Section: Orthopedics

Original Research Article

PROSPECTIVE STUDY OF FUNCTIONAL OUTCOME OF DISPLACED MIDDLE THIRD CLVICULARFRACTURES TREATED BY PLATE OSTEOSYNTHESIS

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ABSTRACT

Background: Aim: To know the functional outcomes of surgical management of middle third displaced clavicle fracture by ORIF with locking compression plate.

Materials and Methods: It was a prospective Interventional study. The current study was conducted in the Department of Orthopaedics, NRI Institute of Medical Sciences, Visakhapatnam, Andhra Pradesh, India. **The study was conducted during the period from** 16 months from August 2022 – November 2023. It was a prospective Interventional study The study was interventional, as surgery was done to patients – that is treatment of middle 1/3rd of clavicular fractures using plate method. After getting approval from the Ethics Committee, patients admitted at Orthopaedics ward at NRIIMS, Sangivalasa, Visakhapatnam with fractures of Middle 3rd clavicle were taken as study sample.

Results: The current study was done on 30 patients with displaced middle 1/3rd of clavicular fractures. 30% of the patients were aged 41 to 50 years, 26.67% were aged 21 to 30 years.90% of subjects were males. 96.67% had road traffic accident. 63.33% underwent surgery for 60-70 mins. 50% had right sided fracture of clavicle. 60% had 2C AO/OTA of fracture of clavicle. 26.67% had associated minor injuries. 16.67% had associated RIB fractures Fracture union time was 11 to 12 weeks for 36.67% of patients. 3.33% had non-union. Mean DASH score is 15.2 at 3months. 10% developed infection postoperatively. 10% had more than 7 days of hospital stay. There is significant association between age & infection. Patients aged above 50 years developed infection due to co morbid conditions like DM. There is a significant association between age & duration of hospstay, as they were treated with IV antibiotics for superficial infection, so the duration of hospital stay was prolonged.

Conclusion: The current study was done on 30 patients with middle 1/3rd of clavicular fractures. This interventional study concluded that use of locking plates for displaced midshaft clavicle fractures results in union with very good functional outcome and is associated with low complication rates. All the patients were discharged in stable condition. A Interventional randomized prospective study is suggested to prove the superiority of operative management over conservative treatment.

Keywords: Clavicle fracture, ORIF, locking compression plate, DASH, Functional outcome.

INTRODUCTION

Clavicle fractures are common injuries seen among adults (2- 5%).[1] Fracture of the middle 1/3rd of clavicle constitutes for 70-80% of fractures, lateral end fracture contributes to 15-30% and medial end fractures contribute to 3% of fractures which are least common.

The Incidence was more during 3rd decade of life.[2] Nonoperative treatment is not valid in treating clavicular fractures with good functional outcomes.[3] In certain studies the non–union rate was reported as 15% in when treated conservatively.[4] Mid-shaft fractures treated with axial shortening cause non-union, and malunion.[5] Other symptoms include restricted shoulder movement, neurological complications, and protuberant callus is cosmetically unfavorable for the patient.

Patients with high activity levels and routine work may not accept the conservative treatment due to prolonged recovery time and restricted shoulder movements. Early fixation of the clavicle provides better shoulder functions and comfort to the patient. Surgical interventions for middle 1/3rd clavicle fracture include plate osteosynthesis fixation (POF) and intramedullary nailing like "TENS" nailing.

Open reduction and internal fixation (ORIF) with plating provide early functional recovery with less incidence of non-union and malunion. Non-surgical management is not considered optimum for managing clavicle fractures.

Surgical treatment of middle shaft fracture has less incidence of non-union compared to conservative treatment.[6]

Certain recent studies indicated that the incidence of nonunion and malunion rates in displaced middle 1/3rd clavicle fracture is around 15–20%, with low shoulder outcome scores if managed conservatively.[7,8,9] So, internal fixation of these fractures helps to to achieve early return of function. But Internal fixation of these fractures also has certain complications. Nonunion, skin irritation, implant breakage, paresthesia around surgical scar and infection are some common complications,[10,11] especially with plate fixations.

Aim & objectives

Aim

To know the functional outcomes of surgical management of middle third displaced clavicle fracture by ORIF with locking compression plate.

Objectives

1. To study efficacy of fixation by precontured Locking plate.
2. To assess the functional outcome of fracture clavicle with plate osteosysnthesis postoperatively.
3. To assess post operative complications associated with ORIF with LCP.

MATERIALS AND METHODS

The current study was conducted in the Department of Orthopaedics, NRI Institute of Medical Sciences, Visakhapatnam, Andhra Pradesh, India.

Study period: 16 months from August 2022 – November 2023

Type of study: prospective Interventional study

The study was interventional, as surgery was done to patients – that is treatment of middle 1/3rd of clavicular fractures using plate method

Source of data

After getting approval from the Ethics Committee, patients admitted at Orthopaedics ward at NRIIMS, Sangivalasa, Visakhapatnam with fractures of Middle 3rd clavicle were taken as study sample.

Sample size calculation

The incidence of clavicular fractures are 30 per 10,000 persons or 0.0003% as per the previous study.33

Sample size=N=Z2PQ/E2 N-sample size Prevalence= 0.0003%

P-Proportion E-Error:0.15 %

Confidence level:99.999% N=30

30 is the minimum sample size.

So, finally 30 patients were included.

Eligibility Criteria

Inclusion Criteria

1. middle third displaced clavicle fractures
2. Patients of age >18years and < 55years
3. Unilateral clavicle fractures
4. Displacement >2cm
5. Presence of Comminution

Exclusion Criteria

Patients who are

- Pathological fractures
- Open fractures
- Lateral end clavicle fractures
- Medial end clavicle fractures
- Patients with

1. Vascular injury
2. neurological deficit
3. Floating shoulder
4. Polytrauma patients

Methodology

- Demographics like age, gender, occupation were recorded.
- Thorough history from every patient was taken.
- History of trauma and associated injuries was taken.
- Details on comorbidities were noted.
- Blood and urine examinations were ordered as follows: Blood; Hb%, Bleeding time, Clotting time, Blood grouping and Cross matching, Fasting and Post prandial blood sugar, Blood urea and Serum **Creatinine. Urine:** Albumin, Sugar, Microscopic examination. Plain radigraph in ap view of affected shoulder with clavicle taken and Chest radiograph in necessary patients. All the patients were evaluated for associated medical problems and were referred

to respective department and treated accordingly.

- Associated injuries were evaluated and treated simultaneously. The patients were operated on elective basis after overcoming the avoidable anaesthetic risks.
- Specific investigations of all associated medical illness were carried out.
- Pre op anaesthetic fitness & physician fitness done.
- Adequate blood reserved in blood bank, Shaving of affected extremity, written informed consent of patient & relatives for internal fixation taken.
- All the patients were kept fasting overnight.

Operative Technique

Anesthesia

Under general anesthesia/ regional anesthesia.

Position and preparation

The patient is positioned in beach chair with a sandbag placed between medial boarder of scapula and spine.

Shoulder is then prepared and draped, and an incision is made over the site of the fractured clavicle.

Surgical approach (anterior approach):

Land marks and skin incision- sternal notch is the most medial landmark and ac joint is the most lateral landmark, make an incision following S - shape clavicular anatomy, beginning from medial end. length of the incision depends upon extend of the fracture.

The supra clavicular nerve branches were identified during the subcutaneous dissection and protected, which is usually difficult.

The platysma was divided to expose the clavicle periosteum at the deltotrapezial fascia

The periosteum was then minimally dissected to expose the fracture site. Bone fragments were not detached from the periosteum.

Plate was then kept in position (antero-superiorly) on the reduced bone and temporarily fixed with plate holding forceps.

The plate is secured over the bone on superior surface, aim for atleast 3 screws in medial and lateral fragments in most cases, ensuring preservation of soft tissue attachments.

Closure involved suturing the delto-trapezial fascia with interrupted number-1 absorbable sutures as a distinct layer, followed by skin closure.

Instruments and implants Used

1. 2.7mm drill bit
2. 3.5mm universal drill guide
3. 3.5mm precontured side specific locking compression plates
4. 3.5mm cortical screws (locking and non locking) of various lengths (12- 22mm).
5. 3.5mm Screwdriver
6. K wires
7. Instruments such as hohmann spike retractors and 3.5mm tap

POSTOPERATIVE CARE AND REHABILITATION

- The arm sling pouch given immediate post op for upto 2weeks.
- Pendulum movements of shoulder was started within two days with limb rested in arm sling.
- Sterile dressing were done on 2nd and 5th post op day
- Suture removal was done on the 12th to 14thpost operative day.
- After two weeks, the wound status was assessed and use of the sling was discontinued and active assisted range-of-motion exercises of the shoulder in the scapular plane were started.
- After four weeks, full active motion was initiated.
- When there were clinical and radiographic signs of union noted (usually at six to eight weeks), strengthening and resistive exercises of the rotator cuff, deltoid and trapezius were started.
- After clinical and radiological union, most patients were allowed to participate in sports activities usually by three to four months.
- All the patients were reviewed on 2nd week, 4th week and 12th week.
- At 3 months follow up, patients functional outcome were assessed using DASH questionnaire.
- Radiological evaluation of the union was done by taking serial x- rays. Radiological union was assumed to be achieved when there were bridging trabeculations across the fracture site on three of four cortices at the fracture line. Any changes in the alignment, screw pullout or implant failure were also noted. Functional outcome was based on DASH score.

Statistical Analysis

The data were entered into MS Excel 365 and analysis was done using Epi info version 7.2.6.0 free version. Frequencies and percentages were also used. Mean and SD was used. Categorical variables were assessed using chi square test.

Ethical considerations

Permission from the Institutional ethical committee attached to NRIIMS, Visakhapatnam was taken before conducting the study.

RESULTS

30% of the patients were aged 31 to 40 years, 26.67% were aged 21 to 30 years.

And mean age group is 35.06 years.

Table 1: AGE

AGE	Frequency	Percent
21 TO 30	8	26.67%
31 TO 40	9	30.00%
41 TO 50	7	23.33%

BELOW 20	2	6.67%
ABOVE 50	4	13.33%
Total	30	100.00%

30% of the patients were aged 31 to 40 years, 26.67% were aged 21 to 30 years.
And mean age group is 35.06 years

Table 2: Gender

GENDER	Frequency	Percent
M	27	90.00%
F	3	10.00%
Total	30	100.00%

In my study ,90% of the patients were males.

Table 3: Comorbidities

COMORBIDITIES	Frequency	Percent
CAD	1	3.33%
DM	4	13.33%
DM, HTN	1	3.33%
HTN	2	6.67%
NIL	21	70.00%
RA	1	3.33%
Total	30	100.00%

13.33% of the patients had DM, and HTN. 70% had no comorbidities.

Table 4: Mode of Injury

MODE OF INJURY	Frequency	Percent
SPORTS	1	3.33%
RTA	29	96.67%
Total	30	100.00%

96.67% of the patients had road traffic accident.
96.67% of the patients had road traffic accident.

Table 5: Duration of Surgery

DURATION OF SURGERY	Frequency	Percent
60-70 MIN	19	63.33%
70-80 MIN	9	30.00%
80-90 MIN	2	6.67%
Total	30	100.00%

63.33% of the patients underwent surgery for 60-70 mins.

Table 6: Laterality

LATERALITY	Frequency	Percent
LEFT	15	50.00%
RIGHT	15	50.00%
Total	30	100.00%

50% of the patients had right sided fracture of clavicle, and the remaining 50% with left sided fracture.

Table 7: AO/OTA TYPE

AO/OTA TYPE	Frequency	Percent
15.2A	5	16.67%
15.2B	7	23.33%
15.2C	18	60.00%
Total	30	100.00%

60% of the patients had 15.2C AO/OTA of fracture of clavicle.

Table 8: Association of minor injuries

ASSOCIATED INJURIES	Frequency	Percent
YES	8	26.67%
NO	22	73.33%
Total	30	100.00%

26.67% of the patients had associated minor injuries.

Table 9: RIB FRACTURES

RIB FRACTURES	Frequency	Percent
NO	25	83.33%
YES	5	16.67%
Total	30	100.00%

16.67% of the patients had associated RIB fractures.

Table 10: Union Time

UNION TIME	Frequency	Percent
9 to 10 weeks	10	33.33%
10 to 11weeks	9	30.00%
11 to 12 weeks	11	36.67%
Total	30	100.00%

Fracture union time was 11 to 12 weeks for 36.67% of patients.

NON-UNION

3.33% of the patients had non-union. In this study, if the fracture doesn't show progressive signs of healing for 3 consecutive months, this fracture is considered as non union. The U.S FDA (Food and Drugs Administration) defines nonunion as established when a minimum of 9months has elapsed since fracture with no visible progressive signs of healing for 3months.

Table 11: Non-Union

NONUNION	Frequency	Percent
NO	29	96.67%
YES	1	3.33%
Total	30	100.00%

Table 12: Superficial Infection

INFECTION	Frequency	Percent
YES	3	10.00%
NO	27	90.00%
Total	30	100.00%

10% of the patients developed infection postoperatively.

Table 13: Duration of HOSP Stay

DURATION OF HOSP STAY	Frequency	Percent
BELOW 7 DAYS	27	90.00%
MORE THAN 7 DAYS	3	10.00%
Total	30	100.00%

10% of the patients had more than 7 days of hospital stay.

Table 14: Age & Infection

	AGE					
INFECTION	21 TO 30	31 TO 40	41 TO 50	ABOVE 50	BELOW 20	Total
NO	8	9	7	1	2	27
YES	0	0	0	3	0	3
TOTAL	8	9	7	4	2	30

There is significant association between age & infection. Patients aged above 50 years developed infection.

Table 15: Age & Duration of HOSP Stay

	AGE					
DURATION OF HOSP STAY	21 TO 30	31 TO 40	41 TO 50	ABOVE 50	BELOW 20	Total
BELOW 1 WEEK	8	9	7	1	2	27
MORE THAN 7 DAYS	0	0	0	3	0	3
TOTAL	8	9	7	4	2	30

There is a significant association between age & duration of hosp stay. Duration of hospital stay was more among patients with advanced age.

Table 16: Dash score pre OP and post OP

	DASH BEFORE	DASH AFTER
Mean	66.4	15.2
Variance	67.28276	10.23448

Observations	30	30
Pooled Variance	38.75862	
Hypothesized Mean Difference	0	
df	58	
t Stat	31.85161	
P(T<=t) one-tail	0.000	

There is significant improvement in DASH score after surgery. Mean DASH scorebefore surgery was 66.4 and it was 15.2 after surgery.

DISCUSSION

The current study was done on 30 patients with displaced middle 1/3rd of clavicular fractures.

Approv et al,[12] did a prospective study involving 20 subjects treated for clavicle fractures and monitored for up to 2 years, all subjects underwent ORIF using precontoured plates and screws. Middle-third fractures were addressed with precontoured S-shaped plates, while lateral-third fractures received plates with lateral extensions.

On final follow-up, assessments were conducted using DASH score, Constant score, and Nottingham score. Mean age was 35.15 years, with the majority falling within the 15 to 30 age group. Among patients, 55% were male and 45% were female. Apoorv et al,[12] reported that the leading causes of injury were roadside accidents and falls from height. Similarly in my study the mean age is 35.06 years 96.67% had road traffic accident.

Dominique et al,[13] did a study to understand functional and anatomical outcomes following screw-plate fixation of displaced mid-shaft clavicular fractures with three or more fragments.

They conducted a comprehensive search of our database spanning from 2012, to 2016, which yielded 410 cases of clavicular fractures. Among these, 250 cases underwent surgical management, with 172 meeting the inclusion criteria and having complete data.

Most of the patients were males (154 patients, 89.5%). The left clavicle fractures were 51.5% and right clavicle fractures were 48.5% patients. In my present study also, most of the patients were males.50% had right sided fracture of clavicle and 50% had left sided clavicle fractures in the current study

Dominique et al13reported that among the cases, sports-related injuries consituted for 84.5%, with skiing (26%), cycling (21%), and mountain biking (18.5%) being the most common activities leading to fractures, while in the present study, RTA was the most common reason for injury.

3.33% had non-union at 12 weeks. 10% developed infection postoperatively. 10% had more than 7 days of hospital stay.

Hundekar et al,[14] did on 20 cases cases of middle 1/3rd clavicle fractures, characterized by displacement more than 2 cm, underwent treatment through ORIF using precontoured locking plates and screws. union was seen in all fractures in 10–16 weeks. In present study union is seen in majority of cases at 11 to 12 weeks There is significant improvement in DASH score after surgery. Mean DASH score before surgery was 66.4 and it was 15.2 after surgery in the current study.

Cristopher et al,[15] did a systematic review and Meta-Analyses guidelines. Their search included multiple databases and trial registries from their inception until March 2022.

Risk of bias and quality was assessed using ROB version 2 tool and ROBINS- I tool. Confidence in the estimates was rated and described as per recommendations provided by the GRADE working group.45 studies were included, and 43 were included in final subsequent meta-analysis. The nonunion rates stood at 3% for superior locking plates. Incidence of complications like hardware failure, nonunion, hardware irritation, wound dehiscence, superficial infection, keloid formation, deep infection, delayed union, malunion, and/or persistent pain and the rates varied from 3% to 17%. No cases of keloids, malunion, hardware irritation were seen in the present study. Non union was seen in 3% of patients but no difference in functinal outcome.

Pramod et al,[16] did a study on 40 Patients diagnosed with mid-shaft clavicle fractures showing displacement above 2 cm underwent treatment involving ORIF using pre-contoured locking plate. The functional outcome was assessed up to 3 months post-surgery. Radiological evidence of union was seen in 10-12 weeks.

van der ven denise,[17] (2015) studied plate fixation versus conservative treatment in displaced middle 3rd clavicle fractures to assess functional outcome and patient satisfaction.97 patients were included in the study, he reported that mean DASH score was significantly better 15.7 in operative patients.similarly the mean DASH score in my study is 15.2

Raghuraj kundanga,[18] (2019) studied clinical outcome of internal fixation of middle 3rd clavicle fractures (AO/ATO type 2) using LCP: comparison between open plating and MIPO.A total of 37 patients taken in the study, majority were with AO/OTA 15.2C type, mean duration of the surgery was 65.31 mins for open plating and 55.7mins for MIPO. he concluded that internal fixation of middle 3rd clavicle fractures with LCP is equally effective as open plating in terms of union rates and functional outcome.in my current study majority of the fractures were also of AO/OTA 15.2C type and 63.5% patients underwent 60 -70 mins surgery duration

Limitations

Single center study. Follow up was done for 6 months only Constant score was not assessed.

CONCLUSION

The current study was done on 30 patients with middle 1/3rd of clavicular fractures. This interventional study concluded that use of locking plates for displaced midshaft clavicle fractures results in union with very good functional outcome and is associated with low complication rates. All the patients were discharged in stable condition. A Interventional randomized prospective study is suggested to prove the superiority of operative management over conservative treatment.

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