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Internal fixation or hemiarthroplasty for undisplaced intracapsular hip fractures: a randomized trial

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Introduction: **Currently the recommended treatment for an undisplaced intracapsular hip fracture is internal fixation. Recent studies have questioned this practice and suggested arthroplasty may be a more appropriate treatment method.**
Methods: **54 patients with an undisplaced intracapsular fracture were randomised between a cemented polished tapered stem hemiarthroplasty and internal fixation with Targon hip screws. The principle outcome was regain of mobility. Secondary outcomes included degree of residual pain, mortality, secondary surgery and surgical complications. Follow-up was by a nurse blinded to the implant and continued till three years from surgery for the surviving patients.**
Results: **No significant differences in the primary outcome of regain of mobility were noted. Arthroplasty was associated with lower degrees of residual pain. No surgical complications were encountered in the arthroplasty group. In the fixation group there was one case of later fracture around the implant requiring surgery and two cases of avascular necrosis of the femoral head. There were no notable differences in mortality, hospital stay or general medical complications between the two groups.**
Conclusions: **Arthroplasty may lead to improved outcomes compared to internal fixation in the treatment of an undisplaced intracapsular fracture in the elderly but further studies are required to confirm this.**

Keywords: Randomised trial, Undisplaced intracapsular hip fracture, Surgical treatment.

INTRODUCTION

A hip fracture is one of the most common reasons for an elderly patient to be admitted to an acute orthopaedic ward. Global numbers for hip fractures are estimated to rise to between 7 and 21 million by 2050[1]. Half of these fractures with be intracapsular with approximately 10% of these being classified as undisplaced[2]. Customarily an undisplaced intracapsular fracture in an elderly patient is treated by internal fixation of the fracture[3,4]. Complications of this method of treatment are mainly failure of the fracture to heal (non-union) or later avascular necrosis of the femoral head[5-10]. Non-union is related to failure of the implant to hold the fracture in a stable position whilst the fracture heals and avascular necrosis is caused by damage to the precarious blood supply to the femoral head. The overall incidence of these complications has been reported to be between 5-20% for this type of fracture treated by internal fixation[5-10]. Arthroplasty involve replacing either just the femoral head (hemiarthroplasty), or replacing both the femoral head and the acetabular surface (total hip replacement). An arthroplasty will avoid the fracture healing complications of non-union and avascular necrosis, but incurs the potential complications of dislocation, sepsis, acetabular wear, loosening and peri-prosthetic fracture. An overall risk of these complications from arthroplasty is 5-15%[6,9].

Because of the perceived lower complication rate after internal fixation, this method of treatment has been customarily recommended for this fracture[3,4]. Clinical reports have suggested a progressive increase in the occurrence of fracture healing complications after internal fixation associated with the increasing ageing and fragility of the hip fracture population[5]. This has led to the suggestion that arthroplasty may produce superior results, but to date there is only very limited evidence from randomised trials on this topic[11,12]. This study aims to add to the evidence base to determine which method of treatment produces the best results. We have conducted a single centre study, randomizing

suitable patients between hemiarthroplasty and internal fixation using contemporary surgical methods.

PATIENTS AND METHODS

All patients admitted to Peterborough City Hospital between September 2016 and April 2019 with an undisplaced intracapsular fracture and evaluated by the lead trialist (MJP) were considered for inclusion in the study. Evaluation of the radiographs for inclusion was based on the anteroposterior radiographs alone. The fracture had to have either no displacement of the fracture or impaction, that is a Garden grade I or II fracture[13]. Fractures with angular displacement on the lateral radiographs were included. Patients of all ages were considered for inclusion. Exclusion criteria were those who were unable to provide informed consent and had no next of kin or legal guardian to provide assent, pathological fractures, Paget's disease at the fracture site, degenerative arthritis of the hip, those treated conservatively and those considered unfit for arthroplasty. Patients who were deemed too active and with a good life expectancy were excluded and treated by internal fixation. This included those patients who were able to walk independently out of doors with no more than the use of a stick and not cognitively impaired. The pre-operative characteristic for all included patients was recorded. This included the mobility and social dependency grade (Table I), Mental test score,[14] ASA grade[15] and haemoglobin. All operations were undertaken or supervised by the lead trialist and when not available patients were not considered for the study (Figure 1).

Written patient or relative consent was obtained prior to surgery by MJP. The study was approved by the Hospital Research and Development Committee and the West Midlands – Coventry & Warwickshire Research Ethics Committee (reference 16/WM/0124 Sponsor – North West Anglia NHS Foundation Trust, Trial registration NCT02996383). Randomisation was by opening in order, numbered sealed identical opaque envelopes containing details of the operation to be used. The envelopes were prepared by a person independent to the study.

Surgical treatment with either a cemented unipolar double tapered stem hemiarthroplasty (CPT Zimmer/Biomet, Warsaw, USA) inserted via a direct lateral approach or Targon Hip Screws (BBraun ltd, Tuttlingen, Germany)[16,17]. Fixation was undertaken using the fracture table and image intensification. Fractures with angulation on the lateral view were

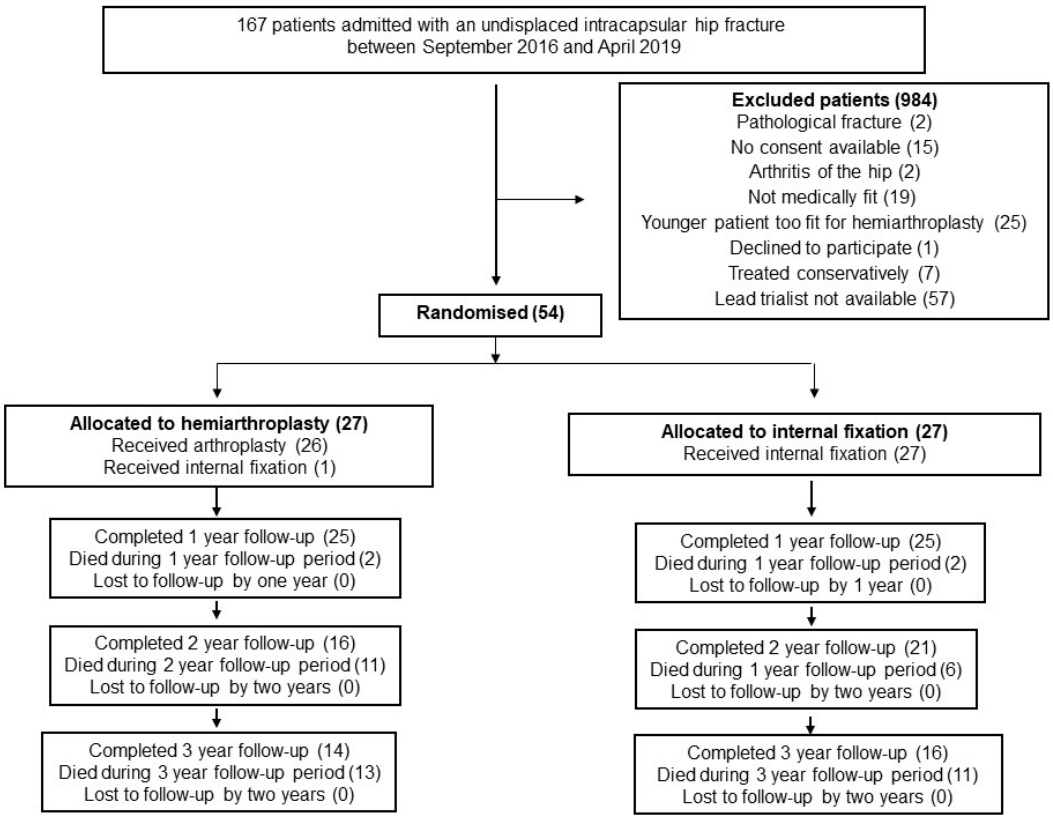

Fig. 1 — Flow chart of patients included and excluded. Patients may have been excluded for more than one reason.

Table I. — Method of assessment of patients.

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	Mobilizes 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	Mobilizes 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	Mobilizes 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	

reduced by internal rotation prior to fixation. The fixation involved a 4cms lateral incision to place a small locking plate on the lateral proximal femur. Three sliding telescrews were fixed in the femoral head and two screws to the proximal femur[17]. After surgery all patients in both groups were mobilized fully weight bearing and no post-operative restrictions on weight bearing or hip movement were used.

Follow-up assessment was firstly in a hip fracture clinic at approximately eight weeks from discharge and including a radiographic review. Any implant radiographic complication was noted. Functional assessments, hip movements, limb shortening from clinical examination and pain scores were assessed by a research nurse blinded to the treatment allocation. Subsequent assessments were by the same nurse using phone calls at three, six, nine, twelve months and one two and three years from injury. Implant related complications reported at any follow-up call were recorded. Pain was assessed on a scale of one (no pain) to eight (constant and severe). The patients walking ability was assessed using a mobility scale and social dependence with a dependency score (Table I)[18].

The primary outcome for this study was regain of mobility at one year using a mobility score. 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[19,20]. To allow for loss of patients from follow-up (normally 2-3%) and due to deaths (30% mortality at one year), then a total study number of 400 patients (200 in each group) would be required for an adequately powered study[19,20]. Because of the limited patients numbers being availably annually for this study, logistical reasons and to allow the study to be completed in a reasonable time-frame the study was limited to a recruitment period of two and a half years.

Statistical analysis. All results were analysis on an intention-to-treat principle. Binary outcomes for the two groups were analysed using Fisher exact test

and continuous outcomes with the unpaired t-test. Continuous outcomes were analysed in Graph pad to determine if the data was parametric. (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

54 patients were randomised. Figure 1 details the flow diagram for the patient recruitment. All surviving patients were followed-up for three years by the research nurse with no surviving patient lost to follow-up. One patient in the arthroplasty group, after randomisation was considered not to be fit for arthroplasty and treated by internal fixation. All the remaining patients received the treatment to which they were allocated.

The characteristics of the two groups of patients are detailed in Table II. There was no statistically significant differences between groups. Table III details the peri-operative outcomes and mortality. The surgical time was approximately 20 minutes less for the fixation group and the blood loss approximately 160mls less. Table IV details the general complications encountered during the hospital stay and subsequent follow-up period. There were no deep wound infections in either group. None of the differences between groups for complications was statistically significant. Complications related to the fracture were encountered only in four patients in the fixation group. One patient had a fracture below the implant and this

Table II. — Patient characteristics.

	Arthroplasty	Internal fixation
Number of patients	27	27
Mean age in years [range]	81.9 [71-96]	81.4 [66-99]
Number male (%)	11 (40.7%)	6 (22.2%)
From own home (%)	23 (85.2%)	23 (85.2%)
Mean mobility grade	3.3	3.7
Mean social dependency grade	3.1	3.1
Mean mental test score	7.6	7.3
Mean ASA score	2.8	2.8
ASA grade one or two (%)	9 (33.3%)	8 (29.6%)
Mean haemoglobin on admission g/l	119.5	125.8

Table III. — Peri-operative details and mortality. (%)[standard deviation].

	Arthroplasty	Internal fixation	P value (95% CI)
General anaesthesia	8 (29.6%)	11 (40.7%)	0.40 #
Mean length of anaesthesia (minutes)	70.9 [18.3]	51.3 [9.7]	<0.0001* (-27.60 to -11.60)
Mean length of surgery (minutes)	52.0 [17.3]	31.7 [9.4]	<0.0001* (-28.25 to - 12.36)
Mean operative blood loss (mls)	272.4 [146.6]	114.2 [73.1]	<0.0001* (-221.46 to -94.94)
Required blood transfusion	3 (11.1%)	2 (7.4%)	1.00 # (0.25 to 7.73)
Mean total hospital stay in days	23.3	19.4	0.51* (-15.61 to 7.81)
Mean loss of flexion (mm)	17.9 [14.68]	12.9 [13.39]	0.39 (-16.90 to 6.90) *
Mean shortening (mm)	0.73 [1.68]	0.45 [11,1.51]	0.69 (-1.69 to 1.15) *
30 day mortality	1 (3.7%)	0	1.0 #
1 year mortality	2 (7.4%)	2 (7.4%)	1.0 #
2 year mortality	11 (40.7%)	6 (22.2%)	0.24 (0.79 to 4.25) #
3 year mortality	14 (51.9%)	11 (40.7%)	0.59 (0.71 to 2.28) #
*Unpaired t test, # Fisher exact test.			

Table IV. — General complications.

	Arthroplasty	Internal fixation
Superficial wound infection	1	0
Haematoma	1	0
Pneumonia	1	1
Myocardial infarction	0	1
Deep vein thrombosis	0	1
Pressure sores	0	1
Delirium	1	2
Gastrointestinal bleed	1	1

was treated by revision to an intramedullary nail. Three other patients later developed pain in the hip and had radiographic evidence of avascular necrosis. One of these patients required removal of the implant, one was treated conservatively and one is awaiting a total hip arthroplasty.

Figures 2-4 details the results for the assessments for pain, regain of mobility and regain of social independence. The only significant difference was an increased degree of residual pain for those treated by internal fixation. The mean pain score at nine months was 1.2 for arthroplasty versus 1.7 for fixation (p=0.022, 95% confidence interval of the difference 0.72 to 0.87).

DISCUSSION

The principal finding of this study was a tendency to a reduced level of pain for those treated by arthroplasty (Figure 2). Despite the small number of patients, this difference was present at all time periods and also statistically significant at nine months and two years. The difference in pain scores varied from 0.3 to 0.8 on the eight-point scale which should represent a clinically relevant difference. The recording of this subjective outcome using a blind observer makes this finding more robust but larger patient number would be needed to make this finding unequivocal. Other significant differences were the reduced surgical times (approximately 20 minutes) and operative blood loss with internal fixation. This difference is to be expected given the lesser surgical procedure associated with internal fixation. No other notable difference in outcome were noted within the restrictions of limited patient numbers involved.

The strengths of this study are the secure randomization of patients, the high proportion of patients receiving the treatment to which they were allocated (98%), no surviving patient being lost to follow-up and the blinded assessment of residual pain and function. Weaknesses of the study are the restricted number of patients. The study was underpowered for detecting the minimal significant difference for its primary outcome, which was a change in mobility, however there was a significant difference in pain levels between groups which was not expected on the original study planning.

To date to the best of the authors knowledge and literature review, there have been only two previous randomized trials on this topic. Dolatowski and

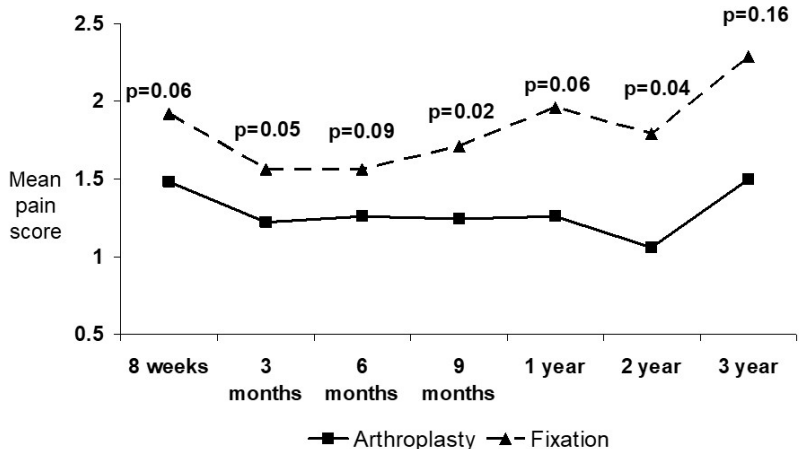

Fig. 2 — Mean pain scores.

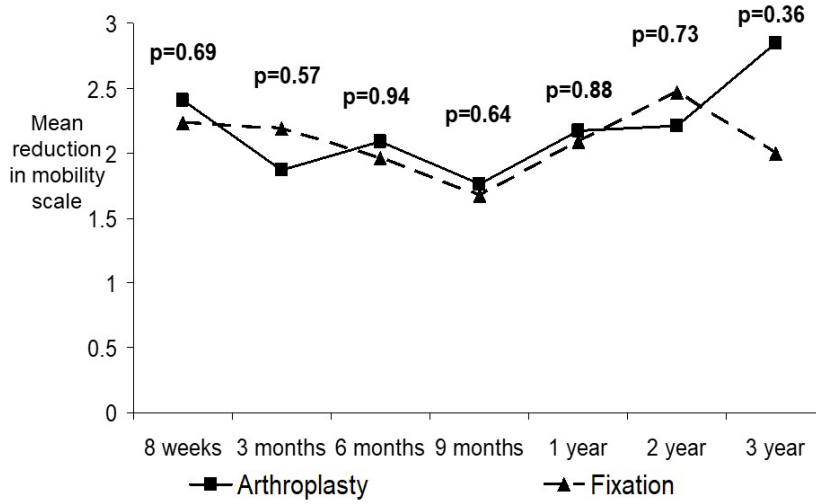

Fig. 3 — Mean change in mobility scale.

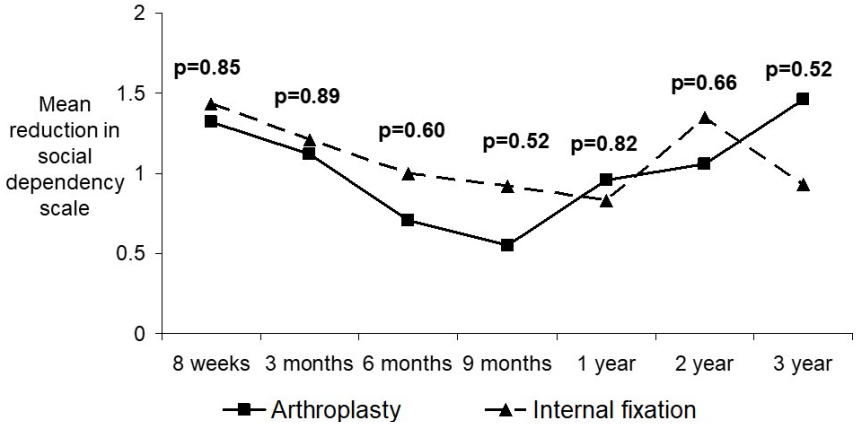

Fig. 4 — Mean change in social dependency scale.

colleagues in a multicentre study, randomised 219 patients with an undisplaced intracapsular fracture to screw fixation or hemiarthroplasty[11]. Fixation was using two screws and the hemiarthroplasty was a mixture of cemented and uncemented implants. Functional outcomes were assessed was using a blinded assessor. The primary outcome was the Harris hip score for which there was no significant difference between groups. There was an improved regain of mobility, assessed by the timed get up and go test, for those allocated to hemiarthroplasty. Re-operation was more common in the fixation group (22 versus 5 cases) and surgical time and intra-operative blood loss was less in the fixation group. The pain scores at follow-up tended to be higher, representing more pain, in the fixation group but none of the differences were statistically significant. Lu and colleagues randomized 78 patients between a cemented hemiarthroplasty and three cannulated screws[12]. Re-operations were more common in the fixation group (9/41 versus 2/37). There was a better hip function in the early follow-up for those in the arthroplasty group as measured by the Harris hip score. Operative times and blood loss were reduced for the fixation group.

Numerous case series reports have documented the outcomes of treatment for patients with an undisplaced intracapsular fracture[5,7,8]. These studies document the higher re-operation rate after fixation compared to arthroplasty but are unable to determine if there are significant differences in functional outcomes or residual pain between fixation and arthroplasty. A review of 14,757 patients from the Norwegian hip fracture register, compared patients with a displaced fracture treated by arthroplasty, a displaced fracture treated by internal fixation with those with an undisplaced fracture treated by internal fixation[6]. Secondary surgery was less for arthroplasty and of the three groups, those treated with arthroplasty had the lower degrees of residual pain, were more satisfied with the outcome and had the highest quality of life. Conservative treatment has also been used for this fracture but has been reported to have a

higher risk of fracture non-union (31% versus 7%) and avascular necrosis (10% versus 8%) compared to internal fixation[21]. The single randomised trial to compare conservative versus operative treatment, reported markedly improved outcomes for operative treatment[22].

Whilst this study and the two earlier randomised trials suggest that arthroplasty may produce improved outcomes compared to internal fixation, fixation should still be considered appropriate for the very frail. Fixation was shown to be a less extensive surgical procedure and may therefore be associated with a reduced morbidity or mortality in this frailer group of patients. Fixation is also appropriate for the younger patient in which preservation of the femoral head is desirable as arthroplasty in this group of younger patients with good long-term survival will lead to a significant risk of later revision arthroplasty[23].

This study and the previous studies also included those fractures that show some displacement on the lateral view. These fractures are traditionally also termed undisplaced as radiographic classification of intracapsular fractures only use the anterior-posterior view[13,24]. However those fractures with some displacement have been noted to have a high risk of fracture healing complications compared to those fractures that are undisplaced on both radiographs[25]. Restricting fixation to those fractures that show no displacement on either radiograph may lead to improved outcomes for the fixation group. The patient numbers within this study were too small to allow any sub-analysis related to fracture displacement.

In summary, the results of this study indicate a slight tendency to improved outcomes for this fracture if treated by arthroplasty rather than internal fixation. This is supported by the two previous randomised trials on this topic[11,12] and a large register study[§]. However differences in outcome are small and to date the patient numbers included with randomised trials is limited, so further randomised trials are indicated to confirm these findings.

Conflict of interest: M. Parker has received expenses and honorarium from a number of commercial companies and organizations for giving lectures on different aspects of hip fracture treatment. In addition he has received royalties from BBrawn ltd related to the design and development of the Targon FN implant used in this study. S Cawley has no conflict of interest related to this study.

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