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MIDSHAFT CLAVICLE FRACTURE;
COMPARISON OF POLY ARM SLING AND FIGURE OF EIGHT BANDAGE

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ABSTRACT… Introduction: Fracture of clavicle is common, occurring most commonly in males accounting for approximately 2.5%of all fracture presenting to orthopedic surgeon.[1] This study has been conducted to compare the broad arm sling and figure of eight bandage in the first 21 days of treatment with primary outcome measure of pain and disability. **Study Design:** Comparative study. **Setting:** Department of orthopedic surgery, Dow International Medical College, Dow University hospital. **Period:** February 2015-2016. **Material and Methods:** 60 eligible patients with a mean age of (15-60 years) were randomized to conservative treatment with either a broad arm sling or figure of eight bandage. After detailed counseling taking informed consent we did non stratified randomization in blocks of two using the sealed envelope method. Patients were kept in strict follow up to complete the outcome measures the next day and on day seven, fourteen and twenty one. On each visit a Performa was filled known as SPADI having two components of pain and disability and VAS on day one, seven, fourteen and twenty one. **Results:** Seventy patients were enrolled initially, out of them ten patients were dropped out due to different reasons. Of the remaining 60 patients 30 were treated with broad arm sling and 30 were treated with figure of eight bandage. The two groups were randomized fulfilling the inclusion criteria. The Mean VAS on the first day of treatment in the broad arm sling group was 5.433 SD 1.04 (p= 0.034, 95% CI 0.10 -2.46) where as in figure of eight group was 8.9 (SD 10.8). On subsequent visits (Day 7,14,21) VAS of broad arm sling was 3.83, 1.40,1 whereas figure of eight was 5.76, 4.3, 3.469. This result clearly shows good pain control in broad arm sling group as compared to the figure of eight group. The mean SPADI on the first day of treatment was 94.52(SD 2.273) in broad arm sling group, on the other hand it was 93.87(SD 2.239) in figure of eight group. In follow up visits of day 7, 14 and 21 score was as follows in broad arm group 3.83 (SD 0.79), 1.4(SD 0.49), 1(SD 0.0), it was 5.76(SD 1.04), 4.3(SD 0.740), 3.4(SD0.68) in figure of eight group. It also shows better result in terms of pain and functional outcome. **Conclusion:** Fracture clavicle is still managed conservatively in majority of the cases, either with the figure of eight bandage or polyarm sling. Patient's outcome in terms of pain management and functional range of motion in poly arm sling is better than figure of eight bandage.

Key words: Polyarm Sling, Clavicle Fracture, VAS (Visual Analogue Score).

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INTRODUCTION

Fracture of clavicle is common, occurring most commonly in males accounting for approximately 2.5%of all fracture presenting to orthopedic surgeon.[1] It is commonly in the mid third of the shaft with incidence of about 69-82%.[2] 8.7%patients usually present with a history of fall on to the shoulder, 7% as a direct blow and 6% described in as fall on to an outstretched hand.[3] Conservative treatments (including figure of eight and poly arm sling) has a high union rate and good clinical outcome in majority of cases.[4,5] During the last decade the concept that bone union can be achieved even if both ends of the clavicle are widely separated has been widely disputed.[6] Many authors have given superior results after surgical reconstruction in fracture with severe combination and displacement.[7,8] While it may become the reference treatment for completely displaced mid shaft fracture, still there remains a role of non-operative treatment.[9] Literature shows union rate of 96.9% of cases treated conservatively and the time of union was not different when treated with a sling, a collar

and cuff or figure of eight bandage.[10,11,12] Broad arm sling and figure of eight bandage are the most widely used modality for the conservative treatment of fracture clavicle, despite their wide use; very few randomized studies have yet been conducted to compare the two modes of treatment.[13,14]

Rationale of this study is to compare the broad arm sling and figure of eight bandage in the first 21 days of treatment with primary outcome measure of pain and disability.

METHODOLOGY

This comparative study was conducted in the department of orthopedic surgery, Dow International Medical College, Dow University hospital from February 2015-2016. 60 after taking approval by Institutional review board Dow University of health sciences Karachi. Eligible patients with age of between 15-60 years were randomized to conservative treatment with either a broad arm sling or figure of eight bandage. After detailed counseling taking informed consent we did, non-stratified randomization in blocks of two using the sealed envelope method.

Patients meeting our inclusion criteria were those who were between age group of 15-60 years, who sustained mid shaft clavicle fracture, presented on the day of injury. Our exclusion criteria is patients under 15 years of age, fracture of clavicle other than mid shaft clavicle fracture, open injuries, pathological fractures, presentation of patients 24 hours post injury.

Same medications were prescribed to all patients. The upper limb was immobilized in poly arm sling in internal rotation for three weeks. Those patients who were treated in figure of eight bandage were counseled how to tighten up the bandage when it gets loosened. Patients were kept in strict follow up to complete the outcome measures the next day and on day seven, fourteen and twenty one. On each visit a Performa was filled known as SPADI having two components of pain and disability and VAS on day one, seven, fourteen and twenty one.

Sample Size

Minimum 4 sample size per group with 99% confidence interval and power of the test, but due to low sample size minimum 30 sample size suggested to take.

Statistical Analysis

The Primary outcome measures were SPADI and VAS at day one, seven, fourteen and twenty one. All continuous data were compared using two sample paired student's t test with significance at a P value of < 0.05. For the comparison of categorical variables chi square test was used. All analyses were performed using SPSS Version 16.

RESULTS

Seventy patients were enrolled initially, out of them ten patients were dropped out due to different reasons. Of the remaining 60 patients 30 were treated with broad arm sling and 30 were treated with figure of eight bandage. The two groups were randomized fulfilling the inclusion criteria.

VAS (0-10)	Broad Arm Sling	Figure of Eight Bandage Group
Day 1	5.433 (SD 1.04)	8.9(SD10.8)
Day 7	3.83(SD 0.79)	5.76(SD1.04)
Day 14	1.40(SD 0.498)	4.3(SD 0.749)
Day 21	1.0(SD 0.0)	3.469(SD 0.687)

Table-I.

Demographic features of two treatment groups	
Mean age of the patient	34.1667(SD 9.57)
Gender Distribution	
Male	44(72.1%)
Female	16(26.2%)
Arm involved	
Right:	39(63.9%)
Left:	21(34.4%)

Table-II.

The Mean VAS on the first day of treatment in the broad arm sling group was 5.433 SD 1.04 (p= 0.034, 95% CI 0.10 -2.46) where as in figure of eight group was 8.9 (SD 10.8). On subsequent visits (Day 7, 14, 21) VAS of broad arm sling was 3.83, 1.40,1 whereas figure of eight was 5.76, 4.3, 3.46. This result clearly shows good pain control in broad arm sling group as compared to the figure of eight group.

The mean SPADI on the first day of treatment was 94.52(SD 2.273) in broad arm sling group, on the other hand it was 93.87(SD 2.239) in figure of eight group. In follow up visits of day 7, 14 and 21 score was as follows in broad arm group 3.83(SD 0.79), 1.4(SD 0.49), 1(SD 0.0), it was 5.76(SD 1.04), 4.3(SD 0.740), 3.4(SD0.68) in figure of eight group. It also shows better result in terms of pain and functional outcome.

SPADI (0-100)	Broad Arm Sling	Figure of Eight Bandage	p-value
Day 1	94.52(SD2.273)	93.87(SD 2.329)	0.86
Day 7	3.83(SD 0.79)	5.76(SD 1.04)	0.79
Day 14	1.4(SD 0.49)	4.3(SD 0.740)	0
Day 21	1.0(SD 0.0)	3.46(SD 0.68)	0

Table-III.

DISCUSSION

The aim of this study was to compare the results of the cases managed with the broad arm sling and figure of eight. Clavicle fractures are generally treated conservatively because it has excellent powers of repair that guarantee a good final consolidation of the lesion. Conservative treatment consists of the application of a figure-of-eight bandage (FEB) or a broad arm sling to restore the retro-positioning of the shoulder, resolving the superimposition of the stumps and limiting clavicular shortening.[15]

This is still a matter of debate that either the conservative treatment is the optimal treatment or the surgical indications should be extended.[16,17] Literature shows lower than 1% nonunion rate with conservative method.[18,19] In our study 55patients completed treatment period, all fractures healed successfully and no case of nonunion were observed.

Our study shows better results after treatment with poly arm sling as compared to figure of eight bandage in terms of improvement in VAS score and SDADI. Mean VAS Score in the group of patient treated with poly arm sling on day 1was 5.43, 3.83 on day 7,whereas 1.4 on day 14 and1.0 on day 21.whereas mean VAS in group treated with figure of eight bandage was 5.9, 5.76,4.3 and 3.469 on day 1,7,14 and 21 respectively. On the other hand the group treated with broad arm sling had a mean SPADI 94.52, 3.83, 1.4,1 respectively. Whereas mean SPADI score of the group treated with figure of eight bandage on day 1 was 93.87, 5.76on day 7, 4.3 on day 14, and 3.4 on day 21.

A randomized controlled study by Ersen et al which are very similar to our study, shows the results that mean VAS on the first day after treatment was significantly lower (p=0.034) than in the figure of eight group at 6.8(SD 1.7) On the other hand they show the mean VAS on the day 3,7,14,21 were statistically similar which contradicts our study which shows significant decrease in score on subsequent visits.[20]

Hoofwijk and Vander Werken did a single center randomized controlled study. He reported a statistically significant difference (i.e. mean difference o.8o, 95% CI 0.34 to 1.26) in the favor of broad arm sling in terms of pain after 15 days. Our study shows the same results in terms of pain relief and functional outcome.[21]

De Giorgi et al. BMC Research Notes in their study shows the results according to the criteria described for the Simple Shoulder Test, 51 participants (71.8%) were satisfied with the conservative treatment, and 21 (29.6%) patients were dissatisfied.[15] In our study we used SPADI to assess pain and disability of patient in order to compare modes of treatment.

Kjeld Andersen et all in their randomized trial comparing treatment with the figure of eight bandage and a simple sling Seventy one out patients with mid clavicle fracture were included out of which sixty one patients completed the study, mentioned the results which shows that simple arm sling caused less complications and discomfort than with figure of eight bandage. Figure of eight bandage is used widely but it often causes skin problems, pain, loosening and occasionally neurovascular problem or fracture displacement. Moreover it demands regular readjustment throughout the period of treatment, imposing on patient unnecessary inconvenience, complications and discomfort.[13] These results are very similar to our study which shows better pain control (Assessed via VAS) and improved

shoulder pain and disability score(SPADI).

Bajuri et al based on their 70 patients study to analyze the outcomes of clavicle fractures in adults treated non-surgically, results showed that 34 patients (48.6%) had reduced shoulder function on the affected side, whereas 36 patients (51.4%) did not experience reduced shoulder function. The Constant shoulder score varied from 39 to 94, with a mean of 77.19.[22]

CONCLUSION

Fracture clavicle is still managed conservatively in majority of the cases, either with the figure of eight bandage or poly arm sling. Patient's outcome in terms of pain management and functional range of motion in poly arm sling is better than figure of eight bandage.

CONFLICT OF INTEREST

No external funding was done. All the expenses in the research project was beared by authors themselves.

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The biggest communication problem is we do not listen to understand. We listen to reply.

– Unknown –

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Nusrat Rasheed	Concept of the study, Questionnaire designing, Data collection, Data entry, literature search.	
2	Jagdesh Kumar	Literature search, Data entry.	