Abstract

Background: Middle one third fractures of the clavicle bone comprise around 80% of all clavicle fractures. Nonsurgical methods have been practising for management of clavicle fracture, but with some problems like “non-union”, “mal-union” and shoulder asymmetry. Two surgical procedures are commonly used to repair displaced mid shaft clavicular fractures internally: plating & intramedullary nailing with titanium elastic nail (TEN). The choice of surgical treatment remains controversial but Intra-medullary nailing of the clavicle has been shown to have considerable benefits over other forms of fixation.

Materials & Methods: This prospective study was performed in Department of Orthopaedics at Teerthankar Mahaveer Medical College and Research Centre, Moradabad for duration of one year on patients with clavicular fractures who were managed by Elastic Intra-medullary Nailing were enrolled in the research fulfilling, inclusion and exclusion criteria. The functional ability of shoulder was checked with DASH score for each follow-up. Radiological Assessment was done by checking – signs of Non Union.

Results: Total 22 patients of clavicular fractures managed by elastic nailing. The mean difference DASH Score at different follow up duration with respect to the mean DASH score at 4 weeks was observed as statistically significant (p <0.05). The final outcome was studied and the majority of patients yielded good result (42.8%) and excellent (42.8%) result.

Conclusion: The intra-medullary fixation of clavicle fractures with TENS is a reliable, minimally invasive procedure in specific cases and provides good functional results and cosmetic results in our research.

Keywords: Clavicle, Fracture, Intramedullary nailing, DASH Score

Introduction

Clavicle is the most commonly fractured bone usually, accounting for up-to 12% of all adult fractures [1]. Middle 3rd fractures of the clavicle bone comprise around 80% of all clavicle fractures [2]. Clavicle fractures are normal with male dominance in active and early age groups (male female ratio is 2:1) [3]. It accounts for 2.5 to 5% of all trauma. These fractures more commonly occurred in men (68%) than women (32%) with road-traffic accidents (RTA) being the most regular cause of the injury [1].

Displaced mid-shaft clavicle fractures have historically been overlooked as it was believed that these fractures uniformly heal without complications. Modern literature has confronted this belief, and many studies had disclosed unacceptably high non-union rates of 15.1% as well as related pain, strength loss and quick fatigability when these were administered with conservative methods [2].

The treatment grade for almost all clavicle fractures has been non-operative in nature, frequently consisting of a simple sling [4]. But evidence suggests that after non-surgical treatment, patients can have chances of high non-union rates, chronic pain, or shoulder function disability. It can also be connected with venous congestion of arms & a displaced fragment can compress the brachial plexus leading to neuropraxia after conservative management. Furthermore reduced shoulder working because of shortening of clavicle, more than “1 to 2” cm, post conservative Treatment has been reported [3]. Surgical intervention minimizes suboptimal outcomes. Surgical procedures commonly used to repair DMCF (Displaced Midshaft Clavicular Fracture) internally are plating & intramedullary nailing with titanium elastic nail (TEN). Intramedullary nailing of the clavicle has been shown to have considerable benefits over other forms of fixation as there is limited periosteal stripping and minimal compression of the periosteal blood supply which promotes union [2]. Thus elastic intra-medullary nail is a safe, minimally invasive, promotes rapid healing with good cosmesis and provides an excellent functional outcome with fewer complications in terms of patient satisfaction [5].

In 2002, TEN was firstly applied in the management of displaced mid-clavicular fractures, and showed great clinical therapeutic results as an alternative to conservative
management but with the drawbacks of anti-rotation & anti-shortening [6]. Common TEN (titanium elastic nail) might induce different complications as well as hardware irritations, medial perforations, lateral penetrations, TEN breakage and dislocation [7].

**Materials & methods**

This prospective study was performed in Department of Orthopaedics at Teerthankar Mahaveer Medical College and Research Centre, Moradabad for duration of (From December 2017 to December 2018) one year on patients with clavicular Fractures who were managed by Elastic Intramedullary Nailing. Age range between 18-60 years, all clavicle fractures up to 2 weeks old, all closed clavicle fractures, open fractures Grade 1 according to Gustilo Anderson Classification were included in the study. Pathological fractures, multiple injuries of same limb, open fractures of Gustilo Anderson Grade 2 or more, patients with other disease which affect the functions of upper limbs (e.g. polyarthritis, neurovascular injuries etc.) were not included.

**Operative Technique:** The procedure was done under general anesthesia in ‘Beach Chair’ position with sand bag below Inter-scapular area. 2 cm of incision was given at the sternal end, parallel to it. An awl was used to make the entry through cortex (anterior), approximately one point five to two cm lateral to the joint (sterno-clavicular). An elastic nail (diameter of 2.5 mm on average) was placed and moved across the fracture. (Figure 1) Subsequently, the fracture was reduced by closed reduction technique. If CRIF is not feasible, a one to two cm incision at the fracture site was made to reduce the fracture openly or semi-openly. Reduction was maintained using reduction forceps. The nail was then progressed with gentle rotational motions through the fracture into the lateral part. Skin above the nail was stitched after cutting the medial end.

All patients were given arm sling after operation for 4 weeks. Pendulum Exercise started as soon as the pain was reduced. Physical therapy with abduction below 90° was initiated post-surgery for the first 3 to 4 weeks. Following surgery, the shoulder joint flexion and extension movement ranges were reported till final follow-up. The functional ability of shoulder was checked with DASH (range: zero to hundred points, best: 0) for each follow-up. [every 4 weeks up to 16 weeks then after every 3 months up to 9 months]. Radiological Assessment was done by checking– signs of Non Union (presence of callus, sclerosis, margins) Angulation Displacement, nail position, clavicle length at 8 weeks, 6 months & 9 months. (Figure 2)

**Results**

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- The radiological outcome with their respective follow up duration was assessed and one patient was lost to follow up, rest all have maintained Clavical Length and nail was placed centrally, fracture united. (Figure 3)

The final outcome of the patients was and the majority of patients yielded good result (42.8%) and excellent (42.8%) result. (Figure 4)

The association of final outcome with DASH Score was found to be statistically insignificant (p>0.05) (Table 2)

- One way ANOVA test

The status of nailing in the studied patients was that, in majority of patients nails was not removed (63.6%) and was removed in 36.4%.

Clinical photographs at 9 months follow up is given below (Figure 5)

Discussion

Clavicle Fractures are common and constitute approximately 2.6 percent of all Fractures. The majority of fractures of the clavicle (80 to 85 per cent) occur in the mid-shaft. Clavicle fractures can be managed by non-surgical methods. However, there is increasing evidences of superiority of operative treatment over non operative treatment. Many modalities for the management of fracture of clavicle are there, there is a trend towards an operative approach that consists of two main methods, plate or nail, While plating has been recognized as a normal procedure, some drawbacks, such as a large scar, non-union and difficult to apply and remove the plate are associated with this [8]. The present study, done on 22 patients to assess the functional and radiological outcome of clavicular fractures managed by elastic intra-medullary nailing” as a prospective study at Teerthanker Mahaveer Medical College and Research Center, Moradabad. There was a specific follow up of the studied patients to analyse the recovery and satisfaction level at 4 week, 8 week, 12 week, 16 week, 6 month and 9 month (DASH SCORE). One patient was lost to follow up. Shokouh HK et al (2014) conducted the study in 2013 with 13 sample size and they concluded that, there is controversy over intra-medullary nail fixation of clavicle fracture, our outcomes using this method for displaced mid-shaft fracture of clavicle ranged from satisfactory to good and excellent [8]. Kadakia AP et al (2012) performed their study in 2012 comprising of 38 patients with the conclusion that ESIN (elastic stable intra-medullary nailing) is safe and minimally invasive with high patient satisfaction, cosmetic outcome and overall result [9]. Kumar H et al (2018) in 50 sample size (June 2012 to June 2014) concluded that flexible intramedullary nailing is a minimally invasive technique for treatment of clavicle fractures and It is a simple procedure with an outstanding functional result in terms of faster return to work and a high patient satisfaction level with a very good cosmetic result [10]. Kumar M et al (2018) with 42 sample size concluded that pre-

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Table 1: Mean DASH scores at different follow up duration

| Follow up duration | Mean DASH score (minmax) | Mean difference from 4 weeks | p value* |
|--------------------|--------------------------|-----------------------------|---------|
| At 4 weeks         | 35.52±11.69 (16-61)      | -                           | -       |
| At 8 weeks         | 27.10±12.96 (9-58)       | -8.43                       | 0.001   |
| At 12 weeks        | 21.57±7.12 (12-39)       | -13.95                      | <0.001  |
| At 16 weeks        | 17.05±5.32 (9-33)        | -18                         | <0.001  |
| At 6 month         | 14.10±5.28 (6-21)        | -20.95                      | <0.001  |
| At 9 month         | 11.45±6.32 (7-35)        | -23.6                       | <0.001  |
contoured locking compression plates gave better functional outcome and were associated with complications in fewer cases as compared to titanium elastic nails when used for operative management of displaced mid one third shaft fractures of clavicle [11]. In the present study the mean age of the studied patients was 30.0±11.5 years ranging 18 to 60 years and the male patients were in dominance (72.7%) while the females were 27.3%. Kumar H et al (2018) in their study reported the mean age of patients as 31.2 years ranging from minimum 18 years to maximum 54 years. Males were 32 and females were 18, which was similar to the present study [10]. Kadakia AP et al (2012) reported 32 males and 6 females in his study, 27.6 years was the mean age (range, 14 to 57 years) [9]. This highest incidence in young age group is seen because they are most commonly involved in traveling, driving, sports activities, and also are victims of assault. Displaced mid-shaft fracture clavicle was seen predominantly in males probably due to type of society in which outdoor activities are predominantly preferred by males which predispose them to work accidents. In our study the fractured side of the bone was analyzed and the majority of patients have fractured their left side (63.6%) followed by right side (36.4%). Bithrey JW and Van der Merwe JF (2017) reported 9 right and 6 left clavicle fractures were assessed. Our findings were contrasting to the above mentioned studies and this may be by a matter of chance that the majority of patients left side was affected [2]. In the present study the mean difference DASH Score at different follow up duration with respect to the mean DASH score at 4 weeks was taken and the association was found to be significant (p less than 0.05). Disability of Arm Shoulder and Hand (DASH) score was calculated on a scale of 0-100, considering score 0 best and 100 worst. Minimum mean DASH score was 6(best), and the maximum was 61 (worst) it was 6.8 (0–43) [8], 2.5 (0.5–8.0) [9], and 3.4 (± 4.8) [10] which was in accordance with the present study. The radiological outcome in our study with their respective follow up duration was assessed and one patient was lost to follow up, rest all have maintained Clavical Length and nail was placed centrally, fracture united. Kumar H et al (2018), all 50 cases (100%) had fracture union [10]. The only complications that occurred in the studied patients was Impingement at Medial End (98.7%), while 14.3% patient showed no complications (14.3%). Kadakia AP et al (2012) in Accordance to the present study, there were no infection, scar neuromas, non-union or posterior cortex perforation [9]. Kumar H et al (2018) stated that overall, it can be stated that in their study, there was no any major complication (infection, scar neuroma, non-union) regarding management and healing leading to reoperation [10]. Kumar M et al (2018) reported that 3 (15.98%) patients had delayed union and 6 (31.58%) patients had skin impingement by nail at entry site [11]. This was the main indication for implant removal in nailing. Hartman F et al (2008) reported all fractures healed clinically and radiologically. Non-union or infections were not observed [12]. The final outcome of the studied patients (based on DASH Scoring) in our study, had good result in 42.8% and excellent also in 42.8% while poor result was obtained in 9.6% patients. Beigang Fu et al (2016) 86.11% of patients had excellent results and 13.89% had good results [6]. Saha P et al (2014) recorded 28 excellent and 6 good results in the elastic nailing category [13]. The status of nailing in the studied patients in the present study was analyzed and in 61.9% of patient nails was not removed (61.9%) and was removed in (38.1%). Kumar H et al (2018) reported that in their study, nail removal was done in 45 cases, and in 5 cases, implant was not removed because of refusal of patients [10]. Clavicle fracture fixation by titanium elastic nail is a new technique that can be a fixation method to treat clavicular fractures. With this approach, we had positive results. This procedure is challenging and in old comminuted clavicular fractures, we do not recommend it.

**Conclusion**

This study shows early pain relief in conjunction with good shoulder function after acute surgical treatment with Titanium Elastic Nailing System (TENS) resulting in a fast return to work and a high patient satisfaction level. TENS is therefore a promising minimally invasive therapy for fixation of fractures of clavicle, an alternative to open reduction internal fixation, with plates or even non-operational treatmen

| Table 2: Association between final outcome DASH Score |
|----------------|----------------|----------------|----------------|----------------|----------------|
| Final Outcome  | At 4 weeks     | At 8 weeks     | At 12 weeks    | At 16 weeks    | At 6 months    |
| Excellent (9)  | 35.33±9.64     | 23.0±9.31      | 20.11±6.21     | 16.0±4.09      | 11.78±5.35     |
| Good (9)       | 37.67±14.69    | 30.78±16.37    | 23.22±9.1      | 19.25±6.7      | 16.63±4.72     |
| Satisfactory (1)| 35.0±0.0       | 29.0±0.0       | 21.0±0.0       | 16.0±0.0       | 18.0±0.0       |
| Poor (2)       | 27.0±8.48      | 28.0±15.56     | 21.0±0.0       | 13.5±3.54      | 12.5±4.95      |

P value: 0.743, 0.68, 0.852, 0.479, 0.238, 0.895
The intra-medullary fixation of clavicle fractures with TENS is a reliable, minimally invasive procedure in specific cases and provides good functional results and cosmetic results in our research.

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