Title

Comparison of Outcomes between non-operative and operative treatment of displaced middle third fractures of the clavicle: A systematic review

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ABSTRACT

Background

Fractures of the clavicle are common and make up 5 to 12% of all fractures. The majority heal with non-operative treatment.

Objectives

The objectives were to investigate any differences in non-union rates, patient satisfaction and function outcomes between groups treated operatively and non-operatively for displaced middle third clavicle fractures.

Methods

Electronic searches on Cochrane Bone, Muscle and Trauma Group Specialised Register (to February 2010), Cochrane Register and Cochrane Library (to March 2010), Embase (1980 to 2010),Pubmed (to March 2010), current controlled trials, the UK National Research Register, LILACS and WHO International Clinical Trials Registry. Two Randomised Control Trials were selected. Data from the trials was analysed using tables The Data was not combined for analysis.

Results

One trial compared non-operative treatment to plate fixation and the other non-operative to fixation with a modified Hague pin. The latter was under-powered and did not yield any differences. The one good trial demonstrated superior outcomes for operative treatment.

Introduction

Fractures of the clavicle are common making up 5% to 12% of all fractures and up to 44% of all shoulder girdle fractures. The majority of these fractures occur in the middle third of the clavicle (1). The middle third of the bone is the weakest, being the junction of the medial anteriorly convex and lateral, posteriorly convex segments. This middle third portion has very little cancellous bone and less of a soft tissue envelope compared to the rest of the bone (2). The bone is firmly anchored on either end by strong ligaments and acts as a strut connecting the shoulder girdle to the axial skeleton. It is subjected to massive forces by muscles acting along its length. Movement of the scapula as the arm is elevated, produces rotational movement of up to 40 degrees within the clavicle (2). Fractures to the clavicle are caused by direct and indirect mechanisms. Direct forces occur through skiing and cycling accidents. Indirect mechanisms involve falling on outstretched hand, fall on to the shoulder and direct blows to the shoulder (3). Several classifications exist for clavicle fractures. A commonly used classification is the Alman classification, which divides the clavicle fractures into Groups, group1 being middle

third, 2 lateral third and 3 medial third fractures. Neer and later Rockwood further devided group 2 and 3 fractures (4). Following a fracture in the middle third the weight of the arm becomes a deforming force and muscle action around the fracture site causes shortening, displacement and angulation. The action of the pectoralis major muscle depresses the distal fragment while the sternocliedomastoid muscle elevates the proximal fragment (5) Displaced clavicle fractures are associated with complications such as non-union, malunion, subclavian vessel injury, brachial plexus paresis, haemo-pneumothorax, post-traumatic arthritis and refracture (6). Fractures of the clavicle largely heal when treated conservatively. However a certain group of displaced Group 1 fractures develop complications and require open reduction and internal fixation. Indications for surgical interventions that have been put forward are open fractures, neurovascular compromise distal to the fracture, severe communition or angulation with skin compromise, patients with multiple injuries or coma, inability of the patient to undergo prolonged immobilisation and symptomatic non-union (7). It is important that we evaluate the role of surgery in the treatment of these fractures. This review looks at outcomes for patients who have been treated non-operatively compared to those who have been treated operatively.

Description of intervention

There is a general agreement between many authors that fractures of the clavicle should be treated non-operatively (8). Treatment options vary from plaster spica casts, straps, figure of eight bandage to slings. However some fractures cannot be treated by these closed means, requiring surgical intervention (7). Further it has been demonstrated that conservative treatment is associated with functional deficits (9). Surgical management may be in the form of screws, wire loops, pins and plate fixation. External fixation can also be used.(10). Eskola et al found a 3% non-union rate in fractures of the middle third of the clavicle treated conservatively (1). Apart from non-union in these fractures treated conservatively, there is increasing evidence that patient satisfaction and overall function are compromised with non-operative treatment. This dissatisfaction in outcomes has been attributed to strength deficit and associated complications (11). This evidence comes from studies employing patient oriented outcome measures such as the Disability of the Arm, Shoulder and Hand (DASH) scores or the Single Numeric Evaluation (SANE) scores (11). Rowe noted that a displaced fracture of the middle third of the clavicle is a very painful condition and these fractures are underrated greatly in terms of the pain and disability they produce. It is almost impossible to immobilize a fracture of the middle third of the clavicle with closed means (7). Having said that some authors (Rowe, Neer) have found a higher rate of non-union in patients treated surgically (3.7 and 3.6% respectively), compared to patients treated non-operatively (0.8 and 0.1% respectively) (12).

Importance of this Review

There are no clear guidelines regarding the management of displaced fractures of the middle third of the clavicle because there is insufficient evidence. There is no published systematic review or meta-analysis on Randomised Controlled trials comparing non-operative to operative management of middle third clavicle fractures as of December 2009. There is one systematic review on non-operative treatment of middle third clavicle

fractures (13) and one systematic review on Surgical management of middle third fractures (10).

Objectives

The main objective of this review was to determine whether there is any significant differences in non-union rates between patients who received operative treatment for displaced middle third clavicle fractures and those who received non-operative treatment. The secondary objectives were to establish if operative treatment of these fractures produced any different outcomes in terms of patient satisfaction, function and complication rates.

Outcomes of Interest for the review

The outcome of interest for the review were non-union rates, patient satisfaction and function scores (DASH, Constant, SANE and L'Insalata)

Inclusion criteria

Only Randomised Controlled Trials comparing non-operative treatment to operative treatment were included.

Methods

Search methods for identifying studies

Electronic searches were made by the author on Cochrane Bone, Muscle and Trauma Group Specialised Register (to February 2010), Cochrane Register and Cochrane Library (to March 2010), Embase (1980 to 2010) and Pubmed (to March 2010). Searches were also made in current controlled trials, the UK National Research Register, LILACS and WHO International Clinical Trials Registry. Reference lists were searched and expert opinion was requested where possible.

Selection of Studies

Over 2500 references were found on searching clavicle fracture and the author eliminated most of these by going through the titles. Further elimination was made by reading through the abstracts. In the absence of abstracts the original article was sourced. The Cochrane library yielded two relevant systematic reviews one on non-operative treatment of middle third clavicle fractures and one on operative treatment of middle third clavicle fractures. The search was narrowed down to nine relevant studies by eliminating studies without comparisons of intervention. Four of these studies were on surgical intervention were then excluded because there was no attempt to randomise treatment. Two studies were Randomised control trials on various non-operative interventions and so were also excluded. One Study, a retrospective study comparing non-operative to operative interventions was removed because it did not eliminate selection bias and was unable to assess patient satisfaction and function outcomes. Two Randomised Control Trials were finally selected.

Data extraction

Data from the studies was collected and organised into five tables. Table 1 presents a summary and side to side comparison of the demographic information. Tables 2 and 3

present functional scores, DASH in one study and SANE, L'Insalata scores respectively for the studies. Table 4 is a comparison of patient outcomes for the studies and Table 5 a comparison of complications.

Methodological quality assessment

The modified version of the Cochrane Bone, Joint and Muscle Trauma Group's former Quality assessment tool was used. The author answered twelve questions assessing various aspects of the studies' methods (10).

Outcomes of the Review

Study types

There are two randomized controlled trials included in this review. One (14), carried out by the Canadian Orthopaedic Association (Altamimi et al), was a multicenter prospective randomized clinical trial involving eight centers between February 2001 and June 2003. This study looked at and compared outcomes of non-operative to surgical plate fixation of displaced mid-clavicle fractures. The other study (Judd et al) (15), was a randomized trial comparing outcomes for non-operative treatment with internal fixation using a modified Hague pin. This was carried out between April 2001 and December 204.

Ethical considerations

In both studies relevant ethical considerations were made. Institutional approval was obtained with the research ethics board in the case of the multi-centre trial and with the research ethics board for the other trial.

Intervention types

In the Altamimi trial, patients were treated non-operatively using sling immobilisation for six weeks. For the Judd trial, the sling immobilisation period was not specified. The participants in the Judd trial received shoulder motion as tolerated with some activity restrictions until the fractures healed. The surgical interventions were open reduction and internal fixation with plates in the Altamimi trial and modified Hague pins for the Judd trial. Plate fixation was on the superior surface of the clavicle using LCDC and reconstruction plates within a period of 28 days of the injury. No bone grafts were used. Fixation with pins in the Judd trial involved a small incision followed by antegrade insertion. All pins in this study were inserted within two weeks of injury. The pins had to be removed in the clinic after a mean duration of 10.9 weeks.

Participants

A total of 132 patients were enrolled in the Altamimi trial. These were further randomised by the research nurse using sealed envelopes assigning them to one or other of the treatment groups. Fifty-seven (57) patients were included in the Judd trial. They were also randomly allocated to treatment groups using sealed envelopes and both the surgeon and patient remained blinded to treatment groups until the time of consenting them for surgery. In this trial, 7 patients who met the inclusion trial declined to participate.

Inclusion criteria

The Altamimi trial included patients with completely displaced midshaft fracture of the clavicle which could be plated with three screws proximal and distal to the fracture, patients aged between sixteen and sixty years, patients fit for anaesthesia and only those who provided informed consent. The Judd trial included patients with acute, closed and displaced fractures of the middle third of the clavicle who were between the age of seventeen and forty.

Exclusion criteria

The Altamimi trial excluded those less than sixteen and over sixty, fractures in the proximal and distal third of the clavicle, open fractures, pathological fractures, fractures older than 28 days as well as patients with head injuries and those with associated neurological deficits. They also excluded patients with associated upper extremity fractures, unable to give consent or those likely not comply with follow up or not fit for surgery. In the Judd trial, they excluded open fractures, fractures outside the middle third and those with associated neurological deficits.

Outcomes of Interest

Disability of the Arm Shoulder and Hand (DASH) scores where the primary outcome of interest in the Altamimi trial. Secondary outcome measures were the Constant shoulder score, complication rates, union rates and radiographic evaluation. In the Judd trial they used the single Numeric Evaluation (SANE) and L'Insalata shoulder scores.

Union was determined using radiographic evidence by the treating surgeon. This was defined as complete cortical bridging on both cortices of proximal and distal fragments. Non-union was defined as lack of complete bridging with pain and motion at the fracture site at one year. Radiographic malunion was deemed to be loss of normal contour of the clavicle and symptomatic mal-union as shortening, angulation or displaced position with some associated pain, shoulder asymmetry or neurological symptoms.
An adverse event or complication was any event requiring treatment or a second procedure.(14).

Sample size

The Altamimi trial calculated a sample size of 60 based on primary outcome of shoulder scores assuming a beta error of 0.05 and power of 80. They had a sample size of 132. The Judd trial did not specify the calculation and adequacy of the sample size.

Follow-up

Patience in the Altamimi trial were followed up at twelve, twenty-six and fifty-two weeks, whereas those in the Judd trial had follow up at three, six, twelve and fifty-two weeks. At each follow up visit, the relevant assessments were done to score the patients.

Statistical analysis

Altamimi and colleagues analysed DASH and Constant scores using SPSS and further used two way analysis of variance of treatment and time. The student t test was used for comparing means of variables. Other tests used were chi squared test, fisher exact test and pearson correlation co-efficient. The Judd trial also used SPSS and performed analysis of variance on the SANE and L'Insalata scores.

Analysis

There was no demographic differences between the treatment groups in both trials. The Altamimi trial showed no difference in the treatment groups in terms of the Injury Severity Scores (ISS), but he Judd trial did not report on the ISS of the treatment groups. These results are presented in table 1.

Table 1 Comparison of Demographics and Injuries between treatment groups and between trials

Non-operative vs. operative group parameter	**Altamimi et al**	**Judd et al**
Demographics	No difference	**No difference**
Mechanism of injury	No difference	**No difference**
ISS	**No difference**	**?**

Constant and DASH scores showed significantly superior outcomes in favour of surgical treatment for the Altamimi trial. Significantly higher SANE and L'Insalata sores ($p<0.05$), for the operative group were noted for the Judd trial between 3 weeks and 6 months of follow up. These results are demonstrated in table 2 for the Altamimi trial and table 3 for the Judd trial. A metanalysis was not feasible due to differences in assessing parameters.

Table 2 Comparison of Constant scores between treatment groups - Altamimi et al

(14)	**Non-operative**	**Operative**
Constant score	↓ **(lower score)**	↑ **(p<0.01)**
DASH score	↑ **(i.e. inferior outcome)**	↓ **(p<0.01)**

Table 3. Mean SANE and L'Insalata scores and SD's – Judd et al

(15)	**Non-operative**	**Operative**
SANE score	↓	↑ **superior**
L'Insalata	↓	↑ **superior**

Patient satisfaction, range of motion of the shoulder and general appearance of the shoulder were noted to be higher in the operative treatment group for the Altamimi study (Table4) The authors in the Judd trial did not specify outcomes on these same parameters. There was no reporting of patient satisfaction. They had no objective tests for functional outcomes on Range of shoulder motion. Judd et al did not report on time to union and shoulder appearance in their treatment groups. Both studies reported superior radiographically determined anatomical reduction for the operative groups.

Table 4: Comparison of functional parameters between treatment groups and between study trials

Non-operative vs. operative group parameter	Altamimi et al	Judd et al
Patient satisfaction	**Non-operative < operative ($p<0.05$)**	**?**
Range of Motion	**No difference**	**?**
Time to Fracture union	**Non-operative > operative ($p<0.01$)**	**?**
Patient satisfaction on appearance of shoulder	**Non-operative < operative**	**?**
Anatomic reduction (Radiographic outcome)	**Non-operative < operative**	**Non-op < operative**

Both studies found the main complications of the interventions to be non-union, malunion, Hardware problems (sometimes warranting removal), wound problems, complex regional pain syndrome (CRPS) and mechanical failure. Non-union was higher (14.2%) in the non-operative group compared to 3.2% in the operative group(14) There was no difference in non-union rates between the treatment groups for the other trial (15). The complications for the two trials are presented in Table 5.

Table 5: Adverse reactions for trials and treatment groups

Adverse reaction	Altamimi et al		Judd, Pallis et al. 2009	
	Non-op (49)	Operative (62)	Non-op (28)	Operative (29)
Non-union	**14.2% (7)**	**3.2% (2)**	**3.5%**	**3.5%**
malunion	**9**	**0**	**1**	**1**
Hardware irritation	**0**	**5**	**0**	**3**
Wound problems	**0**	**3**	**0**	**6**
CRPS	**0**	**1**	**0**	
Neurological deficit	**7**	**8**	**0**	**1**
Mechanical failure	**0**	**1**	**1**	**1**
other	**2**	**2**	**0**	**0**
Total	**9**	**20**	**2**	**12**

Methodology quality assessment

Using the tool adopted from lenza et al. the altamimi trial appeared stronger than the Judd trial. The Altamimi trial satisfied all twelve parameters which included randomisation, blinding, intention to treat analysis, inclusion and exclusion criteria and sample size. The Judd trial fell short on intention to treat analysis and adequacy of sample size. These findings are tabulated in table 6.

Table 6. Results of assessment of methodological quality

	Item	(14)	(15)
1	Was the assigned treatment adequately concealed prior to allocation?	**Yes**	**Yes**
2	Were the outcomes of participants who withdrew described and included in the analysis (intention-to-treat)?	**yes**	**No**
3	Were the outcome assessors blinded to treatment status?	**Yes**	**Yes**
4	Were important baseline characteristics reported and comparable?	**Yes**	**Yes**
5	Were the trial participants blind to assignment status after allocation?	**Yes**	**Yes**
6	Were the treatment providers blind to assignment status?	**Yes till consent**	**Yes till consent**
7	Were care programmes, other than the trial options, identical?	**Yes**	**Yes**
8	Were the inclusion and exclusion criteria for entry clearly defined?	**Yes**	**Yes**
9	Were the outcome measures used clearly defined?	**Yes**	**Yes**
10	Were there clinically useful diagnostic tests	**Yes**	**Yes**
11	Was the duration of follow up useful	**Yes**	**Yes**
12	Was the sample size big enough	**Yes**	**No**

Adopted from (10) 2009

Discussion

Results of non-operative treatment of clavicle fractures that have been reported are very good. In one series of over 3000 fractures it was 0.4% (1). In a different study a non-union rate of 6.2% was found at 24 weeks (16). Non-union rates following open reduction have been variable. Neer and Rowe found a rate of 4.5% (8). Clavicle fracture non-union at 24 weeks occurs very rarely, but some authors believe a certain subgroup of patients may be predisposed , maybe through intrinsic factors or through injury pattern (16)

In the only systematic review on midshaft clavicle fractures, comparing various surgical interventions, no non-union rates were given (10). Similarly in the only systematic review comparing non-operative midshaft clavicle fracture treatment, the authors report that most of the studies reviewed were under-powered. They therefore could not draw any conclusions and non-union rates were not reported (13)

This review found non-union rates of 14.2% in the non-operative group and 3.2% in the operative group for one study (14). In the other study, they found no differences in the non-union rates for the non-operative and operative intervention groups, 3.5% (15). The latter result is not surprising as the study was under-powered, committing a type 2 error. This review also demonstrated superior patient treatment satisfaction and function outcomes for patients treated with surgery compared to those who had non-operative treatment. One of the trials reviewed, however was weaker in the sense that they did not include objective shoulder function parameters of strength and range of motion. Further this trial included some minimally displaced midshaft clavicle fractures affecting their results (15).

Conclusion and Recommendations

The review was based on two randomised clinical trials, one of which was under-powered, making it difficult to draw any meaningful conclusions. Further Randomised Control Trials are recommended to substantiate any differences in non-union rates for the two interventions. These new trials should assess similar patient satisfaction and functional outcomes in similar ways to allow meta-analysis.

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