



JOURNAL CLUB: 7th October 2011
Chairman: Mr. Bijayendra Singh, Consultant.
Medway NHS Foundation Trust

Fractures of the shaft of clavicle – Operative vs non operative treatment

The issue is very topical and continues to be debated. We reviewed five articles published over the last 4 years.

It seems that operative intervention in patients who have a high energy injury, displaced and comminuted fractures

Canadian Orthopaedic Trauma Society. Non Operative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures: A Multicentre Randomised Clinical Trial. J Bone Joint Surg [Am] 2007;89-A:1-10.

Study design: Systematic Review

Reviewer: Mr Phinal Patel, Senior House Officer, Medway NHS Foundation Trust

Objectives:

To investigate the different clinical outcomes of operative vs nonoperative treatment of midshaft clavicular fractures.

Sample Size:

Randomised, 132 patients (65 treated nonoperatively, with 16 dropouts; 67 treated operatively, with 5 dropouts). Patients were recruited from 8 Canadian centres from April 2001-December 2004. A power analysis was undertaken beforehand to identify that a minimum of 60 patients would be needed in each group to obtain meaningful results.

Methods/Materials:

Roughly 50% of recruited patients were anonymised into each category, by means of a sealed envelope. Recruitment included informative measures by doctors and a dedicated team of

research nurses to those with a traumatic midshaft clavicular fracture, seen either in the ED or in Clinic.

Inclusion Criteria & Outcome measures:

- Age 16-60, able to consent, and no contra-indications to a GA.
- Sustained fractures must be traumatic only, with no neurovascular deficit.
- Fracture age and treatment (whichever category patients fell into) must have been within 28 days.
- No open fractures, but must be totally displaced.
- All patients received a standard sling for 6 weeks, with follow up strengthening physiotherapy following healing (under x-ray surveillance).
- All Operative patients received a small fragment plate with a minimum of 3 screws either side of the fracture line; all carried out under general anaesthetic, and all receiving prophylactic antibiotics, with no use of bone grafts or drains.
- All patients were followed up at 6 weeks, 3 months, 6 months and 12 months, which is where the study terminated.
- Outcome Criteria for all included Clinical follow up, the Constant Shoulder Score, DASH score and x-rays.

Results:

Operative patients scored better than non-operative patients across the 2 shoulder scores, having a greater patient satisfaction at 1 year. There was no significant difference in the range of movement between the 2 groups at 1 year. General appearance of the shoulder (anteriorly) proved to be better in the operative patients, except for operative incisions leaving scars and incisional numbness. 84% of patients expressed satisfaction in the operative group, compared to 53% treated non-operatively. A larger proportion of patients in the non-operative group expressed complications such as non-union, malunion and complex regional pain syndrome. A larger proportion of patients in the operative group expressed complications such as wound infection/dehiscence and hardware irritation requiring removal. Overall, statistically, only 37% operative patients experienced complications compared to 63% in the non-operative group.

Conclusion:

Operative treatment of traumatic midshaft clavicular fractures show a better outcome and patient satisfaction compared to non-operative management.

Strengths:

This is a clear and focussed study looking specifically at one type of fracture, within a set of fixed criteria. A simple but effective measure of randomized sampling avoided selection bias, within the chosen age group. A wide variety of outcome criteria were identified and published, enabling the study to reach a firm conclusion favouring operative over nonoperative treatment. Follow up criteria were sufficient to collect data to a satisfactory level for the objective highlighted in the study.

Weaknesses:

Given a multicentre (8) data collection over 3 years, it is disappointing that sample sizes in both groups are not larger. The study was unable to keep to its aim of at least 60 patients per group, due to dropouts, which highly affected the non-operative group. This should have been anticipated beforehand, knowing the pitfalls of follow up non-attendees, and should have been incorporated into the initial sample size. This meant that the power analysis of sample sizing was not met, and questions the reliability of the results to the degree of accuracy one would expect.

Summary:

A definitive study, managing to reach a respective conclusion to meet the needs of the objectives and hypothesis stated, however, only with a sub-optimal sample size.

A radiological study to define safe zones for drilling during plating of clavicle fractures

Sinha A, Edwin J, Sreeharsha B, Bhalai V, Brownson P.

J Bone Joint Surg [Br] 2011;93-B:1247–52.

Reviewer: Dr Jay Vyas, F2 South Thames Foundation Trainee, Medway Foundation NHS Trust

Background

There is a consensus that non-displaced clavicle fractures should be managed conservatively. However, when displaced there are increased rates of non-union when managed conservatively compared to surgically.

Aim

To establish safe drilling zones to stop iatrogenic vessel injury during plating of the clavicle.

Method

This study of 26 CT arteriograms of the head and neck aimed to investigate the anatomical relationship between the clavicle and adjacent subclavian vessels. The clavicle was split into three zones to try and establish safe drilling zones to stop iatrogenic vessel injury during plating.

Results

They found that the vessels lay posterosuperior to the medial clavicle and inferior to the lateral clavicle. This study created a traffic light system whereby they found plating the medial clavicle held the greatest risk and laterally the least risk to subclavian vessels.

Critique

This study gave a good insight into the neighbouring anatomy of the clavicle and overall this study provides a basic guide to the iatrogenic risk to vessels when plating the clavicle.

However, the scans used were of clinically abnormal patients, mainly with ischaemic symptoms which could alter the anatomy and distance of vessels from the clavicle.

The mean age was 51 years whereas this is predominantly an injury of the young.

Images were taken in the supine position which does not correspond to the normal surgical position and also alters the diameter of vessels.

Nonoperative treatment of closed displaced midshaft clavicle fractures

C Faldini, M Nanni, D Leonetti, F Aciri, C Galante, D Luciani, S Giannini

***J Orthopaed Traumatol* 2010;11:229-36.**

Reviewer: Mr Paras Mohanlal, Registrar, Medway Foundation NHS Trust

Objectives: To evaluate the results of 100 closed, displaced midshaft clavicle fractures treated non-operatively.

Materials and Methods: It was a prospective ethically approved study done at the Rizzoli Orthopaedic Institute. One hundred patients with Edinburgh-type 2B clavicle fractures between 2004 and 2006 were included. Open fractures and fractures with neurovascular deficit were excluded. All patients were treated with 'Figure-of-8' bandage. Patients were followed-up at monthly intervals for 3 months and then at last available follow-up. Four authors independently evaluated radiographs at each visit. 'Figure of 8' bandage was used till radiological evidence of callus formation. Shoulder movements were started only after radiological evidence of callus. At final follow-up, four authors independently rated the outcome using the DASH score. The correlation between type of fracture & healing time and type of fracture & functional outcome was also assessed.

Results: With an average age of 32 (18-67) years, there were 78 males and 22 females. Dominant extremity was involved in 72 cases. With an average follow-up of 3 (1-5) years, 97 fractures healed at an average 9 (8-12) weeks. The average DASH score was 24 (0-78). There was no correlation between type of fracture and healing time or functional score.

Conclusion: Non-operative treatment is appropriate in most cases with clavicular fractures yielding good results.

Strengths:

- Relevant and useful to current practice.
- Prospective study.

Weaknesses:

- Type III study
- Non-randomised
- Small numbers
- No pre-operative scoring system
- Observer bias
- None lost to follow-up?

Rasmussen JV, Jensen SL, Petersen JB, Falstie-Jensen T, Lausten G, Olsen BS. A retrospective study of the association between shortening of the clavicle after fracture and the clinical outcome in 136 patients. *Injury* 2011;42:414–17.

Reviewer: Nicholas McArthur, Clinical Trust Registrar, Medway Foundation NHS Trust

Introduction: A retrospective study which examined the association between clavicle shortening following union of midshaft fractures and clinical outcome. The study also compared the results between two types of non-operative management, a figure of eight bandage and a simple sling.

Patients and methods:

Of the 237 patients invited to participate, only 136 were reviewed. There were 107 men and 29 women with a mean age of 35 years, range 15–70 years. Mean followup time was 55 months, range 24–83 months. Fifty-eight fractures were on the dominant side. The inclusion criteria were a united, non-operatively treated midshaft fracture of the clavicle with no neurovascular deficits and no additional acute or chronic pathological conditions affecting the upper extremities.

Results:

The final clinical outcome was measured using the Constant–Murley Score that includes pain, activity of daily living, range of motion and isometric muscle testing. A maximum of 100 points indicates a shoulder with no disability. A paired t-test was used to determine differences in length and in the Constant–Murley Score between sides.

Student's t-test was used to assess differences between groups. The average shortening was 11.6 mm (SD 8.2), which was significant ($P < 0.001$). Mean Constant–Murley Score of the injured shoulder was 86.3, range 29–100 compared with 93.7, range 81–100 for the contralateral shoulder. Mean difference was 7.3 (SD 10.2), which was significant ($P < 0.001$). Patients with a shortening less than 20mm had a mean difference in the Constant–Murley Score of 7.2 (SD 10.3). Mean difference in shortening between the figure of eight bandage and simple sling groups was 1.2, $P = 0.45$ and mean difference in the Constant–Murley Score was 1.1. There was no correlation between shortening of the clavicle and the clinical outcome ($r = 0.14$, $P > 0.05$).

Discussion:

A shortening of 20 mm or more was not associated with a poorer clinical outcome. The results obtained by conservative treatment with a figure-of-eight bandage or a simple sling showed no difference either in final shortening or in Constant–Murley score.

Study strengths: long term follow up, large sample

Study weaknesses: selection bias, retrospective

Displaced midshaft fractures of the clavicle: Non-operative treatment versus plate fixation (sleutel trial). A multicentre randomised controlled trial
Stegeman et al, *BMC Musculoskeletal disorders* 2011;12:196.

Reviewer: Mr. Rajesh Bawale, Registrar, Medway Foundation NHS Trust

This was a prospective, multicentre randomised controlled trial which aimed to compare fracture consolidation and shoulder function after non-operative and plate fixation treatment.

It was conducted in 21 Hospitals in The Netherlands. It involved 350 patients between 18 and 60 years with displaced clavicle fractures treated operatively and non-operatively.

- Randomisation done by the trial website using TenALEA
- Inclusion criteria – displaced midshaft fractures, age group 18-60
No medical contra-indications for GA, informed consent signed by the patient
- Exclusion criteria – proximal or distal third fracture and more than 14 days old midshaft fracture, pathological fracture, neurovascular and associated head injury, ipsilateral upper limb fracture, inability to comply with follow up, previous shoulder surgery or shoulder problems
- Follow-up 2 years
- Operative management – using plate fixations by the skilled trauma surgeons or residents under supervision
- Non-operative – sling for two weeks
- Outcome measure – xrays, constant and DASH shoulder score,

Study strengths:

1. Good number of case series
2. Level I evidence
3. Types of procedures, post-op care, inclusion criteria well defined.
4. The results and the discussion are well described.

Study weaknesses:

1. Biased selection criteria
2. The results of the trial are not clearly defined

Relevance:

The results of this trial can be used to establish the preferred method of treating the displaced midshaft clavicle fractures in patients between 18-60 yrs of age. As described in this study, the operative treatment depends on the type of fracture, in patients sensitive to mild functional deficits and quick return to normal functions