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Sling Compared with Plate Osteosynthesis for Treatment of Displaced Midshaft Clavicular Fractures-A Randomized Clinical Trial
Kaisa et al.
J Bone Joint Surg [Am] 2012;94-A:1546-53.

Summary

Purpose
To compare the two commonly used treatment modalities in displaced clavicle fractures in adults in terms of function and disability. They hypothesised that there would be no difference between the two groups.

Methods
The study design was a prospective randomised control trial (RCT). The study was carried our at Level 1 trauma centre. Local ethical approval was obtained and the trial was registered. AO classification was used for the purpose of the study. Sample size calculated was calculated using minimum 10 points improvement on the Constant-Murley score. The power was set at 80% and significant was kept at 0.5. With these criteria they needed 26 patients in each group and hence they wanted to recruit 30 patients with 15% drop-out to keep the study adequately powered. Randomisation tables were used and sealed envelopes opened in emergency department where the explanation of the study and consenting took place. SPSS was used for analysis of the results and those patients who did not complete their follow-ups they used 'last observation carried over method'.

The study inclusion criteria were completely displaced fractures, fractures presenting within seven days of injury, age between 18-70 years and patients willingness to participate and consent to the study. The exclusion criteria were undisplaced fractures, open fractures, polytrauma, Neurovascular injury, pathological fractures, Malignancy, previous fractures, more than seven day since injury, Steroid use, pregnancy and uncooperative patient or lack of informed consent.

The post-operative protocol for the -perative group was sling for three weeks with allowance of pendulum movement and thereafter active movement between three and six weeks and return to full activity at three months. The surgery was undertaken by various grades of surgeons. Beech-

chair position was used and Ao reconstruction plate was used for fixing the fractures. Closure was in layers with clips to skin. Post-operative protocol was similar to that of non-operative group.

The primary outcome measures used were Constant-Murley score for function and DASH score for disability. These were measured at three and six weeks and then at three months and one year. Independent physiotherapist assessed the Constant-Murley score at three months and the senior author measured the final score at one year.

The secondary outcome measures used were VAS score (0-100) for pain. Fracture healing confirmed by an independent radiologist. Complication including infection, symptomatic malunion, non union, metal work problems and revision surgery were also noted.

Results

390 patients were assessed for eligibility between August 2004 and September 2007. 330 patients excluded as they did not meet the eligibility criteria's. 60 patients were randomised in to the two groups with 32 in non operative groups and 28 in the operative. Nine patients were lost to follow-up with 7 in non operative group and two in operative group thus making the final numbers 25 in non operative group and 26 in operative.

In both groups the males were the predominant sex. The non operative group comprised of younger cohort (mean age 33) as compared to operative group (mean age 41) and this difference was significant. The injured side, mechanism of injury and smoking status was no different in the two groups. The fractures in both groups were mostly either 2B1 or 2B2 and majority had displacement less than 2 times the clavicular width. In both groups the shortening was 10mm or so. Again these parameters were not significantly different in the two groups.

Comparing the outcomes in the two groups Constant-Murley score showed no difference at three month or one year mark in the two groups. Most patients reached the majority of the improvement at three month mark. Similarly DASH score showed no difference at three month or one year mark in the two groups though most patients continued to improve until their last follow-up. Pain was less in the operative group at three week mark but this difference was not significant and thereafter pain score remained similar in the two groups.

All patients in the operative group united as compared to only 19 (76%) in the non operative group. This difference was significant. When looking at the non union group most patients had more than 1.5 times clavicular width displacement. No difference in the non operative group between united and ununited fractures was noted in terms of fracture type, shortening or smoking. In addition, no difference in the outcome was noted when comparing Constant-Murley score and VAS score between the between united and ununited fractures in the non operative group but DASH score was poorer in the ununited group ($p<0.05$).

The complications in the non operative group (12) were mainly non union and symptomatic malunions (2) and re-fracture. In the operative group there were some minor complications like broken plate, plate irritation and delayed union. Again excluding the non unions the complications in the two groups were not significantly different.

Discussion

This RCT compares two commonly used treatment modalities in displaced clavicle fractures in adults in terms of function and disability. They note that there is no difference between the two groups in terms of functional outcome, disability or pain. They reveal a high non-union rate much higher than other studies. The patients with non union or symptomatic malunion declined further reconstruction option due to minimal disability.

Critique

Strengths

RCT: well constructed
Proper randomisation
Primary and Secondary outcome looking at various issues
Thorough inclusion and exclusion criteria: Select sub-group of mid shaft clavicle fractures.

Metholodigical concerns

Study design:

Numbers: 25/26 patients (under powered non operative group: *26 each minimum*)

Assessments:

Varied: 3m and 1y (different assessors)

Short follow up 1yr

To reveal more symptomatic malunions and complications

Overall Conclusion

- Good study and adds to the management of displaced clavicle fractures.
- Reemphasizes that in a select group non union rate higher with conservative Rx
- Also notes that non union group may not need further intervention.

Evidence

Finally a look at what is out there in terms of evidence for clavicle fracture.

Current Evidence-Based recommendation for clavicle fractures.

	Statement	**Level of evidence**
1	Young, active patients with completely displaced mid-shaft fractures of the clavicle will have superior results with primary fracture fixation.	B
2	Anterior-inferior plating may reduce the risk for symptomatic hardware compared with superior plating.	C
3	There is no difference in outcome between a regular sling and a figure-of-eight bandage.	B
4	There is no difference between plating and intra-medullary nailing of displaced mid-shaft clavicle fracture.	I
5	Factors associated with poor outcome after non operative treatment of displaced mid-shaft clavicle fractures include shortening and increasing fracture comminution	A