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Analysis of Fracture Midshaft Clavicle Treated by Intramedullary Device Versus Conservative

Swapnil Date, Kiran Saoji, Kushal Surana*

J N Medical College, Datta Meghe Institute of Medical Sciences, Wardha-442001, Maharashtra, India

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ABSTRACT

Clavicle fractures account for about 2.6 to 4 % of all fractures. The best method to treat the displaced midshaft fracture of the clavicle remains a topic of debate. Although there is a large number of studies published about this topic, it is still relatively unknown as to which modality provides better long term functional outcomes and low complications rates. In our study, we have analyzed midshaft clavicle fracture treated with intramedullary device versus conservatively in terms of clinical, functional and radiological outcomes. The mean age of the patients in our study was 35.766 years. Male: Female ratio was 5.0:1.0. The mean time interval between injury and intervention was 2.1 days. Out of 30 patients, 11 patients (36.666%) had left sided fractures, while 19 patients (63.333%) had right sided fractures. Out of 30 patients, 12 patients (40%) had type 2B1 fracture according to Robinson's classification, followed by type 11 patients (36.666%) type 2B2, 6 patients (20%) type 2A1 and 1 patient (3.333%) type 2A2 fracture. Inoperative group, the mean Constant and Murley score before the intervention, at 1 month follow up, 3 months follow up and at 6 months follow up were 47.46, 76.73, 82.8 and 90.73, while in a conservative group, it was 47.53, 71.66, 79.2 and 89.46 respectively. Inoperative group, the mean Q-DASH score before the intervention, at 1 month follow up, 3 months follow up and at 6 months follow up were 29.33, 19.33, 16.86 and 13.8, while in a conservative group, it was 31.266, 22.533, 18.8 and 15.66 respectively. The final outcome, on the basis of the final Constant and Murley score in 13 patients (43.33%), was excellent, 11 patients (36.66%) was good and 6 patients (20%) was fair. Inoperative group, complications were seen in 6 patients (40%), while in the conservative group, complications were seen in 10 patients (66.66%). Thus, the functional, clinical and radiological outcome of the patients managed surgically with an intramedullary device was significantly better when compared with patients treated conservatively.

*Corresponding Author

Name: Kushal Surana
Phone: +917020863730
Email: kushmail13@gmail.com

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INTRODUCTION

Clavicle fractures account for about 2.6 to 4 % of all fractures (Crenshaw, 1992). It has an incidence of 29 to 64 cases per 100000 (Robinson, 1998). It accounts for 35 % of all injuries occurring to the shoulder girdle (Postacchini *et al.*, 2002). Male to female ratio of 7:1 (Robinson, 1998). The most commonly affected age group is less than 20 years (Postacchini *et al.*, 2002). The fracture most often results due to direct fall over the shoulder and less commonly due to falling on an outstretched

hand (Nowak *et al.*, 2000). These fractures are usually a result of violent collisions (contact sports) or high-speed falls (vehicular accidents) (Nordqvist and Petersson, 1994). Most clavicle fractures occur at the mid shaft (80 to 85 %), which is the thinnest part of bone and does not have many soft tissue attachments (Throckmorton and Kuhn, 2007). Historically the treatment of choice of most of the fractures of the clavicle, even with large displacement, has been non operative as it was thought that most of the fractures of the clavicle heal without any complications with non-operative treatment and the resulting bony prominence was believed to be better than the unsightly surgical scar. The malunited clavicle was suggested to be of radiological interest only (Neer, 1960) . It was thought that conservative management of clavicle fractures has a nonunion rate of less than 1% as compared with 4% of surgical management (Rowe, 1968).

However, recent studies have shown the opposite result. The result of conservatively treated clavicle fractures especially displaced, is not as favourable as thought earlier and the rate of nonunion is seen to be 10 to 15% (Nowak *et al.*, 2000). So the recent studies in which the clavicle fractures have been properly classified demonstrate high rates of nonunion, long duration pain and shoulder girdle weakness (Nordqvist and Petersson, 1994). In fractures with greater separations of the fragments and interposition of soft tissue, the closed reduction may be impossible (Hill *et al.*, 1997). All the fractures with an initial displacement of more than 2 cm lead to nonunion if treated conservatively (Narsaria *et al.*, 2014). So nowadays, surgery is being done more and more to treat clavicle fractures, as results with conservative management are seen to be poor functionally and radiologically (Wick *et al.*, 2001). Also, over the years, surgical techniques and instruments and implants used for surgical management have evolved tremendously owing to better results (Ledger *et al.*, 2005).

Limitations associated with conservative treatment are risk of nonunion, malunion, poor biomechanics of shoulder girdle, poor cosmesis and weakness of muscles of the shoulder girdle (Stanley *et al.*, 1988). These various factors have lead to an increase in the usage of surgical management in the treatment of clavicle fractures. Nowadays, surgery is being done more frequently to treat midshaft clavicle fractures, as outcomes with conservative management are seen to be poor functionally and radiologically (Canadian, 2007). Also, over the years, surgical techniques and instruments and implants used for surgical management have evolved tremendously owing to better results (Lewonowski and Bassett, 1992).

The best method to treat the displaced midshaft fracture of the clavicle remains unknown. Although many studies have been conducted regarding the topic, the method which gives better long term radiological and functional results is yet to be identified. But with shifting, trends and patients not only wanting the fracture union but also wanting better cosmesis and quicker return to the daily routine, surgical interventions are gaining popularity. We have chosen this topic for our study to develop a better understanding of both the methods for treatment for midshaft clavicle fractures regarding various outcomes, associated complications and to compare those. In our study, we have evaluated midshaft fractures of clavicle treated either conservatively or surgically in terms of clinical, radiological and functional outcome.

Aim

To compare outcomes of fracture midshaft clavicle treated conservatively and operatively with the intramedullary device.

Objective

The objectives of the study include,

To study following outcomes in fracture midshaft clavicle treated conservatively versus operatively with the intramedullary device,

1. Clinical
2. Radiological
3. Functional

MATERIALS AND METHODS

A prospective observational study of 30 patients with midshaft clavicle fracture managed either non-operatively or operatively on OPD and IPD basis in A.V.B.R Hospital, Sawangi, Meghe during the study period between May 2018 to October 2020.

Patients having midshaft clavicle fractures were enrolled after fulfilment of the inclusion and exclusion criteria and taking proper consent, after approval by Institutional Ethical Committee.

Study site

Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe).

Study population

Patients having midshaft clavicle fractures coming to Orthopedic OPD or casualty at A.V.B.R.H. Sawangi treated conservatively with a clavicle brace and arm pouch or surgically with the intra-medullary device.

Study design

Prospective observational study.

Time frame

Study duration was from May 2018-October 2020.

Inclusion criteria

Adults from 18 years and above with acute midshaft clavicle fracture. Patients are willing to participate in the study.

Exclusion criteria

Compound fractures associated with soft tissue injury, Fractures involving medial and lateral ends of the clavicle, Traumatic head injury patients and unconscious patients and Patients not willing to participate in the study.

Methodology

Pre-intervention assessment

The affected upper limb was immobilized with arm sling/pouch application immediately in the emergency department and necessary fluid resuscitation was started. Once the patient's condition was the stable further evaluation of injury and history taking was done. Patient details were noted using pre designed forms. A detailed history was taken, including mode and mechanism of injury. History of associated illnesses was enquired (Diabetes mellitus type II, Systemic hypertension etc.) and noted. Detailed general and systemic examination of the patient was done and noted. A detailed local examination was done to ascertain the site of clavicle fracture, deformity, displacement and other associated injuries. Plain AP radiographs of the shoulder with clavicle were taken for all the patients. Wherever suspected, special views were done to rule out associated injuries. Site of clavicle fractured, fracture pattern, comminution, displacements, associated fractures of scapula were noted based on X-Ray. Robinson's classification of diaphyseal fractures of the clavicle was used to classify all fractures (Robinson, 1998). Standard pre-operative workup was done, which included CBC, KFT and LFT, blood grouping, random blood sugar levels, Chest X-Ray and electrocardiograph.

Patients were operated on depending upon fitness for surgery and availability of the operation theatre. Pre-intervention functional assessment was done using Constant-Murley score (Constant, 1997) and Quick Disabilities of Arm Shoulder and Hand (Q-DASH) (Gummesson *et al.*, 2006). Pain assessment was done using Visual Analogue Score (VAS) of all the patients were noted (Cline *et al.*, 1992). Clavicle length of the fractured site and the normal site was measured and shortening was calculated and noted (Cunningham *et al.*, 2013). All this assessment was noted using predesigned proforma. Patients were then divided into 2 groups, i.e. conservative group and the surgical group and then were treated accordingly.

Intervention

Conservative Group

Patients in the conservative group were treated preferably on an outpatient basis. In cases of associated injuries, patients were admitted till the general condition improved. In this group, closed reduction of the clavicle fracture was made by immobilization with a clavicle brace and arm pouch. Post reduction, the position of the fractured fragments was confirmed under fluoroscopy guidance or with the help of a radiograph. In cases of minimal displacement, no attempt was made for reduction and a clavicle brace was applied as it is

Surgical group

Preoperative preparation of patients

Patients were not allowed orally 6 hours before the surgery. All complications related to surgical procedure and anaesthesia was explained to the patient and consent was taken. Required parts were prepared for surgery, i.e. whole affected upper limb (from shoulder to fingers), chest and axilla. Injection Cefriaxone 1000 mg IV was given to all the patients 30 minutes prior to surgery. Most surgeries were performed under general anesthesia, but wherever possible regional block was used.

Surgical technique

Before inducing the patients, the availability of Image Intensifier Television (IITV) and all the required instruments and implants (Screw intramedullary nail or J nail) were confirmed. Under suitable anaesthesia patient made to lie down supine on the OT table. A small bolster inserted beneath the opposite side scapula to make nail insertion easier. The entire affected upper limb from the chest with the clavicular region, shoulders to fingers was scrubbed, painted and draped. A nail length assessment was done before making the incision. All the surgeries were performed through a small incision of 2 cm taken over the medial end of the clavicle. Underlying soft tissue was dissected, including platysma, to reach the bone. Cortex was perforated using a bone owl and entry into the medullary canal was made.

Serial reaming of the medullary canal was done using reamers of 2,2.5 and 3 mm diameter. All the surgeries were performed by a minimum of 2 surgeons, reducing the fracture and main-

taining the reduction and other surgeons passing the intramedullary nail. The fracture was reduced by traction and manipulation and reduction maintained by one operating surgeon. The intramedullary nails were driven across the fracture site by another operating surgeon by rotating and advancing the nails. The nail was advanced till subchondral area distally and in the case of screw intramedullary nail, the nail was advanced till the threaded portion of the nail engages the metaphyseal area. All the surgeries were performed under Image Intensifier guidance. Fracture reduction and implant positioning were confirmed under image intensifier guidance by taking at least 3 views, i.e. 1 standard anteroposterior view, 1 axial view and oblique view. Wound closure and the dressing was done. In certain cases where gross comminution is seen or where anatomical reduction is not possible by closed manipulation, a mini open approach was taken. A small incision was given over the fracture site of approximately 3 to 5 cm and the fracture was then reduced and maintained using reduction clamps. All the intra-operative complications were noted. Also, duration of surgery, blood loss (calculated with the help of counting soaked mops), anaesthesia used, details of the implant used, length of the incision were also noted as secondary outcome measures.

Post-intervention protocol

Conservative Group

After the closed reduction and application of the clavicle, brace reduction was confirmed immediately with a check X-Ray or under image intensifier guidance. Patients with isolated clavicle fractures were discharged immediately from the hospital, while patients with polytrauma were admitted to the hospital till general condition improved and till management of the other injuries. Oral/systemic analgesics administered as required. Immobilization of the affected limb was done with the help of an arm pouch. Physiotherapy of the affected limb was started immediately. Gradual increment in the intensity of physiotherapy was done. Elbow, forearm, wrist mobilization was started immediately.

Operative group

Patients were not allowed orally 6 hours after the surgery. Injection Ceftriaxone 1000 mg IV BD was given for 2 days followed by Tablet Cefixime 200 mg 1 tablet BD for 3 days. Oral/systemic analgesics were administered as per requirement. Immobilization of the affected limb was done with the help of an arm pouch. A post-operative X-Ray was done on the 2^{nd} post-operative day when the pain got reduced. Check to dress of the wound done on the same day. Suture removal was done on the 10^{th} or 12^{th} day after the surgery, depending upon the condition of the wound. After suture removal, patients were discharged. Physiotherapy of the affected limb was started from 1^{st} day post-operatively. Gradual increments in the intensity of physiotherapy was done. Elbow, forearm, wrist mobilization was started from 1^{st} day post-operatively.

Follow up

Regular follow ups were done every month, i.e. 1^{st}, 2^{nd}, 3^{rd} and then 6^{th} month after surgery or till bony union. X-Rays were taken on every follow up to know the status of union and implant placement, as shown in Figures 1 and 3. Functional assessment of shoulder was done at every follow up with the help of Constant and Murley score and Q-DASH score, as shown in Figures 2 and 4. The final outcome was calculated with Constant and Murley scores. Assessment of the pain was done at every follow up with VAS. At final follow up the clavicle length of the affected side and normal side was again measured to know the final shortening. Also, at the final follow up, an anteroposterior radiograph of the chest was done to compare the lengths of both clavicles. Also, the parameters like duration of union, duration of return to work, patient satisfaction were also noted during the follow up period or final follow up. Any complications during the pre, intra and post-intervention period were noted. The final outcome assessment was done with Constant and Murley scores.

Implant removal

Implant removal was done in most of the cases after clinical and radiological fracture union. All the implant removals were done under local anaesthesia in the minor procedure room. A stab incision was given over the previous scar mark and implant removal done with the help of a screwdriver or t handle. Patients were discharged immediately after the procedure and were asked to come for suture removal after 10 days. Tablet Cefixime 200 mg 1 BD for 3 days was given along with oral analgesics as per the need.

Data analysis

Clinical and consequential data were documented using predesigned proforma. Results were judged based on observations during the pre and post-intervention period and a comparison was made between the 2 groups. The observations were graphically depicted with the help of data from the pre and post-intervention period and conclusions were derived based on observation and discussion. The data obtained were compiled in tabular form

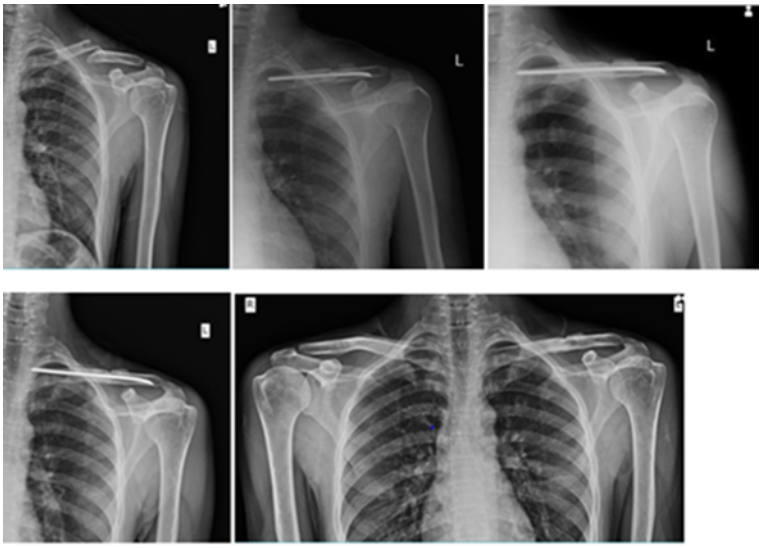


Figure 1: Plain radiographs before the intervention, at 1 month follow up, 3 months follow up, 6 months follow up and after implant removal of a case from the operative group

Figure 2: Shoulder range of motion at final follow up of a case from the operative group

and descriptive statistics were used to present the tabular form. Data analysed with the help of SPSS software and suitable statistical tests were applied wherever required.

OBSERVATIONS AND RESULTS

Age wise distribution

The mean age of the patients in our study was 35.766 years with a standard deviation of 10.798 with a range from 18 to 60 years. Most of the patients were from the age group 25 to 44 years, i.e. 19 patients (63.333%). The mean age of the patients in the operative group was 32.466 years with a standard deviation of 9.022 and 18 to 50 years. The mean age of the patients in the conservative group was 39.066 years with a standard deviation of 11.695 and range from 18 to 60 years (Table 7).

Gender wise distribution

In our study, out of 30 patients, 25 males (83.333%) and 5 females (16.666%). Male: Female ratio was 5.0:1.0. Inoperative group, there were 12 males (80%) and 3 females (20%) with a Male: Female ratio of 4.0:1.0. In the conservative group, there were 13 males (86.666%) and 2 females (13.333%). Male: Female ratio of 6.5:1.0 (Table 8).

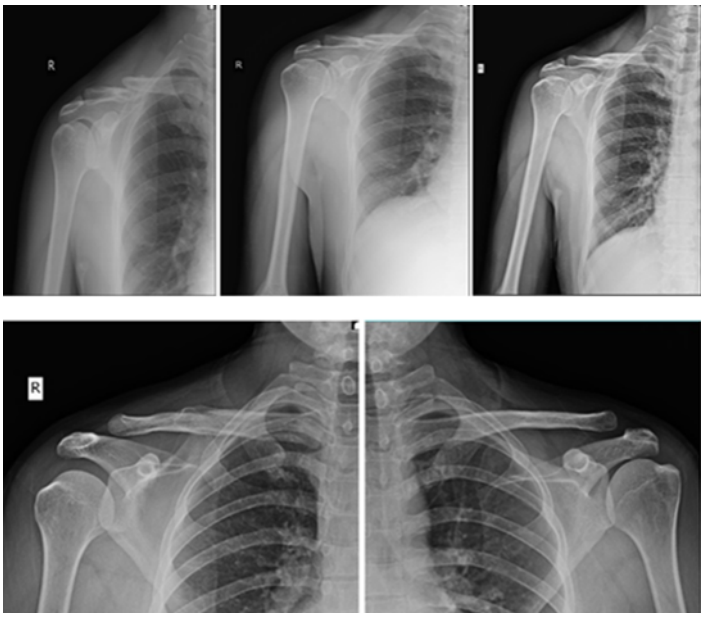


Figure 3: Plain radiographs before the intervention, at 1 month follow up, 3 months follow up and 6 months follow up of a case from the conservative group

Figure 4: Shoulder range of motion at final follow up of a case from the conservative group

Table 1: Comparison of age distribution of various studies

	Mean age (in years)		
Study Name	All patients	Conservative group	Operative group
Present study	35.766	39.066	32.466
Marinelli *et al.* (2017)		37.4	39.5
Eden *et al.* (2015)		41	34
Fu (2016)	33.3		
Gadegone and Lokhande (2018)	36.6		
Govindasamy *et al.* (2017)	30.6		

Table 2: Comparison of the gender distribution of various studies

	Male: Female ratio		
Study Name	All patients	Conservative group	Operative group
Present study	5.0:1.0	6.5:1.0	4.0:1.0
Marinelli *et al.* (2017)		5.0:1.0	13.0:1.0
Fu (2016)	5.0:1.0		
Gadegone and Lokhande (2018)	3.5:1.0		
Govindasamy *et al.* (2017)	2.6:1.0		

Table 3: Comparison of the affected side of various studies

	Side affected		
Study Name	Total no of patients	Right sided fractures	Left sided fractures
Present study	30	19	11
Marinelli *et al.* (2017)	58	25	33
Fu (2016)	36	22	14
Govindasamy *et al.* (2017)	54	28	26

Table 4: Comparison of mode of injuries of various studies

	Mode of injury				
Study name	Total no of patients	High velocity RTA	Low velocity RTA	Sports injury	Fall from height
Present study	30	25	3	0	2
Fu (2016)	36	16	10	10	0
Gadegone and Lokhande (2018)	36	21	0	3	12
Govindasamy *et al.* (2017)	60	35	6	0	19

Table 5: Comparison of type of fracture according to Robinson's classification

	Type of fracture according to Robinson's classification				
Study name	Total no of patients	Type 2A1	Type 2A2	Type 2B1	Type 2B2
Present study (Total patients)	30	6	1	12	11
Present study (Operative group)	15	0	0	6	9
Present study (conservative group)	15	6	1	6	2
Fu (2016)	36	0	4	32	0
Gadegone and Lokhande (2018)	36	0	2	18	16
Eden *et al.* (2015)	24	0	0	17	7
Eden *et al.* (2015)	37	0	0	24	13

Table 6: Comparison of Mean Constantand Murley scores at various follow up periods of various studies

	Mean Constant and Murley score		
Study name	1 month follow up	3 months follow up	Final follow up
Present study (Operative group)	76.73	82.8	90.73
Present study (conservative group)	71.66	79.2	89.46
Lars eden et al (Operative group)	84	92	97
Lars eden et al (conservative group)	73	86	91
Gadegone and Lokhande (2018)	71.80	83.63	94.0
Fu (2016)			93.389
Govindasamy *et al.* (2017)			97.8

Table 7: Age wise comparison of all the patients in operative and conservative group

Age (in years)	Operative group	Conservative group	Total
18-24	4(26.66%)	2(13.33%)	6(20%)
25-34	5(33.33%)	2(13.33%)	7(23.33%)
35-44	4(26.66%)	8(53.33%)	12(40%)
>44	2(13.33%)	3(20%)	5(16.66%)
Total	15	15	30

Table 8: Gender wise comparison of all the patients in operative and conservative group

Gender	Operative group	Conservative group	Total
Male	12(80%)	13(86.66%)	25(83.33%)
Female	3(20%)	2(13.33%)	5(16.66%)
Total	15	15	30
Ratio	4.0:1.0	6.5:1.0	5.0:1.0

Table 9: Comparison of interval between injury and intervention between operative and conservative groups

Time between injury and intervention	Operative group	Conservative group	Total
1 to 3 days	9	14	23
4 to 7 days	6	1	7
Total	15	15	30
Mean	3.266	0.933	2.1
SD	1.98	1.032	1.5
Range	1 to 6	1 to 3	1 to 7

Table 10: Comparison of types of fractures on basis of Robinson's classification between operative and conservative groups

Robinson's classification	Operative group	Conservative group	Total
2A1	0	6(40%)	6(20%)
2A2	0	1(6.66%)	1(3.33%)
2B1	6(40%)	6(40%)	12(40%)
2B2	9(60%)	2(13.33)	11(36.66%)
Total	15	15	30

Table 11: Comparison of the mean Constant and Murley scores before intervention and at various follow up periods in operative and conservative groups

Mean Constant and Murley scores				
Pre-intervention	1 month follow up	3 months follow up	6 moths follow up	Study name
47.46	76.73	82.8	90.73	Operative group
47.53	71.66	79.2	89.46	Conservative group
47.5	74.2	81	88.1	All patients

Table 12: Comparison of the mean Q-DASH scores before intervention and at various follow up periods in operative and conservative groups

Mean Q-DASH scores				
Pre-intervention	1 month follow up	3 months follow up	6 moths follow up	Study name
29.33	19.33	16.86	13.8	Operative group
31.266	22.533	18.8	15.66	Conservative group
30.3	21.233	17.833	14.733	All patients

Table 13: Comparison of the mean VAS scores before intervention and at various follow up periods inoperative and conservative groups

Mean VAS				
Pre-intervention	1 month follow up	3 months follow up	6 moths follow up	Study name
8.2	3.866	2.4	0.66	Operative group
7.66	3.86	2.2	0.866	Conservative group
7.933	3.86	2.3	0.766	All patients

Table 14: Comparison of final outcome between operative and conservative groups

Final outcome	Operative	Conservative	Total
Excellent	9(60%)	4(26.66%)	13(43.33%)
Good	5(33.33%)	6(40%)	11(36.66%)
Fair	1(6.66%)	5(33.33%)	6(20%)
Total	15	15	30

Interval between injury and intervention

In our study, the mean time interval between injury and intervention was 2.1 days with a standard deviation of 1.9 and a range of 1 to 7 days. Most of the patients, 24 (80%), were managed within 1 to 3 days. The mean time interval between injury and intervention in the operative group was 3.266 days with a standard deviation of 1.98 and a range of 1 to 6 days. The mean interval between injury and intervention was 0.933 days in a conservative group with a standard deviation of 1.032 and a range of 0 to 3 days Table 9.

Affected limb

Out of 30 patients, 11 patients (36.666%) had left sided fractures, while 19 patients (63.333%) had right sided fractures. Out of 30 patients, in

Table 15: Details of complications

Complications	Yes	No
Operative group	6(40%)	9(60%)
Conservative group	10(66.66%)	5(33.33%)
Total	16(53.33%)	14(46.66%)
Complications	**Number**	**Percentage**
Implant related complications	6	37.5
Malunion	6	37.5
Delayed union	1	6.25
Other	3	18.75
Total	16	100

29 patients (96.666%) right hand was dominant, while only 1 patient (4.333%) had a left dominant hand. In our study, out of 30 patients, 19 patients (63.333%) had dominant side fracture while 11 patients (36.666%) had non-dominant side fracture.

Distribution of mode of injury

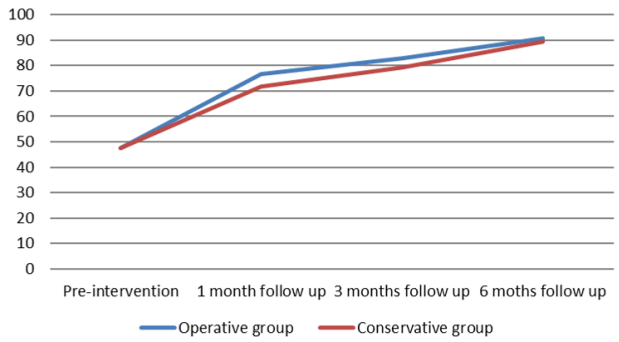
Out of 30 patients, in 25 patients (83.333%), the mode of injury was high velocity road traffic accident, followed by 3 patients (10%) due to low velocity road traffic accident and 2 patients (6.666%) due to falling from height.

Distribution of mechanism of injury

In our study, out of 30 patients, in 28 patients (93.333%), the mechanism of injury was direct blow to the shoulder. While in 2 patients (6.666%), it was fall on an outstretched hand.

Associated injuries

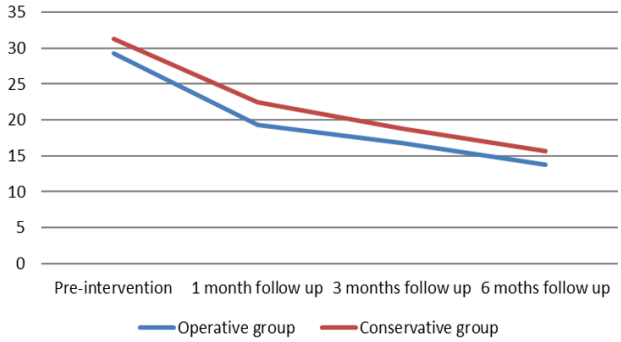
Out of 30 patients in our study, 19 (63.333%) had associated other injuries, while 11 (36.666%) didn't have any associated injuries. When associated injuries were divided region wise, it was seen that out of 19 patients with associated injuries, 8 patients (42.105%) had injuries to the head, neck and face region, followed by 5 patients (26.315%) who had injuries involving upper limbs, 3 patients (15.789%) had lower limb injuries and 3 (15.789%) had injuries to thorax and abdomen.



Graph 1: Comparison of the mean Constant and Murley scores before intervention and at various follow up periods in operative and conservative groups

Robinson's classification

Out of 30 patients, 12 patients (40%) had type 2B1 fracture according to Robinson's classification, followed by type 11 patients (36.666%) type 2B2, 6 patients (20%) type 2A1 and 1 patient (3.333%) type 2A2 fracture. Inoperative group, out of 15 patients, 9 (60%) had Type 2B2 fracture according to Robinson's classification and 6 (40%) had type 2B1. There were no patients having 2A1 and 2A2 type fractures. In conservative group, out of 15



Graph 2: Comparison of the meanQ-DASH scores before intervention and at various follow up periods in operative and conservative groups

patients, 6 (40%) had type 2A1 and 2B1 fracture while 2 (13.333%) had 2B2 while 1 (6.666%) had 2A2 type of fracture(Table 10).

Constant and Murley score

In our study, the mean Constant and Murley score of all patients before the intervention, at 1 month, 3months and 6 months follow up, were 47.5, 74.2, 81 and 88.1, respectively. Paired t test showed that the Constant and Murley score increased significantly at different time intervals in all the patients. Inoperative group, the mean Constant and Murley score before the intervention, at 1 month follow up, 3 months follow up and at 6 months follow up were 47.46, 76.73, 82.8 and 90.73, while in a conservative group, it was 47.53, 71.66, 79.2 and 89.46 respectively as shown in Table 11. Paired t test was applied to these variables. It showed that Constant and Murley score increased significantly at different time intervals in both operative and conservative groups. The mean Constant and Murley scores of the operative group were significantly higher than the conservative group at all the follow ups. When the graph was plotted, it was noted that there was a large difference in mean Constant and Murley score at 1 month and 3 months follow up in both the groups as compared to 6 months follow up (Graph 1).

Mean Q-DASH score

The mean Q-DASH scores of all the patients in our study before the intervention, at 1 month follow up, 3 months follow up and 6 months follow up were 30.3, 21.233, 17.833 and 14.733, respectively. Paired t test was applied to these variables. It showed that Q-DASH scores decreased significantly at different time intervals in both the operative and conservative groups. Inoperative group, the mean Q-DASH score before the intervention, at 1 month follow up, 3 months follow up and at 6 months follow up were 29.33, 19.33, 16.86 and 13.8, while in a conservative group, it was 31.266, 22.533, 18.8 and

15.66 respectively as shown in Table 12. Paired t test was applied to these variables. It showed that Q-DASH scores decreased significantly at different time intervals in both the operative and conservative groups. The mean Q-DASH scores of the operative group were significantly lower than the conservative group at all the follow ups (Graph 2).

Mean VAS

In our study, the mean VAS of all the patients before the intervention, at 1 month follow up, 3 months follow up and at 6 months follow up were 7.933, 3.866, 2.3 and 0.766, respectively. Paired t test was applied to these variables. It showed that VAS decreased significantly at different time intervals in both operative and conservative groups. Inoperative group, the mean Vas before the intervention, at 1 month follow up, at 3 months follow up and at 6 months follow up were 8.3, 3.866, 2.4 and 0.66, while in a conservative group, it was 7.66, 3.86, 2.2 and 0.86 respectively as shown in Table 13. Paired t test was applied to these variables. It showed that VAS decreased significantly at different time intervals in both the operative and conservative groups. When the means of both the groups were compared, there was no significant difference in both groups at different time intervals.

Clavicle shortening

In our study, the mean clavicle shortening in all the patients before intervention and at 6 months follow up was 1.313 and 0.5, respectively. Paired t test was applied and it was seen that there is a significant reduction in clavicle shortening with intervention in all the patients. Inoperative group, pre-intervention and 6 months follow up mean shortening were 1.753 and 0.146, while in a conservative group, it was 0.873 and 0.853. Paired t test showed that there was a significance reduction in clavicle shortening in the operative group as compared to a conservative group. Thus in the operative group, there was a better restoration of the length of the clavicle.

Duration of union

In our study, the mean duration of the union of all patients was 4.066 months. Inoperative group, it was 3.6 months, while in the conservative group, it was 4.533 months. Chi squared test was applied and it was seen that the duration of the union of the operative group is significantly shorter in the operative group compared to the conservative group.

Duration of return to work

In our study, the mean duration of return to work in all patients was 3.466 months. In the operative group, it was 2.866 months, while in the conservative group, it was 4.066 months. So patients managed surgically with intramedullary devices returned to work earlier as compared to patients managed conservatively.

Patient satisfaction

In our study, 14 patients (46.666%) patients had excellent satisfaction, 12 (40%) had good, 3 (10%) fair while 1 (3.333%) poor. In operative group, 10 patients (75%) had excellent satisfaction, 4 (20%) good while 1(5%) had poor satisfaction. In conservative group, 4(26.66%) excellent, 8(53.33%) good and 3(20%) fair satisfaction.

Final Outcome

The final outcome, on the basis of the final Constant and Murley score in 13 patients (43.33%), was excellent, 11 patients (36.66%) was good and 6 patients (20%) was fair. Inoperative group, the outcome in 9 patients (60%) was excellent, 5 patients (33.33%) was good and 1 patient (6.66%) was fair. In the conservative group, the outcome in 4 patients (26.66%) was excellent, 6 patients (40%) was good and in 5 patients (33.33%) was fair, as shown in Table 14. Chi square test was applied to these variables and p value was 0.00553, suggesting that the outcome was significantly better in the operative group.

Complications

Out of 30 patients in our study, complications were seen in 16 (53.333%), while in 14 patients (46.666%), there were no complications. Inoperative group, complications were seen in 6 patients (40%), while in the conservative group, complications were seen in 10 patients (66.66%). The complications rate was significantly higher in the conservative group as compared to the operative group. Among complications, 6 patients (37.5%) had implant related complications, 6 (37.5%) mal union, 1 (6.25%) delayed union, 3 (18.75%) other complications. Various complications seen in our study are shown in Table 15.

Hospital stay

In our study, the mean hospital stay in all patients was 6 days. Inoperative group, it was 10.933 days, while in the conservative group, it was 1.066 days. Statistical test was applied, which showed that hospital stay was significantly shorter in the conservative group.

Details of surgical group

Out of 15 patients from the operative group, in 9 patients (60%), open reduction of the fracture was required, while in 6 patients (40%), closed reduction of the fracture was achieved. This proportion

was significantly higher. Out of 15 patients in the operative group, 11 (73.33%) were operated under general anaesthesia, while 4 (16.66%) were operated under the regional block. The mean duration of surgery was 54 minutes with a standard deviation of 11.054 minutes. The mean length of the incision required was 3.8 cm with a standard deviation of 1.897cm. Out of 15 patients, in 10 patients (66.66%), screw intramedullary nail was used, while in 5 patients (33.33%), J nail was used. The mean blood loss was 67.333 ml with a standard deviation of 23.744 ml. Out of 15 patients from the operative group, intra-operative complications were seen in 8 patients (53.33%), out of which in 7 patients, difficulty in closed reduction was seen and in 1 patient, inability to reduce anatomically.

Implant removal

Out of 15 patients, implant removal was done in 8 (46.66%) patients during the duration of the study. Most common reason for implant removal being medial skin irritation in 4 patients (50%), followed by elective in 3 patients (37.5%) and due to implant back out in 1 patient (12.5%). The mean duration of implant removal in our study was 5.5 months with a standard deviation of 2.39 months.

Comparison of outcome with different variables

Comparison of outcome with age

When the test of significance was applied, it was seen that the proportion of patients with an excellent outcome in the operative group from the age group 25 to 44 years was significantly higher than the other age groups. When the test of significance was applied to these variables, it was seen that there was no significant difference in the outcomes of various age groups in the conservative group.

Comparison of outcome with gender

When the test of significance was applied, it was seen that there was no significant difference in outcomes of different genders.

Comparison of outcome with time between injury and intervention

When the test of significance was applied to these variables, it was seen that there was no statistically significant difference in the outcomes of the patients with different intervals between injury and intervention in the operative and conservative groups.

Comparison of outcome with the type of fracture according to Robinson's classification

When the test of significance was applied to these variables of the conservative group, it was seen that the proportion of patients with the excellent outcome with fracture type 2A1 according to Robinson's classification was significantly high as compared with other fracture types. When the test of significance was applied to these variables of the operative group, it was seen that number of patients with excellent to a good outcome with fracture type 2B2 was significantly higher than the other fracture types.

Comparison of outcome with initial clavicle shortening

When the test of significance was applied to these variables, it was seen that the proportion of patients with excellent to good results is significantly higher in the patients with initial shortening <1 cm as compared to the patients with initial shortening of >1 cm in the conservative group. When the test of significance was applied to these variables, it was seen that there was a significant difference in the proportion of the patients with excellent to good outcomes with various initial clavicle shortening.

DISCUSSION

The present study of patients with midshaft clavicle fractures was compared with a study in which 36 patients with midshaft clavicle fracture were treated with screw intramedullary nail (Gadegone and Lokhande, 2018). Out of 58 patients with a midshaft clavicle fracture, 30 were treated with conservative management and 28 with intramedullary nailing (Marinelli *et al.*, 2017).

A study in which out of 61 patients with midshaft clavicle fractures, 37 were treated conservatively and 24 with the intramedullary device (Eden *et al.*, 2015).

36 patients of displaced midshaft clavicle fracture were treated with intramedullary nailing (Fu, 2016). A study in which 54 patients with midshaft clavicle fracture were treated with intramedullary nailing (Govindasamy *et al.*, 2017).

Interval between injury and intervention

In our study, the mean time interval between injury and intervention was 2.1 days with standard deviation of 1.9 and range of 0 to 7 days.

The mean time interval between injury and intervention in the operative group was 3.266 days with standard deviation of 1.98 and range of 1 to 6 days.

The mean interval between injury and intervention was 0.933 days in the conservative group with standard deviation of 1.032 and range of 0 to 3 days.

Fu (2016) referred that, All the surgeries were carried out within 7 days. Gadegone and Lokhande (2018) referred that, All the patients underwent surgeries within 1^{st} 10 days.

Clavicle shortening

In our study, the mean clavicle shortening in all the patients before intervention and at 6 months follow up was 1.313 and 0.5, respectively. Paired t test was applied and it was seen that there is a significant reduction in clavicle shortening with intervention in all the patients. In the operative group, pre-intervention and 6 months follow up mean shortening were 1.753 and 0.146, while in a conservative group, it was 0.873 and 0.853.

In Marinelli *et al.* (2017) referred that, Inoperative group in 25 patients, there was statistically significant improvement of the shortening while in 3 patients there wasn't. There was no patients with shortening more than 2 cm at final follow up. In the conservative group, 23 patients didn't have any improvement in shortening, while improvement was seen in only 6 patients.

In Gadegone and Lokhande (2018) referred that, out of 36 patients, a shortening of 3 to 5mm was seen in 10 patients.

Govindasamy *et al.* (2017) referred that, out of 60 patients, there was clavicle shortening of 1 cm in 6 patients (21%) and 0.5 cm in 4 patients (14%). Rest of the patients, there was no shortening post-operatively.

Duration of union

In our study, the mean duration of the union of all patients was 4.066 months. In the operative group, it was 3.6 months, while in the conservative group, it was 4.533 months.

Fu (2016) referred that, the mean union time was 11.583 $\pm$ 2.729 weeks. Gadegone and Lokhande (2018) referred that, Out of 36 patients, 31 achieved union by 11.3 weeks while 5 required more than 16 weeks. Govindasamy *et al.* (2017) referred that, The mean fracture union time was 7.5 weeks.

Duration of return to work

In our study, the mean duration of return to work in all patients was 3.466 months. In operative group, it was 2.866 months, while in the conservative group, it was 4.066 months.

Marinelli *et al.* (2017) the mean duration of return to work in the conservative group was 6 months, while in the operative group, it was 3 months. Eden *et al.* (2015) referred that, the average duration of return to work in the conservative group was 9.4 weeks, while in the operative group, it was 4.5 weeks.

Complications

Out of 30 patients in our study, complications were seen in 16 (53.333%), while in 14 patients (46.666%), there were no complications. Inoperative group, complications were seen in 6 patients (40%), while in the conservative group, complications were seen in 10 patients (66.66%). The complications rate was significantly higher in the conservative group as compared to the operative group. Among complications, 6 patients (37.5%) had implant related complications, 6 (37.5%) mal union, 1 (6.25%) delayed union, 3 (18.75%) other complications like shoulder stiffness.

Marinelli *et al.* (2017) referred that, there were no major complications. 1 case (3.33%) of non union seen in the conservative group. 1 case (3.57%) of superficial infection and hypertrophic scar, each seen in the operative group. 3 cases (10.71%) of persistent pain at the fracture site seen. Lars eden et al., referred that, 2 cases of the non union were noted in the conservative group (out of which 1 required surgical intervention). 1 case of non union (requiring surgical intervention), 1 case of delayed union, 2 cases requiring early implant removal due to displaced implants and 2 cases of the prominent nail (1 requiring surgical trimming of the nail under local anaesthesia) were seen operative group.

Fu (2016) referred that, 2 cases with persistent pain at the back of the shoulder, 1 case of the prominence of the nail, 1 case of cortical splitting at the insertion of nail and 1 case of postoperative shoulder stiffness were noted. Gadegone and Lokhande (2018) referred that, Out of 36, 11 patients had complications like 3 patients with a prominence of the nail at sternoclavicular joint, 5 patients with delayed union and 3 patients with shoulder stiffness. Govindasamy *et al.* (2017) referred that, Out of 54 patients, 15 (27%) had medial skin irritation, 3 (5.6%) had superficial skin infection at the site of the entry, 1 case had lateral implant migration, while 5 cases had local numbness at the site of the entry of the nail which resolved on its own by 3 weeks. So our study is comparable with other similar studies.

CONCLUSIONS

In our study, we have compared the outcome of midshaft clavicle fractures treated surgically using an intramedullary device with those treated conservatively. Following conclusions were drawn: Patients treated operatively with the intramedullary device had better functional outcomes than those treated conservatively in mean Constant and Murley scores, mean Q-DASH scores and mean VAS at various follow ups. In patients treated operatively, there was a better restoration of clavicle length than those treated conservatively. Midshaft clavicle fractures treated operatively with intramedullary

devices united more rapidly as compared to those managed conservatively. Patients managed surgically with intramedullary devices returned to work earlier as compared to patients managed conservatively. Patients in the operative group had better satisfaction in terms of cosmesis and functional outcome than the patients in the conservative group. The proportion of patients with excellent to good outcomes was higher in an operative group than that of the conservative group. The radiological outcome was better in an operative group than the conservative group as cases of malunion and clavicle shortening were significantly less in the operative group. Finally, comparing the complications, the complications rate was significantly higher in the conservative group as compared to the operative group. Thus, the functional, clinical and radiological outcome of the patients managed surgically with an intramedullary device was significantly better when compared with patients treated conservatively.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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