

Original Article Orthopaedics

A COMPARATIVE STUDY BETWEEN LOCKING COMPRESSION PLATING VERSUS INTRA MEDULLARY NAILING FIXATION FOR THE MANAGEMENT OF DISPLACED DIAPHYSEAL CLAVICLE FRACTURE

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Article submitted on: 22 March 2019

Article Accepted on: 26 March 2019

Abstract

Introduction: Clavicle fractures account for 2-4% of all fractures occurring in the adults and 69-82% of the clavicular fractures occur in the middle shaft. Out of the operative management techniques, plate fixation and intramedullary nailing with Titanium Elastic Nail (TEN) are commonly used nowadays for internal fixation of displaced diaphyseal clavicle fractures.

Objectives: I. To analyze the differences in functional outcome of each of the two surgical procedures namely plate fixation and TENS

Materials and Methods: This Prospective, Non-randomized, two arm, concurrent parallel, experimental study was conducted among 50 patients with type 2B and 2B1 displaced diaphyseal clavicle fracture who underwent either of the two types of surgical fixation of the clavicle fractures which include Group A: compression locking plate fixation and Group B: Intramedullary nailing (TENS). A detailed history including socio-demographic details and medical events prior to surgery was obtained and recorded in a proforma. Follow-up details and operative notes were recorded later during the course of stay in the hospital. the functional outcomes were assessed and compared using modified Murley score and DASH score.

Results: The mean age of the study participants was 32.9 ± 12.8 years. Majority of the study participants were males (92%) compared to a very small proportion of females (8%). Majority of patients with type 2B fractures

underwent TENS (62.5%) whereas most of those with type 2B1 fractures underwent plate fixation (61.5%). Three patients who underwent TENS had radiological union at 6 weeks compare to other patients who had radiological union in 4 weeks. Patients underwent plate fixation encountered implant breakage (n=2, 8%); those underwent TENS had cord injury (n=1, 4%), nail protuberance (n=3, 12%) and infection (n=1, 2%) as complications. Among the participants 8 (32%) in the plate group and 11 (44%) in the TENS group had excellent Murley score. The mean DASH score was not significantly between the plate fixation (7.95 ± 0.9) and TENS (7.92 ± 1.9) surgical groups.

Conclusion: The study established that plate fixation was a better surgical technique with good functional outcomes and lesser complications when compared to TENS.

Keywords: Displaced diaphyseal clavicle fractures, TENS, plate fixation.

Introduction

Clavicle (also called “*Collarbone*”) is a subcutaneous, curved anterior bone of the shoulder (pectoral) girdle that functions as a strut to support the shoulder. Clavicle is one of the most common bones to be fractured accounting to almost 50% of all the fractures in the shoulder girdle due to its superficial location and anatomical dimensions.[1] The middle third of the clavicle is more prone for fractures which is evident from the fact that 69-82% of the clavicular fractures occur in the middle shaft. [2] Earlier the treatment of clavicle fractures was done preferably by non-operative conservative methods like immobilisation using a brace, figure of eight bandages and strapping. The chance of non-union, mal-union and cosmetic deformity increased considerably over decades from less than 2% to 15% in the present. [3] Out of these operative techniques, plate fixation and intramedullary nailing with Titanium Elastic Nail (TEN) are commonly used nowadays for internal fixation of displaced diaphyseal clavicle fractures.

Plate fixation of clavicle fractures is a gold standard technique which has been in vogue for many years. It has a few disadvantages like extensive periosteal stripping increasing the destruction of the blood supply at the fracture site, thereby hindering fracture healing. Stress shielding produced by rigid plates can lead to an 8% re-fracture rate after plate removal. [4]

TENS is a relatively newer technique which has more positive connotations including minimal exposure of surgical site and provides fixation that is more consistent with the physiologic bone structure to permit early functional exercise, leads to faster functional recovery,

provides early pain relief and avoids the complications associated with longer operating time and periosteal stripping. However TENS has its own drawbacks but most of it is related to the surgical technique than the functional outcome of the surgery and radiation exposure. [5]

The present study aims at comparing the two surgical techniques namely plate fixation and Intramedullary nailing fixation for the management of displaced diaphyseal clavicle fracture and providing the highest evidence by adopting a trial based study design in evaluating the surgical and functional outcomes of the patients undergoing the surgeries.

Methodology

The Prospective, Non-randomized, two arm, concurrent parallel, experimental study was conducted among 50 patients attending to the Department of Orthopaedics, at Sri Venkateshwaraa Medical College Hospital and Research Centre, Ariyur, Puducherry, with type 2B and 2B1 displaced diaphyseal clavicle fracture during the period December 2016 to December 2018. Approval from the Institutional Ethics Committee was obtained prior to start of the study. The patients recruited for the study were clearly informed in their own local language about the study and the nature of the investigations and surgical procedures carried out during the course of the study and written informed consent was obtained. The patients selected for the study were evaluated and early conservative methods were used to stabilize the fracture temporarily. Open fractures were not included in the study. The patients were subjected to routine clinical examination and blood investigations. They were allocated

into group A or Group B in sequence depending on the decision fit for the management as felt by the operating surgeon and the patient. All the patients included in the study were admitted to the hospital and managed as in-patients. All the patients included in the study were evaluated and the fractures were classified based on Robinson Classification system and only Type 2B and Type 2B1 were included.

The included participants underwent either of the two types of surgical fixation of the clavicle fractures which include: Group A: compression locking plate fixation and Group B: Intramedullary nailing (TENS).

A detailed history including socio-demographic details and medical events prior to surgery was obtained and recorded in a proforma. Follow-up details and operative notes were recorded later during the course of stay in the hospital.

Operative Procedure of Locking Compression plate fixation

Under general anesthesia, patient was kept supine on table. A sandbag was kept in the inter-scapular region to get reduction of fragments. Under sterile conditions draping was done over the affected side of the clavicle. A 7-9 cms long incision was made along the lower border of the clavicle. The skin, subcutaneous tissue and platysma were divided without undermining the edges followed by the overlying fascia and periosteum. Fracture fragments were reduced and plate was applied over the superior aspect of the clavicle. The locking compression plate was fixed to the medial and lateral fragment with locking screws/ cortical screws and at least three screws in medial and lateral fragment were applied. [Figure

1] Wound was closed in layers after ensuring meticulous haemostasis and sterile dressing was applied.

Follow up

Post-operatively patient was supported with fluids and intravenous antibiotics. Early mobilisation was initiated immediately as patient gains consciousness with flexion movements followed by extension and abduction at the shoulder joint as the pain permits. Patients were discharged on the 3rd post-op day. Suture removal was done on the 10th post-op day. They were advised to review once in 4 weeks at the outpatient department. During follow up, patients were checked for any signs of infection, tenderness, instability, deformity. Range of movements at the shoulder joint was recorded. On each visit X-ray examination was done to assess fracture healing. Physiotherapy was advised according to the postoperative time and stage of fracture union. Patients were followed up till radiological union of the fracture was confirmed.

Operative Procedure of Intra-medullary fixation (TENS)

Under general anesthesia, patient was placed in supine position with a sand bag positioned in the inter-scapular region. After preparing the parts, an incision measuring 1-2 cm was made over the sternal end of the clavicle. Soft tissue was cleared and using a bone awl, entry was made through the anterior cortex about 1.5 cm lateral to the sterno-clavicular joint. A titanium elastic nail of average diameter 2 mm was inserted using a T handle and advanced to the fracture site. The fracture site was then reduced in a closed manner under fluoroscopic guidance. In the eventuality of not

being able to reduce the fracture in a closed manner, the fracture site was opened through a 1.5-2 cm incision, fracture was reduced and the nail was gently passed into the distal fragment with gentle rotational movements. The medial end of the nail was then cut, bent and buried under the soft tissue. The skin was then closed using ethilon or skin staples.

Follow-up

Post-operatively, the operated limb was supported with an arm pouch. Check radiograph was taken for checking alignment and fixation. Two doses of intravenous antibiotics were administered post-operatively. Sutures were removed on the twelfth post-operative day. Rehabilitation was started 2 weeks after surgery in the form of pendulum exercises. At 4 - 6 weeks, active range of movements was started as tolerated by the patient with a limited abduction of 90 degrees. After 8 weeks active full range movements were encouraged in all planes with shoulder strengthening exercises. Patients were followed up regularly at 3 weeks, 6 weeks, 12 weeks and thereafter every 2 months up to a minimum period of 1 year. During each visit, patients were assessed for tenderness, implant prominence or evidence of infection and check radiographs were taken to assess union.

Statistical Analysis

The data entry and analysis was done using SPSS version 21.0. The summary measures were expressed using balapercentages and frequencies for categorical variables and mean \pm SD for numerical continuous and discrete variables. The statistical significance between two means was tested using Independent Student t-test and between categorical variables

was tested using Chi-square test. For all statistical tests of significance, a p-value of less than 0.05 was considered significant within 95% confidence limits.

Results

The mean age of the study participants was 32.9 ± 12.8 years; majority being males (92%). In the age group, 15-30 years, majority (n=16, 59.3%) underwent plate fixation whereas in the age group 31-45 years majority underwent TENS (n=10, 66.7%) and this difference was statistically significant [$p < 0.05$]. Except one (2%) all the patients (98%) included in the study were admitted to the hospital following road traffic accident. Majority of patients with type 2B fractures underwent TENS (62.5%) whereas most of those with type 2B1 fractures underwent plate fixation (61.5%) [$p = 0.78$]. The duration of stay in hospital was longer (7.9 ± 2.9 days) among those patients who underwent Plate fixation compared to those who underwent TENS (5.8 ± 2.2 days) ($p < 0.04$). The complications in both procedures are given in table 1.

Table 1: Complications encountered in both surgical procedures

Complications	Plate fixation (n=25)	TENS (n=25)	Total (n=50)
Nil	22 (88)	20 (80)	42 (84)
Cord injury	0 (0)	1 (4)	1 (2)
Implant breakage	2 (8)	0 (0)	2 (4)
Nail protuberance	0 (0)	3 (12)	3 (6)
Surgical site infection	1 (4)	1 (4)	2 (4)

Figures in () indicate column percentages; Chi-square test: $\chi^2=6.09$, $df=4$, $p=0.19$, not significant

The complications were comparatively higher among TENS patients compared to plate fixation. The functional outcome as assessed by Murley score and DASH scores showed no significant differences. [Table 2]

Table 2: Functional outcome assessed by Murley and DASH scores

	Plate fixation (n=25)	TENS (n=25)	p-value
Murley score			
Good	17 (68)	14 (56)	0.39*
Excellent	8 (32)	11 (44)	
DASH score	7.95 \pm 0.9	7.92 \pm 1.9	0.2**

* Chi-square test; **student unpaired t-test for means

Discussion

The Clavicle fractures occur in equally both genders and no age group is spared from a trivial fall. In the present study, in the age group, 15-30 years, majority (n=16, 59.3%) underwent plate fixation whereas in the age group 31-45 years majority underwent TENS (n=10, 66.7%) and this difference was statistically significant. It is expected that, since TENS has cosmetic advantages and minimal exposure, it would be the preferred method of fixation in a younger population compared to the middle aged. But there exists a paradox in our study as well as previous literature where majority of the younger patients underwent plate fixation. The stipulated reasons may be higher implant failure rates in younger age group, higher dynamic mobility at a younger age, difficulty in insertion of pin into the lateral fragment and so on. In the study by *Elango et al.*, [6] the mean age of participants undergoing surgery by plate fixation technique

was 34.2 years and by TENS was 37.1 years respectively. Even though the difference in age was not statistically significant; the age group undergoing TENS was a little higher than those who underwent plate fixation.

In the present study, the duration of stay in hospital was longer (7.9 \pm 2.9 days) among those patients who underwent Plate fixation compared to those who underwent TENS (5.8 \pm 2.2 days). In the study by *Elango et al.* [6] the mean duration of stay in hospital was 12.4 \pm 2.94 days for patients who underwent plate fixation and 6.92 \pm 3.35 days for patients who underwent TENS (p=0.0001). The study further added a reason for the longer duration of stay in hospital following plate fixation was due a considerably larger wound size and most patients prefer to stay longer till the time of suture removal. In the present study also we found similar reasons. The patients tend to estimate the toughness of the surgery based on the size of the wound and since plate fixation has a larger

wound compared to TENS, there is a requirement for daily cleaning and dressing and hence patients are advised to stay till the suture removal is done and then discharged. Similar results were documented in the study by *Jiang et al.* [7] in which the author compared locking compression plates with MIPPO and found a longer duration of stay (8.1 \pm 2.2 days) in the LCP group compared to the MIPPO. The mean DASH scores of patients in the study showed no significant difference (p=0.2) between the plate fixation (7.95 \pm 0.9) and TENS (7.92 \pm 1.9) surgical groups. In the study by *Yun-feng Chen et al.* [8], the DASH scores were 2.5 \pm 1.9 which was very low compared to our study results. In the study by *Kadakia et al.* [9] the mean DASH scores were consistent with our study results reporting 7.91 \pm 1.2 for plate fixation and 7.4 \pm 1.3 for TENS.

Conclusion

Plate fixation was a better surgical technique for management of displaced diaphyseal fractures with lesser complications like cord injury and implant irritation, longer duration of stay in hospital with subjective cosmetic derangement yet better functional outcomes when compared to TENS.

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