Short Term Outcome Evaluation Of Conservative Versus Operative Treatment Of Fracture Clavicle A Prospective Observational Study

Dr. Sagar RK*, Dr. Pinakin I Vora**

*3rd Year Orthopedic Resident, ** Associate Professor, Department of Orthopaedic, Govt. Medical College, Bhavnagar, 364001.

Abstract: Background: Clavicle fracture is a common condition mostly treated conservatively. Newer operative modalities have come up to obtain early fixation. Accurate reduction and fixation is important for complication-free management of clavicle fractures. However, there is still doubt amongst orthopaedic surgeons regarding the choice of management for clavicle fractures. Study aimed at analysis of the outcomes and complications of the operative management and its compare with conservative modality. Material And Methods: Ethics committee permission was taken and 30 patients with middle-third clavicle fracture were included in this study. The affected limb was treated either conservatively (Figure of 8 brace and sling) or operatively (OR+IF using recon plate or AO pre-contoured plate or TEN). Regular followup till 1 year post-treatment was done. The functional outcome was assessed by Constant and Murley score. Descriptive statistics and Chisquare test were applied for analysing the data. Result: 15 patients were treated conservatively while 15 operatively. 23 (69.7%) had excellent or good functional outcome at 4 weeks irrespective of the treatment. The patients in the operative group who showed excellent results were significantly more than that in the conservative group (p = 0.0324). Average union time in the conservative group was 9.4 weeks, more than the 7.8 weeks seen in the operative group. Mal-union was present in 7 of 17 patients treated conservatively. Superficial infection, implant failure and keloid formation were seen in one patient of operated group. Conclusion: Clavicle fractures managed operatively had better functional outcome with lesser post-operative complications. [RK S Natl J Integr Res Med, 2020; 11(3): 28-32]

Key Words: Conservative Management, Operative Management, Midshaft Clavicle Fracture, Functional Outcome and Post- Operative Complications.

Author for correspondence: Dr Pinakin I Vora, Associate Professor, Department of Orthopaedic, Govt. Medical College, Bhavnagar, 364001. E-Mail: drpinakinvora@yahoo.in

Introduction: The name clavicle originates from the Latin word clavis which means key. Clavicula is a diminutive of clavis and means small key, referring to its size and the fact that the clavicle is able to rotate around its axis enabling full range of motion of shoulder girdle. Clavicle acts as bony connection between thorax and shoulder girdle while contributing to movements around the shoulder¹. Most commonly used nonoperative method is clavicle brace and an arm sling. It has advantage of being noninvasive and absence of exposure to anesthesia. However, nonoperative methods are said to be associated with risk of non-union, residual deformity and patient dissatisfaction. Most clavicular fractures still are treated closed and heal uneventfully without serious consequences⁷. Nonoperative management was widely recommended for middle third fracture given higher union rate with nonunion of 0.03 to 6.2%^{1.} However, with recent studies showing nonunion rates upto 15% and patient dissatisfaction of upto 31%, here is increasing trend for operative management².

Two types of fixation are available for middlethird clavicle fractures. Intramedullary devices and plates. Intramedullary fixation can be accomplished with smooth or threaded K- wires, Steinman pins, Knowles pins, Hagie pins, or cannulated screw. With intramedullary devices, there is less surgical dissection and soft tissue stripping with less hardware prominence. However, there is the possibility of pin migration and poor rotational control during overhead abduction of shoulder¹.Plating of acute clavicle fractures, when indicated, is advocated as the preferred fixation method by many authors. Biomechanically, plate fixation is superior to intramedullary fixation as it better resists the bending and torsional forces that occur during elevation of the upper extremity above shoulder level.

Patients treated with plate fixation can be allowed full range of motion once their soft tissues have healed. Disadvantages of plate fixation include the necessity for increased exposure and soft-tissue stripping, potential damage to the supraclavicular nerves, which cross through the surgical field, slightly higher infection rates and the risk of refracture after plate removal. These complications can be reduced by careful soft tissue handling, minimal periosteal stripping and meticulous plate fixation⁸. In our study, we will compare the functional outcome of conservative and operative management of midshaft displaced clavicular fracture.

Material & Methods: Patients of the age between 18-60 years having closed fracture of the clavicle who were admitted to Department of Orthopaedics, Sir T hospital Bhavnagar were enrolled for study after obtaining their written informed consent. This was a prospective study from October 2018 to October 2019. Male and female patients aged 18-60 years with closed displaced middle third clavicular fracture who had given their consent for the procedure and Patients who were medically fit for surgery were included in our study. Open fracture of the clavicle, Undisplaced fracture, Patients <18 yrs and >60yrs, patients medically unfit for surgery, patients not willing for surgery, communited fracture of the clavicle, fracture lateral end clavicle, patients with neurovascular deficits were excluded from our study.

General information as Name, Age, Sex, Occupation and Address were noted. Mode of injury as direct injury, fall on an outstretched hand. Road traffic accident were recorded. History of Past medical illness was noted. Anemia, jaundice, lymphadenopathy, pulse rate, blood pressure noted. Respiratory, Cardiovascular and Neurological system were examined. Plain radiographs of clavicle, anteroposterior view and 45degree cephalic tilt view was taken to assess the site of fracture, type of fracture, displacement of fracture and comminution. The fracture was classified according to OTA (Ortho Trauma Association) and classification. Robinson's Affected arm immobilized witharm-sling or clavicle brace.

Laboratory Investigations: complete haemogram, renal function test, ECG and Chest X-ray were done and PAC (pre anaesthetic check up) completed. All the patients were operated on as early as possible once the general condition of the patient was stabilized. For preoperative preparation fasting for 8 hours before surgery, neck, chest, axilla, shoulders and arm were prepared. A written informed consent for was taken. Inj.ceftriaxone surgery 1gm intravenously was administered 30minutes before surgery. All patients were operated under general anaesthesia.

<u>Operative Procedure:</u> Patient was placed in supine position with sand bag between the

scapulae. Keeping the sand bag allows the shoulder girdle to falls backward. It restores the length and increases the exposure to clavicle.

Make an incision along the axis of the clavicle, centering the fracture site. Subcutaneous tissue along with platysma incised together and mobilized. Myofascial layer was incised and elevated. Fracture site exposed. Periosteum elevated. Fracture ends freshened. Fracture reduced using bone clamps. If there was a comminuted wedge fragment was fixed with a lag screw. Precontoured reconstruction plate or anatomical clavicular plate was used. The Plate is placed over the superior surface of the clavicle.2.7mm drill bit was used. Screw size measured with depth gauge. Tapping was done with 3.5mm tap. 3.5 mm cortical screws were used for reconstruction and locking screws in locking plate. Minimum of six cortical purchases was attained on either side of the fracture.

Myofascial layer followed by skin and sub cuticular tissue sutured. Sterile dressing applied and immobilized in a shoulder immobilizer. Patients were kept nil orally for 4 to 6hours postoperatively. Intravenous fluids were given as needed. Antibiotics were continued for 5days.

Analgesics and tranquilizers were given according to the needs of the patient. The operated upper limb was immobilized in an arm pouch. Check xrays were taken to study the alignment of fracture fragments. The wound was inspected at 2nd postoperative day. Suture removal was done on12th postoperative day. Patients were discharged with armpouch.

The objectives of rehabilitation are to improve and restore the function of the shoulder for activities of daily living, vocational and sports activities. Rehabilitation of the affected extremity were done according to the stage of fracture union and time duration from day of surgery.

Pendulum movements/ codman's exercises started from 3rd post operative day. On 2nd week: The sling discontinued and unrestricted range of motion exercise allowed. They are followed every two weeks till 3 months followed by every 4 weeks till 6 months and every 8 weeks till one year. Sports activities and heavy weighting were avoided till 12 weeks.

Table 1 Sex Ratio			
	Conservative ORIF With Tota		Total
		Planting	
Female	04	01	05
Male	11	14	25
Total	15	15	30

Table 2 Age Group

Age	Conservative	ORIF With Plating	Total
18-30	03	02	05
31-45	10	12	22
46-60	02	01	03
Total	15	15	30

Table 3 Mode Of Trauma

	Conservative	ORIF With Plating	Total
Fall Injury	01	01	02
RTA	14	14	28
Total	15	15	30

Table 4 Complications

Complication	Conservative	ORIF With Plating
Non Union	00	00
Delayed Union	03	01
Malunion	07	01
Infection	00	01
Loosning Of Screws	-	01
Implant Failure	-	01
Visible Deformity	05	00

Functional Outcome Of Each Patient Was Noted At 1 Month By CONSTANT AND MURLEUY SCORF And Graded As Below.

Total Score	Result	
90-100	Excellent	
80-89	Good	
70-79	Adequate	
0-70 Poor		

In Our Study We Found Following Results.

	Conservative	ORIF	Total
Excellent	3	9	12
Good	7	4	11
Adequate	3	1	4
Poor	2	1	3

Complication	Conservative	ORIF With Plating
Non Union	00	00
Delayed Union	03	01
Malunion	07	01
Infection	00	01
Loosning Of Screws	-	01
Implant Failure	-	01
Visible Deformity	05	00

From the total of 30 patients, 23 (69.7%) had excellent or good functional outcome at 4 weeks irrespective of the treatment. 7 of the 15 patients who were managed conservatively had satisfactory to poor scores as compared to 3 patients out of 15 who were managed operatively. The functional outcome results, assessed by the Constant and Murley Score.

The number of patients in the operative group who showed excellent results were significantly more than that in the conservative group (p =0.0324).Out of the 15 operated patients, 12 (80%) of them were treated with the help of a reconstruction plate while 3 (20%) of the patients were operated using pre-contoured locking plate.

In our study, the 15 patients who were operated upon had an average union time of 7.8 weeks. Average union time in the conservative group was 9.4 weeks, which was more than the 7.8 weeks seen in the group treated operatively.

Mal-union was present in 7 of the 15 patients treated conservatively, and 5 of these 7 had a visible deformity. Out of these patients with malunion 1 had poor functional outcome, 3 had good to excellent outcome and 3 had satisfactory functional outcome. 4 of these had restricted movements terminally and 2 had pain on movement. In surgically treated group, 1 patient suffered from superficial infection while another 1 experienced implant failure in forms of loss of reduction and implant separation from distal fragment.

Discussion: For a long time, clavicle fractures have been treated by conservative means using measures like sling "figure of 8 bandage". However, the interest in operative treatment has increased and it has progressed from open reduction and fixation to closed reduction with fixation. Extra medullary fixation have been performed by using dynamic compression plate,

reconstruction plate, pre-contoured plates, locking plates and now 3-D contoured plates.

According to various studies, conservative therapy of displaced middle third clavicle fracture has been associated with poor outcomes.^{3,4,5}In this study we have classified fracture of mid-shaft clavicle according to Robinson classification. Majority of patients in this study were in B1 (14 i.e. 42.4%) group followed by A2 (08 i.e. 24.2%) ,B2 (06i.e.18.2%) and A1 (5i.e.15.2%). Not even a single patient belonged to the 2A1 class in the operative group. Oliver et al, 1956 studies have also used the Robinson classification to classify clavicle fractures. Robinson155 evaluated over 1,000 consecutive fractures of the clavicle, and developed a classification scheme based on prognostic variables from the analysis of their data⁴. It continues the traditional scheme of dividing the clavicle into thirds, and adds variables that are of proven diagnostic value intra-articular extension, displacement, and comminution.

So Robinsons classification is better than other classification. However, they do not show any particular preponderance of any specific type of mid-shaft clavicle fractures in the participants. [Rockwood and green,18th edi ,fracture clavicle, pg 1437] In our study the clavicle fracture are more common in male than females. There were 25 male and 5 female patients. This is comparable with other studies by Elidrissi Mohammed et al where out of 34 patients 32 were male and two were females¹⁰. In a study by Dhoju et al out of 20 patients 16 were males and 4 were females. From this we can conclude that it is more common in active individuals.

In our study right side clavicle is commonly involved than left side. This is also comparable with the study by Elidrissi Mohammed et al where out of 34 cases 28 were on right side and 6 were left side. From this we can come to conclusion that dominant hand involves usually⁹.In our study Road Traffic Accident was the most common cause for clavicle fractures. Fall on out stretched hand was the commonest mechanism of injury. We studied the fracture pattern (intra operatve finding) based on mode of injury and mechanism of injury. From this Robinson type 2b2 (comminuted mid shaft fracture) is associated with high velocity injury and direct impact on the shoulder⁹.

We assessed the functional outcome using constant score. In our study, the functional outcome was excellent in 12 cases (36.4%), good in 11patients (33.3%), satisfactory in 4 cases (12.1%), adequate in 1 participant (3%) and poor in 5 patients (15.2%). Out of all the excellent outcomes, 3 cases (17.6%) were from conservative group while 9 patients (56.3%) In operative group. On Fisher's exact test, it was found that the difference between the number of excellent outcomes between the two groups was significant (p<0.05). A previous study states that though the non-operative group did approach the functional outcome of the operative group with plates at 18 months, a significant difference was still evident'.

In our study, the 15 patients who were operated upon showed an average union time of 7.8 weeks.. Average union time in conservative group was 9.4 weeks. It was noteworthy that malunion was a major concern in the conservatively managed group, with 7 out of 15 patients (41.1%) suffering from it. Kulshrestha V, Roy T, Audige L. f 2011;25:1-8 (16)found tht .all fractures in the operative group showed normal union, whereas eight fracture patients in the non-operative group reported non-union (29%) (P=0.002). In addition, 10 patients (35.7%) in the non-operative group experienced a symptomatic malunion compare with two (4.4%) surgically treated patients⁸.

In the operative group of our study, one patient suffered from superficial infection at the operative site which was treated successfully with debridement and oral antibiotics. One patient suffered from implant failure in the form of reduction loss and implant separation from the distal fragment. In a previous study, 2 patients in the operative group (4.5%) had implant deformation associated with a delayed union. Both fractures united in that study but with angulation⁸.

This study did not assess the individual modalities of treatment (like'figure of 8' management or plate fixation). There is a need to study the various individual treatment options, especially the outcomes between the various newer operative modalities like plate fixation and titanium elastic intramedullary nail fixation.

Conclusion: From our study based on patients of mid-shaft clavicle fractures, it can be concluded

that the operative group had significantly higher excellent outcomes as compared to the conservatively-managed group, based on the Constant and Murley score. The number of malunion reported in the conservatively treated group was significantly more with that in the operative group. The average union time observed in the non-operative group was more as compared to that in the operative group. Thus, clavicle fractures managed with operative modalities had a better outcome with much lesser post-operative complications. Our result is consistent with strict inclusion criteria, by extending inclusion criteria, different results may be found.

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