



Journal Club: 29 June 2015

Chairman: Mr A Sinha

Attendees: WY Man (ST3), A Sinha (Cons), D A O'Kelly (Cons), V Kumar (Clinical Fellow), AS Miller (ST4), A Goel (Clinical Fellow), P Appukuttan (Staff Grade), J Jayadeep (Speciality Doctor), LN Banks (Cons), T Muthukumar (Associate Specialist), A Hanna (Cons), A Mirza (Cons), P Sathyamoorthy (Cons)

Glan Clwyd Hospital, Rhyl, Department of Trauma & Orthopaedics

Reviewer: Mr Wing Yum Man

Theme: Surgical vs nonsurgical management of proximal humerus fractures

Presented papers:

Olerud P, Ahrengart L, Ponzer S, Saving J, Tidermark J. Internal fixation versus nonoperative treatment of displaced 3-part proximal humeral fractures in elderly patients: a randomized controlled trial. *Journal of Shoulder and Elbow Surgery* 2011;20:747-755.

Rangan A, Handoll H, Brealey S et al. Surgical vs. nonsurgical treatment of adults with displaced fractures of the proximal humerus: the PROFHER randomized clinical trial. *JAMA* 2015;313:1037-1047.

Importance

- Account for 5-6% of all adult fractures
- Approximately 706 000 occurred worldwide in 2000
- Most often sustained as a result of a fall
- Cochrane review (2012) found insufficient evidence from RCTs to conclude whether surgical intervention produces better outcomes than non-surgical treatment
- Increasing trend to manage these injuries surgically
- Given increasing incidence due to aging population, establishing optimal treatment is a priority

1. **Olerud et al.** Internal fixation versus nonoperative treatment of displaced 3-part proximal humeral fractures in elderly patients: a randomized controlled trial

METHODS

- A prospective single-centered RCT in Sweden
- Published in 2011 (JSES)
- 60 patients with 3-part proximal humeral fractures were randomly allocated to surgical or nonsurgical treatment groups. After 2 years of follow-up, both groups were assessed on functional and quality of life scores. The results of the study indicate an advantage in functional outcome and HRQoL in favor of surgical group compared to the non-operative group.

Inclusion criteria

- N = 60
- 3-part fracture of the surgical neck according to Neer's classification

Detailed fracture inclusion criteria:

- Based on radiograph and CT
- Completely displaced head-shaft fractures, and valgus impacted fractures excluded

Patient inclusion criteria:

- Age of 55 or older
- A fracture sustained after low-energy trauma
- No previous shoulder problems
- Independent with living conditions
- No severe cognitive dysfunction (as defined by 10-item short portable mental status questionnaire)

Intervention

- All procedures performed by 1 of 2 experienced shoulder surgeons
- Within a mean of 6 days (SD 4.1)
- Given 2 g of cloxacillin preoperatively
- Modified beach chair position utilizing deltopectoral approach and Philos plate used
- Fractures of the lesser or greater tuberosities with displacement were fixed with non-absorbable sutures
- Post-op: arm placed in sling for 4 weeks
- Pendulum exercises and passive elevation/ abduction up to 90° were started from first postoperative day
- After 4 weeks, the patients were allowed free active range of motion

Comparison group

- Non-operative group

- Arm immobilized in a sling for 2 weeks after which they were allowed to use it at their own convenience
- After 2 weeks patients referred to physiotherapist, and pendulum exercises and passive elevation/ abduction up to 90° were started
- After 4 weeks they were allowed a free active ROM

Outcome

- Patients were followed-up at 4, 12 and 24 months
- The final follow-up was performed by an independent orthopaedic surgeon not previously involved in treatment
- Each follow-up included an x-ray AP/LAT
- Functional outcome was assessed using the Constant and DASH scores
- Constant score best possible score 100: pain, ADLs, ROM, and strength
- DASH questionnaire 30 item disability/ symptom score specific to upper limb
- HRQoL was assessed using the EQ-5D
- EQ-5D has 5 dimensions: mobility self-care, usual activities, pain/ discomfort and anxiety/ depression
- Pain also assessed on visual analogue score
- Cognitive assessments (SPMSQ), ASA, ADL, BMI also recorded

RESULTS

2 yrs	Surgical	Non-surgical	P-value
EQ-5D	0.70	0.59	.26
VAS	17	20	.94
DASH	26	35	.19
Constant	61	58	.64
Flexion	120°	111°	.36
Abduction	114°	106°	.28

CRITIQUE

Strengths of the study

- Detailed and justified inclusion and exclusion criteria
- Only 2 surgeons involved minimising confounding variable
- Specifically relates to treatment of displaced 3-parts fracture
- Primary outcome (EQ5D) assessed at baseline
- Radiographic and clinical assessment data included in outcomes

Methodological concerns

- No power calculation as insufficient published data
- Power calculation performed with obtained data. Recommended n = 180
- Results not statistically significant
- Primary outcome that EQ5D which is significant just compares follow-up values to baseline value
- Conclusion does not account for in surgical group 9 underwent further surgery (4 major surgery)
- Conclusion does not correlate with actual findings

2. **Rangan A, Handoll H, Brealey S et al.** Surgical vs. nonsurgical treatment of adults with displaced fractures of the proximal humerus: the PROFHER randomized clinical trial. JAMA. 2015;313:1037-1047.

METHODS

- Prospective, multi-centered (33), Pragmatic RCT
- Published in 2015 (JAMA)
- 250 patients with displaced proximal humerus fracture were randomized to surgical management with either internal fixation or hemiarthroplasty or conservative management with sling immobilization. The purpose of this study was to compare the treatment methods based on outcome of the Oxford Shoulder Score, as well as incidence of complications. Follow-up was conducted at 3, 6, 12 and 24 months. No significant differences were observed between groups in Oxford Shoulder Score at any time point.

Inclusion criteria

- N = 250
- Aged 16 or older
- Presenting within 3 weeks of injury
- Displacement had to be severe enough for surgical intervention to be considered
- Neer's classification not used
- Randomization included stratification by tuberosity involvement
- Standardized rehabilitation protocol was used for both groups
- Those not fit for theatre excluded

Intervention

Surgical group:

- Internal plate fixation
- Hemiarthroplasty

- To avoid learning curve issues, surgeons and physiotherapists used interventions and procedures which they were familiar

Non-surgical comparison group:

- Patients were allocated to non-operative management with sling immobilization
- Leaflet on personal care during sling immobilization
- Basic physiotherapy guide
- Promotion of home exercises
- Physiotherapy as an inpatient and outpatient

Outcome

- Data collection via hospital forms for baseline characteristics
- Patient questionnaires at 3,6, 12, and 24 months
- Primary outcome was the Oxford Shoulder Score
- Oxford shoulder score provides a total score based on the patient's subjective assessment of pain and function
- 0 worst outcome – 48 (the best)
- Secondary outcomes included the Short Form 12 questionnaire, EQ-5D and incidence of complications
- Fracture classification – 2 blinded independent shoulder surgeons characterized all fractures from baseline radiographs

RESULTS

- There was no statistically significant differences between the 2 treatment groups during the 2 year period ($p=0.48$)
- Power calculation based on unpublished data 2014
- Response bias minimized using a multilevel model
- Missing data was assessed with a “post hoc sensitivity analysis using multiple imputation by chained equations”?!

Subset analyses performed:

- Age
- Tuberosity involvement
- Smoking
- Patient preference

Strengths of the study

- High powered
- Multi-centered
- Recent
- Validated outcome measurement

- Comprehensive statistical analysis
- Transparent with results

Methodological concerns

- Difficult to criticize
- Follow-up limited to 2 years
- Age of 16+ is a large demographic
- No baseline OSS scores
- No radiological or clinical follow-up data
- Differing threshold for surgery- effects inclusion criteria
- Not specific with recommendations for particular fracture configurations
- Conclusion not satisfying

Discussion of theme

- Olerud et al focuses on the management of displaced 3-part fractures
- Using clinical and radiological outcomes over a 2 year follow-up
- No statistical significance between 2 groups, but state LP group fared better
- Overlook 30% of surgical group underwent further surgery
- Rangan et al produce a landmark paper
- High powered with comprehensive statistical analysis
- Suffers from lack of radiological and clinical outcome data, however OSS is a well-validated score
- Unclear in its recommendations in how to treat specific fractures
- Unfortunately both papers only yield 2-year follow-up data
- Further research into longer-term follow-up needed