

A COMPARATIVE STUDY OF CONSERVATIVE TREATMENT VERSUS PLATE OSTEOSYNTHESIS OF DISPLACED MIDDLE THIRD FRACTURE OF CLAVICLE

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Abstract

Background: Clavicle fractures are one of the commonest fractures encountered in orthopedic practice. About 81% of these occur in the middle-third (mid-shaft) of clavicle and 48% of these are displaced fractures. These fractures can be treated non-operatively as well as operatively. The present study was taken up to radiological union and functional outcome in patients who underwent plating for mid-shaft fracture of clavicle and in patients who were treated conservatively. The study also assessed the complications in the two modalities of treatment. **Materials and Methods:** A total of 72 patients of the age-group 16-70 years having displaced mid-shaft fractures of clavicle were randomly allocated to surgical and conservative group. The non-operative treatment consisted of the use of a sling and figure-of-eight splinting whereas the operative management consisted of open reduction internal fixation with plates and screws, intramedullary nail fixation and sometimes external fixation. The independent variables used were sex, age, side of injury and mode of injury. The outcome variables were DASH and Constant scores, length of shortening, radiological union, return to work duration, patient satisfaction and associated complications. **Result:** For conservative treatment figure-of-eight bandage was applied on for a mean (SD) duration of 26 (3) days. Majority of them (25; 69%) had complaints of tightness in the axilla with paraesthesia in the upper limbs and required repeated application at subsequent follow-up visits. All 36 cases showed fracture union but all had shortening by an average of 1.3cm. No thoracic outlet syndrome or shoulder pain or weakness was present. Among the surgical group, there was no significant intra-operative complications except that in 24 (67%) of them, the pre-contoured anatomical plates did not fit the S-shaped curvature on the superior surface especially at the lateral end of the bone. Post-operatively one patient had surgical wound infection. Post-operatively, all had post-operative cutaneous hypoesthesia underneath the incision. A total of 26 patients (72%) had hardware prominence. No hardware failure was detected. A total of 33 (92%) patients in the conservative group were satisfied about the cosmetic outcome while only 20 (56%) patients in the surgical group were satisfied. This difference was statistically significant ($p=0.001$). Among the patients in the surgical group radiological union was achieved at a mean duration of 14 weeks whereas, for the conservative group it took a mean duration of 28 weeks. Patients in the conservative group returned to work at an average of 11 weeks while for the patients in the surgical group it was 08 weeks. The mean Constant score and the mean DASH score was significantly better in the surgical groups ($p<0.001$ in both). **Conclusion:** Our study suggests that, in displaced mid-shaft clavicle fractures, the functional outcome is significantly better with surgical treatment. Yet, conservative treatment has fewer cosmetic and hardware-related complications. Yet our findings are to be digested keeping in mind of the small sample size and relatively shorter follow-up period.

INTRODUCTION

Clavicle fractures are one of the commonest fractures encountered in orthopedic practice. It accounts for 2.6-10% of all fractures.^[1] About 81% of these occur in the middle-third (mid-shaft) of clavicle and 48% of these are displaced fractures.^[2]

These fractures can be treated non-operatively as well as operatively.^[3] The absolute indications for surgical management are open fractures and fractures with impending skin perforation.^[4] The non-operative treatment consists of the use of a sling and figure-of-eight splinting whereas the operative management consists of open reduction internal fixation with plates and screws, intramedullary nail fixation and sometimes external fixation.

Aims & Objectives: The present study was taken up to radiological union and functional outcome in patients who underwent plating for mid-shaft fracture of clavicle and in patients who were treated conservatively. The study also assessed the complications in the two modalities of treatment.

MATERIALS AND METHODS

A randomized clinical trial was conducted in the Department of Orthopedics, JNIMS, Imphal, Manipur during the period May 2019 to Nov 2021. The study participants were patients with mid-shaft clavicle fractures admitted in the same department who were of the age-group of 16-70 years, sustained injury within two weeks of reporting and were fit for surgery. Patients with pathological fractures, non-union/malunion or neurovascular injuries and open fractures were excluded.

Considering proportion of excellent outcome in 17.6% in one arm and 56.3% in the other arm from a previous study^[5], taking alpha error of 0.05 and a power of 90% a sample size of 36 in each of the two arms was determined. Randomization in blocks of two and four was done for allocating patients in the two arms. Thus, equal number of participants were subjected to the two arms of management namely the operative treatment and the conservative treatment. The non-operative treatment consisted of the use of a sling and figure-of-eight splinting whereas the operative management consisted of open reduction internal fixation with plates and screws, intramedullary nail fixation and sometimes external fixation

A proforma was used to collect data which had sections patient's profile, Constant score and disability of arm, shoulder and hand (DASH) score and laboratory investigations. The independent variables used were sex, age, side of injury and mode of injury. The outcome variables were DASH and Constant scores, length of shortening, radiological union, return to work duration, patient satisfaction and associated complications. DASH consisted of a 30-item disability/symptom scale scored from zero (no disability) to 100 (most severe disability). The

Constant score which was used to assess the functional outcome also had a score range of zero to 100.

All the study participants were followed up at second week, sixth week, third month, sixth month and first year or until union happened whichever was earlier. At each visit assessment was done using clinical examination, X-ray clavicle and chest x-ray with bilateral joint, Constant score and DASH score.

All data were entered and analyzed using SPSSv22 software. Descriptive data was presented using mean, standard deviation and proportions. Chi-square test with its modifications was used for comparing between the two arms. A p value of less than 0.05 was considered as statistically significant.

Ethical approval of the study was obtained from Intuitional Ethics Committee, JNIMS. Informed written consent was taken from all eligible participants before the start of the study. Strict confidentiality was maintained.

RESULTS

Data could be collected from 72 patients. Majority of the patients were from the age-group of 20-40 years (86% both in conservative treatment and surgical treatment). Males outnumbered females in both the groups in the ratio of 3:1. Majority of the patients (63; 88%) sustained clavicle fracture by direct fall on the shoulder during road traffic accidents. A total of 42 patients (58%) sustained the injury on the non-dominant side. A total of 32 patients (92%) and 29 patients (81%) in the conservative and surgical treatment had Robinson type 2B1 fractures, the remaining having type 2B2 fractures.

All cases that underwent surgical intervention were operated within two weeks from the time of admission to the hospital. All surgeries were completed in an average duration of 45 minutes.

For conservative treatment figure-of-eight bandage was applied on for a mean (SD) duration of 26 (3) days. Majority of them (25; 69%) had complaints of tightness in the axilla with paraesthesia in the upper limbs and required repeated application at subsequent follow-up visits. All 36 cases showed fracture union but all had shortening by an average of 1.3cm. No thoracic outlet syndrome or shoulder pain or weakness was present.

Among the surgical group, there was no significant intra-operative complications except that in 24 (67%) of them, the pre-contoured anatomical plates did not fit the S-shaped curvature on the superior surface especially at the lateral end of the bone. Post-operatively one patient had surgical wound infection. Post-operatively, all had post-operative cutaneous hypoesthesia underneath the incision. A total of 26 patients (72%) had hardware prominence. No hardware failure was detected [Table 1].

A total of 33 (92%) patients in the conservative group were satisfied about the cosmetic outcome while only 20 (56%) patients in the surgical group were satisfied. This difference was statistically significant ($p=0.001$)

Among the patients in the surgical group radiological union was achieved at a mean duration of 14 weeks whereas, for the conservative group it took a mean duration of 28 weeks. Patients in the conservative group returned to work at an average of 11 weeks while for the patients in the surgical group it was 08

weeks. The mean Constant score and the mean DASH score was significantly better in the surgical groups ($p < 0.001$ in both) [Tables 2 & 3]. There was no significant loss of range of movement in both the groups.

Table 1: Complications in the study

Adverse event	Conservative group (n=36)	Surgical group (n=36)
Non-union	0	0
Malunion	36	0
Shortening	36	0
Wound infection	-	1
Implant failure	-	0
Prominent surgical scar	-	19
Cutaneous hypoesthesia	0	36

Table 2: Constant score results

Follow-up period	Mean Constant score	
	Conservative group	Surgical group
6 weeks	64.64	74.64
12 weeks	74.64	84.67
24 weeks	79.67	89.67
52 weeks	83.64	93.53

Table 3: DASH score results

Follow-up period	Mean DASH score	
	Conservative group	Surgical group
6 weeks	48.92	39.19
12 weeks	36.08	26.08
24 weeks	31.11	21.11
52 weeks	28.33	19.11

DISCUSSION

From the current study, it was found that displaced mid-shaft clavicle fractures are seen more commonly among the males (86%). Also, the injuries were seen mainly on the non-dominant side (58%). These observations are comparable with the findings made by Postacchini F et al.^[2] In our study, maximum prevalence of the injury was found in the age-group of 20-50 years with the mean age of 35.3 years. Toogood P et al found the mean age to be 29.3 years.^[6] Probably the difference in the study setting may explain this discrepancy.

In the present study no non-union could be seen. Khan et al reported a non-union rate of 1-15% which might rise up-to 11-40% in conservatively treated patients.^[7] Brinker et al also found a non-union rate of 20-33%.^[8] Zlowodzki et al, from their meta-analysis also showed a non-union rate of 2.2% after plate fixation and 15.1% with conservative treatment.^[9] The small sample size in the present study might have masked this effect.

With conservative treatment a final shortening of approximately 20 mm was found by Hill et al.^[10] The mean shortening observed in the present study was 13 mm.

In 2007, the Canadian Orthopaedic Trauma Society found that the Constant scores and the DASH scores were significantly improved with the operative fixation group compared to conservatively treated group.^[5] Our study finding was in accordance with their finding.

CONCLUSION

Our study suggests that, in displaced mid-shaft clavicle fractures, the functional outcome is significantly better with surgical treatment. Yet, conservative treatment has fewer cosmetic and hardware-related complications. Yet our findings are to be digested keeping in mind of the small sample size and relatively shorter follow-up period.

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