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Treatment of the displaced intracapsular fracture for the 'fitter' elderly patients: A randomised trial of total hip arthroplasty versus hemiarthroplasty for 105 patients

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ABSTRACT

Controversy exists for the optimum method of surgical treatment for the 'fitter' elderly patient with a displaced intracapsular fracture. 105 patients were randomised to treatment with either a cemented polished tapered stem hemiarthroplasty or a cemented total hip arthroplasty (THR) with a cemented acetabular cup. All patients were followed up for a minimum of one year using a blinded assessment of functional outcome.

Those patients treated with a THR had a tendency to a longer hospital stay and increased medical (12 versus 62) and surgical complications (4 versus 2) in comparison to those treated by hemiarthroplasty. Mean operative times (842 versus 52 min) and operative blood loss (335mls versus 244mls) were increased for THR. Final outcome measures of residual pain and regain of function were similar for both methods of treatment.

We recommend that caution should be exercised regarding the increased promotion of THR for intracapsular hip fractures until further studies are completed.

Introduction

An intracapsular hip fracture is one of the commonest reasons for an elderly patient to be admitted to an acute orthopaedic ward. Global numbers for hip fractures of 1.3 million in 1990 have been estimated with numbers increasing to between 7 and 21 million by 2050 [1]. Local reports continue to document the increasing numbers of hip fracture patients [2,3] Half of these fractures will be intracapsular with the majority of these being classified as a displaced fracture. Customarily a displaced intracapsular fracture in an elderly patient is treated by a replacement arthroplasty. Controversy exists as to whether the arthroplasty should just involve replacing the femoral head (hemiarthroplasty) or also replacing the acetabular surface (total hip replacement (THR). One potential adverse effect of hemiarthroplasty is wear of the acetabular cartilage which may lead to pain and reduced function. THR therefore removes this potential complication but entails a more extensive surgical procedure. Furthermore the addition of an acetabular resurfacing may increase the risk of prosthetic dislocation [4,5].

The Cochrane group have identified fourteen randomised trials to date on this topic involved 1523 patients in total. [4] Whilst these have suggested a tendency to better function after THR, the limited patient numbers preclude definite conclusions being made [4,5]. Arthroplasty register studies have highlighted the selection biases that occurs for case series reports with fitter patients receiving the THR [6,7]. To supplement the evidence base on this controversy we have conducted a single centre study, randomising suitable patients between hemiarthroplasty and THR with full reporting of the results and blinded assessment of outcome.

Patients and methods

All patients admitted to Peterborough City Hospital hospital with a displaced intracapsular fracture were evaluated by the lead trialist (MJP) and considered for inclusion in the study. Inclusion criteria were being able to walk independently out of doors with no more than the use of a stick (mobility scale 3 or less, Table 1) [8], not cognitively impaired (mental test score 8 or more) [9] and medically fit for either procedure. Exclusion criteria were those with impaired mobility prior to the injury (mobility scale 4 or more, Table1), age less than 60 years, age 60 and above in which

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Table 1
Assessment scales used.

Score	Pain	Mobility scale	Social dependence
1	No pain at all in the hip	Never uses any walking aid and no restriction in walking distance	Completely independent. Requires no assistance in basic or advanced activities of daily living (ADL) including shopping
2	Occasional and slight pain. May occasionally take mild analgesia such as paracetamol	Never uses any walking aid but walking distance limited to less than one kilometer	Minimal assistance. Requires occasional help up to twice a week from family, friends or others services with some activities such as shopping or gardening
3	Some pain when starting to walk, no rest pain. Occasional analgesia taken	Occasionally uses a walking aid when out walking	Moderate assistance. Requires regular assistance more than twice a week but less than seven times a week with some ADL activities such as bathing, washing or heavy housework
4	None or minimal pain at rest, some pain with activities, frequent mild. analgesia	Normally uses one walking stick or needs to hold onto furniture	Regular assistance. Requires daily help daily to assist with ADL
5	Regular pain with activities which limits walking distance. Occasional or mild rest pain	Normally used two sticks or crutches	Dependent. Requires regular help more than once a day with many basic ADL such as preparing food and housework but remains living at home
6	Frequent rest pain and pain at night. Pain on walking. Regular mild analgesia and occasional stronger analgesia taken	Mobilises with a frame alone, without the need for assistance	Severely dependent. Living in residential care. Full time care facility but independent of at least one basic activities of daily living such as being able to dress or go to the toilet without help
7	Constant pain present around the hip. Regular mild analgesia and frequent strong analgesia	Mobilises with a frame and the assistance of 1 person	Fully dependent. Living in nursing home, skilled nursing home or long-term hospital facility with full time nursing cares. Requires assistance in most activities of daily living such as washing, dressing and getting to the toilet
8	Constant and severe pain in the hip requiring regular strong analgesia such as opiates	Mobilises with a frame and the assistance of 2 people	Hospital in-patient requiring both nursing and medical care
9		Bed to chair (with or without assistance) or wheelchair bound	

internal fixation was felt the be the choice of treatment due to a predicted good long term survival, admission when the lead trialist was not available, those who were not considered to be medically fit for either procedure, patients who declined to participate, significant degenerative arthritis of the hip, acetabular dysplasia, senile dementia and those without the capacity to give informed consent.

Details of the patient mobility and social dependency along with patient demographics immediately prior to the fall were assessed on admission. Written consent for the study was obtained prior to surgery by MJP. The study was approved by the hospital Research and Development Committee and the research ethics committee (NRES Committee London, Stanmore. Sponsor North Peterborough and Stamford NHS TrustWest Anglia NHS Foundation Trust, Trial registration NCT02998359). Randomisation was by opening of numbered sealed opaque envelopes containing details of the operation to be used.

Surgical treatment was with either a cemented unipolar hemiarthroplasty or a cemented total hip arthroplasty. All stems were a polished tapered stem. All acetabular cups were cemented polyethylene, apart from one which was a hybrid hip with an uncemented cup inserted via a posterior approach.Those patients treated with hemiarthroplasty had no restriction on hip function whilst those treated with THR were advised to limit flexion of the hip beyond 90 degrees for bending and sitting and avoidance of crossing the legs and excessive twisting for eight weeks. All patients were allowed to weight bear as able.

After discharge from hospital the first follow-up was an initial review in a hip fracture clinic at eight weeks from admission. Functional assessments and pain scores were assessed by a

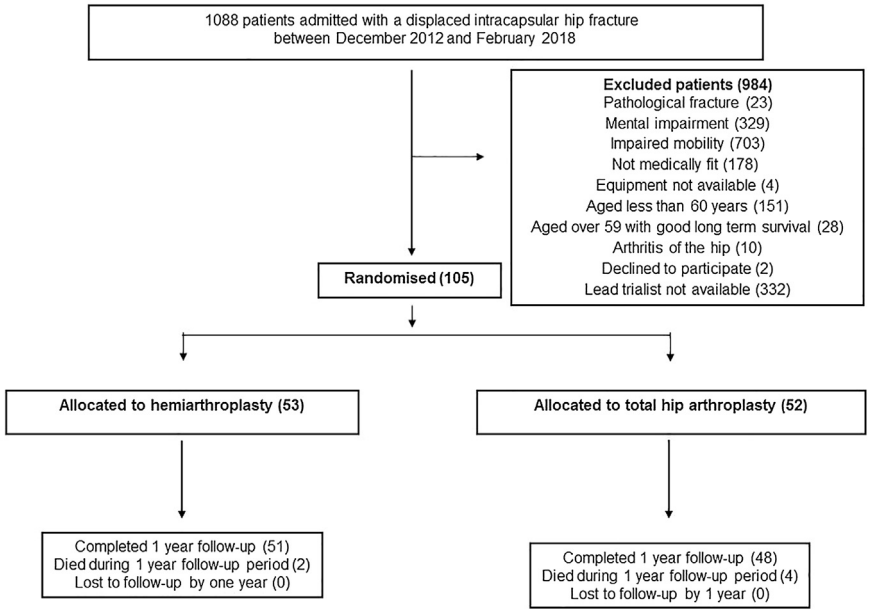

Fig. 1. Flow diagram for patients (patients may have been excluded for more than one reason).

research nurse who was blinded to the treatment allocation. At this visit limb shortening and loss of flexion from the contralateral hip was measured for those patients with a normal contralateral hip. Subsequent assessments were by the same nurse by phone calls at three, six, nine and twelve months from injury and then annually thereafter for up to five years. Fracture healing complications reported at any follow-up visit were recorded. In addition; if any patient was referred back for implant related complications at any time, these complications were recorded and included in the presentation of the results. Pain was assessed on a scale of one (no pain) to eight (constant and severe) (Table 1). The patients' walking ability was assessed using a mobility scale and social dependence with a dependency score (Table 1) [8].

The power calculation for the study was based on the change in mobility scale. Assuming that the outcome measure of mobility has a normal distribution and for a 2-sided significance level of 0.05, power 80% for a difference of 1 point then a total of 264 patients are required using a standard deviation of 2.9 taken from previous studies. To allow for loss of patients from follow-up and deaths, then a minimum number of 300 patients (150 in each group) would be needed. This number proved to be impractical within a reasonable time period so the study was closed to new patients after 105 patients had been recruited.

Statistical analysis. 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. For the length of hospital stay the data was not parametric, so the Mann Whitney U test was used. (GraphPad InStat version 3.00 for Windows 95, GraphPad Software, San Diego California USA). A p-value of $p < 0.05$ was considered as statistically significant.

Results

105 patients were randomised. All patients were treated as per protocol and received the treatment to which they were allocated (Fig. 1). All but eight operations were directly undertaken or supervised by the lead trialist. Two hemiarthroplasties and two THR's were undertaken by orthopaedic consultants and three hemiarthroplasties and one THR by trainee or staff grade surgeons. All except one THR operation used an anterolateral approach. One of these THR's was a hybrid hip inserted via a posterior approach. All arthroplasties were polished double tapered stems. Of the hemiarthroplasties 22 were monoblock Exeter Trauma Stems (Smith and Nephew Ltd), four CPT bipolar hemiarthroplasties (Collarless, polished double-taper, (CPT) Zimmer Corporation ltd) and the remainder CPT modular hemiarthroplasties. For the total hips, 29 were a CPCS stem (Smith and Nephew ltd) and the remainder CPT Zimmer stems. All but one of the cups were a cemented high density polyethylene with a 32 mm internal diameter. One cup was uncemented. Mean follow up was 1080 days with all patients having a minimum follow up of one year and no patient was lost to follow up.

The characteristics of the two groups of patients are given in Table 2 with no significant differences between groups. The mobility and social dependency grade are as detailed in Table 1.

Table 3 details the peri-operative details and mortality up to one year from admission. As to be expected for the less invasive procedure operative times and mean operative blood loss were less for hemiarthroplasty. Limb shortening and hip flexion were measured by the blinded observer at the outpatient assessment six weeks after discharge from hospital. Those treated with a THR had a greater loss of flexion.

Table 4 details the general complications encountered during the follow-up period. Because of the limited numbers of such complications none of the differences were statistically significant.

Table 2
Patient characteristics for the two groups.

	Hemiarthroplasty	THR	P value
Number of patients	53	52	
Mean age in years [range]	77.1 [60–89]	77.1 [67–89]	0.94 *
Number male (%)	8 (15.1%)	12 (23.1%)	0.33 #
From own home (%) - all own home	53 (100%)	52 (100%)	1.0
Mean mobility grade	1.4	1.6	0.22 *
Mean social dependency grade	1.1	1.1	1.0 *
Mean mental test score [9]	8.9	8.7	0.29 *
Mean ASA score [10]	2.0	2.2	0.12 *
ASA grade one or two (%)	46 (86.8%)	36 (69.2%)	0.04 #
Mean haemoglobin on admission	131.6 g/l	132.4	0.75 *

* Unpaired *t*-test.
\# Fisher exact test.

Table 3
Peri-operative details and mortality (%).

	Hemiarthroplasty	THR	P value
General anaesthesia	26	29	0.69
Mean length of surgery (minutes)	52.0	83.9	<0.0001 *
Mean length of anaesthesia	70.8	102.8	<0.0001 *
Mean operative blood loss (mls)	244	335	<0.0001 *
Required blood transfusion	1(1.9%)	4(7.7%)	0.36 #
Mean hospital stay in days	9.2	14.5	0.055 ~
No demonstrable shortening	40/47(85.1%)	35/43 (81.4%)	0.78
Shortening of 10 mm or more	2/47(4.3%)	3/43(7.0%)	0.67
Mean loss flexion in degrees	9.7	16.4	0.004
30 day mortality	0	0	1.0
120 day mortality	1(1.9%)	2(3.8%)	1.0
365 day mortality	2(3.8%)	4(7.7%)	0.68

* Unpaired *t*-test.
\# Fisher exact test.
~ Mann-Whitney test.

Table 4
General complications (%).

	Hemiarthroplasty	THR	p value
Superficial wound infection	2(3.8%)	2(3.8%)	1.0
Deep wound infection	0	0	1.0
Haematoma	0	1(1.9%)	1.0
Urinary retention	2(3.8%)	3(5.8%)	1.0
Deep vein thrombosis	0	2(3.8%)	0.50
Pressure sores	0	1(1.9%)	1.0
Delirium	2(3.8%)	2(3.8%)	1.0
Cerebrovascular accident	0	1(1.9%)	1.0
Fat embolism/cement reaction	0	1(1.9%)	1.0
Patient with complication	6(11.3%)	12(23.1%)	0.19

There was a tendency however to a greater number of patients to have a complication in the THR group (6 versus 12, $p = 0.19$).

Secondary operations were required for six patients. Three patients, two in the THR group and one in the hemiarthroplasty group, had a later peri-prosthetic fracture. These were all treated by internal fixation. One patient in the THR group had revision of the acetabular cup for loosening and one further patient in the THR group had three closed reductions of a dislocated hip. One patient in the hemiarthroplasty group had a single dislocation treated by open reduction.

Fig. 2 details the mean pain scores as assessed by the nurse blinded to the treatment method at the set follow-up times. None of the differences were statistically significant. Figs. 3 and 4 given the mean differences between the mobility scale and social dependency scale at the different time periods after subtraction of the score for the patient prior to the injury. None of the differences were statistically significant.

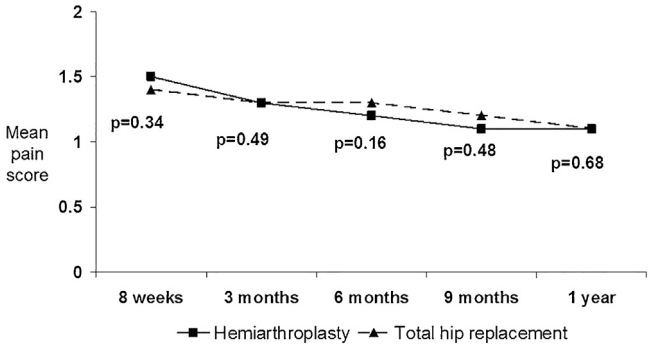

Fig. 2. Mean pain scores.

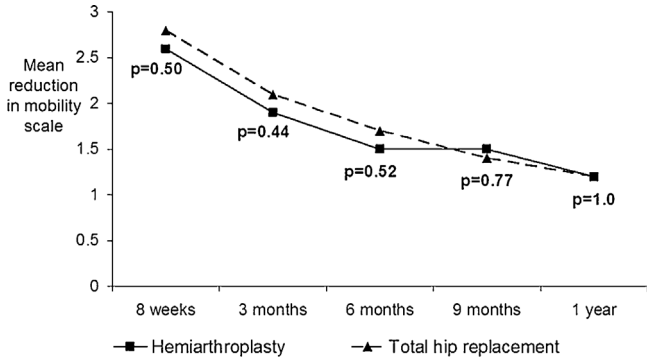

Fig. 3. Mean change in mobility scale.

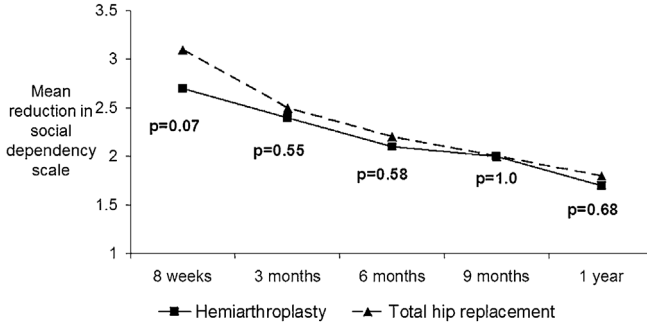

Fig. 4. Mean change in social dependency scale.

Discussion

The conclusions of this study are there was a trend in favour of hemiarthoplasty for many of the outcome measures. There was no outcome for which THR was favoured. Regrettably due to the limited number of included patients only a few outcomes achieved statistical significance.

Strengths of this study are the secure randomisation of patients, all patients receiving the treatment to which they were allocated and blinded assessment of residual pain and function. Weaknesses of the study are the limited patient numbers which precluded firm conclusions being made. This single centre study took over five years to recruit the patients. In addition at present the minimum follow up of one year is limited. It is possible that in the long term there may be increasing complications in the hemiarthroplasty group related to acetabular wear, so follow up is being continued to a minimum of five years. Other limitations were the change in the type of prosthesis used during the study which was due to local purchasing contracts and beyond the control of the trialists. All stems were however similar, being polished tapered stems.

Blinding of the assessment of outcome is essential for studies of this type. Failure to undertake this may results in a potential biases in favour of THR which, being a newer and more extensive procedure may be perceived to be a superior procedure. For the previous randomised trials on this topic, only one previous study of 86 participants has used a blinded assessment of outcome [11].

The main implant related complication was later fracture around the implant. This is now a well-documented complication for the polished tapered stems [12,13]. Joint registries may underestimate the incidence of this condition by not recording cases in which the fracture is treated conservatively or by internal fixation with the implant being retained. The overall occurrence of this complication for this series was three patients within the follow-up period of almost three years. Potential advantages of the smooth polished stem are easier revision surgery using a cement-in-cement revision technique. This is particularly useful if a hemiarthroplasty requires revision to a total hip replacement for acetabular wear.

In recent years there has been increased advocacy for using a total hip arthroplasty for treating intracapsular fractures in those hip fracture patients considered to be more active [14]. The United Kingdom National Institute for Clinical Excellence (NICE) recommends 'offering' a THR for those patients with a displaced intracapsular fracture who are able to walk independently out of doors with no more that the use of a stick and not cognitively impaired and medically fit for the procedure. These recommendations were based on a number of favorable case series reports for THR for hip fractures and the early randomised controlled trials on this topic [4]. The six earlier randomised trials involving only 521 participants with all studies giving results that that appeared to favour total hip arthroplasty [11,15–20]. Patients recruited within these studies were a fitter subgroup of patients than those suggested for consideration of THR by NICE. The inclusion criteria for this study were more in line with that recommended by the NICE guidelines [14]. Frailer patients were excluded as were the younger and healthier patients for which it was felt their expected long term survival meant an arthroplasty should, if possible, be avoided to reduce the risk of later revision arthroplasty. Frailer patients excluded from the study were generally treated by hemiarthroplasty.

The most recent and largest randomised study on this topic had 252 participants and used the broader inclusion criteria similar to that for the NICE guidance [20]. This study reported increased complications and re-operations for the THR with no difference in functional outcomes [20]. These findings are therefore similar to that reported in this study. The results of a larger multicenter randomised trial [21] on this subject are awaiting and we feel increased caution is required before recommending the increased use for THR for this condition. In summary the results of this study suggest that total hip arthroplasty may not be an appropriate method for routine treatment for all patients within the inclusion category of this study. Hemiarthroplasty is a less invasive procedure with a lower risk of complications and equivalent functional outcomes.

Responsibilities

MJ Parker was responsible for the design and initiation of the study, recruitment of participants, data collection and analysis and writing the manuscript. S Cawley was responsible for the blinded assessment of the patients.

Declaration of Competing Interest

Neither of the authors has received any benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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