Prospective Comparative Analysis of Functional Outcome of Operative – Titanium Elastic Nailing System (TENS) Versus Non Operative Treatment of Midshaft Clavicle Fractures

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ABSTRACT

Introduction: Clavicle fractures account for 2.6% of all fractures. Most common type is mid shaft fracture (80%). Operative treatment is playing an increasingly important role. Most of the conservative treatments need regular adjustment, are cumbersome and inconvenient to the patients.

Material and Methods: Study is conducted in the Department of Orthopaedics, Karnataka Institute of Medical Sciences, Hubballi Karnataka on patients with displaced/comminuted clavicle fractures middle third, from January 2016 to August 2017. Patients divided into Group A (operative fixation with TENS) and Group B (managed conservatively).

Results: In all patients of GROUP A union of bone was observed. 15 patients were satisfied with their shoulder functions. Range of movements were better in GROUP A compared to GROUP B.

Conclusion: TENS Nailing for clavicle middle third fractures provides an acceptable alternative method for the fixation of displaced midshaft clavicular fractures and delivers better results than conservative management.

Keywords: Functional Outcome, TENS, Midshaft Clavicle Fractures

INTRODUCTION

Of all fractures clavicle fractures account for 2.6%. Among the clavicle fractures most common type is mid shaft fractures (80%). Functional outcome of mid shaft clavicle fracture is not only related to its union, but also to its length. Clavicle acts as a "strut" that keeps the upper limb away from the torso for efficient shoulder and upper limb function, while also transmitting forces from upper limb to the trunk.

Traditionally, clavicular fracture is treated non-operatively with a figure-of-eight bandage or broad arm sling. Time-honored treatment of fracture midshaft clavicle has been in the form of a simple sling, figure of eight clavicular brace, crepe bandage as a figure of eight, etc. But most of the conservative treatments need regular adjustment, are cumbersome and inconvenient to the patients. Outcomes of non-operative treatment are not always excellent.

In Rockwood and Green's Fractures in Adults they observed that there has been increasing evidence that the outcome of non-operatively treated (especially displaced or shortened) midshaft fractures is not as optimal as was once thought.[1]

Mueller et al[2] (2008) –In his study, up to 31% of cases who were treated for mid shaft clavicular fractures non-surgically lead to unsatisfactory results such as nonunion, brachial plexus irritation, shortening and limited function of the shoulder.

Robbin C.MeKee et al (2012) studied 421 patients with randomized clinical trials comparing operative versus non-operative care for displaced midshaft clavicular fractures. They concluded that operative treatment provided a significantly lower rate of nonunion and symptomatic malunion and an earlier functional return compared with non-operative treatment.[3]

Kong L et al (2014) - A total of 507 patients from 6 Randomized Controlled Trials were subjected to meta-analysis. They concluded that operative treatment has an effect on improving function, which is demonstrated by significantly higher Constant scores and lower DASH scores. The rate of nonunion and the rate of malunion were significantly lower in operative group compared with that in non-operative group.[4]

Therefore, operative treatment is playing an increasingly important role in the clinical setting, mainly using compression plating or intramedullary nail fixation. Although plating is accepted as a standard technique, it has some disadvantages like large scar, nonunion, and difficult application and removal of the plate. The second method, intramedullary nailing of clavicular fracture is a relatively new technique done using elastic titanium nails. This technique was attractive when first presented by Jubel et al. Some articles have recommended it as a technique with little complications, rapid union rate, easy insertion and removal, small scar and no breakage.

So we decided to evaluate functional outcome in patients treated operatively using Intra-medullary fixation by titanium elastic nail and non-operative treatment on the mid shaft clavicle fractures. Our study discusses elastic stable intramedullary nailing of midshaft clavicular fractures as it produces excellect cosmetic and functional results.

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The aim of the study was Prospective comparative analysis of functional outcome of operative TENS Vs non-operative treatment on mid shaft clavicle fractures in terms of union, complications and functional outcome.

Objective of the study was to analyse the functional and clinical outcome in patients with midshaft clavicle fractures treated surgically using TENS nail and those cases managed conservatively.

Anatomy of clavicle

The only bone to attach the trunk and the upper limb is clavicle.

Mechanisms of injury

Most commonly, direct blow on the point of the shoulder,[5,6,7,8] which can occur in a number of ways, including being thrown from a vehicle or bicycle during sports events, from the intrution of objects or vehicle structure during a motor vehicle accident, or fall from a height.

Clinical assessment

Painful deformity and localized tenderness over the site of clavicular fractures. The weight of the upper limb causes often downward displacement of the lateral fragment and medial fragment is elevated due to sternocleidomastoid muscle pull in the posterosuperior direction.[9]

Shortening of the clavicle should be measured clinically with a measuring tape.

Radiographic assessment

With the routine anteroposterior view of shoulder, an apical oblique view must be taken for better visualization of the fracture pattern and displacement.

To obtain apical oblique view, a sand bag or roll is placed under the uninjured scapular region, which one brings the injured shoulder flat over the radiographic cassette (a true AP). The beam in angled 10 to 20 degrees cephalic, which brings image of the clavicle away from thoracic cage.[9]

MATERIAL AND METHODS

Study is conducted in the Department of Orthopaedics, Karnataka Institute of Medical Sciences, Hubballi Karnataka on patients with displaced/comminuted clavicle fractures middle third, from January 2016 to August 2017 after ethical clearance was obtained from the ETHICAL committee of KIMS Hubballi.

Group A 19 patients were treated with 2 mm titanium elastic nail.

Group B 19 Patients treated by conservative management by means of figure of eight bandage with cuff and collar.

Criteria for inclusion

Patients were included in the study if they had

- Simple mid shaft clavicle fracture with >2cm displacement.
- Comminuted fracture mid-shaft clavicle.
- Fractures associated with neurovascular injury.
- Age: 20-50 yrs.

Criteria for exclusion

Patients were excluded from the study if they had

- Undisplaced fracture.
- Compound fractures of clavicle.
- Pathological fractures.
- Hemiparesis (on the affected side).
- Patients not willing for surgery.

Non Operative Treatment

Non-operative treatment consists of the use of figure-of-eight splinting with a sling for comfort.[9]

Operative treatment: Intramedullary Fixation

More recently, titanium elastic intramedullary nails have been used, with good results reported in a number of studies. Frigg et al. reported a reduction in complications from 60% to 17% with the use of an end cap, converting to open reduction after two failed attempts at closed reduction, using careful manual passage of the nail, obtaining intraoperative oblique radiographs to rule out lateral perforation, and limiting postoperative range of motion to 90 degrees for 6 weeks.[1,9]

Advantages

- Cosmetic - very small incision.
- Incidence of infection – less.
- Minimally invasive.
- Less periosteal stripping.
- Relative stability to allow callus formation.
- Short post op stay at hospital.

Disadvantages

- Technical difficulty because of varying degree of curvature of clavicle.
- Damage to underlying vital structures.
- Intrathoracic migration.
- Nail breakage.
- Proper operation theatre setup (fracture table, c-arm).

Pre operative preparation

Patients underwent a pre-operative evaluation including the following parameters

- Basic blood invesstigations.
- X-ray shoulder.
- Chest X ray with both shoulders.
- 0-15^{o} lordotic view.
- 15-30^{o} cephalad tilted view.

Anaesthesia

General anesthesia/regional (supraclavicular) nerve block.

Patient positioning

- Patients are positioned in supine position.
- A small bag is placed behind the ipsilateral scapula.
- The head is placed on a round support and rotated to opposite side of surgery.
- The upper limb is drapped free to aid in closed reduction of fragments.

Operative technique

- At the sternal end of the clavicle, a skin incision of 2 cm is made parallel to the clavicle.
- The anterior cortex is opened with an awl about 1.5 cm lateral to the sternoclavicular joint.

- A titanium elastic nail of appropriate size is inserted and advanced to the fracture site.
- Subsequently, the fracture is reduced in a closed manner.
- Reduction is maintained provisionally with a small reduction forceps
- The nail is subsequently advanced across the fracture into the lateral fragment with gentle rotational movements.
- Care was taken that the implant is not advanced too laterally in order to avoid penetration into the acromioclavicular joint.

Post operative and follow up

- Postoperatively the limb was immobilised with sling. Active range of motion (ROM) exercises -elbow, wrist and hand under the supervision of a physiotherapist was started.
- Immediately after surgery, the affected limb was supported with a shoulder immobiliser for 3 weeks.
- The sling prevented the arm from drooping and interfering with bone union while allowing passive exercises.
- At 4th week the range of movements of the pendulum swings increased gradually up to 90°
- At 6th week full range of movements were obtained. All patients were advised to return to light work and day to day activities as long as tolerable and radiologically acceptable.

Assessment

- Both an anteroposterior and a 10-20° cephalad tilted radiographs were made for each patient.
- All patients were assessed with standard protocol in which they were assessed at fourth week, sixth week, and once in a month with clinical and radiological parameters for proper alignment of fragments, fracture union, non union, malunion, infection and functional parameters.
- Using CONSTANT SCORE and DASH SCORE objective and subjective shoulder function was measured.

STATISTICAL ANALYSIS

The information collected regarding all the selected cases were recorded in a master chart. Data analysis was done with the help of computer by using SPSS software and Sigma Stat 3.5 version. Using this software, percentage, mean, standard deviation and 'p' value were calculated through one way ANOVA, and p value of less than 0.05 was taken as significant.

RESULTS

Time to bony union

In all patients of GROUP A union of bone was observed, and mean time required to bony union was 13.16 weeks (range from 11 to 20 weeks). 15 patients were satisfied with their shoulder functions.

Range of Movements: Range of movements were better in Group A compared to Group B.

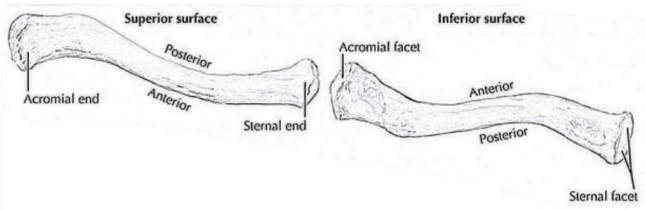

Figure-1:

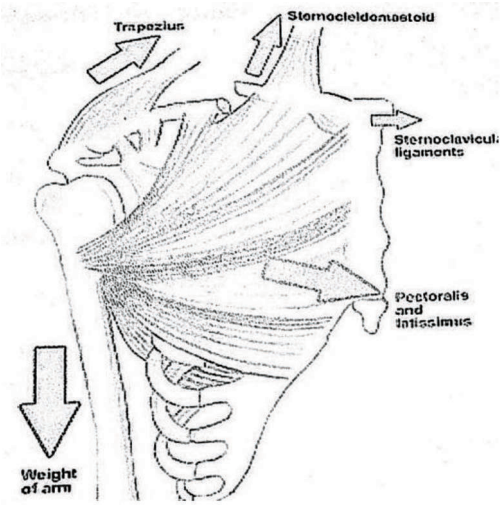

Figure-2:

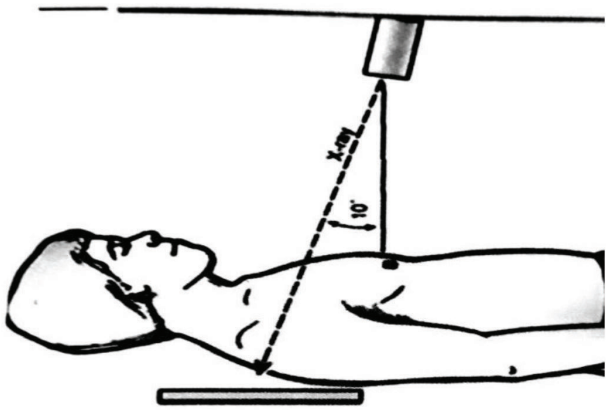

Figure-3:

Figure-4:

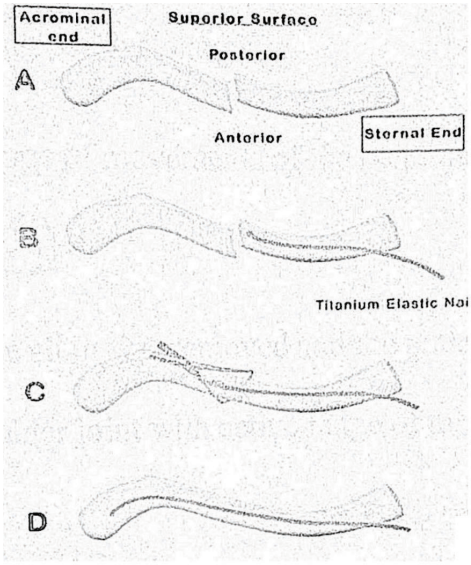

Figure-5:

Shortening Of Clavicular Length (in mm)	Group A	Group B
Mean	4.83	9.92
Standard deviation	0.77	1.02
P value Unpaired t test	<0.0001	

Table-1:

Constant shoulder score distribution	Group A	Group B
Mean	71.16	55.63
Standard deviation	2.95	5.82
P value Unpaired t test	<0.0001	

Table-2:

The disabilities of the arm, shoulder and hand (DASH) score distribution	Group A	Group B
Mean	91.11	73.84
Standard deviation	4.08	8.63
P value Unpaired t test	<0.0001	

Table-3:

Age distribution

In group A 9 patients were <30 years (47%), next common age group was 31 to 40 years (32%)

In group B 10 patients were <30 years (52%).

Gender

In group A 13 patients were male and 6 were female.

In group B 15 patients were male and 4 were female.

Fracture laterality distribution

In group A 11 patients were right sided and 8 were left sided.

In group B 14 patients were right sided and 5 were left sided.

Shortening of clavicular length

After union, shortening of clavicular length was measured radiologically as the linear difference of clavicle lengths from sternal end to acromial end between operated and normal side.

Clavicular lengths were significantly better maintained by TEN (P <0.0001) than by non operative management.

Constant shoulder score

The Disabilities Of The Arm, Shoulder And Hand (DASH) Score

Complications

Among 19 patients in Group A, following complications were seen. 2 patients had infection which was controlled with oral antibiotics, 4 patients had hardware prominence for which 2 underwent surgery i.e. implant removal done after the 3rd month of surgery and shoulder functions improved. In Group B, one patient had non union.

DISCUSSION

In our study, we found that closed or limited open reduction and internal fixation with TENS in the treatment of midclavicular fractures in adults resulted in a high fracture healing rate, rapid functional recovery and minimal complications. The procedure is minimally invasive and achieved high patient satisfaction.

Some systematic reviews on clavicle fracture treatment have been reported in previous studies. For example, Zlowodzki et al[10] showed that the non union rate can reach 4% by operative treatment and 6% by non-operative treatment. However in our study we were having 0% non-union rate in operative treatment with 5.26% non-union rate in non-operative treatment. The non-union rate of non-operative treatment is consistent with Zlowodzki et al.[10]

Our study shows that mid shaft clavicular fractures more commonly occurs in the young active adults, males were four fold affected than female. This result is consistent with many other studies (Hassan Keihan Shokouh et al[11], Yun-feng Chen[12], Bing-fang Zeng et al[13]). The union rate of our study for operative treatment is 13.16 weeks. This result is consistent with Anish et al (2012) - in his study they noted 100% union at an average of 12.3 weeks.

The mean Constant score and DASH score were comparatively better than non operative method. This result is consistent with the following studies - Kong L et al (2014), Smekal V (2009).[2]

The results showed that there were statistical differences in the non-union, malunion and neurological complication rates between operative and non-operative treatment, suggesting operative treatment could decrease the incidence rate of these adverse events.

Plating is the standard technique for operation of clavicle fracture when surgery is required, But fixation of clavicle fracture by elastic titanium nails is a new technique and can be used on demanding patients. We had favourable results with this technique in cases with midshaft clavicular fracture. Our study had some limitations namely the smaller sample size and surgery performed by different surgeons.

CONCLUSION

Based on the results of the study the following conclusions were made. This study shows that early primary fixation of fractures of clavicle with TENS result in earlier return to function. Operative treatment reduces the nonunion, malunion and neurological complication rates of clavicle

fractures. It increases the functional outcome of the patients. For clinical application, we should make decisions in accordance with specific conditions. In order to avoid the risk of adverse events, operative treatment is a better therapeutic method if it is matched to the individual patient.

To conclude, TENS Nailing for clavicle middle third fractures provides an acceptable alternative method for the fixation of displaced midshaft clavicular fractures and delivers good results.

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