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ORIGINAL RESEARCH ARTICLE

CONSERVATIVE VERSUS OPERATIVE MANAGEMENT OF MID-CLAVICULAR FRACTURES

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ABSTRACT

Background: Mid-clavicle fractures were traditionally managed by non-operative means which led to stiffness and painful shoulder. Surgical treatment on the other hand had the advantage of reducing malunion and allowing early shoulder movements, but also had incidences of infection. This study was carried out with the objectives of comparing functional outcome, fracture union rates, patient satisfaction rates and complications of both treatments.

Methods: In this observational study done from October 2020 to September 2021 in the Orthopedics and Emergency department of KIST Medical College Teaching Hospital, Lalitpur, Nepal, 40 patients with mid-clavicle fractures were treated either conservatively or operatively according to their choice. 20 patients in each group were assessed functionally in each follow-up using the Constant and Murley score and union and complications were also assessed. Data collection and entry was done using the statistical package for social science version 22 and analyzed by using statistical tools like mean, frequency and Independent samples t-test.

Results: At 6 months, there was no statistical difference in the Constant and Murley score between the two groups, but the scores were statistically better in the operative group at 6 weeks. Mean fracture union time in operative group (12.67 weeks) was statistically better than that in conservative group (14.89 weeks). Complications in operative group were mainly hardware related while stiffness was more common in conservative group.

Conclusions: Operative treatment led to earlier fracture union, regain of shoulder function and return to work, but had the disadvantage of high cost and risk of infection as compared to conservative treatment.

INTRODUCTION

Clavicle is a subcutaneous bony link between thorax and shoulder girdle.[1,2] Clavicular fractures, a result of direct injury to the shoulder in 94% of cases, account for 4% of all fractures in adults and about 35% of all fractures that occur in the shoulder region.[3,4] Allman classified these fractures into 3 types: middle third (70-80%), lateral third (12-15%) and medial third fractures (5-8%).[1,5]

Traditionally mid-clavicular fractures, even displaced ones, were treated by non-operative means as Neer in 1960 described the non-union rate to be just 0.1% and clavicular malunion was described as being of radiographic interest only.[6,7] However, recent studies have shown non-operative treatment to have a non-union rate of 15% and unsatisfactory patient-oriented outcomes of 32% in one series and unsatisfactory outcome of 31% in another series. [7,8] Problems like malunion, cosmetic deformity, altered shoulder mechanics, decrease in shoulder strength and endurance were also frequent.[9,10] Hence the trend to surgically treat these fractures has grown.[11]
Operative fixation has been cited to decrease non-union, help quicker return to activities and improve functional result by restoring the clavicular anatomy.[9] Three types of fixation have been described for mid-clavicular fractures: intramedullary devices, plates and external fixators.[12] Among these, open reduction and internal fixation using plates and screws is the preferred option by many surgeons as it provides rigid immobilization, pain relief, facilitates early mobilization and return to pre-injury activities.[10,13]

In our study, we aimed to compare the outcome of mid-shaft clavicle fractures treated by conservative and operative methods and assess the patient satisfaction.

METHODS

This was a hospital-based observational study, conducted from October 2020 to September 2021 in the Orthopedics and Emergency department of KIST Medical College Teaching Hospital, Lalitpur, Nepal. Ethical approval clearance was taken from the institutional review committee KISTMCTH (reference number 077/078/10).

The primary outcome measure in the study was the Constant-Murley score (CMS) at the end of 6 months. A score of more than 90 was assigned to be excellent and evaluation of studies by Canadian Orthopaedic society, Robinson et al and Smekal et al was done.[7,14,15] We found excellent score in more than 90% of patients of operative group and 65% excellent scores in non-operative group in those studies. Using these values, we calculated the sample size using the formula:

$n = (Z\alpha/2+Z\beta)2 * (p1(1-p1)+p2(1-p2)) / (p1-p2)2$

where Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84) and p1 and p2 are the expected sample proportions of the two groups.A reference to this formula can be found in the paper by Wang et al.[16] Hence, Sample size (n) calculated was 40(20 in each group).

Patients in the age range of 16-60 years with closed, mid-clavicular fractures who presented in the Emergency and Orthopaedics out-patient department were explained clearly about the pros and cons of the two treatment modalities i.e conservative and operative methods and their preference was noted.Then they were kept in two groups: group A which underwent conservative management and group B which underwent open reduction and internal fixation with plate and screws. The patients were enrolled in the study only if they were operated within 1 week of injury. Patients with non-union after conservative treatment who were later operated were not included in this study. Radiological parameters like significant overlap was not taken as a criteria to go for surgical treatment, the method of treatment was purely on the basis of patient's choice. Patients with lateral or medial end clavicle fractures, open fractures, pathological fractures were excluded from the study along with those with associated head injury, ipsilateral multiple fractures, associated neurovascular injury. Patients unfit for general anaesthesia, those who did not provide consent and those lost in follow-up were also not included.

After enrolling in the study, thorough history was taken with regards to demographic details, injured side, dominant hand and mechanism of injury. Clinical examination was done and radiograph of the chest showing both shoulders in antero-posterior view was taken. All the findings were recorded in a proforma and written informed consent was obtained. 20 Patients in group A were managed conservatively using an arm pouch sling and a commercial clavicular brace in which limb was immobilised for 6 weeks. After 6 weeks, rehabilitation and range of mothion exercises were started. For the 20 patients in group B, surgical treatment was done under either general anaesthesia or regional scalene blocks. Patients were placed in a modified beach-chair position and after proper cleaning and draping, an oblique incision was made along the superior border of the clavicle. Fixation was performed following fracture reduction with minimal periosteal stripping. Precontoured plate was used to fix the fracture with 3 screws on each side (either simple or locking) and lag screw was used if necessary. Postoperatively patients were given intravenous antibiotics for a period of 3 days and then discharged and asked to do wound dressing every alternate day. The patients were given arm sling for 2 weeks. After 2 weeks suture removal was done and range of motion exercises and rehabilitation was started.

First follow-up for both groups was done at 2 weeks, then patients were asked to visit every 4 weeks until clinico-radiological union occurred. In each follow-up, functional assessment was done using CMS score and clinical and radiological assessment was done to check for fracture union and complications. All the findings were recorded in the patients' proforma. At the end of 6 months, data entry was done using the software statistical package for social science version 22 and analyzed by using statistical tools like mean, frequency and Independent samples t-test. A p-value of less than 0.05 was considered statistically significant.

Figure 1: Patient managed conservatively with clavicle brace and arm sling pouch, seen from the front (a) and the back (b)

Figure 2: Intra-operative picture of clavicle fracture fixation by precontoured plate and screws

RESULTS

The youngest patient in our study was 18 years old and oldest was 55 with an average age of 32.65. There were 14 males and 6 females in the conservative group, while operative group had 16 males and 4 females.

Road Traffic Accident was the commonest mode of injury, seen in 22 patients (Figure 3).

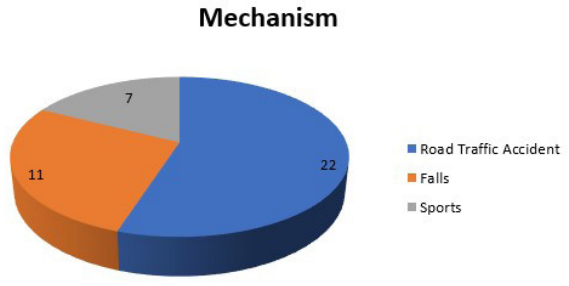

Figure 3: Mechanism of Injury

Fracture union was seen in 18 patients each in both the groups with two non-unions in each group. The mean fracture healing time was 14.89 weeks in conservative group while it was 12.67 weeks in the operative group. On performing the independent samples t-test, p-value was found to be 0.025 which was a statistically significant finding.

Table 1: Mean fracture union time

	Conservative group	Operative group
Mean fracture union time	14.89 weeks	12.67 weeks

Constant and Murley Scoring (CMS) was used to assess the functional status of patients in each follow-up. The mean CMS at 6 weeks follow up in conservative group was 69.4 while it was 82.15 in the operative group. This was a statistically significant difference as the p-value was 0.03 on the independent samples t-test. This difference indicates early functional recovery in the operative group, hence early return to work.

The following figure shows the trend analysis of the Constant and Murley Score in both the groups.

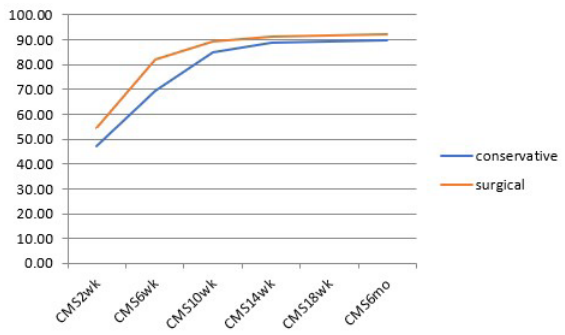

Figure 4: Trend analysis of Constant-Murley Score in various follow-ups

This chart shows that although there is significant functional recovery in the operative group in early stages, the patients of conservative group catch up in later stages and the CMS scores at 6 months follow ups are almost similar, i.e. 89.9 in the conservative group and 92.15 in the operative group.

The complications seen in this study are tabulated below.

Table 2: Complication patterns conservative and operative groups

Complication	Conservative group	Operative group
Infection	N/A	4
Painful shoulder	3	1
Stiffness	5	1
Screw loosening	N/A	1
Hypertrophic scar	N/A	2
Malunion	7	0
Implant failure	N/A	1
Delayed union	7	2
Non-union	2	1

At the final follow-up at 6 months,the patients were inquired about their satisfaction regarding the treatment they received. 16 patients were satisfied with their choice of treatment in conservative group while 17 patients were satisfied in the operative group.

Table 3: Patient satisfaction at 6 months

	Conservative group	Operative group
Satisfied patients	16	17
Unsatisfied patients	4	3

Figure 5: Functional range of motion of Right shoulder at 18 weeks follow up of conservative group patient (a) abduction (b) flexon (c) external rotation (d) internal rotation

DISCUSSION

Clavicle, the bony link between thorax and shoulder girdle, when fractured in the mid-shaft has been traditionally treated by non-operative means as the non-union rate was cited to be very low.[1,6] However, recent studies point to non-union rates of upto 15% along with other complications like visible deformity, shoulder weakness and alteration of shoulder biomechanics.[10,17] Hence open reduction and fixation with plate and screws is preferred by many authors.[7,18] In our study, we compared the functional results and patient satisfaction rates of operative versus non-operative management of mid-shaft clavicle fractures.

Clinical assessment and x-rays were done in each follow up to assess fracture healing, functional recovery and complications.

The primary outcome measure of our study was the use of Constant and Murley scoring(CMS) at the end of six months for functional assessment. The mean CMS at the 6 month follow up was 89.9 for the conservative group while it was 92.15 for the operative group. This finding indicates no statistical difference in functional outcome at the end of 6 months (p-value=0.8); but the mean CMS at the end of 6 weeks was 69.4 for the conservative group and 82.15for the operative group. This statistically significant finding (p-value=0.03) points to the fact that those patients who are operated for mid-clavicular fractures regain their shoulder function earlier and hence it helps early return to normal work. The trend analysis of CMS among two groups as shown in figure 4 also indicates early functional recovery in operative group. Better CMS score in operative patients was also seen in studies by Jha et al, Wang et al and in the multicenter RCT by Canadian Orthopaedic Trauma Society; while no difference in CMS scores between the two groups was seen in a study by Virtanen et al.[7,11,12,17]

Secondary outcome measure of our study was fracture union time, patient satisfaction at 6 months and evaluation of complications. The patients treated conservatively were found to have a longer duration of fracture healing i.e. mean 14.89 weeks as compared to those treated operatively (mean 12.67 weeks). This was a statistically significant difference (p=0.025). Similar difference was also seen in studies by Patel et al, Dhoju et al and the multicenter randomized control trial by the Canadian Orthopaedic Trauma Society.[1,7,10] Patient satisfaction was assessed by a simple yes/no question at the end of 6 months. 16 patients in conservative group and 17 patients in operative group expressed their satisfaction over the treatment method they chose. Similar assessment was done in the study by Jha et al and RCT by Canadian Orthopaedic Trauma Society, but they found patients in operative group to be much more satisfied than those in conservative group.[7,12]

Most common complication in the conservative group was radiological malunion seen in 7 patients, but since all the 7 cases had asymptomatic malunion, no further intervention was done. Among the conservatively treated patients, 7 patients had delayed fracture union and mild shoulder stiffness was seen in 5 patients, while 3 had mild pain in extremes of motion. There were 2 cases of non-union and these patients are being planned for open reduction and internal fixation with plate and screws.

The commonest complication seen in the operative group was surgical site infection seen in 4 cases; among them 3 had superficial infection which was treated by debridement and antibiotics based on swab culture and sensitivity. One patient had deep infection leading to screw loosening and implant failure. In this patient, the plate was removed and wound was debrided. He still has not achieved union and further plan is to perform plate and screw fixation along with bone graft after infection subsides. Complications like shoulder stiffness and pain at extreme of motion were seen in 1 patient each and hypertrophic scar was seen in 2 patients.

Studies by Canadian Orthopaedic Society, Patel et al. and Vaithilingam et al. also found higher rate of malunion and non-union in conservative group while study by Judd et al. had equal nonunion rates in both groups.[1,2,7]

The limitations of our study were that since it was conducted in a single center, the catchment area was less and sample size was also small. Operative treatment using precontoured plates is expensive as compared to conservative management, so cost factor demotivated some patients who wanted surgery. The subjective assessment of patient satisfaction at 6 months had variable response by patients for the same problem according to their optimistic or pessimistic attitude, so true picture could not be seen.

CONCLUSION

Mid-shaft clavicle fractures when treated surgically with plate and screws had earlier union as compared to conservative treatment. Functional outcome at 6 weeks was significantly better for surgical group which allowed the patients to return to work earlier. Although the functional outcome and patient satisfaction rates at the end of 6 months were similar for both groups, we still recommend surgical treatment because the operated patients regained their upper limb functions early and absence from productive work was less. Complications like more malunion in conservative group and more infection in surgical group were treatment specific and didn't hinder functional recovery.

CONFLICT OF INTEREST: None

FINANCIAL DISCLOSURE: None

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