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Mid Shaft Clavicle Fractures in Adults – Conservative Treatment no more a Gold Standard Care

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Abstract **Original Research Article**

Most of the displaced midshaft clavicular fractures (DMCF) with shortening in adults will unite with non-operative treatment but studies have reported shoulder dysfunction and patient dissatisfaction with high prevalence of malunion, nonunion and cosmetic deformity. ***Objectives:*** The present study is undertaken with a primary objective of comparing these parameters among non-operated and operated patients and draw evidence based conclusions. The secondary objective was to find out the incidence, and appraise the real burden of DMCF among all fractures attending orthopedic emergency department. ***Methods:*** During the study 98 mid shaft clavicular fractures with displacement of ≥1.5 cm in adults were studied. After applying exclusion criteria 62 remained in the study. They were randomized in to 2 groups. Group-I was treated by non-operative management and Group-II by operative treatment. 25 patients from Group-I and 28 from Group-II were followed up at 3 months, 6 months and 9-12 months and reviewed with radiographs and DASH scoring system. Complications noted during the reviews were documented. At the final review final radiographs and DASH scores were analyzed statistically using the Chi-square test/Fisher's test. ***Results:*** The DASH scores measured at 3 and 6 months were significantly better in the Group-II than in the Group-I, whereas the DASH scores of Group –II and Group –I at the end of 9-12 months were almost similar. Union rates at the end of 3 months were significantly better in Group-II. At the end of 9-12 months the difference in the union rates of Group-II and Group - I were statistically not significant. At the end of 3 months 32% of Group-I and 7% of Group-II had non-union which reduced to 16% and 4% respectively by the end of 9-12 months. Other complications observed in the Group-1were malunion in 32% cases, shortening of clavicle in 24% and bony prominence in 60%. ***Conclusions:*** Early primary plate fixation of DMCF results in: Improved patient-oriented outcomes, earlier return to function, decreased rates of nonunion, malunion, shortening and bony prominence, and improved range of movements at shoulder. Therefore we feel operative treatment is the gold standard treatment for DMCF in adults when the displacement is ≥1.5 cm.

Key words: Displaced - Midshaft fracture clavicle in adults – Surgery - Gold standard.

INTRODUCTION

"When, a clavicle fracture has recently taken place, the patients attach much importance to it, as supposing the mischief greater than it really is, and the physicians bestow great pains in order that it may be properly bandaged; but in a little time the patients, having no pain, no impediment to their walking or eating, become negligent; and the physicians finding they cannot make the parts look well, take themselves off, and are not sorry at the neglect of the patient, and in the meantime the callus is quickly formed" – Hippocrates.

Clavicle 'the little key' serves as the only rigid support that suspends the scapula and upper limb, locks the humerus at certain distance from the thorax to enhance the range of motion of the shoulder girdle and acts as a flexible, crane like strut that transmits the physical impact from the upper limb to the axial skeleton. Being the least protected bone by muscle or fat, clavicle is the most commonly broken bone in the human body accounting for 5% to 10% of all fractures seen in hospital emergency department [1-3]. Because of thin cortex (mean cortical thickness of 2.05 mm) and the slight curve of middle third of clavicle, 80% of clavicle fractures involves mid shaft, often seen in young active males following direct blow to shoulder as in motor vehicle accidents, sport related injuries rather than fall on out stretched arm [4, 5]. Mid shaft fractures are usually complete and are either oblique or transverse though often multifragmentary. These

fractures primarily occurs lateral to sternocledomastoid muscle and medial to coraco-clavicular ligaments, medial fragment rotates superiorly and posteriorly due to the sternocledomastoid and the lateral fragment is pulled inferiorly and rotated anteriorly by the weight of the shoulder. The pull of the trapezius, pectoralis, and latissimus on the shoulder medially, shortens the fractured clavicle [6-8]. In 73% of cases midshaft fractures are displaced without any contact of the bone fragments [9]. As a consequence fractures of clavicle are prone to malunion, nonunion and or shortening combined with restricted shoulder function, obvious deformities and imminent danger of skin perforation [10, 11].

Most of the displaced midshaft clavicular fractures (DMCF) generally unite with immobilization and so non-operative treatment was considered the gold standard of care for these fractures. This policy was based on studies conducted in 1960s, which reported nonunion percentage of 0.1-0.8% among non-operatively treated patients and 3.7-4.6% in operatively treated patients [12, 13]. These studies had a large number of patients, but the inclusion of children makes it difficult to consider them applicable to adults. More recent studies have shown a nonunion rate of 15-18% in non-operated and healing with good union rates of 97-100% among operatively treated displaced mid shaft clavicular fractures [14, 15]. Studies also demonstrated that displaced midshaft clavicle fractures treated non-operatively have a lower functional ability and 30 to 50% dissatisfaction rate with the appearance or function of patient's shoulders [14, 16].

Though number of studies has assessed the effectiveness of operative versus non-operative treatment the results are inconsistent and inconclusive with regards to complications like malunion, nonunion, shortening and functional outcome. Therefore the present study is undertaken with a primary objective to compare these parameters among operated and non-operated patients with DMCF and draw evidence based conclusions. The secondary objective was to find out the incidence of DMCF and to appraise the real burden of DMCF among all fractures attending orthopedic emergency department.

PATIENTS AND METHODS

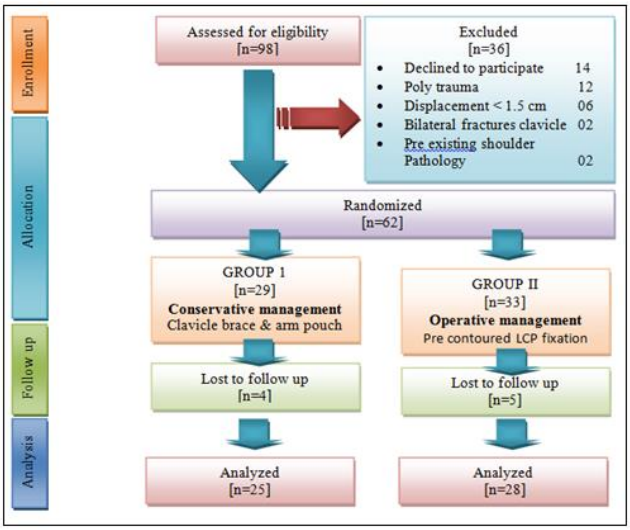

Fig-1: Methodology

Present study is a prospective, observational, cross sectional, cohort study conducted on economically productive adults with displaced midshaft fracture clavicle (DMFC) admitted in the Department of Orthopedic Surgery of Rajiv Gandhi Institute of Medical Sciences Hospital, Kadapa - a tertiary care teaching hospital serving the Rayalaseema region of South India. The study was conducted over a period of 3 years from January 2016 to December 2018.

The inclusion criteria were: 1) Age >20 yrs and <40. 2) Closed mid shaft clavicle fractures with displacement of 1.5 to 2 cm. and the exclusion criteria were: 1) Age < 20 yrs and >40, 2) Lateral third, medial third and open fractures of clavicle, 3) Pathological fractures, 4) Undisplaced / displacement <1.5 cm mid shaft fractures, 5) Fractures associated with head injury, 6) Fractures associated with neurovascular injury, 7) Fractures associated with acromio-clavicular joint dislocation, 8) Bilateral clavicle fractures, 9) Ipsilateral upper limb injuries 10) Preexisting shoulder pathology.

During the study period a total of 98 patients with acute DMCF in the age group of 20-40 years were studied. After applying exclusion criteria 62 patients remained. These patients were randomized into 2 groups after explaining both the methods of management and obtaining consent from them to be a part of either of the groups. Group-I consisted of 29 patients and was managed non-operatively by applying

clavicle brace and arm pouch and immobilization. Mobilization and physiotherapy exercises were advised at 6 weeks. Group-II consisted of 33 patients and was managed operatively under inter scalene block. The postoperative protocol included immobilization arm on an arm pouch for a period of three weeks. Suture removal was done on 10th postoperative day and shoulder mobilization and physiotherapy exercises were begun at 4 weeks. The surgical technique involved positioning the patient in a beach chair position by placing pillow between the two scapulae. The skin incision was centered over the fracture extending from the sternal notch to the anterior edge of acromion. The lateral platysma was released and clavipectoral facia was incised along its attachment. Dissection was performed along the fragment and the fracture site was exposed. The reduction was performed and held temporarily with k wire. A seven or eight holes pre contoured locking compression plate (LCP) was selected and fixed with minimum of 3 screws inserted on either side of the fracture. Wound was closed in layers. 25 patients from Group-I and 28 from Group-II were followed up at 3 months, 6 months and between 9 and 12 months and reviewed with radiographs and Disabilities of the Arm, Shoulder, and Hand (DASH) scoring system. 4 patients from Group-I and 5 from Group-II were lost during follow up. Complications noted during the reviews were documented. At the time of the final review the final radiographs and DASH scores were analyzed statistically using the Chi-square test/Fisher's test. Ethical clearance was obtained from institutional ethical committee. No source of funding and no conflict of interest involved in the study.

RESULTS

During the study period a total of 5252 patients with fractures attended the orthopedic emergency department of this institution. Of these 268 patients presented with acute fracture clavicle. Among them 228 patients had fracture middle third of clavicle and of these 170 presented with displacement. 98 patients with DMCF were reported in the age group of 20 to 40 years. After applying exclusion criteria 62 patients remained in the study group; 29 in Group – I [Conservative] and 33 in Group II [Operative] [Table – 1].

Table-1: Incidence of Fracture Clavicle

1	Total number of patients admitted with fractures during the study period	5252 [100%]
2	Patients with fracture clavicle	268 [5%]
3	Patients with fracture middle third of clavicle	228 [85%]
4	Patients with fracture lateral third of clavicle	28 [10.5%]
5	Patients with fracture medial third of clavicle	12 [4.5%]
6	Patients with fracture middle third of clavicle with displacement	170 [75%]
7	Patients with fracture middle third of clavicle with displacement in the age group of 20-40 years	98 [58% of 170]

Table-2: Demographic Variables

SNO	Parameter	Group-I [n=29]		Group-II [n=33]		P - Value
1	Age	Mean	SD	Mean	SD	0.5600
		27.82	± 5.50	27.40	± 3.64	
2	Gender	Male	Female	Male	Female	0.7626
		24 [83%]	2 [17%]	27 [82%]	3 [18%]	
3	Side	Right	Left	Right	Left	0.9061
		18 [62%]	11 [38%]	20 [61%]	13 [39%]	
		Dominant	Non dominant	Dominant	Non dominant	0.8242
		15 [52%]	14 [48%]	18 55%]	15 [45%]	

Demographic variables like age, gender and side of fracture among both the groups were comparable. The findings in Group-I and Group-II respectively were as follows: mean age with standard deviation 27.82 ± 5.50 vs. 27.40 ± 3.64 with P-value 0.5600; gender wise males 24 [83%], females 2 [17%] vs. 27 [82%] males, 3 [18%] females with p-value 0.7626; side wise right 18 [62%], left 11 [38%] vs. 20 [61%] right, 13 [39%] left with P-value 0.9061; dominant 15 [52%], non-dominant 14 [48%] vs. 18 55%] dominant, 15 [45%] non dominant with P-value 0.8242. P-values of all the variables were statistically not significant indicating both the groups were comparable as far as demographic variables are concerned [Table - 2].

4 patients from Group-I and 5 from Group-II were lost during follow up. Remaining 25 patients of Group -I and 28 of Group-II were followed up at 3 months, 6 months and 9-12 months. At the end of 3 months the DASH score was 28 [inter quartile range 20-50] for Group-I and 16 [inter quartile range 9-32] for Group-II. The DASH scores measured at 3 months were significantly better in the Group-II (operative group) than in the Group-I (non operative group): 16 [inter quartile range 9-32] vs. 28 [inter quartile range 20-50] respectively with P-value of <0.001. DASH scores measured at 6 months were also better in the Group -II than in the Group-I: 5 [1.5-14] vs. 9 [2.5-23.3] respectively with P – value of <0.001. Whereas the

DASH scores of Group-II and Group-I at the end of 9-12 months were almost similar with statistically no significant difference: 1.5 [0-5] vs. 2.5 [0-8]; [P- value 0.123] [Table – 3][Figure – 2].

Table-3: Comparison of DASH Scores at 3 months, 6 months and 9-12 months

Treatment	Follow up					
	3 Months		6 Months		9 -12 Months	
	Median	Inter-quartile Range	Median	Inter-quartile Range	Median	Inter-quartile Range
Group – I [n=25]	28	20-50	9	2.5-23.3	2.5	0-8
Group – II [n=28]	16	9-32	5	1.5-14	1.5	0-5
P-value	<0.001*		<0.001*		0.123*	

*Differences in median estimated using quartile regression

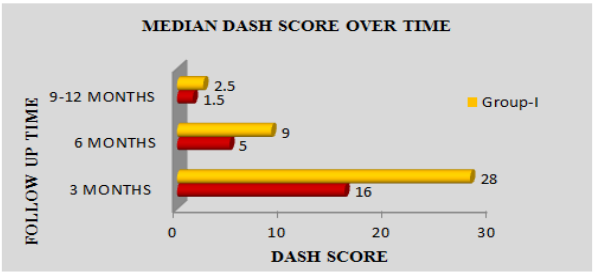

Fig-2: Median DASH score over time

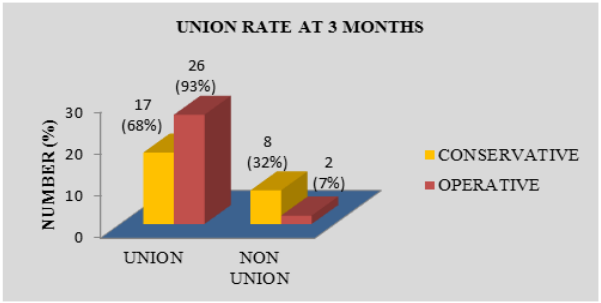

Fig-3-A: Union rate after 3 months

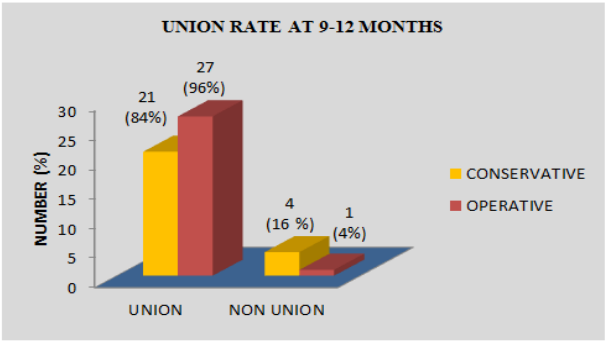

Fig-3-B: Union rate after 9-12 months

Table- 4: Comparison of union rate at 3 months and 9-12 month

Time after treatment	Radiological evaluation for union		P-value
	Union	Non-union	
3 months			
Group - I [n=25]	17 [68%]	8 [32%]	0.0296*
Group - II [n=28]	26 [93%]	2 [07%]	0.0335**
9-12 months			
Group - I [n=25]	21 [84%]	4 [16%]	0.1234*
Group - II [n=28]	27 [96%]	1 [04%]	0.1761**

*Fisher's exact hyper geometric probability
**Fisher's exact two-tailed probability

Union rates at the end of 3 months were significantly better in Group-II compared to Group-I: 28 [93%] vs. 17 [68%]; [P-value 0.0296]. At the end of 9-12 months the difference in the union rates of Group-II and Group-I was statistically not significant: 27 [96%] vs. 21 [84%]; [P-value 0.1234]. At the end of 3 months 8 [32%] of Group-I and 2 [7%] of Group -II had non-union which reduced to 4 [16%] and 1 [4%] respectively by the end of 9-12 months. Other complications observed in the Group-1were malunion in 8 [32%] cases, shortening of clavicle in 6 [24%] and bony prominence in 15 [60%]. In Group-II one patient with non-union required reoperation for loss of fixation and the patient subsequently had union. There were no surgical site infections in this study] [Figure – 3-A& B] [Table – 4].

Patient satisfaction rate at the end of 3 months and 6 months was significantly better in Group-II compared to Group-I [P-value <0.0001 and 0.0006 respectively] At the end of 9-12 months patient satisfaction rates among Group-II and Group-I were similar and the difference was not significant statistically. [P-value 0.072][Figure – 4] [Table –5].

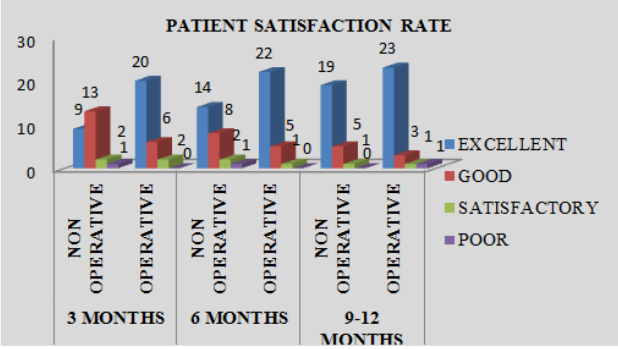

Fig-4: Patient satisfaction

Table - 5: Patient satisfaction

Time of evaluation	Patient satisfaction [Number/Percentage]				P-Value
	Excellent	Good	Satisfactory	Poor	
3 months					
Group - I [n=25]	09 [36%]	13 [52%]	02 [08%]	01 [04%]	<0.0001
Group – II [n=28]	20 [71%]	06 [22%]	02 [07%]	00 [00%]	
6 months					
Group - I [n=25]	14 [56%]	08 [32%]	02 [08%]	01 [04%]	0.0006
Group – II [n=28]	22 [79%]	05[18%]	01 [03%]	00 [00%]	
9-12 months					
Group - I [n=25]	19 [76%]	05 [20%]	01 [04%]	00 [00%]	0.072
Group – II [n=28]	23 [82%]	03 [11%]	01 [3.5%]	01[3.5%]	

DISCUSSION

Since 1960s the gold standard treatment for DMCFs was non-operative because the reported nonunion rates were <1% as against 5% following operative treatment [12, 13]. Recent studies observed poorer outcome with conservative treatment in terms of non-union, malunion, pain, clavicular shortening with associated deficit in range of movements and strength at the shoulder [17, 18]. This might be due to modified scoring systems in assessing disabilities of the arm, shoulder, and hand, higher patient demands and outcome expectations and, a more differentiated self-assessment by the patient. In the light of improved functional and patient satisfaction scoring systems the present study was undertaken to compare the complications, functional outcome and patient satisfaction rates following non-operative (Group-I) and operative management (Group-II) and draw evidence based conclusions.

During the study period 5252 patients were admitted in the orthopedic department of this hospital with different fractures. Incidence of fracture clavicle was 5%. Of these 85% had fracture in the middle third, 10.5% in the lateral third and 4.5% in the medial third of the clavicle. 75% of the middle third fractures were associated with displacement. Of these 58% were reported in the age group of 20-40 years of age. Studies of Robinson CM *et al.* and Brin YS *et al.* reported similar findings [9, 19].

The strength of the present randomized study is the balance of demographic parameters like age, gender and side of the arm of both the groups, which otherwise could have confounded the results and the conclusions drawn. The mean ages were 27.82 ± 5.50 and 27.40 ± 3.64; males were 83% and 82%; females were 17% and 18%; right 62% and 61%; left 38% and 39%; dominant 52% and 55%; non dominant 48% and 45% in Group-I and Group-II respectively. Similar

findings were observed by Sananth Kumar Shetty et al. (2017) wherein the age group affected maximum was 25-35 years with males 83.3% and females 16.7% [20]. As observed in our study, Marcel JST *et al*. also noticed that right and left were equally involved and dominant side was affected more commonly[21].

A total of 53 patients with completely displaced midshaft clavicular fractures were randomized to conservative and operative groups and were followed up at 3 months, 6 months and 9-12 months interval for maximum therapeutic benefit assessed by DASH scoring system. Group-II showed superior (lower scores) at every time point of the study compared to Group-I. Moreover the difference was statistically significant at 3 months and 6 months with P – value of <0.001. At the end of 9-12 months the DASH scores for Group-II were better though the difference was not significant statistically. Despite similar long-term reported DASH scores in both the groups return to normal work was earlier in Group-II. Similar findings were reported by Jubel, COTS, Smekal and Virtanen studied [22-25].

Table - 6: Comparison of DASH scores from literature

SNO	STUDY	DASH SCORES	
		OPERATIVE	CONSERVATIVE
1	Jubel *et al*. [22]	2	10
2	COTS [23]	5.2	13
3	Smekal *et al*.[24]	0.5	3
4	Virtanen *et al*.[25]	4.3	7.1

Complications observed in the present study were nonunion, malunion, shortening and bony prominence. Nonunion rates were significantly lower in Group-II (7% vs. 32%) at the end of 3 months and also better at the end of 9-12 months though the improvement was not significant statistically. Studies by COTS [23] and Judd [26] also reported similar nonunion rates. Kulshrestha [27] noticed less malunion rates among patients treated with surgical fixation. Present study revealed no malunion among Group-II patients as reported by Smekal *et al*. [25] and Virtanen *et al*. [25]. Other complications noticed in the conservative group were shortening of clavicle in [24%] and bony prominence [60%]. Guo-dong Liu [28] observed similar findings in their meta-analysis. Shoulder deformity due to shortening of the clavicle and bony prominence (non operative group) seemed to be of greater cosmetic concern than a scar (operative group). Patient satisfaction rate at any point of the study was significantly higher in surgically treated patients, despite similar long-term patient reported outcomes with non-operative treatment. Tutuhatunewa ED *et al*. in their retrospective multicentre study observed similar findings.

CONCLUSIONS

Early primary plate fixation of displaced midshaft claviculat fracture results in

- Improved patient-oriented outcomes,
- Earlier return to function
- Decreased rates of nonunion, malunion, shortening of the clavicle and bony prominence
- Improved range of movements at shoulder
- Therefore we feel operative treatment is the gold standard treatment for DMCF when the displacement is ≥1.5 cm. in adults.

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