients in operative group (66.67%, ($P=0.014$)). Odds ratio for functional outcome, excellent vs good and excellent vs fair results, 4.20 and 8.89, respectively.

Table 2: Comparison of operative and conservative treatment outcomes

| Parameters | Type of Procedure | | P values |
|----------------------------|-------------------|--------------|----------|
| | Operation | Conservative | |
| Rehabilitation Time | | | |
| Immediate | 30 | 0 | <0.001** |
| Delayed | 0 | 30 | |
| Complication Status | | | |
| Complication | 5 | 18 | <0.001** |
| No Complication | 25 | 12 | |
| Functional Outcome | | | |
| Excellent | 20 | 9 | 0.014* |
| Good | 9 | 17 | |
| Fair | 1 | 4 | |

Note: * and ** indicates P value of <0.05 and <0.001, respectively, statistically significant values.

Table 3: Complications in groups

| Groups | Complications | Cases |
|-----------------|-----------------|-------|
| Conservative | Malunion | 16 |
| | Non union | 5 |
| | Deformity | 12 |
| Operative group | Infection | 1 |
| | Implant failure | 2 |
| | Skin | 2 |

Significant difference was noticed in union time between the groups (p value <0.01), [Figure 2]

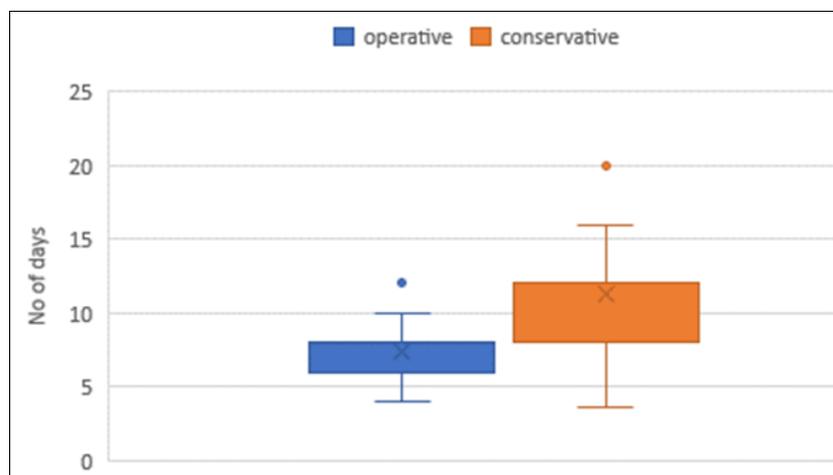


Fig 2: Comparison of union time between operative and conservative procedures

In the operative group, slightly better outcome was seen in the nail group (Table 4). CMS score was also seen to be higher (90.64). However, Nail surgeries took a longer time for union. No significant difference was seen between the two types of surgeries ($p>0.05$).

Table 4: Comparison of different types of implants in operative procedures

| Types of implants | Excellent | Good | Fair | Union time (in weeks) |
|-------------------|------------|-----------|----------|-----------------------|
| Nail | 11(68.75%) | 5(31.25%) | 0 (0%) | 7.88±2.0 |
| Plate | 9 (64.29%) | 4(28.57%) | 1(7.14%) | 6.86±2.03 |

Discussion

All midshaft clavicular fractures were previously treated conservatively. A figure-of-8 bandage or sling was used to align the displaced fragments in manner that is acceptable and resultant functional outcome is good [14]. However, recent studies are not very approving of this method as they opine that the union rate for displaced midshaft fractures of the clavicle may not be as favourable as once thought [16]. The study focused on comparison between operative and conservative management, and evaluated the efficacy of internal fixation of severely fractured clavicle by surgical method.

Male preponderance was seen in the study similar to Naveen *et al.* [14]. This can be explained by greater physical activity in men. Mid shaft clavicular fractures occur in two sets of populations. The first being young individuals who are active and generally associated with motor vehicle accidents. The second being elderly individuals with simple falls. This would explain the age of study population and the mode of injury. The clavicle tends to fracture in the mid shaft region as this is the narrowest part of the bone with minimal soft tissue envelopment [17].

Final outcome was associated with gender and age. As the predominant gender in the study population was male it would explain the association of gender. As age increases, there is an increased risk of delayed union or in some cases non-union [18]. Most fractures were present on right side which in most people is the dominant side in contrast to other studies [19-21].

Road traffic accident was the most common mode of injury. Most patients suffered from 'simple or wedge comminuted' (B1) type of fracture. The variability of fracture type was could be attributed to different blows of forces.

Treatment methods had shown association with rehabilitation time, complications, functional outcomes. In the operating group, immediate rehabilitation, less complications and mean union time observed, similar to previous studies [22, 23]. Surgery within first 7 days might have contributed to higher rates of bony union [14]. Malunion was seen in more than fifty percent of the cases treated conservatively. Previous literature suggests that the conservative treatment is generally accompanied by malunion as a complication [24]. Conservative treatment require longer immobilization and its outcome is associated with lesser patient satisfaction. Functional assessment as measured by Constant shoulder score was higher in surgically treated patients as reported in previously [23]. In the operative group, implant failure was the most common complication. However, implant failures were very less compared to other studies [25-28]. The presence of complications did not affect the outcome of the patients. Hence conservative treatment can be considered in minimally displaced fractures and depending on the expectations of the

patient. Excellent outcome was seen in majority in the operative group while good outcome was seen in the conservative group.

Internal fixation of clavicular fracture in most cases were done by nail method and remaining were done by plate fixation. A higher number of cases showed excellent outcome by nail fixation although there was no statistical significance between the two [29]. More rigid fixation was provided in surgical cases and immobilization wasn't required for longer periods.

The study has few limitations primarily its sample size is small, allocation bias, patients who did not complete the assessment period. Also, Plate was not removed till the completion of the study. Hence refracture is not seen.

Conclusion

The surgical management could be used in, severely displaced mid-shaft clavicular fractures and specific subset of population (younger age), because of higher bony union and less rehabilitation time. Further trials are required, with longer follow up period, and usage of DASH score to evaluate its efficacy.

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