#### Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15 (6); 1567-1578

**Original Research Article** 

# Functional Outcome of Intramedullary Screw Nail Fixation versus Conservative Management in Displaced Midshaft Clavicle Fractures: A Randomized Controlled Trial

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Received: 20-04-2023 / Revised: 30-05-2023 / Accepted: 24-06-2023 Corresponding author: Dr. Yash. M. Dhanwani Conflict of interest: Nil

### Abstract:

**Background**:-Non-operative treatment is the treatment of choice for midshaft clavicle fractures. There may arise some problems like impairment of ROM of shoulder, disfigurement of the local area with bump at the site for the fracture which may be cosmetically distressing to patient and nonunion can occur when grossly displaced fractures are treated non-operatively. Patients with displaced clavicle fractures can be managed with

either ORIF with plating or CRIF with intramedullary nailing. Problem with intramedullary nailing of clavicle was implant migration which has been solved with newer implant i.e SCREW NAIL. Article includes the comparison of clinical outcomes of patients with displaced clavicle fracture managed conservatively and surgically i.e with intramedullary screw nail.

**Material And Methods**:- 30 patients suffering from midshaft clavicle fracture were included in the study. 15 patients were managed conservatively with figure of 8 clavicular brace and 15 were managed surgically with CRIF with intramedullary screw nail fixation. 30 subjects were equally allocated into two groups using a computer generated random allocation plan determined by www.graphpad.com software. Outcomes were measured using the UCLS scoring system of the clavicle. Follow-up was taken on 1st month, 3rd months, 6th month postsurgery.

**Results**:-A statistically significant difference(p value =0.0001) was found in the UCLS shoulder score between the operative and conservative group at 1 month post-operative follow-up probably due to the early mobilisation in the operative group. The average UCLS score in the operative group was found to be  $24.27 \pm 3.13$  whereas in the conservative group it was found to be  $16.4 \pm 1.18$ . A statistically non significant (p value=0.0524) result was found at 3 months follow-up between the conservative and the operative group. The average UCLS score for the operative groups were found to be  $27.64 \pm 2.59$  whereas average UCLS score for the conservative group was  $25.47 \pm 3.14$ . It was found that there was statistically significant (p value=0.0003) difference in the UCLS score between the operative group and the conservative group at the end of 6 months. Most of the patients in the conservative age group were not able

to achieve the

highest functional scores compared to the operative group. The average UCLS score in the operative group was found to be  $31.54 \pm 1.39$ .whereas the average UCLS score for the conservative group was  $29.27 \pm 1.49$ .

**Conclusion**:-Open reduction internal fixation with intramedullary screw nail is a reliable method in management of the displaced fractures of midshaft clavicle with high union rates and better functional outcomes with surgery done by trained person compared to conservative management. There were no reported complications like implant migration with screw nail. The University of California and Los Angeles shoulder score at the end of 6 months were found to be better for the subject who underwent open reduction internal fixation with intramedullary screw nail compared to those managed conservatively. The time of union was found to be less for the subject who underwent ORIF with intramedullary screw nail compared to those managed conservatively.

**Keywords:** Intramedullary screw nail fixation, Conservative management, displaced Midshaft clavicle fractures.

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#### Introduction

Clavicle fractures account for 2.6% of total fractures. Out of the fractures involving the shoulder girdle, 44% are clavicle fractures. Clavicle fractures mostly involve active males. Left side constitutes 61% of all clavicle fractures. Fractures of the clavicle most commonly occurs at middle 1/3 of shaft (81%). Out of the total fractures involving mid-shaft clavicle, 48% are displaced and 19% are comminuted. Fractures of the medial 1/3 constitute only 2% of the clavicle fractures. Displaced clavicle fractures are more common in adults. Vehicular accidents are the most common cause of the injury [1]. Nonoperative treatment is the treatment of choice for mid-shaft clavicle fractures. There may arise some problems like impairment of ROM of shoulder. disfigurement of the local area with bump at the site for the fracture which may be cosmetically distressing to patient and nonunion can occur when grossly displaced fractures are treated non-operatively. Indications of surgical fixation of the midshaft clavicle fracture are displacement of more than 20 millimetre (2cm), skin indentation, shortening of 2cm, nerve or vascular injury and floating shoulder injury. Open reduction with plating has been most

modality used commonly for the management of displaced fractures of midshaft clavicle. However plating has some disadvantages like large incision, greater periosteal stripping, Need of another surgery for removal of plate. Intramedullary nailing is a reliable option for management of the diaphyseal clavicle fracture but had a problem of implant migration and implant back-out [2]. To cope up with the problem of implant migration, addition of screw head to the nail might solve this problem. Dr Ayaman khalil tried the screw fixation in clavicle fracture for first time and concluded that screw fixation is Simple, affordable technique for fixation clavicle fracture. It allows compression at the fracture site mostly at intramedullary level and provides good levels of stability, stress sharing, better bio-environment fracture with less periosteal stripping and early mobilisation after surgery.

There are minimal chances of complication like implant migration [3,4,5,6]. Gadegone et.al carried out a study on 36 patients to assess the functional outcomes of intramedullary elastic screw nail fixation in displaced mid-shaft clavicle fractures [2]. There are very few studies comparing the outcomes of fixation of mid-shaft clavicle fracture with screw nail versus conservative management [2].



Figure 1: Implant design-screw nail, credits:-Gadegone et.al

Hence objective of the study was to evaluate the functional outcomes of intramedullary screw nail fixation as compared to conservative management of displaced clavicle fractures by university of California and Los Angeles (UCLA) scoring system postoperatively at the end of 6 months.

**Materials and Methods:-** A Randomised Controlled Trial of 30 patients carried out in Department of Orthopaedics of Tertiary care teaching hospital during period of October 2019 till February 2021. All the patients with displaced mid-shaft clavicle fulfilling the inclusion criteria were included in the study and were randomly allocated into 2 groups i.e. conservative management and the intramedullary screw nail fixation by either closed or open reduction method. 30 subjects will be equally allocated into two groups using a computer generated random allocation plan determined by www.graphpad.com software. Patients fulfilling exclusion criteria were excluded. Patient operated with open/closed reduction with intramedullary fixation using the screw nail were included as the cases. Patients treated with the conservative management using figure of 8 brace and analgesics were included as the control.Fractures were classified using the NEER's classification. Outcomes were measured using the UCLS scoring system of the clavicle. Follow-up was taken on 1st month, 3rd months, 6th month post surgery. Patient in age group more than 18 years and with a clinical and radiological diagnosis of displaced clavicle fracture (Type 1 and type 3 clavicle fractures according to the NEER's classification) were included in study. Patient less than 18 years of age, lateral end

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clavicle fractures (Neers type 2 fractures), grade 3 open clavicle fractures and infected clavicle fractures were excluded from study. Sample size for the study was 30, 15 patients were enrolled in conservative group and 15 patients were enrolled in operative group.On admission to the institute detailed history of the patient was taken. A detailed systemic and general examination was carried out to evaluate complete status of the patient. Clinical examination of the fracture was done including skin and the soft tissue and radiographic investigations( x ray of shoulder with clavicle anteroposterior and lateral view) were done. Anaesthesia and physician fitness was taken. The interval between admission and surgery varied, though the aim was to take up patient as soon as surgically fit. Understanding the fracture anatomy and taking comminution consideration into was of utmost importance before attempting the open reduction of fracture. In few cases the canal in the distal fragment was too narrow for negotiation of the intramedullary device. Preoperative Measurement of the canal diameter in the distal fragment and deciding the nail diameter preoperatively was important. Patient within the conservative group were treated with figure of 8 clavicle brace and analgesics.

Surgical **Technique:-**Surgery was performed under general anaesthesia in supine position. Few of the patients were

supra-clavicular block for the given postoperative pain control. Ring pillow was placed under the head and the face turned on the opposite side. A bolster was placed between the medial border of the scapula and the spine for ease during surgery. Medial end of the clavicle was palpated. 2-4cm incision was taken over the clavicle about 1 cm medial to the sterno-clavicular joint/medial end of the clavicle. Entry was made with the bone Awl about 1 cm medial to the medial end of the clavicle under the guidance of the c-arm guidance. After the canal has been opened with the bone awl, serial reaming was done with 1.5, 2, 2.5 sized reamers depending on the canal diameter. Closed reduction was tried and a trial to pass nail was given. If it was not possible to reduce the fracture with closed reduction a 2-4 cm incision was taken directly over the fracture site. Fracture was reduced under direct vision and held in position.

Now the screw nail was negotiated through the fracture. After adequate wash with normal saline. Fascia was closed with the 2-0 absorbable suture material. Skin was closed using the subcuticular sutures. Sterile dressing was done. After the surgery the patient was given an arm sling pouch. Patients were kept NBM for 6 hours postoperatively. Patients were shifted for post operative x ray immediately after stabilisation of vitals in anaesthesia recovery room.



Figure 2: Entry-1 cm lateral to the sternoclavicular joint **International Journal of Pharmaceutical and Clinical Research** 



Figure3: Reduction- reduction held with bone clamps through 2-3 cm incision to expose fracture site

#### **Statistical Analysis and Results**

Patient's identity and information was kept confidential. Validity of the data was checked periodically by guides and experts. Qualitative data was expressed in terms of percentages and proportions. Quantitative data was expressed in terms of Mean and deviation. Standard Mean standard deviation and percentage were calculated. Paired T test was used for the data analysis. All the information related to the patient was presented in the form of mean, standard deviation and the error of mean. P value of <0.05 was said statistically significant P value <0.001 was said to be highly significant. All patients coming to Lata Mangeshkar hospital with displaced midshaft clavicle were randomly allocated to either the conservative group or the operative group using the online software www.graphpad.com. A total of 30 patients were enrolled in study, 15 patients with displaced mid-shaft clavicle were treated with open reduction internal fixation with intramedullary screw nail fixation and 15 patients were treated with conservative management which included figure of 8 bandage and analgesics. The operative group consisted of maximum patients in the

age group of 31-40 years i.e. 33.33% followed by 21-30, 41-50, 51-60 years consisting of 20% of patient each with lowest patient in age group of 61-65 years i.e. 6.67%. Conservative group the highest no of patients were in 21-30 years i.e. 40% followed by 41-50 years consisting of 20% of patients with lowest patients in 61-65 years i.e. 6.67%. Out of the 15 patients in operative group 13 were males i.e. 86.67% and 2 were females i.e. 13.33% Out of the 15 patients in the conservative group 13 were males i.e 86.67% and 2 were female i.e.13.33%. Out of the 15 patients in the operative group 7 patients (46.67%) were left sided, 8 patients (53.33%) were right sided. Out of the 15 patients in the conservative group 4 patients (26.67%) were left sided, 11 patients (73.33%) were right sided. In both the groups 60% of patients sustained trauma due to the road traffic accident and 40% patient sustained trauma due to the fall on out stretched hand. Out of the 15 subjects in the operative group 8 subjects i.e. 53.33% suffered from some co-morbidity in the form of type 2 diabetes mellitus, hypertension, asthma etc. Out of 15 patients in the conservative group 6 patients i.e. 40% suffered from some comorbidity.

The average time required in the surgery for the operative group was 60-120 minutes in the operative group. The patients in the operative age group had an average blood loss of about  $44 \pm 7.12$  ml. The average intra-operative exposure was found to be  $43.13 \pm 4.21$  fluoroscopic shoots. The patients in the conservative group only suffered from the radiological exposure due to the follow-up x rays. All the subjects in the conservative were treated as out-patient with figure of 8 brace and the analgesics while the patients treated operatively had an average hospital stay of  $4.33 \pm 1.84$  days. The average time of union for operatively managed patient was found to be 1.73  $\pm$ 0.39 months while in the conservative group it was found to be  $2.5 \pm 0.52$  months. The average UCLS score in the operative group was found to be  $24.27 \pm 3.13$  whereas in the conservative group it was found to be  $16.4 \pm 1.18$ (statistically significant). The average UCLS score for the operative groups were found to be  $27.64 \pm 2.59$ 

whereas average UCLS score for the conservative group was 25.47 +insignificant). 3.14(statistically The average UCLS score in the operative group was found to be  $31.54 \pm 1.39$ .whereas the average UCLS score for the conservative group was  $29.27 \pm 1.49$ .(statistically significant). 2 patients suffered from complication. 1 patient had deep surgical site infection for which implant removal was done at 1 month post-operatively and 1 patient had non-union due to the bending of the screw nail in immediate post-operative period which required revision surgery in the form of screw nail removal with open reduction internal fixation with plating.

There were 2 complications, 1 patient suffered from non-union at 6 months with restricted shoulder movements and another patient suffered from the restriction of the shoulder function secondary to prolonged immobilisation.



Figure 4: UCLA score at 1 month follow-up



Figure 5: UCLA score at 3 month follow up



Figure 6: UCLA score at 6 months follow up

Discussion: Clavicle fracture accounts to 2.6% of the total fractures and 44% of the fractures involving the shoulder girdle [1]. commonly used method Most of management of the mid-shaft clavicle is However conservative. conservative management is associated with some pitfalls i.e. limitation of shoulder function

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due to the prolonged immobilisation, disfigurement of the local area due to the palpable bump over the local site and chances of non-union[2,3,4,5]. Mid-shaft clavicle fractures with displacement of more than 20 millimetre (2 cm), skin indentation, shortening of 2 cm, nerve or vascular injury and floating shoulder injury needs to be fixed surgically either with intramedullary or extra-medullary fixation[2]. ORIF with plating has been used most commonly for fixation of the displaced clavicle fractures but it has some disadvantages i.e. larger incision, greater periosteal stripping and need for a subsequent surgery for the removal of the plate[2]. Open/closed reduction internal fixation with intramedullary nail is a good method of fixation of fractures of mid-shaft clavicle. Intramedullary fixation of the midshaft clavicle was associated with chances of the implant migration(8). Modification of the intrameduallary device with adding of the screw head for a better cortical purchase solved this problem[2].

The average time required in the surgery for the operative group was 60-120 minutes. The patients in the operative age group suffered from an average blood loss of about  $44 \pm 7.12$  ml. There was statistically significant difference in the radiation exposure in the treatment of the mid-shaft clavicle by the operative and conservative method. The operative group suffered from a higher level of the radiation exposure consisting of the follow-up x-rays and the intra-operative exposure due to the fluoroscopy. The average intra-operative exposure was found to be  $43.13 \pm 4.21$ shoots of fluoroscopy. The patients in the conservative group only suffered from the radiological exposure due to the follow-up x rays. There was statistically significant (p value=0.001) difference in the shoulder mobilisation in the operative and the conservative group. The patients in the operative group were mobilised early i.e.15 days post-operatively when the surgical wound was good and surgical pain was

reduced significantly whereas in the conservative group, 10 subjects were immobilised in figure of 8 clavicular brace for 5 weeks while 5 subjects were immobilised for 6 weeks. The UCLS functional score was measured for patients in both conservative and operative group at every follow-up. A statistically significant difference(p value =0.0001) was found in the UCLS shoulder score between the operative and conservative group at 1 month post-operative follow-up probably due to the early mobilisation in the operative group. The average UCLS score in the operative group was found to be  $24.27 \pm 3.13$  whereas in the conservative group it was found to be  $16.4 \pm 1.18$ . A statistically non-significant (p value=0.0524) result was found at 3 months follow-up between the conservative and the operative group. The average UCLS score for the operative groups were found to be  $27.64 \pm 2.59$  whereas average UCLS score for the conservative group was 25.47  $\pm$ 3.14. It was found that there was statistically significant (p value=0.0003) difference in the UCLS score between the operative group and the conservative group at the end of 6 months. Most of the patients in the conservative age group were not able to achieve the highest functional scores compared to the operative group. The average UCLS score in the operative group was found to be  $31.54 \pm 1.39$ . Whereas the average UCLS score for the conservative group was  $29.27 \pm 1.49$ . The final outcomes of the shoulder function at the end of 6 months were found to be better in patient treated compared to the conservative group.

In 2009, Smekal et.al compared the outcomes of the operative treatment with intramedullary fixation of the midshaft clavicle fracture with the conservative management. The study included 60 patients with the fresh midshaft clavicle fracture with the random allocation to the operative and the conservative group. It was observed that none of the patient in the operative group suffered from the nonunion as the complication whereas 3 out of 30 patients in the conservative group suffered from the nonunion and some impairment of the shoulder function. However implant migration was observed in 7 patients of the operative group. Revision surgery for the implant failure was done in 2 patients. Patients with the operative management were found to be more satisfied and had better cosmetic results. In this study the operative management of the clavicle was found to be more satisfactory with no case of non-union and better cosmetic outcomes and patient satisfaction[10]. The results of our study were different from the above study. In our study out of the 15 patients in the operative group, 2 patients suffered from complication. 1 patient had deep surgical site infection for which implant removal was done at 1 month postoperatively and 1 patient had non-union due to the bending of the screw nail in immediate post-operative period which required revision surgery in the form of screw nail removal with open reduction internal fixation with plating. While in the conservative age group, there were 2 complications, 1 patient suffered from nonunion at 6 months with restricted shoulder movements and another patient suffered from the restriction of the shoulder function secondary to prolonged immobilisation. There was a statistically significant (p value=0.0002) difference in the time of union in between the operative and conservative group. The average time of union for operatively managed patient was found to be  $1.73 \pm 0.39$  months while in the conservative group it was found to be 2.5  $\pm$ 0.52 months. Good union rates were observed in the operative group. There was a statistically significant difference (p value=0.0001) in the hospital stay in the operative group between and conservative group. All the subjects in the conservative were treated as out-patient with figure of 8 brace and the analgesics while the patient treated operatively had a average hospital stay of  $4.33 \pm 1.84$  days.

Gadegone et.al conducted a case series to clinical study the outcomes of intramedullary screw nail in displaced midshaft clavicle fractures in 36 patients. There were 28 males and 8 females. The mean age was 36.6 years. Constant-Murley score was used at 1 month, 3 month, 6 months to study the clinical outcomes of the modality. 21 patients were treated with closed reduction while 15 patients required mini open for the reduction. The average time of union was 11.6 weeks in 31 cases. Five out of 36 showed delayed union. 3 patients showed medial nail protrusion which required early implant removal[2]. Compared to above study our study included 30 patients.15 patients were treated with operative method with intramedullary screw nail. The average time of union for operatively managed patient was found to be  $1.73 \pm 0.39$  months while in the conservative group it was found to be  $2.5 \pm 0.52$  months. We used university of California and Los Angeles score (UCLS) at 1 month, 3 month, 6 months. No complication was seen in study Gadegone bv et.al. However 2 complications were seen in our study. 1 patient suffered from deep surgical site infection which was treated with implant removal and another patient suffered from the malunion due to implant failure which required revision surgery with plating.

All the operatively treated patients in our study required open reduction of the fracture with mini-open of the fracture site. Ayaman khalil carried out study to access the outcomes of Intrameduallry screw fixation for mid-shaft fractures of the clavicle. Also he described the technique of intramedullary screw fixation in displaced midshaft clavicle fracture. He used the DASH scores to access the functional outcomes. 37 patients were enrolled in the study. 35 of these were treated with 6.5 partially threaded cancellous screw. The screw was inserted from the medial fragment after retrograde drilling of the fragment. Patients were followed for an average period of 21 months. Average time of union was 6-8 weeks. 2 cases had intraoperative failure of the fixation. 9 patients suffered from the hardware problem due to the prominence of the head of the screw. 3 had symptoms of frozen shoulder[11]. Compared to above study none of the patient in our study had intra-operative failure of the fixation. None of the patient in our study had prominence of the screw head at the medial end.



**Figure 7: results** 

## Conclusion

From our study we can safely conclude that operative management in the form of open reduction internal fixation with intramedullary screw nail is a reliable method in management of the displaced fractures of midshaft clavicle with high union rates and better functional outcomes with surgery done by trained person compared to conservative management. There were no reported complications like implant migration with screw nail. The University of California and Los Angeles shoulder score at the end of 6 months were found to be better for the subject who underwent open reduction internal fixation with intramedullary screw nail compared to those managed conservatively. The time of union was found to be less for the subject who underwent ORIF with intramedullary screw nail compared to those managed conservatively. The shoulder ROM was started early in the patients managed with the ORIF with intramedullary nailing patients managed compared to the conservatively which reduced the chances of restriction of shoulder function due to prolonged immobilisation .The hospital stay for those patients managed conservatively was significantly less compared to operative group as most of the patients with conservative management were managed as out-patient. Chances of non-union were found to be higher with the conservative group compared to operative group. Surgery related complication like

surgical infection was found in 1 patient managed with the operative modality.

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