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A comparative study of Clavicle mid shaft fracture fixation by anatomical clavicle plate vs TENS nailing

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Abstract:

Background: Clavicle fracture is a common fracture in orthopaedics practice because of its subcutaneous anterior position. Clavicle fracture constitutes approx. 40-44% of injury to shoulder. About 80% injury involve the midshaft portion, with more than 70% found displaced. The two most common type of fixation surgery includes ORIF with anatomical plate and CRIF with TENS intramedullary nailing have been used. But the optimal fixation strategy is still controversial as each technique has its own advantages and disadvantages

Methods: 40 patients were selected with displaced middle-third clavicle fracture & prospectively divided into 2 groups of 20 each, Group-A (plating group) and Group-B (nailing group). The duration of study was 1 year & the outcomes were evaluated based on post-operative VAS score, post-operative DASH score, Union time, delayed union, mal-union, hospital stay, and any other side effect.

Results: 9 (45%) of Group A patients achieved union in 6 months and 11 (55%) in 8 months, mean average union time being 7 months. 4 (20%) had implant prominence, 3 (15%) had hypertrophic scar, 1 (5%) had plate-end protrusion post union, and 2 (10%) had surgical site infection managed by intravenous antibiotics.

In group B, 16 (80%) patients achieved union by 7 months and 4 (20%) by 8 months, mean average union-time being 7.5 months. 3 (15%) patients had nail end prominence, 3 (15%) had nail-end irritation by 4 months, 1 (5%) had nail-end protrusion by 6 months, and 1 (5%) had medial migration by 8 months. No surgical site infection occurred.

Conclusion: Both Plate fixation & Intra-medullary TENS nailing are safe &effective methods of displaced mid shaft clavicle fracture fixation. On one side Plating provides firm fixation & greater rotational stability, in comparison on other side Intra-medullary TENS nailing provide good functional outcome and allow early return to occupational activities, with very less chance of any complications.

Keywords: Clavicle, Fracture fixation, Intra medullary, Titanium, Plating.

INTRODUCTION

The clavicle provides structural support between the axial and appendicular skeleton. Clavicle play an important role in transmitting force from the upper limb to the axial skeleton. The clavicle has several important functions[1]. It acts as a bridge connecting the upper limb to the thoracic cage, which helps to stabilize the shoulder girdle, while allowing the arm to perform a full range of movement. In addition, it functions as an attachment for muscles, provides protection to vital neurovascular structures, supports respiratory function and has a significant aesthetic role in a person's physical appearance[2]. These important

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functions can be damaged by fracture of the clavicle. Traditionally, middle-third clavicle fractures have been treated non-surgically with strapping and clavicular brace, figure of eight bandage, but these sometimes leads to “mal-union” “non-union” which are being reported more recently leading to a gradual shift towards internal fixation as a treatment alternative[3-5]. Due to the drawbacks of conservative management, a number of plate and intra medullary fixation devices such as dynamic compression plate (DCP), tubular plates, reconstruction plates, Knowles pin, rock wood pin, titanium elastic nail, external fixator have been used. Plate fixation and intra medullary nailing are two frequently used surgical methods. However, there is conflicting information regarding their relative efficacy. As per various studies conducted, Plate fixation provides immediate rigid fixation and may be less technique sensitive. Intra medullary fixation is less invasive, with benefits of immediate stability to the involved bone segment which permits early mobilization and returns to normal activities with low complications, reduced implant prominence and better cosmetic results[6]. The objective of this prospective study is to assess and evaluate the clinical outcomes of plate fixation versus intra medullary treatment for displaced middle-third clavicular fractures.

METHODS The current study is a prospective study carried out for one year from December.2017 to January 2018. A total of 40 patients with displaced middle-third clavicle fractures were included in this study. The mean age of the participants in the study was 41 years.

Inclusion criteria : Age more than 10 years & less than 70 years with middle third shaft fractures of clavicle.

Exclusion criteria :Age less than 10 years & more than 70 years.

Lateral 1/3rd shaft fractures.

Comminuted fracture of clavicle.

Associated neurovascular injury.

Open fracture.

The patients were randomly allocated into two groups, Group A (plating group) and Group B (nailing group), with an equal number of 20 patients in each group.

Procedure: After all preoperative investigation & fitness for surgerys, informed and written consent from the patient and pre-anaesthetic examination done & the patient is prepared for the surgery. In the operation theatre (OT) patient is instructed to lie down on the OT table in supine beach chair position. Brachial block is administered and the parts are prepared, scrubbed, painted and draped.

Anatomical plate fixation: A sterile longitudinal incision is taken over the fracture site in line of clavicle, superficial soft tissue dissection is done and fracture site is exposed. Reduction is attempted with bone holding forceps and an anatomically contoured plate is fixed with 3 or 4 screws on either side of reduced fracture. Reduction is confirmed under C-ARM guidance. Thorough wash is given with saline and betadine and suturing is done in layers and the surgical wound is closed. An arm pouch is provided for the operated arm.

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TENS nailing: A sterile longitudinal incision was made vertically about 2 cm lateral to the sternoclavicular joint and a bone awl was used to make an entry in the anterior cortex of the bone. The TENS of appropriate size according to intra medullary canal diameter was inserted from the medial end and advanced through the fracture site until the tip of the nail was engaged in the supero-lateral cortex of the lateral end of the clavicle. Throughout the procedure, accurate anterior-posterior (AP), caudal, and cranial views were obtained. The nail's size was determined by multiplying the canal diameter in millimeters by 0.4. Wound was closed surgically and sterile dressing done. Operated arm was supported by arm pouch.

Post-operative protocol and follow-up: postoperative patients of both the groups were given 5 days of intravenous antibiotics, followed by 7 days of oral antibiotics. An arm pouch was used to immobilize the operated arm. On the second post-operative day, the wound was examined and a X-ray was taken to examine the alignment of the fracture fragments. The patients were discharged with the arm pouch. Patients were examined at interval of two weeks, one month, six months and one year & assessed clinicoradiologically. After two weeks, rehabilitation was started. Gentle pendulum exercises were allowed within the arm pouch. In the first two months, a limited range of motion was permitted for the shoulder, with abduction restricted to 80 to 90 degrees. After three months, active range of motion in all planes was allowed. Results were evaluated in relation to union, visual analogue scale for pain, and complications We evaluated shoulder function using the DASH score.

RESULTS: A total of 40 patients, 20 in each group, were studied in this study. The clinical and demographic characteristics did not significantly differ between the two groups. The factors which were insignificant on comparison included the above demographic factors (age, sex, side, mechanism of injury} as well as visual-analog scale, range of motion and DASH Score at 6 months, being similar for both groups. Significant factors on comparison between the two groups included intra-operative blood loss, duration of surgery, union time and post-operative complications including pain, bledding, urine incontinence/retention. All being less in the nailing group compared to the plating group.

Table No. 1:

Demographic Character		Group A plating No of patients	%	Group B Nailing No of patients	%
Age group(Years)	11-30 31-50 51-70	4 10 6	20% 50% 30%	6 8 6	30% 40% 30%
Gender	Male Female	16 4	80% 20%	14 6	70% 30%

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Mechanism of injury	Fall RTA	9 11	45% 55%	7 13	35% 65%
Side of injury	Right Left	12 8	60% 40%	13 7	65% 35%

S. No.	Factors of significance	Plating Group Mean	S.D.	Nailing Group Mean	S. D.	P value (<0.05 is significant)
1.	Intra operative blood loss (in ml)	117.75	19.499	67.80	13.652	<0.001
2.	Duration of surgery (in mints)	114.00	20.105	68.40	12.696	<0.001
3.	Union time (in months)	7.50	0.607	7.10	0.553	<0.03

In Group A patients, Union was attained by 9 (45%) in 6-7 months and by 11 (55%) in 8 months, with a mean union time span of 7.5 months. The mean DASH score at the end of 6th month for plating group was found to be 18.7. Four (20%) had prominence around the implant, three (15%) had hypertrophic scars (Figure 3A), one (5%) had post union plate-end protrusion (Figure 3B), and two (10%) had surgical site infections treated with intravenous antibiotics.

In group B patients, the mean union time was 7.1 months, with 16 patients (80%) reaching union by 6-7 months and 4 patients (20%) by 8 months. The mean DASH score at the end of 6th month for nailing group was found to be 11.88. Three (15%) of the patients had nail-end prominence, three (15%) had nail-end irritation by four months, one (5%) had nail-end protrusion by six months, and one (5%) had medial migration by eight months. These complications were managed post-union by implant removal. There was no surgical site infection.

DISCUSSION: In our study we evaluate & compare, the efficacy & safety of the most commonly accepted worldwide protocol, in the treatment of displaced mid shaft clavicle fractures by plate fixation & by intra medullary nail fixation surgery. The clavicle plays a crucial role in upper extremity function as well as the mechanics of the pectoral girdle[7]. The clavicle allows for optimal function of the upper extremity as well as protects the upper extremity by dispersing the amount of force transmitted from direct contact. Its strut-like mechanics allow the scapula to glide smoothly along the posterior wall which is critical for

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full upper extremity motion. The anatomical location also protects neurovascular structures, including the brachial plexus, subclavian artery, and subclavian vein which on non-union & malunion would greatly increase morbidity. Clavicle fractures account for 5% of all fractures in adults[8]. Approximately 80% of clavicular fractures involve the midshaft and more than 70% of such fractures are usually displaced. The majority of clavicle fractures are treated non-operatively with good outcomes. But in recent times, there has been a shift toward surgical intervention, especially for mid-shaft displaced fractures. Clavicle fracture receiving surgical management has shown better functional outcomes when compared to conservative measures[9].

Several authors have analyzed the biomechanical characteristics of plates and intra medullary implants for fractures in middle-third clavicle fractures. Golish et al. demonstrated that plate fixation provides a superior construct, demonstrating decreased displacement at fixed loads, as well as greater loads at fixed levels of displacement during a wider range of movements. This may be of benefit in early/accelerated rehabilitation protocol. But surgeons need to be aware that drilling and manipulating the fracture carries a higher risk of harming the underlying neurovascular structures. The complications associated with plate fixation are; infection, non-union, mal-union, further surgery, scarring, re fracture after plate removal and intra-operative vascular injury. It has been demonstrated that intra-medullary fixation causes fewer complications because it retains the soft tissue envelope and periosteum with less tissue dissection and is more cosmetically acceptable. Clinical outcomes with intra medullary fixation vary, and many surgeons prefer plate fixation as the preferred operational treatment for clavicle fractures or non-unions[10]. However, because of its minimally invasive method, intra medullary fixation is particularly effective for individuals with multiple injuries or additional shoulder conditions. During the course of the present study, various factors were noted in both plating & nailing groups, and were analyzed and compared.

The factors which showed no significance on comparison and did not influence the outcome of the study included demographic details of the patients such as age, sex, side of injury as well as mode of injury, duration of injury. It was found that patients with certain co-morbidities such as diabetes mellitus were at risk of developing surgical site infection especially in case of plating group, as the incision taken is of substantial length[11]. The factors which were found to be of significance in the comparison included the intra-operative blood loss, duration of the surgery and time taken for fracture union. The mean intra-op. blood loss was found to be more in case of Plating than nailing group, i.e. 117.75±19.499 ml and 67.80±13.652 ml respectively. The mean duration of surgery was also found to be more in case of Plating group than nailing group i.e., 114±20.105 minutes and 68.40±12.696 minutes respectively[12-13]. Outcome in terms of the range of motion and dash score was observed to be similar and acceptable for both plating and nailing groups. However, the DASH score in case of plating group was slightly higher than nailing group, mainly due to the incidence of complications such as hypertrophic surgical scar, implant prominence, irritation in case of plating which being cosmetically less appealing, affected the DASH score in terms of capability and confidence of the patient. Limitations of the study were, the study duration was confined to a period of only 2 years & the sample size comprised only 40 patients.

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CONCLUSION: The findings of my study concluded that plate fixation & intramedullary nailing both provide good anatomic fracture reduction, stable fixation, early return to daily activities & satisfying functional results. There was no significant difference in functional outcome, time of union & complications in both the groups. The only difference we found is decrease in hospital stay in case of intramedullary TENS naling surgery.

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