Cemented versus uncemented hemiarthroplasty for displaced intracapsular hip fractures; a three-year follow-up of a randomised trial of 400 patients.

Abstract

Aims and methods

This report details the three-year follow up for a series of 400 patients with a displaced intracapsular fracture who were randomised between a cemented polished tapered stem hemiarthroplasty and an uncemented Furlong hydroxyapatite coated hemiarthroplasty. Follow-up was by a nurse blinded to the implant at set intervals for up to three years from surgery.

Results

210(52.5%) of patients died within three years of injury. One patient was lost to follow-up. Regain of mobility was superior for those treated with the cemented implant, although by three years this difference had become statistically insignificant. Long term mortality was reduced for those treated with the cemented implant (p=0.029, log rank test). There was no noticeable difference in the pain scores between groups and neither was there any diffidence in the occurrence of implant complications or revision surgery between the two groups.

Conclusions

These results give further support the use of a cemented hemiarthroplasty for the routine management of a patient with a displaced intracapsular fracture.

Introduction

An intracapsular fracture is one of the commonest reasons for an elderly patient to require admission for acute orthopaedic surgery. Most of these fractures are displaced and they are generally treated using a replacement arthroplasty.[1] Debate exists as to whether this implant should be cemented in place. [2] We have previously undertaken a large randomised trial on this topic involving 400 participants using contemporary implants. [3] This reported details the final follow-up results as all surviving patients have now been followed up to three years from injury.

Patients and methods

Full methods for this study have been previously published. [3] From a series of 1345 patients admitted with an intracapsular hip fracture to a single centre between August 2013 and June 2018, 400 patients were randomised between either a cemented hemiarthroplasty, or an uncemented hydroxyapatite coated implant. Inclusion criteria for patient to be considered was any patient with an intracapsular fracture. The exclusion criteria from these patients were those patients with an undisplaced fracture, younger patients in which either internal fixation or a total hip arthroplasty were considered appropriate. This included those patients who are able to walk independently out of doors with no more than the use of a stick, were not cognitively impaired and had a good predicted long-term survival. Some of these patients were considered for concurrently running randomised trials of hemiarthroplasty versus total hip replacement or fixation versus arthroplasty. Also excluded were patients considered unfit for a cemented arthroplasty, patients with significant degenerative

arthritis of the hip and pathological fractures from tumour. For those patients with mental impairment the assent of the next of kin was sought and if this was not obtained the patient was excluded. In addition, patients were not recruited when the lead trialist was not available. One further patient was excluded due to an abnormal femur from polio and one when equipment was not available. (Figure 1) Written consent, or the assent of the next of kin, was obtained from all included participants.

Randomisation was achieved using identical sealed numbered opaque envelopes. These were prepared by a person independent to the study, numbered from 1 to 400 and opened in this order. Surgical treatment with either a cemented unipolar double tapered stem hemiarthroplasty (Exeter Trauma Stem, Stryker Medical or CPT Zimmer/Biomet) or an uncemented fully hydroxyapatite coated Furlong hemiarthroplasty (JRI Orthopaedics ltd, Sheffield, United Kingdom). All operations were using a Hardinge direct lateral approach to the hip. All but eight operations surgery was undertaken or directly supervised by the lead trialist (Figure 1). After surgery all patients were mobilized fully weight bearing with no post-operative restrictions on weight bearing or hip movement. Two patients allocated to a cemented hemiarthroplasty received an uncemented implant and a further one internal fixation due to being considered too high a risk from cement at the time of surgery. One patient in the uncemented group received internal fixation as at the time of surgery as they were considered too high a risk for the more prolonged operation of arthroplasty.

All surviving patients where invited to be reviewed in the follow up clinic at six weeks from discharge. Continued phone call follow up of the patients at three monthly intervals till one year then annually to a minimum of three years from injury was undertaken by a research nurse blinded to the initial treatment method. If the patient could not be contacted the patients' relatives or general practitioner were contacted to determine outcome. One patient was lost to follow-up after the one-year assessment. For the follow-up interview details of the patient degree of residual pain, walking ability, function and need for any additional surgery was recorded. [4] The study was approved by the hospital research and development committee and the Coventry and Warwick National Research Ethics Committee (reference 13/WM/0049 Sponsor – North West Anglia NHS Foundation Trust, Trial registration NCT02998034).

Statistical analysis. The primary outcome for the study was the regain of mobility, for which a power calculation indicated 400 patients were required in the study. [3] All results were analysed on an intention to treat basis. Binary outcomes for the two groups were analysed using Fisher exact test and continuous outcomes with the unpaired t-test. (GraphPad InStat version 3.00 for Windows 95, GraphPad Software, San Diego California USA). 95% confidence intervals and p values were calculated for all outcomes. A p-value of $p < 0.05$ was considered as statistically significant. Mortality was plotted using a Kaplan Meier graph and statistical analysis was the Log-rank test.

Results

400 patients were randomised, 200 to each group. The mean age of the patients was 85 years, 68% were female. (Table 1) As previously reported the uncemented arthroplasty was five minutes shorter surgical time but had an increased need for blood transfusion (14% versus 7%). [3] No statistically significant difference between groups was seen for the occurrence of general medical or wound healing complications. [3]

Mobility was assessed on a scale of 1-9 (full mobility without aids to no mobility at all). There was a constant trend to better regain of mobility at all time points for those treated with the cemented arthroplasty (Figure 2, Table 2). This difference was statistically significant at three months and one year whilst the difference was less pronounced beyond one year. Table 3 and Figure 3 detail the mortality for the two groups. After 5 months there was a trend to reduced mortality in the uncemented group with the maximum difference at two years from injury. Log rang test for Kaplan Meir graph gives a p value of 0.029 for the difference. Pain at follow-up was assessed on a scale of 1-8 (no pain to constant severe pain). There was no difference in the pain scores between groups at any time interval (Figure 4, Table 4). There was no difference between groups in the number of patients returning to their own homes or social dependence.

Regarding surgical complications and revision surgeries, by three years the most prevalent surgical complication was later peri-prosthetic fracture with six cases in

each group. Other complications were two dislocations in each group, one fracture non-union in a patient allocated to cemented hemiarthroplasty who received internal fixation due to poor health at the time of surgery, three cases of acetabular wear and one case of subluxation of the implant all in the uncemented group and all revised to total hip arthroplasty. Secondary surgical procedures for the hip were required for 10(5.0%) of patients in the cemented group versus 14(7.0%) in the uncemented group. Of these procedures the number of revision arthroplasties was 5(2.5%) in the cemented group versus 9(4.5%) in the uncemented group. None of these differences was statistically significant

Discussion

The primary outcome set for this study was regain of mobility and a constant trend to better regain of mobility was found for those treated with a cemented implant. This difference was less pronounced and not statistically significant after one year from injury. This finding of better regain of mobility for the cemented implants has also been reported by other randomised studies and again documented in the Cochrane systematic review. [6,7,8]

This longer term follow up study also documented a statistically significant reduction in mortality for those treated with the cemented implants. Possible explanations for this are the better function achieved in those allocated to a cemented implant. Whilst other randomised trials have noted a trend to a lower mortality for the cemented implants, no previous randomised trial on this topic has been able to demonstrated a statistical difference in this outcome. The recently reported multi-centre study of 610

participants reported a one year mortality of 23.9% for the cemented group versus 27.9% for the uncemented group (odds ratio 0.80; 95% CI, 0.62 to 1.05).[6] The Cochrane review on this topic reported data from 15 randomised studies involving 3727 participants with a one-year mortality rate of 455/1862(24.4%) for cemented stems versus 528/1865(28.3%) for the uncemented stems. This difference, with the adequate patient numbers, was reported as being statistically significant (RR 0.86, 95% CI 0.78 to 0.96). [7]

The strengths of this study are the secure randomisation of patients, the high proportion of patients receiving the treatment to which they were allocated, minimal loss to follow-up and the blinded assessment of outcomes. Information was recorded for all patients admitted to the study centre and this ensured that the patients admitted to this study were representative of these elderly patients with a displaced intracapsular fracture (figure 1). Weaknesses of the study are the limited patient numbers, which precludes definite conclusion being made for some of the outcomes, such as surgical complications.

The main complication leading to revision surgery of patients was peri-prosthetic fracture accounting for most of the revision arthroplasties within this series. The cemented stems used in this study were all polished tapered stems. It is possible that changing to a composite beam type of stem would reduce this complication. [9] This study did not include a cost analysis between the two implants. A cost-utility report on the randomized study of Fernandez and colleagues [6] showed the cemented implant to be cost effective when compared against an uncemented stem.[10]

In summary the results of this study indicate that a contemporary fully hydroxyapatite coated uncemented hemiarthroplasty stem leads to an increased mortality and a tendency to an inferior regain of mobility in comparison to a cemented arthroplasty. A modern uncemented implant may still be appropriate but only for those at very high risk of bone cement implantation syndrome.[11] For the majority of patients with a displaced intracapsular fracture, who are deemed fit for the procedure, a cemented prosthesis should be the implant of choice.

References

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Tables

Table 1.

Patient characteristics (%).

	Cemented hemi-arthroplasty	Uncemented hemi-arthroplasty	p value	Relative risk	95% confidence interval
Number of patients	200	200			
Mean age in years [range]	84.2[60-102]	85.3[58-98]	0.15	1.10*	-0.41 to 2.61
Number male	67 (33.5%)	60 (30.0%)	0.52	1.12	0.84 to 1.49
From own home	160 (80.0%)	169 (84.5%)	0.30	0.95	0.86 to 1.04
Mean mobility grade[4]	4.0	4.1	0.97	0.1*	-4.6 to 4.8
Mean social dependency grade[4]	3.4	3.5	0.97	0.1*	-5.5 to 5.7
Mean mental test score [5]	6.6	6.4	0.96	0.2*	-8.8 to 8.4
Mean ASA score	3.0	3.0	1.0	0*	-1.0 to 1.64
ASA grade one or two	36 (18.0%)	34 (17.5%)	0.90	1.01	0.69 to 1.62
Mean haemoglobin on admission	125	124	0.97	1*	-52.4 to 50.4

*= mean difference

Table 2.

Change in mobility scale.

	Cemented hemiarthroplasty	Uncemented hemiarthroplasty	p value	Mean difference	95% confidence interval
8 weeks	1.8 (1.8,167)	2.2 (1.8,173)	0.041	0.4	0.02 to 0.78
3 months	1.5 (1.7,165)	2.1 (1.9,165)	0.003	0.6	0.21 to 0.99
6 months	1.3 (1.6,156)	1.8 (1.9,150)	0.013	0.5	0.11 to 0.89
9 months	1.3 (1.7,150))	1.7 (1.9,142)	0.059	0.4	-0.01to 0.81
1 year	1.1 (1.9,147)	1.7 (1.9,135)	0.008	0.6	0.15 to 1.05
2 years	1.5 (2.0,120)	1.7 (2.0,101)	0.42	0.2	-0.31 to 0.75
3 years	1.7 (2.2,100)	1.9 (2.0,79)	0.55	0.2	-0.44 to 0.82

Table 3.

Mortality (%).

	Cemented hemiarthroplasty	Uncemented hemiarthroplasty	p value	Relative risk	95% confidence interval
1 year mortality	51 (25.5%)	64 (32.0%)	0.18	0.80	0.58 to 1.09
2-year mortality	73 (36.5%)	93 (46.5%)	0.05	0.79	0.62 to 0.99
3-year mortality	95 (47.7%)	115 (57.5%)	0.06	0.83	0.69 to 1.01

Table 4.

Mean pain score.

	Cemented hemiarthroplasty	Uncemented hemiarthroplasty	p value	Mean difference	95% confidence interval
8 weeks	1.6 (0.77,164)	1.6 (0.88,173)	1.000	0	-0.18 to 0.18
3 months	1.4 (0.58,164)	1.3 (0.75,160)	0.180	0.1	-0.24 to 0.05
6 months	1.2 (0.42,155)	1.2 (0.63,147)	1.000	0	-0.12 to 0.12
9 months	1.2 (0.50,148)	1.1 (0.55,141)	0.107	0.11	-0.22 to 0.22
1 year	1.2 (0.59,146)	1.1 (0.55,134)	0.145	0.14	-0.23 to 0.35
2 years	1.2 (0.72,120)	1.2 (0.84,100)	1.0	0	-0.21 to 0.21
3 years	1.3 (0.78,98)	1.3 (0.94,79)	1.0	0	-0.26 to 0.26

Figures

Figure 1.

Flow diagram of patient recruitment.

Figure 2.

Change in mobility scores.

Figure 3.

Kaplan-Meier mortality graph.

Figure 4.

Mean pain scores.