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Functional Outcome of Unstable fracture of Lateral end of Clavicle treated with Tension Band Wiring and Pre-contoured Lateral end clavicle Locking Plate- A Prospective Randomized Controlled Study

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ABSTRACT

Introduction: Fractures of the lateral end of clavicle went largely undiagnosed in the ancient age, so they have a few mentions in the ancient writings. Historically much has been written about fractures of the mid shaft clavicle as they are easily spotted and more common, unlike fractures of lateral third clavicle. Unstable fractures of lateral end of clavicle require operative treatment due to the high rate of observed non-union and even higher rate of delayed union. Materials: we carried out a prospective randomized control study with 30 patients with unstable fractures of lateral end of clavicle treated by open reduction and internal fixation with Tension Band wiring(TBW) and Pre-contoured locking lateral clavicle plate at Gauhati Medical College and Hospital, Guwahati, Assam, India from 1st April 2021 to 30th March 2022. The patients were evaluated for their functional outcome at the end of 6th month of post-operative follow up using Constant-Murley Scoring System. Results: 30 patients between the age group of 20-60 years with unstable lateral third clavicle fractures were randomly allocated into two groups of treatment as per randomization chart. The maximum number of cases was observed in the age group of 31-40 years. At the end of 6th month of post operative period, "Excellent" score was achieved in 13(86.66%) case and "good" results were obtained in 2(13.33%) in pre-contoured lateral end clavicle plate group. While in Tension Band Wiring group, "excellent" score was achieved in 6(40%) cases and "good" results were obtained in 9(60%). Conclusion: Pre-contoured lateral clavicle plate fixation provides better functional outcome than Tension Band Wiring. TBW has more complications than the lateral clavicle plate.

Keywords*: Unstable lateral end clavicle Fracture, Tension Band Wiring, Pre-contoured lateral end calvicle Plate, functional outcome.*

INTRODUCTION

The clavicle fractures are common injuries in young, active individuals, especially those who participates in activities or sports where high speed falls (bicycling, motorcycles) or violent collisions (football, hockey) are frequent, and they account for approximately 2.6%-4% of all fractures of the body and around 44% to 66% of fractures about the shoulder **[1]**. Middle third fractures account for 80% of all clavicle fractures, whereas fractures of the lateral and medial third of the clavicle account for 15% and 5%, respectively **[2]**. Fractures of the lateral end clavicle went largely undiagnosed in the ancient age so they have a few mentions in the ancient writings. Traditionally, fracture of lateral third clavicle has been managed conservatively. As the radiological investigations are easily available than they were before, the Lateral end clavicle fractures have been diagnosed and addressed more frequently now because of increased functional demand. Neer classified the fracture based on fracture location in relation to the Coraco-Clavicular(CC) ligament on antero-posterior X-ray view. Craig modified the Neer classification which is more detailed and helpful in determining a treatment and prognosis[3]. As per this revised classification system, type 1- fractures occur lateral to the CC ligament with minimal displacement and no involvement of the acromioclavicular (AC) joint; type 2- fractures occur medial to the CC ligament and are divided into two subtypes, subtype 2A (medial to the conoid ligament) and subtype 2B (between the conoid and trapezoid ligaments with a rupture of the conoid ligament); type 3- fractures are similar to type 1 (i.e., also lie lateral to the CC ligament), but they have intra-articular extension; type 4- fractures involve disruption of the periosteal

sleeve and the medial fragment gets displaced upwards in children; and type 5- fractures are similar to type 2 (involve a small inferior fragment attached to the CC ligament) and are comminuted. Type 1 and type 3 are stable fractures and may be managed conservatively. Types 2 and 5 are classified as unstable fractures and patients usually complain of pain and functional incapability if treated them by conservative method. Moreover, unstable lateral end clavicle fractures require operative treatment due to the high rate of observed non union and even higher rate of delayed union with significant residual shoulder disability in patients treated conservatively **[4,5]**. The deforming forces around the fracture cause displacement and inter-positioning between the fracture fragments with continuous motion at the fracture ends, as none of the conservative appliances give efficient immobilization. Consequently, various surgical modalities have been advocated with various techniques of fixation. But still there is no gold standard method of fixation addressed for displaced lateral end clavicle. Although there are generally accepted guidelines for various patterns of fracture management, there are very few clinical trials comparing the method of fixation and claiming the best accepted modality. Contextually, we conducted a prospective randomized controlled study to treat the unstable fracture of lateral end of the clavicle by operative method using the tension band wiring and pre-contoured anatomical lateral end clavicle plate and evaluate their functional outcomes and comparisons.

MATERIALS AND METHODS

The study was carried out in the patients with unstable fractures of lateral third clavicle, attending in the Orthopaedics OPD and the Emergency Department at Gauhati Medical College and Hospital, Guwahati, Assam, India from 1st April, 2021 to 30th March, 2022. The patients were randomized into two groups and treated operatively using either the Pre-contoured lateral end clavicle plate or Tension band wiring with K-wire and SS wire. Subsequently these patients were followed up regularly and functional outcomes were evaluated. All patients underwent preoperative and post-operative x-ray and other necessary investigations and post-operative observation for any complications.

Study design

The study was a prospective randomized controlled study. A sample size was 30 patients who underwent evaluation, intervention and follow up.

Patient selection

Selection of the patient for surgical intervention for each group was done according to the randomization plan. An informed consent was obtained from each patient after discussing the procedure prior to participation in the study. An ethical approval was taken from the Institutional Ethical Committee prior to begin the study.

Inclusion criteria:

a) Patients between 20 and 60 years of age
b) Closed Unstable fracture of lateral end clavicle
c) Duration of injury <14 days
d) Patients who gave consent for operative treatment

Exclusion Criteria

a) Open fractures
b) Compromised distal neurovascular status
c) Patients with ipsilateral upper limb injury or bilateral fracture clavicle
d) Patients who are unfit for surgery

Operative protocol

On receiving the patient, a detailed history of the patient in regard to age, sex, socio-economic background, duration & mode of injury, dominancy of hand and previous illness or treatment, was taken and recorded. A thorough clinical examination was carried out to exclude any associated injury & other medical and surgical illness which may require necessary treatment. The limb is initially supported with an arm sling. Initial radiographs were then advised taking antero-posterior view of clavicle including shoulder joint. The patient and the family member were explained about the nature of the fracture and regarding the need for open reduction and internal fixation. After randomization for the operative technique to be used, all the necessary preoperative investigations were carried out. Each patient received a broad spectrum antibiotic intravenously one hour before putting under general anaesthesia. Patient was placed in supine position with a bolster on the back of operating shoulder and the head turned towards the opposite side. Shoulder girdle and clavicular region of the upper chest was prepared and draped in standard fashion. The skin incision was made directly over the distal clavicle centering the fracture site, extending approximately 2-3 cm past the AC joint. The skin and the subcutaneous layer were developed, cautery dissection was carried out to minimize bleeding and the delto-trapezial myofascial layer was incised directly over the distal clavicle and reflected anteriorly and posteriorly. The AC joint was identified. Every care was taken not to disturb acromioclavicular ligaments. Then the fracture site was identified and cleaned.

For Lateral end clavicular plate fixation: The fracture site was exposed and reduced with temporary K-wire fixation across the AC joint, and the status of the reduction was confirmed. The plate was selected based on the fracture length and the curvature of the clavicle. After provisional stabilization with a K-wire, 2 screws were placed initially, one medial

(3.5-mm cortical screw) and one lateral (2.3-mm locking screw) to the fracture site. K-wire was then removed. The plate was then fixed to the distal fragment using 2.3-mm locking screws and the medial fragment with 3.5-mm cortical locking screws (Figure 1- A,B,C). Intra-operative image intensifier was used to ensure all screws remained extra-articular. After thorough washing, surgical wound was closed in layers and dressing applied. An arm pouch was used to support the operated shoulder prior to send the patient to the recovery room.

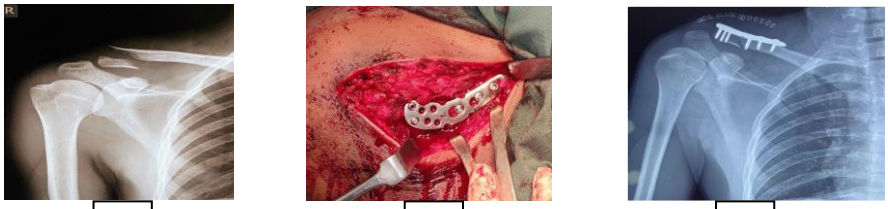

Figure 1(A,B,C): A- Preoperative x-ray of unstable fracture of lateral end of clavicle, B- Intra-operative photo of pre-contoured plating, C- Immediate postoperative x-ray

For Tension Band Wiring: After reduction, tension band wire fixation was performed with 2 parallel K-wires passing from the lateral margin of the distal fragment towards the medial fragment and checked with an image intensifier. An antero-posterior drill hole was made with 2mm drill bit on medial fragment. A 16G stainless steel (SS) wire was passed through the hole. The SS wire was tied in a figure of eight manner keeping the knot superiorly around the K-wires. The K-wires were bent, cut and turned away from the AC joint proper (Figure 2-X, Y, Z). The wound was closed in layers and after dressing an arm sling pouch was applied.

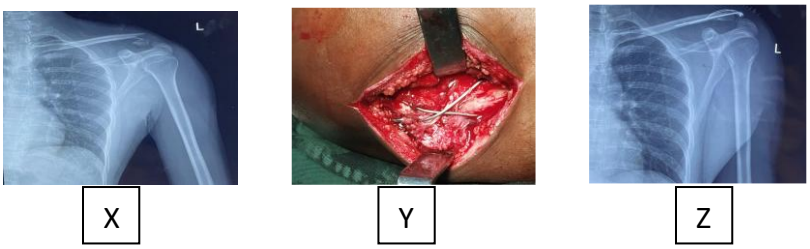

Figure 2(X,Y,Z): X- Preoperative x-ray of unstable fracture of lateral end clavicle, Y- Intra-operative photo of TBW, Z- Immediate postoperative x-ray.

Post-operative care:
The patients were put in an arm sling pouch after the surgical procedure for comfort. The wound was inspected on the third day and dressing changed under aseptic condition. Active range of motion (ROM) exercises of the elbow, wrist, and hand were initiated on the same day postoperatively. The sling was used for 2weeks to provide further protection. Passive mobilization was allowed from the first week postoperatively and gentle active movements were encouraged thereafter. Stitch removal was done at 2 weeks and Pendulum exercises were started. The ranges of motion of pendulum exercises were increased gradually up to 90 degree by 4 weeks.

Follow up:
Assessment included standardized clinical and radiological evaluation for each group based on the protocol which was adopted for the study. Plain antero-posterior radiographs were used to evaluate signs of bony union at 6 to 8 weeks. Signs of bony union were confirmed by clinical and x-ray evaluation. Radiographic union was defined as either a bridging callus over the fracture sites or fracture gap obliteration.

Regular follow up was done at 2 weeks, 4weeks and then 4weekly for 6 months. At 6 months, final evaluation was done using Constant-Murley Scoring System **[6]**, which is comprised of activities of daily living (20 points), shoulder movement (40 points), strength (25 points), and pain assessment (15 points), for a 100-point maximum (Table 1A). Grading of the Constant Shoulder Score is done by taking the difference between affected and unaffected side (Table 1B). Grade less than 11 is considered as excellent, between 11-20 as good, between 21-30 as fair and more than 30 is graded as a poor functional outcome (Table 1C).

Table 1A: Constant - Murley Scoring System for assessment of shoulder function

Individual parameters	**Scoring**
Pain	15
Activities of daily living	20
Range of motion	40
Power	25
Total	100

Table 1B: Simplified assessment form

Individual parameters	**Right side**	**Left side**
Pain		
Activities of daily living		
Range of motion		
Power		
Total		

Table 1C: Grading

Difference between the affected and unaffected side	**Grades**
< 11	Excellent
11-20	Good
21-30	Fair
>30	Poor

RESULTS

30 patients between age group of 20-60 years with unstable lateral third clavicle fractures were randomly allocated into two groups of treatment as per randomization chart. All the patients were followed up for a minimum period of six months. Final assessment was done at the end of 6 months from the date of operation in all the cases. The youngest patient in the study was 21 years of age, while the oldest patient was of 58 years age. The mean age of the patients was 38.43 years. The maximum number of cases was observed in the age group of 31-40 years (Table-2).

Of the 15 patients in the pre-contoured lateral end clavicle plate group, the age ranged from 21 to 58 years (mean 34.86 years), maximum being belonged to the age group of 20-30 and 31-40 years. Of the 15 patients in the TBW group, the age ranged from 26 to 56 years (mean 42 years) and maximum number belonged to the age group of 31-40 years (Table-2).

Table 2: Age distribution of patients each in Pre-contoured plate and TBW groups:

Age groups (Years)	Number of Patients	Pre-contoured plate		Tension Band Wiring	
		Number	Percentage	Number	Percentage
20-30	7	5	16.66%	2	6.66%
31-40	14	5	16.66%	9	30%
41-50	4	3	10%	1	3.33%
51-60	5	2	6.66%	3	10%
Total	30	15	50%	15	50%

Out of 30 patients, 23 male and 7 female patients were in the study. 22 (73.33%) patients were affected on dominant site. The majority of the patients were manual labors and rests were official workers and sports players. The commonest mode of injury was RTA (Road traffic accident) followed by fall. RTA comprises of 66.66%of patients while 23.33% of patient had simple fall, 10% of patients had fall from height. All the patients were operated within 2 weeks of trauma, the average interval being 5.86 days for plating and 6.13 days for TBW groups. We could achieve union in all 15(100%) patients of TBW group and in 15 patients (100%) of pre-contoured lateral end clavicular plate group. The average time of union in the pre-contoured lateral end clavicular plate group was 9.33 weeks (range 8- 10weeks). In the TBW group, union occurred in an average of 12.53 weeks (range10-16 weeks). At the end of 6 months of follow up, the final results were evaluated using the shoulder scoring system of Constant and Murley(Table 3). The mean Constant Score for the pre-contoured lateral end clavicular plate group was 91.86 and that for TBW group it was 86.66 on the affected side. The difference between the mean Constant Murley Score of the unaffected side and affected side of both the groups were analyzed statistically, and p value was found to be <0.0001, which is statistically significant.

Table 3: Functional results in our study

Modality	Excellent	Good	Fair	Poor
TBW	6	9	0	0
Pre-contoured plate	13	2	0	0
Total	19	11	0	0

In our study, both the groups had their own set of local complications. In TBW group, there were 3(20%) cases of K-wire migration and 1(6.6%) case of pin prominence. The hardware related complications namely K-wire migration, pin prominence were appeared at the end of 3rd month. In the pre-contoured lateral end clavicular plate group, there were 1(6.6%) case of superficial wound infection and 1 (6.6%) case complained of pain while carrying backpacks.

i i iii iv v

Case no-1(Lateral end clavicle plate-right side) - i. Preoperative x-ray, ii. X-ray showing bony union at 6th month postoperatively, iii, iv, v- Ranges of movement at 6th month.

(a (b) (c) (d) (e)

Case no-2(Tension Band Wiring-left side)- a) Preoperative x-ray b) X-ray showing bony union at 6th month postoperatively, c,d,e) Ranges of movement at 6th month.

DISCUSSION

It is well acknowledged that displaced lateral end clavicle fractures require internal fixation. Although a wide range of lateral end clavicle fixation device have been employed over the years, still there is controversy regarding the best fixation method for displaced lateral end clavicle fractures. The successful treatment of displaced clavicle lateral end fractures depends on various variables, such as the patient's age, general health, and the time between the fracture and treatment, comminution, type of implant used, concurrent medical treatment. Sufficient knowledge regarding the biological and biomechanical principle of the available methods should be obtained, as each method have advantages and disadvantages. Although fixation with K wires and applying a tension band is an age old technique for distal clavicle fracture it has many disadvantages. This technique is usually done extra-acromially but sometimes the distal fragment will be so small or comminuted that trans-acromial tension band wiring has to be done. Usage of this technique needed no severe soft tissue stripping and no heavy hardware has to be inserted. If not applied trans-acromially AC joint also can be spared. K-wire migration, pin prominence, loss of reduction are significant concerns [7,8]**.** In our study, 3(20%) cases had k-wire migration but none of them had loss of function and 1(6.6%) case had pin prominence with mild discomfort in abduction. Pre-contoured lateral end Clavicular plate is relatively a new implant having broad lateral end for multiple screws which provides stable fixation of a small sized lateral fragment, allows early mobilization and secures bony union. The plate is anatomically designed to fit the contour of the lateral third of clavicle. It allows application of screws in different directions in the lateral third of clavicle and provides the multi-planar fixation and greater stability for small unstable lateral fragment. Although, 1(6.6%) case of plating had superficial infection, it was subsided after meticulous wound care.

The duration of operation in TBW group ranged from 30-50 minutes (mean 39.64 min) while in case of pre-contoured lateral end clavicular plate it ranged from 40-65 minutes (mean 52.33min). On statistical analysis of both the results, the p-value was found to be <0.0001, which is significant. The mean time for union in the pre-contoured lateral end clavicular plate group was 9.33 weeks, and that in the TBW group was 12.53 weeks. Regarding percentage of union, our results are found to be comparable to that of the various studies found in literature Daniel W. Good et al9, Beirer et al10, and Mark A fleming et al11, (Table 4).

Table 4:

Author	Modality	Union (in weeks)	Percentage of union
Daniel W. Good et al[**9**]	TBW	12week	95%
Beirer et al[**10**]	Precontoured plate	6-10 week	100%
Mark A fleming	Precontoured plate	12 (6-16 week)	100%

et al[**11]**			
Present study	**Pre-contoured Plate**	**9.33**	100%
	TBW	**12.53**	100%

The mean Constant-Murley Score for the Pre-contoured lateral end clavicular plate group was 91.86 and that for TBW group it was 86.66 on the affected side. The difference between the mean Constant Murley Score of the unaffected and affected side of both the groups was analyzed statistically and found to be statistically significant ($p< 0.001$). Our results in terms of functional outcome are comparable to that of various literatures as mentioned in table 5 below.

Table 5:

Authors	**Modality**	**Constant Murley score**
Karl Wu et al[**15]**	TBW	86
Yih-Shiunn Lee et al[**12]**	TBW	88
Vaishya et al[**13]**	Pre-contoured plate	92
Mark A fleming et al[**11]**	Pre-contoured plate	91
Kapil-Mani KC et al[**14]**	Pre-contoured plate	92.56
Present study	**Pre-contoured plate**	**91.86**
	TBW	**86.66**

19 (plating-13, TBW-6) out of 30 patient were seen excellent outcome and 11(plating-2, TBW-9) patient had good functional outcomes. Chunlin Zhang et al16, in their study found that mean CM score difference between affected and unaffected side was not significant and majority of their patient had excellent outcomes using pre-contoured lateral end clavicular plate and opined that it was an excellent implant to treat the unstable lateral end clavicle fractures. We found excellent outcome in 13 patients out of 15 treated with pre-contoured plate**.** The pre-contoured plate has a significantly lower rate of complications and symptomatic hardware issues. Ramprasad Rallapalli et al[17] found that there were significant amount of complications in patient treated with TBW for displaced lateral end clavicle fractures. In pre-contoured lateral end clavicular plate group "Excellent" CM score was achieved in 13(86.66%) cases and "Good' results were obtained in 2 (13.33%). While in TBW group "Excellent" score was achieved in 6(40%) cases and "Good' results were obtained in 9 (60%). 100% bony unions were seen in both the groups in our study, though the duration of union was faster in plating. All the patients were able to resume functional activities after 6 months except those sports players who were allowed to join sports activities after 9 to 12 months. 1 case of pin prominence required early implant removal after 6 months of operation. Scheduled implant removal were suggested after 2 years of operation in both the groups.

CONCLUSION AND RECOMMENDATION:

Although clavicle fracture is quite common, displaced fractures of the lateral clavicle is relatively less common. Displaced fracture of lateral end clavicle is highly unstable and requires operative fixation. Non operative treatment results in significant number of nonunion and delayed union cases. Open reduction and internal fixation should be the treatment modality of choice. In terms of final functional outcome, pre-contoured lateral end clavicular plate fixation provides better result than TBW (with K-wire and SS wire). TBW has significantly more complications than pre-contoured lateral end clavicular plate. We recommend early surgical fixation with pre-contoured lateral end clavicle plate coupled with adequate post-op physiotherapy protocol to offer best functional outcomes to the patients.

Consent to participate: Informed and written consent was taken on inclusion into the study

Ethics approval: An ethics approval was taken from the institutional ethics committee prior to study

Conflict of Interest: The authors declared no potential conflicts of interest with respect to the research, authorship and publication of this article.

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Authors' contributions:

Dr Hafizur Rahman: Conceptualization, Methodology, Software, Visualization, Supervision, Writing-original draft preparation, Writing- reviewing and editing, Validation.

Dr Ashraful Alom : Data curation, Investigation, Writing-original draft preparation, Software, Writing- reviewing and editing.

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