



Journal Club: 28/01/2016

Organiser: Mr Tony Antonios (Specialist Registrar)

Attendees: Mr Bajaj (Consultant), Mr Dutta (Consultant), , Ms D Leivadiotou (Consultant), Mr T Antonios (Specialist Registrar), Mr A Wiik (Specialist Registrar), Mr KA Chilimi (Specialist Registrar),) Mr S Lakkol (Specialist Registrar) Mr O Nzeako (Specialist Registrar), Mr V Rajamani (Specialist Registrar), Dr F Ismail (Specialist Registrar).

Reviewer: Mr T Antonios

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Theme: Midshaft clavicle fractures

Robinson CM, Goudie EB, Murray IR, et al. Open reduction and plate fixation versus non-operative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial. *J Bone Joint Surg [Am]* 2013 Sep 4;95:1576-84. PMID: 24005198

AIM

To compare non-operative fixation *versus* operative fixation in midshaft clavicle fractures in terms of union rates, re-operation, functional outcome and economic cost within the first year after injury. The null hypothesis states there would be no significant difference between the two groups within the first year after injury.

METHODS

- Prospective randomisation of 200 patients between 2007 and 2010 into non-operative and operative groups with follow-up over one year.
- Both groups had the same physiotherapy sessions.
- Inclusion and exclusion criteria.

- Outcome measures included: fracture union (CT), function, satisfaction, complication and economic evaluation.
- Follow-up: 3 weeks, 6 weeks, 6 months, 12 months.
- SF-12, DASH, Constant Score.
- Statistical analysis carried out.
- Ethical approval sought.

RESULTS

- The rate of nonunion was significantly reduced after open reduction and plate fixation compared with non-operative treatment ($p = 0.007$).
- Overall, DASH and constant score were better in the operative group after one year ($p = 0.01$).
- When excluding nonunion, there were no difference in DASH or constant score between the two groups.
- The cost of treatment was significantly greater after operative fixation ($p < 0.0001$). Open reduction and plate fixation reduces the rate of nonunion after acute displaced midshaft clavicular fracture compared with non-operative treatment and is associated with better functional outcomes.
- However, the improved outcomes appear to result from the prevention of nonunion by open reduction and plate fixation. Open reduction and plate fixation is more expensive and is associated with implant-related complications that are not seen in association with non-operative treatment. The results of the present study do not support routine primary open reduction and plate fixation for the treatment of displaced midshaft clavicular fractures.

CRITIQUE

Strengths of the study

- Multicentre level I
- Prospective data
- Clear objectives
- Clear inclusion and exclusion criteria
- Group of experts in each centre
- Randomisation and blinding
- Strict follow-up plans
- Good use of statistics

- Reproducible

Methodological concerns

- If patient declined participation, then s/he would be treated non-operatively; are the authors more biased toward conservative management?
- Nonunion on CT: only the senior author decides, and not blinded. Risk of observer error.
- Patient with nonunion: vague description of symptoms.
- Number Needed to Treat (NNT): 6.2. Paper assumes not high enough?
- Calculation of cost: health service utilisation? Not clear how the sums were made.
- 'Perfect' study as not one single limitation was mentioned.
- Recommends non-operative treatment due to mainly high cost, despite union rate and functional outcome which is better in the operative group.
- No analysis of cost and how it was calculated.
- Need further explanation of why NNT of 6.2 is considered low despite its positive impact.
- Be aware of the high nonunion rate in the non-operative group.

OVERALL CONCLUSION

The conclusion of this paper is somehow misleading as it recommends non-operative management on the basis of cost, despite higher nonunion rates. Discussing options with patients, risks and benefits of operative fixation vs non-operative is key in formulating a plan as to what to expect in the first year of treatment.

Canadian Orthopaedic Trauma Society. Non-operative treatment compared with plate fixation of displaced midshaft clavicular fractures. a multicenter, randomised clinical trial. *J Bone Joint Surg [Am]* 2007 Jan;89:1-10.

AIM

To compare patient-oriented outcome and complication rates following non-operative treatment and those after plate fixation of displaced midshaft clavicle fractures.

METHODS

- 132 patients identified from April 2001 to December 2004 at eight centres in Canada.

- Completely displaced midshaft clavicle fractures were randomised to non-operative & operative treatment.
- Outcome scores recorded using DASH, constant score, bone union rate and complication rates.
- Inclusion and exclusion criteria.
- Sample size: to get 15% difference in scores - beta error 0.05
- Randomisation - research nurse (blinded)
 - Non-operative - polysling 6 weeks
 - Operative - oblique incision, plate on superior surface 3 screws on either side. Lagscrew or absorbable suture for fragments. Post-op polysling for 710 days. Physiotherapy and return to sports in 3 months.
- Follow up at 6, 12, 26 & 52 weeks.

RESULTS

- Mean time to fracture union was 16.4 and 28.4 weeks in the operative and non-operative groups, respectively ($p = 0.001$).
- Nonunion and malunion rates were lower in the operative group ($p = 0.042$ and $p = 0.001$, respectively).
- Hardware irritation 9%.
- Operative group had a higher patient satisfaction ($p = 0.001$).

Paper conclusions

Operative fixation of a displaced fracture of the clavicular shaft results in improved functional outcome and a lower rate of malunion and nonunion compared with non-operative treatment at one year of follow-up. Hardware removal remains the most common reason for repeat intervention in the operative group. This study supports primary plate fixation of completely displaced midshaft clavicular fractures in active adult patients.

CRITIQUE

Strengths of the study

- Multicentre randomised prospective study.
- Similar population in both groups.
- Patient controlled outcome scores.
- Specific type of fracture management.

Methodological concerns

- Small sample size.

- Clinical union: risk of observer error?
- Loss of follow-up - more in non-operative group; skewed results?
- Complication rate not clear.

OVERALL CONCLUSION

The findings of this study have indeed changed belief on management of midshaft clavicle fractures in favour of surgical fixation. However, further work is necessary to address the above weaknesses and generate an algorithm of treatment for midshaft clavicle fractures.