

Journal Club: 11 October 2011

Attendees: CA Peach, JC Talbot, M Sabo, C Ng, C Simpson, M Walton

Reviewer: CA Peach

Proceedings from the Wrightington Upper Limb Unit Journal Club

### **Presented Paper:**

Olerud P, Ahrengart L, Pozer S, Saving J, Tidermark J.

Hemiarthroplasty versus nonoperative treatment of displaced 4-part proximal humeral fractures in elderly patients: a randomized controlled trial

*J Shoulder Elbow Surg* 2001;20:1025-33.

### **Summary**

#### **1. Purpose**

The study aims to report outcomes after displaced 4-part proximal humeral fractures in elderly patients allocated to treatment with a hemiarthroplasty or nonoperative treatment in a randomised controlled trial with a 2 year follow up.

#### **2. Methods**

A randomised controlled trial was performed including patients with an acute displaced 4-part fracture of the surgical neck of the humerus over a 5 year period. Inclusion criteria was shaft displacement of more than 10 mm and/or  $>45^\circ$  of angulation relative to the head fragment. Patients needed to be  $\geq 55$ , low energy trauma, no previous shoulder problems, live independently with no severe cognitive dysfunction. Patients were excluded if the shaft was completely displaced from the head fragment as they were considered as having an absolute indication for surgery. Valgus impacted fractures were also excluded. Randomisation was carried out by opening opaque sealed envelopes prepared independently. The operative arm received a cemented hemiarthroplasty.

Outcome measures were primarily a health related quality of life (HRQoL) measure according to the EQ-5D (compared to a recalled pre-injury level) and secondarily according to the DASH and Constant scores. Other outcomes reported were range of flexion and abduction, visual analogue score, humeral head height and tubercle displacement.

### 3. Results

From the initial cohort of 55 patients, there were 24 (89%) patients available for follow up at 2 years in the hemiarthroplasty group (HA) and 25 (89%) in the non-operative group (NO). Demographics of both groups were similar except mean cognitive function in the non-operative group was lower. The EQ-5D was significantly higher in the HA group at two years. The EQ-5D returned to pre-injury level in the HA group by 2 years post op. In the NO group, the EQ-5D significantly reduced after injury and remained low. There was no difference in the DASH or Constant scores between the groups at any post operative visit. The mean pain score (VAS) was 15 in the HA group compared with 25 in the NO group. There was no difference in ROM between either group.

### 4. Conclusions

The authors concluded that there was an advantage in the quality of life outcome after hemiarthroplasty compared with non-operative treatment but that functional outcomes were similar. However they still advocate operative treatment for the healthy elderly patient with high functional demands.

### Critique

This paper asks the valid question of whether elderly patients with 4 part proximal humeral fractures benefit from operative intervention. It provides useful information about how well patients fare treated non-operatively. We feel that the outcome measures used had drawbacks, particularly in relation to the strength component of the Constant score but that, at the time of study design, there were few validated alternatives. At the time of designing the study, reverse shoulder prosthesis was not widely available to be used in the fracture setting, but would have been a useful third arm in hindsight. The results were enough to provide a robust message, however the authors went beyond this and made conclusions that were unsubstantiated by the results presented. The abstract contained misleading conclusions.

### Strengths

- This is a well constructed prospective randomized controlled trial
- It provides unique information on this clinical problem
- It is well powered to answer the primary aim
- The authors used validated outcome measures including patient reported outcome measures.

### Methodological Concerns

- The study was underpowered to detect differences in functional outcomes which were the secondary outcome measures.

- Constant score has drawbacks as an outcome score as the strength is unrecordable in most patients undergoing hemiarthroplasty for fracture.
- Age groups studied were broad and the study would have benefitted observing an older age group.
- HRQoL was compared with a pre-operative score recalled after the fracture to serve as a baseline
- There was no blinding of the observer when reviewing the patients at final follow up
- The significantly reduced cognitive function in the non-operative group raises the possibility of bias in the randomization process.