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Conservative management versus surgical management: A comparative study on displaced midshaft clavicular fractures in adults

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Abstract

Fracture of the clavicle is one of the very common skeletal injury constituting around 5-10% of all bony injuries in adults and around 80% of these occurring in the midshaft ^[3-5]. Despite its high incidence the best treatment modality is still unclear. We prospectively compared the outcomes in terms of rate of radiological union and functional outcome in treatment of midshaft clavicle fractures by conservative (CONS) or operative which had two sub-groups that is treated by plating (PLATE group) or by titanium elastic nail (TENS group).

Keywords: Clavicle fractures, mid shaft clavicle fractures, titanium elastic nailing system (TENS), plating in clavicle fractures

Introduction

29-64 per 1,00,000 adolescent population and adult population suffer a clavicle fracture every year. These fractures are generally managed conservatively. Most commonly, these fractures occur within the middle third of the clavicle and with some degree of displacement. Fractures of the medial or lateral end of the clavicle can be treated conservatively fragments are stable. A fall on an outstretched hand or a direct blow to the shoulder leads to an axial compressive force on the clavicle and it is the most common mechanism of injury of any clavicle fracture ^{[1,} ^{2]}. Males are affected around double as often as females. Most midshaft clavicle fractures unite with any modality of immobilisation. Therefore nonoperative treatment was the most accepted modality in earlier studies. Neer in 1960 reported non-union rate of 0.1% and 0.8% by Rowe in 1968 reported 0.8% with conservative treatment [6, 7]. Recent studies showed suboptimal outcomes with conservative treatment such as impaired function of the shoulder, bony bump due to shortening of clavicle and excess callus formation and higher non-union rates ^[8, 9]. Anatomical alignment and maintaining the clavicle length can prevent these drawbacks. Open reduction and fixation by plating has become a standard mode of management in such fractures surgically. Even plating had its own disadvantages such as hardware prominence, hypertrophic scar, surgical site infection and re-surgery to remove the implant. The use of an intramedullary device such as elastic nails has benefit of small incision, less soft tissue dissection but with relative stability with adequate callus formation.

This study compares the radiological union and functional outcome of displaced mid-shaft clavicle fractures treated either conservatively or operatively by either plating or TENS.

Materials and Methods

This observational study was conducted in the PG Department of Orthopaedics, IMS and SUM Hospital, Bhubaneswar, Odisha. The study period was from November 2017 to September 2019.

A cross sectional comparative study that included middle 1/3rd clavicle fractures with displacement, at least no cortical contact between two fracture fragments. Patients allocated to either Conservative (CONS group) or Operative (PLATE group or TENS group) by randomization. In operative, according to fracture pattern it was randomized for Plating or TENS. 60 cases of middle 1/3rd clavicle fractures were included in our study.

Patients on admission to emergency unit or Out Patient Department were initially resuscitated and stabilized (if required), then screening for other injury done.

Inclusion Criteria

- 1. Age Group: 14-55 years.
- 2. Closed displaced clavicle fractures.
- 3. Patients who have given their consent for the procedure.
- 4. Isolated clavicle fracture.
- 5. Patients who are medically fit for surgery.

Exclusion Criteria

- 1. **Patients age:** <14yrs and >55 yrs.
- 2. Open fractures of the clavicle'
- 3. Un-displaced fractures.
- 4. Pathological fractures.
- 5. Fractures of medial and lateral end of clavicle or any other associated shoulder injuries.
- 6. Patients with neurovascular deficits.
- 7. Patients medically unfit and not willing for surgery.

We then randomized the patient in two groups, 30 patients in Conservative group in which the patients underwent nonoperative management by clavicle brace with/without arm sling and 30 patients in Operative group in which patients underwent closed/open reduction and internal fixation (ORIF) either by TENS(10 cases) or by Plating (20 cases).

Informed written consent was taken from all the patient who met the inclusion criteria post admission regarding the inclusion to the study. The advantages and disadvantages of all available surgical options were said to them and patients consenting for the same were included to the study.

Preoperative Evaluation: All the cases were initially investigated with 20 degree cephalad antero-posterior and thorax showing bilateral clavicle, postero-anterior radiograph to asses fracture type and post traumatic clavicular shortening. Fractures were classified as per AO/OTA Classification. Then the patients underwent following investigation:-

- 1. Routine Haematological investigation (CBC, BT, CT, FBS, S-UREA and Creatinine, S-Na and K)
- 2. Urine and Stool Routine and Microscopic examination.
- 3. ECG and Cardiological check-up.
- 4. Then all were posted for surgery as early as possible after doing all preoperative evaluation.

Surgical Technique for Plating: A single preoperative dose of prophylactic antibiotics was given after skin test. Patient supine with large bump placed between the scapula, allowing the injured shoulder girdle to fall posteriorly, helping to restore length and exposed to the clavicle. The skin incision was centred over the fracture and followed a line connecting the sternal notch to the anterior edge of acromion. Reduction was then performed and held with bone holding clamps. A 3.5mm Recon plate, LCP, one third tubular plate was contoured with bending or anatomical "S" plate for application to the superior surface of the clavicle or anteroinferior surface. The fracture was reduced and fixed on the superior surface or antero-inferior surface of bone using a minimum of three screw in proximal and three screw in distal fragments. In case of long oblique fractures or wedge comminuted fractures, lag screw were used where possible with care taken to preserve soft tissue attachment.

Surgical Technique for Tens: After anaesthesia patients

were placed in supine position. The sterno-clavicular joint was palpated and marked on the affected side. Image intensifier was used in 45 degree cephalad and 45 degree caudal directions. This provided us with images in two-planes, 90 degree apart.

A small incision was made approximately 1cm lateral to the sterno-clavicular joint. The anterior cortex was opened using a sharp pointed awl. A titanium elastic nail (TEN) was inserted (the diameter of the nail varied from 2-3mm depending on the width of the bone). However before introducing the nail, the original curvature of the small and flattened nail tip was straightened to some extent to allow better gliding inside the small medullary canal of the bone.

Closed reduction was done under fluoroscopic control using two pointed reduction clamps applied percutaneously. If percutaneous approach failed, a small mini incision was given over the fracture site for direct manual reduction of the fracture by mobilising the fracture fragments. After ascertaining adequate reduction the nail was further pushed laterally until it was just medial to acromio-clavicular joint. Accurate placement of the nail tip was necessary under fluoroscopic control to avoid penetration of the thin distal cortex.

After reaching the distal end, the fracture site was compressed and the nail was cut close to the entry point to minimize soft tissue irritation taking care to leave behind adequate length behind for easier removal of nail later.

Postoperative Protocol: Both the groups had same post-operative protocols.

- Intravenous Antibiotics was given for 3 days. Then was changed to oral antibiotics for 7 days. Analgesics were given as per the need of the patients. Operated limb was immobilized in an arm sling and early shoulder mobilisation as tolerated by the patient was encouraged with pendulum exercises from second post-operative day. Check x-rays were taken to study the alignment of fracture fragments.
- The wound was inspected at 3rd post-operative day. Suture removal was done on 12th postoperative day. Patients were discharged with the arm sling.
- Rehabilitation of the affected arm was started at the end of 2 weeks or 3weeks as tolerated by the patient. Gentle pendulum exercises of the shoulder in the arm sling was allowed. At 4 to 6 weeks gentle range of motion of the shoulder was allowed but abduction in limited to 80 to 90 degree. At 6 to 8 weeks active range of motion in all planes were allowed.

Follow Up and Outcome Assessment: All patients were assessed on 2nd post-operative day then every 3 weekly till radiological signs of union then at 6month, 9 month and 12 month after surgery. The x-rays were taken in antero-posterior view and 20 degree cephalad AP view for all patient at each follow up for the evaluation of fracture healing and implant position. Radiographic healing was defined as evidence of bridging callus across the fracture site or obliteration of fracture line. Clinically fracture healing is the absence of tenderness on firm palpation over the fracture site, full range of motion and the presence of normal strength of upper extremity.

Subjective pain was measured with a Visual Analogue Scale (VAS) 1 day before and 3 months after conservative and surgical management and final after clinical and radiological union at the last visit. The VAS ranged from 0-10: No pain to

worst pain imaginable. The functional outcomes were assessed by constant and murley scores and DASH Scores.

Results

- Our study consisted of 60 cases of displaced midclavicular fractures, which were randomized into three groups. 30 cases each in Conservative treated by clavicle brace with arm sling and other group by ORIF with either plate or TENS. In Surgical group, 20 cases were fixed with plate and 10 with TENS.
- In all the three groups' patient's age ranged around 18-55 years. The average age in conservative group was observed to be 33.27±10.67 years, in plating group was 29.3±8.13 years while in TENS group it was 29.6±9.37 years.
- In all three group male patients outnumbered the female patients. In Conservative group 60% cases are males, in plate group 70% are males while in TENS group 60% were males.
- RTA was the commonest mode of injury; which was about 40% followed by falling from height, sports related activity and falling on an out stretched hand each having around 20% of involvement.
- In all the groups, dominant side of patient was more affected. Out of 60, 42 patients (70%) injured their dominant limb.
- We used OTA classification system for mid clavicular fractures. According to it 16(53%) in conservative group, 8(40%) in plate group and 6(60%) in TENS group were B1 (simple type) while 14(47%) patients in Conservative group, 12(60%) patient in plate group and 4(40%) in TENS group were B2(wedge type)
- Patients treated by clavicle brace with arm sling in Conservative group. Surgery was done under brachial plexus block or general anaesthesia after doing all requisite pre-operative evaluation. Anatomical Locking compression plate used in 14 cases, recon plate in 4 cases and semi tubular plate in 2 cases. 2-3mm TEN was used in rest 5 cases.
- The follow up period ranged from 9 to 18 months with average of 12 months. None of the case missed follow up.

- In all the group pain was measured by VAS score. The mean VAS score in conservative group 5.27±1.91, in plate group 3±1.03 and in TENS group it was 3.2±1.23.
- The fractures in CONS group united with mean union time 14.84±3.75 weeks, in plate group 11.74±3.35 weeks and in TENS treated group in 11.9±4.61 weeks [TABLE:-1]. 3 cases of non-union was found in CONS group and 1 in plate group. Non-union found to be more in displaced fracture treated by clavicle brace with arm sling than plate.
- No clavicular shortening was found in 60% cases and very minimal (≤5mm) in 20% cases, when treated by either of plating or TENS. Mean shortening found in CONS 11.53±5.33mm, in Plate group 1.3±1.95mm and 1.6±2.46mm in TENS group [Fig:-1].
- Functional outcome was evaluated by the "Constant score" and also the "DASH" score. In the Conservative group mean DASH score was 5.87±1.42 and constant score 83.6±8.77. In plating group average constant score 92.4±10.61 and DASH score 3.53±0.30 and in TENS group average constant score 92.4±8.29 and DASH score was 3.53±0.30.[Table:-3]
- Cosmetically TENS was preferred over Plating or Conservative by the patients with average cosmetic score in TENS group being 4.8±0.42, plate group 3.9±0.85 and in CONS group 2.73±0.69 [Table:-2].
- Regarding complication there was no intraoperative complication in either of plate group or TENS group. In CONS group malunion, delayed union and nonunion were the major problem. In CONS group 20% cases had malunion, 10% nonunion and 6.7% delayed union. In Plate group- 1 non-union, 1 delayed union, 1 superficial infection, 1 hardware prominence, 1 hypertrophic scar and 1 case of refracture. While in TENS group only 1 case had delayed union [Fig:-2].

Table 1: Distribution of radiological union time in the study

Fracture union time (in weeks)	Cons		Plate		Tens	
	Cases	%	Cases	%	Cases	%
9-12	4	13	11	55	6	60
13-15	13	43	5	25	3	30
16-20	6	20	2	10	0	0
>20	2	6.7	1	5	1	10

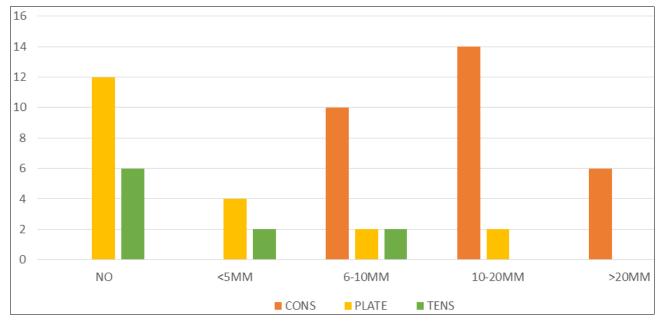


Fig 1: Shortening of clavicle distribution

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Table 2: Distribution of cosmetic outcome in the study

Cosmetic score	Cons		Plate		Tens	
	Cases	%	Cases	%	Cases	%
1	2	7	0	0	0	0
2	6	20	2	10	0	0
3	20	66	4	20	0	0
4	2	7	10	50	2	20
5	0	0	4	20	8	80

Table 3: Distribution of functional outcome in the study

Functional outcome	Cons	5	Plate)	Tens	
F unctional outcome	Cases	%	Cases	%	Cases	%
Excellent	6	20	12	60	6	60
Good	14	47	4	20	2	20
Fair	4	13	2	10	2	20
Poor	6	20	2	10	0	0

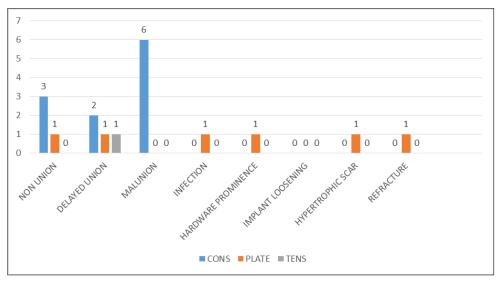


Fig 2: complications distribution



Fig 3: Malunion with Shortening [Complications of CONS] Non-union

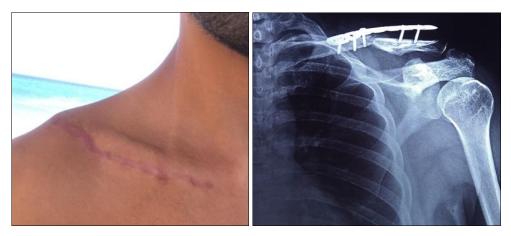


Fig 4: Hypetrophic Scar [Complications of Plating] Refracture

Discussion

The clavicle in the skeletal system has a very important role in the pectoral girdle mechanism as well as in upper extremity function. It is the only bone to attach the trunk to the upper limb. Plate fixation has been the standard operative fixation method. A recent meta-analysis showed higher rates of nonunion in displaced fractures treated conservatively [15.1%] as compared to surgically [2.2%] with plating. A multicenter trial showed better functional outcomes, lesser rates of malunion and non-union and a shorter interval to union with plating ^[10, 11]. Saha concluded that the use of minimally invasive antegrade TEN for fixation of displaced clavicle

midshaft fractures is recommended in view of faster fracture union, lesser morbidity, better cosmetic results, easier implant removal and fewer complications; although for comminuted fractures plating remains the procedure of choice^[12]. MK Nizamoddin Khateeb in his study stated intramedullary nailing (TENS) of displaced midclavicular fractures is a safe, cosmetically preferred, minimally invasive technique with fewer complications, excellent functional results and early pain relief ^[13]. Gadegone and Lokhande concluded that screw intramedullary nail is a safe, minimally invasive surgical technique with a lower complication rate, faster return to daily activities, excellent cosmetic and good functional results, and can be used as an equally effective alternative to plate fixation in displaced midshaft clavicle fractures ^[14]. In our study, the mean union period in conservative set was 14.84±3.75 weeks and plate group 11.74±3.35 weeks while TENS group 11.9±4.61 weeks. Surgical fixation was better in terms of radiologic union for middle 1/3rd clavicular injuries in which PLATE group showed earlier union. P value found to be .0511 which is statistically not significant. The value is not significant may be due to low number of data. P value for CONS vs Plate was 0.0044 which is statistically significant as well as CONS vs TENS (0.0496). In our study mean constant score in conservative group is 83.6±8.77 and plate group 92.4±10.61 while TENS group had 92.4±8.29. Patients treated by plating and TENS showed excellent outcome. Sixty percent of the patients treated by plating as well as TENS demonstrated excellent result, however TENS group were very satisfied as compared to Plate and CONS group in cosmetic outcome. P value compared between CONS versus Plate (0.0025) and CONS versus TENS (0.0083) was statistically significant. DASH score in our study found in conservative group 5.87 ± 1.42 and plate group 3.5 ± 1.05 while TENS group 3.53±0.30. Patients treated with Plate and TENS were found to be better in terms of CONSTANT and DASH SCORE than the conservatively treated by clavicle brace with arm sling. Functional results in either subgroups of surgical management was similar in terms of CONSTANT and DASH SCORE. P value compared between CONS versus Plate (<0.0001) and CONS versus TENS (<0.0001) was statistically significant. Cosmetically TENS was better in patients with mean cosmetic score higher than Plate or the non-operative group which is statistically very much significant. P value CONS versus Plate (<0.0001), CONS versus TENS (<0.0001) and also Plate versus TENS (0.0039) was significant statistically showing TENS provides far superior cosmetic outcome than the other two methods.

Conclusion

Surgical management despite its minimal complications such as the cost or expense, infection, anaesthesia, implant removal; hold superiority over conservative management which led to marked increased VAS score, increased fracture union time, far more mean shortening with mal-alignment, non-union and fairly poor functional outcomes compared to operative methods either by Plating or TENS. Surgical measures led to accurate fracture reduction, early mobilisation, and rapid relief of pain, early union, and earlier return to daily activities as well as improved shoulder range of motion.

While in the surgical group taking aside the cosmetic scoring Plating held slightly an upper hand against TENS with respect to union time, functional outcomes, shortening as well as the VAS score. fractures plating is the better mode of treatment compared to TENS as well as conservative method.

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Therefore we conclude that in displaced midshaft clavicle