

Primary total hip arthroplasty versus hemiarthroplasty for displaced intracapsular hip fractures in older patients: systematic review

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ABSTRACT

Objective To determine whether total hip arthroplasty is associated with lower reoperation rates, mortality, and complications, and better function and quality of life than hemiarthroplasty for displaced fractures of the femoral neck in older patients.

Design Systematic review and meta-analysis of randomised trials, quasirandomised trials, and cohort studies.

Data sources Medline, Embase, Cochrane register of controlled trials, publishers' databases, and manual search of bibliographies.

Study selection Randomised controlled trials, quasirandomised trials, and cohort studies (retrospective and prospective) comparing hemiarthroplasty with total hip arthroplasty for treating displaced femoral neck fractures in patients aged more than 60 years.

Data extraction Relative risks, risk differences, and mean differences from each trial, aggregated using random effects models. Analyses were stratified for experimental and non-experimental designs, and two way sensitivity analyses and tests for interaction were done to assess the influence of various criteria of methodological quality on pooled estimates.

Data synthesis 3821 references were identified. Of the 202 full papers inspected, 15 were included (four randomised controlled trials, three quasirandomised trials, and eight retrospective cohort studies, totalling 1890 patients). Meta-analysis of 14 studies showed a lower risk of reoperation after total hip arthroplasty compared with hemiarthroplasty (relative risk 0.57, 95% confidence interval 0.34 to 0.96, risk difference 4.4%, 95% confidence interval 0.2% to 8.5%), although this effect was mainly driven by investigations without concealed treatment allocation. Total hip arthroplasty consistently showed better ratings in the Harris hip score (three studies, 246 patients, weighted mean difference 5.4, 95% confidence interval 2.7 to 8.2) after follow-up periods of 12 to 48 months. The standardised mean difference of different scores from five studies was 0.42 (95% confidence interval 0.24 to 0.61), indicating a medium functional advantage of total hip arthroplasty over hemiarthroplasty. Total hip arthroplasty was

associated with a slightly higher risk of dislocation (relative risk 1.48, 95% confidence interval 0.89 to 2.46) and general complications (1.14, 0.87 to 1.48).

Conclusion Single stage total hip arthroplasty may lead to lower reoperation rates and better functional outcomes compared with hemiarthroplasty in older patients with displaced femoral neck fractures. However, heterogeneity across the available trials and distinct subgroup effects preclude definitive statements and require further research in this area.

INTRODUCTION

Hip fractures in older patients are associated with impaired mobility, excess morbidity and mortality, and loss of independence. With the reversing ageing pyramid and the high prevalence of osteoporosis, hip fractures remain a public health concern. Incidence estimates vary considerably among industrial countries.¹⁻⁹ Models aimed at projecting the contribution of hip fractures to the future global burden of disease produced inconclusive results,¹⁰ and depended on assumptions about the effectiveness of multifaceted interventions for preventing falls and managing osteoporosis.¹¹⁻²⁰

Typical predilection sites for fractures of the proximal femur are the femoral neck and the intertrochanteric and subtrochanteric regions. Displaced, unstable fractures of the femoral neck generally represent an indication for early surgical intervention. Established treatment options include internal fixation with cannulated or sliding hip screws, hemiarthroplasty, or total hip replacement. Well recognised goals of surgical treatment are immediate pain relief, rapid mobilisation and ambulation, accelerated rehabilitation, and maintenance of independent living. In addition to these prerequisites, the ideal implant must be associated with a low risk of surgical complications and subsequent revision. At best, patients should not be hampered by the treated hip during their remaining lifetime.

Evidence is now compelling from randomised controlled trials that, in displaced femoral neck fractures, primary arthroplasty outperforms internal fixation for complication and revision rates, function, and health

Table 1 | Summary of key criteria of individual investigations

Study	Recruitment period	Indication	Mean duration of follow-up (months)	Treatment assignment	No of validity criteria met (out of 12)	Outcome measures recorded and analysed
Baker 2006 ⁴⁸	NS	Displaced femoral neck fractures	40	Randomised, sealed envelopes	8	Reoperations, dislocations, infections, general complications, mortality, function (Oxford hip score), quality of life (SF-36)
Blomfeldt 2007 ⁴⁹	NS	Displaced femoral neck fractures	12	Randomised, sealed envelopes	9	Reoperations, dislocations, infections, general complications, mortality, quality of life (EQ-5D)
Dorr 1986 ⁵⁰	1980-2	Displaced femoral neck fractures Garden III/IV	24	Odd and even hospital number	9	Reoperations, dislocations, infections, mortality, quality of life (EQ-5D)
Eyssel 1994 ⁵²	1984-92	Displaced femoral neck fractures Garden III/IV	1	NS	7	Reoperations, dislocations, infections, general complications, mortality
Gebhard 1992 ⁵³	1973-86	Displaced femoral neck fractures	55	NS	6	Reoperations, dislocations, infections, general complications, mortality
Healy 2004 ⁵⁴	1993-6	Displaced femoral neck fractures Garden III/IV	71	NS	5	Reoperations, infections
Keating 2006 ⁴⁵	1996-2000	Displaced femoral neck fractures	24	Randomised, computerised telephone service	8	Reoperations, dislocations, infections, general complications, quality of life EQ-5D
Levi 1996 ⁵⁵	1990-3	Femoral neck fractures, 97% Garden III/IV	3	NS	2	Infections, mortality
Macaulay 2008 ^{42 43}	NS	Displaced femoral neck fractures Garden III/IV	24	Randomised, opaque sealed envelopes	4	Reoperations, dislocations, infections, general complications, mortality, function (Harris hip score), quality of life (SF-36)
Mouzopoulos 2008 ⁵¹	1999-2002	Displaced femoral neck fractures Garden III/IV	48	Fixed alternating sequence	3	Reoperations, mortality, function (Harris hip score), quality of life (SF-36)
Narayan 2006 ⁵⁶	1997-2002	Displaced femoral neck fractures Garden III/IV	58	Dependent on availability	5	Reoperations, dislocations, general complications, function (Oxford hip score), quality of life (SF-36)
Ravikumar 2000 ⁴⁶	1984-6	Displaced femoral neck fractures Garden III/IV	156	Day of week	1	Reoperations; dislocations; infections; mortality; quality of life (EQ-5D)
Schleicher 2003 ⁵⁷	1991-4	Displaced femoral neck fractures	98	NS	4	Reoperations, dislocations, infections, general complications, mortality, function (Oxford hip score), quality of life (SF-36)
Squires 1999 ⁵⁸	NS	Displaced femoral neck fractures	46	Different treatment policy at two district general hospitals	3	Reoperations, dislocations, general complications, function (Melzer hip score)
Xu 2002 ⁵⁹	1987-98	Displaced femoral neck fractures	70	NS	4	Reoperations, dislocations, infections, mortality

NS=not specified.

related quality of life.²¹⁻²³ This is reflected in recent clinical guidelines that assigned a grade A recommendation for arthroplasty to treat these fractures in older, biologically less fit patients.²⁴

Hemiarthroplasty is a quick and highly standardised procedure that allows for early weight bearing and recovery. However, most patients with a hip fracture have osteoarthritis, which may necessitate secondary conversion to total hip replacement, especially in active elderly people with higher physical demands. Single stage surgery with acetabular replacement seems straightforward to avoid secondary admission to hospital and operation with its possible risks and extra costs. These potential benefits, however, must be traded off against the potential harms of prolonged and more invasive surgery.

Uncertainty as to which type of endoprosthesis is the ideal choice for treatment of fractures in older patients leads to significant variation in the use of each intervention internationally.^{25,26} Total hip replacement is three times more likely to be used to treat hip fractures in Sweden than it is in England and Wales, and twice as likely than in Canada.²⁷

To provide greater clarity about outcomes with primary hemiarthroplasty or total hip arthroplasty for displaced intracapsular hip fractures in older patients, we

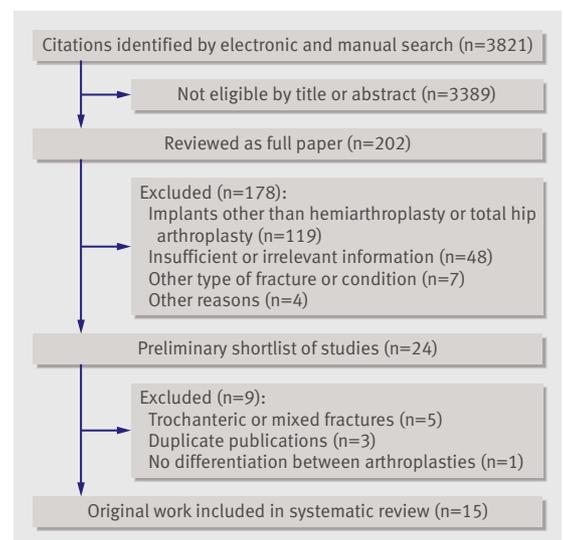


Fig 1 | Review profile and study selection process

Table 2 | Description of interventions received by each treatment group

Study	Design	Surgical approach	Total hip arthroplasty		Hemiarthroplasty		
			Fixation	No	Type	Fixation	No
Baker 2006 ⁴⁸	Randomised controlled trial	Transgluteal lateral	Cemented	40	Bipolar	Cemented	41
Blomfeldt 2007 ⁴⁹	Randomised controlled trial	Modified Hardinge anterolateral	Cemented	60	Bipolar	Cemented	60
Dorr 1986 ⁵⁰	Lesser quality randomised controlled trial	Posterior	Cemented	39	NS	Cemented or uncemented	50
Eyssel 1994 ⁵²	Retrospective cohort	Transgluteal	Cemented	213	Bipolar	Cemented	150
Gebhard 1992 ⁵³	Retrospective cohort	NS	Cemented	44	NS	Cemented or uncemented	122
Healy 2004 ⁵⁴	Retrospective cohort	NS	Cemented	23	Unipolar or bipolar	Cemented	43
Keating 2006 ⁴⁵	Randomised controlled trial	Posterior or lateral	Cemented	69	Bipolar	Cemented	111
Levi 1996 ⁵⁵	Retrospective cohort	Posterior	Cemented	98	Unipolar	Cemented or uncemented	123
Macaulay 2008 ^{42 43}	Randomised controlled trial	Posterolateral or modified Hardinge anterolateral	Cemented or uncemented	17	Unipolar or bipolar	Cemented or uncemented	23
Mouzopoulos 2008 ⁵¹	Lesser quality randomised controlled trial	NS	Cemented	43	Bipolar	NS	43
Narayan 2006 ⁵⁶	Retrospective cohort	NS	Cemented or uncemented	29	Bipolar	Cemented or uncemented	32
Ravikumar 2000 ⁴⁶	Lesser quality randomised controlled trial	Posterolateral	Cemented	91	Unipolar	Uncemented	89
Schleicher 2003 ⁵⁷	Retrospective cohort	NS	Hybrid	54	Bipolar	NS	52
Squires 1999 ⁵⁸	Retrospective cohort	Posterolateral or modified Hardinge anterolateral	Cemented or uncemented	32	Unipolar or bipolar	Cemented or uncemented	43
Xu 2002 ⁵⁹	Retrospective cohort	Posterior	Cemented	32	Unipolar or bipolar	Cemented	24

NS=not specified.

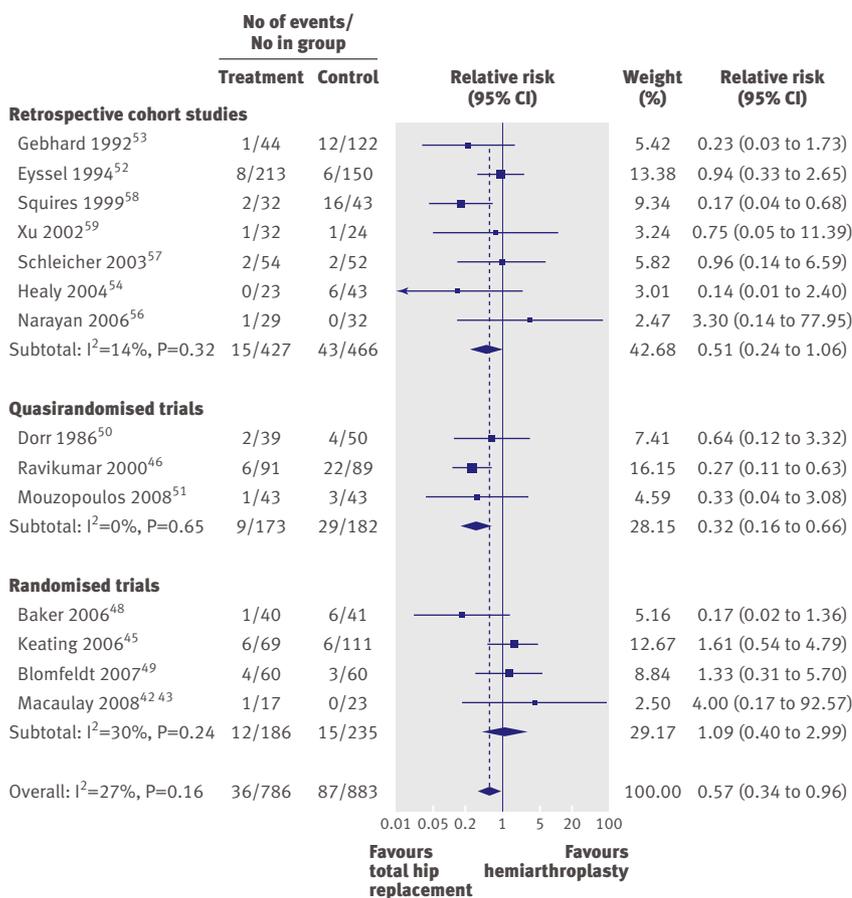


Fig 2 | Random effects meta-analysis comparing relative risk of reoperation after total hip arthroplasty and hemiarthroplasty for displaced intracapsular hip fractures

carried out a systematic literature review and meta-analysis of all clinical studies that aimed for a head to head comparison of either implant. We investigated complication rates and mortality and determined whether similar differences in these events, if any, could be found in randomised trials and the wider body of non-experimental studies. We also summarised patient centred outcomes such as function and health related quality of life, and investigated variables that may contribute to the observed effects.

METHODS

Two reviewers (CH and DS) independently carried out a comprehensive search (last update 27 March 2010) of Medline, Embase, the Cochrane register of controlled trials, and publishers' databases for randomised controlled trials, quasirandomised trials, and cohort studies (both retrospective and prospective) that compared hemiarthroplasty with total hip arthroplasty for treating displaced femoral neck fractures in patients aged more than 60 years. We excluded registry data and case series—that is, studies that investigated either total hip arthroplasty or hemiarthroplasty for treating hip fractures.

We used medical subject headings (or their equivalents in other databases), including the following key search and wild card terms: hip, femoral neck, intra-articular, intra-articular, fracture*, surg*, hemi*, total*, bipolar, unipolar, arthroplast*, replacement, random*. Terms were connected by the Boolean operators "AND" and "OR".

Reviewers traced the bibliographies of all retrieved trials and other relevant publications, including reviews and meta-analyses, for citations missed by the

Table 3 | Characteristics of patients included in individual studies

Author	Mean (SD) age (years)		Male patients (%)		Comorbidity and preoperative risk stratification		Cognitive and physical status prefracture	
	Total hip arthroplasty	Hemiarthroplasty	Total hip arthroplasty	Hemiarthroplasty	Total hip arthroplasty	Hemiarthroplasty	Total hip arthroplasty	Hemiarthroplasty
Baker 2006 ⁴⁸	74 (6)	76 (5)	20	22	Median ASA 2 (1-3)	Median ASA 2 (1-3)	Mini-mental score 10 (7-10)	Mini-mental score 10 (9-10)
Blomfeldt 2007 ⁴⁹	81 (5)	81 (5)	22	10	Ceder A/B 88%	Ceder A/B 83%	SPMSQ 9 (SD 1), ADL A/B: 97%	SPMSQ 9 (SD 1), ADL A/B: 98%
Dorr 1986 ⁵⁰	69 (9)	69 (12)	41	30	NS	NS	Oriented and ambulatory patients only	Oriented and ambulatory patients only
Eyssel 1994 ⁵²	78 (9)	84 (7)	9	21	Comorbidity 76%	Comorbidity 87%	Ambulatory 99%	Ambulatory 92%
Gebhard 1992 ⁵³	75	76	NS	NS	Mean ASA 3	Mean ASA 3	NS	NS
Healy 2004 ⁵⁴	80		NS	NS	NS	NS	NS	NS
Keating 2006 ⁴⁵	75 (6)	75 (7)	25	17	Comorbidity 80%	Comorbidity 70%	Oriented and ambulatory patients only	Oriented and ambulatory patients only
Levi 1996 ⁵⁵	80	80	22	22	NS	NS	NS	NS
Macaulay 2008 ^{42, 43}	82 (7)	77 (9)	59	39	Mean No of comorbidities 4 (SD 2)	Mean No of comorbidities 4 (SD 3)	Oriented and ambulatory patients only	Oriented and ambulatory patients only
Mouzopoulos 2008 ⁵¹	73 (5)	74 (4)	24	29	Mean ASA 2 (SD 2)	Mean ASA 2 (SD 3)	Oriented and ambulatory patients only, mean SPMSQ 8 (SD 3)	Oriented and ambulatory patients only, mean SPMSQ 8 (SD 3)
Narayan 2006 ⁵⁶	59	63	NS	NS	NS	NS	NS	NS
Ravikumar 2000 ⁴⁶	81	82	10	10	No significant differences in age, sex, preoperative mobility, or comorbidity			
Schleicher 2003 ⁵⁷	81 (12)	81 (10)	17	13	ASA 3/4 94%	ASA 3/4 91%	Ambulatory 91%	Ambulatory 100%
Squires 1999 ⁵⁸	69	71	12	6	NS	NS	Oriented and ambulatory patients only	Oriented and ambulatory patients only
Xu 2002 ⁵⁹	72 (5)	75 (6)	46	46	NS	NS	NS	NS

NS=Not specified.

electronic search. See the web extra for a summary of the search strategy.

Selection process

Two reviewers (CH and DS) reviewed titles and abstracts first, and independently decided whether the papers potentially contained sufficient information. If deemed eligible by either reviewer, the full paper was obtained for a detailed review. We included studies published in languages that could be read and understood by the reviewers (English, German, Dutch, Swedish, French, Spanish, and Italian). Eligible studies compared hemiarthroplasty and total hip arthroplasty in a head to head fashion and provided sufficient numerical information on at least one of the following prespecified end points: reoperation for any cause, dislocation, deep infection, one year mortality, and any general perioperative complication (including nosocomial pneumonia and urinary tract infection, as well as a thromboembolic or cardiovascular event). General complications were handled as a composite end point. We also investigated function and health related quality of life (if assessed by valid scoring systems or questionnaires).

Data abstraction and assessment of methodological quality

Two reviewers (CH and DS) independently abstracted data in duplicate, including general information

(author, publication year), type of study, fracture classification, period of patient enrolment, mean patients' age, sex distribution, prefracture comorbidity, cognitive function and mobility, average length of follow-up, type of prosthesis, and use of bone cement. The reviewers also extracted and entered into an electronic database event rates with nominators and denominators for different end points, as well as means and standard deviations of functional score and quality of life assessments.

Three reviewers (CH, DS, and MW) independently assessed the methodological quality of papers according to the set of items used by Parker in two previous Cochrane reviews related to this subject.^{28,29} Quality criteria included concealment of allocation; description of entry criteria, demographic profiles, and outcomes; adherence to the intention to treat principle; blinding; handling of withdrawals; explanation of cointerventions; and a minimum follow-up of one year after surgery. The reviewers resolved disagreement by discussion.

Data analysis

We analysed binary end points (for example, reoperation and mortality) by calculating relative risks and corresponding risk differences. For differences in functional scores and quality of life instruments we calculated the weighted mean difference and the pooled

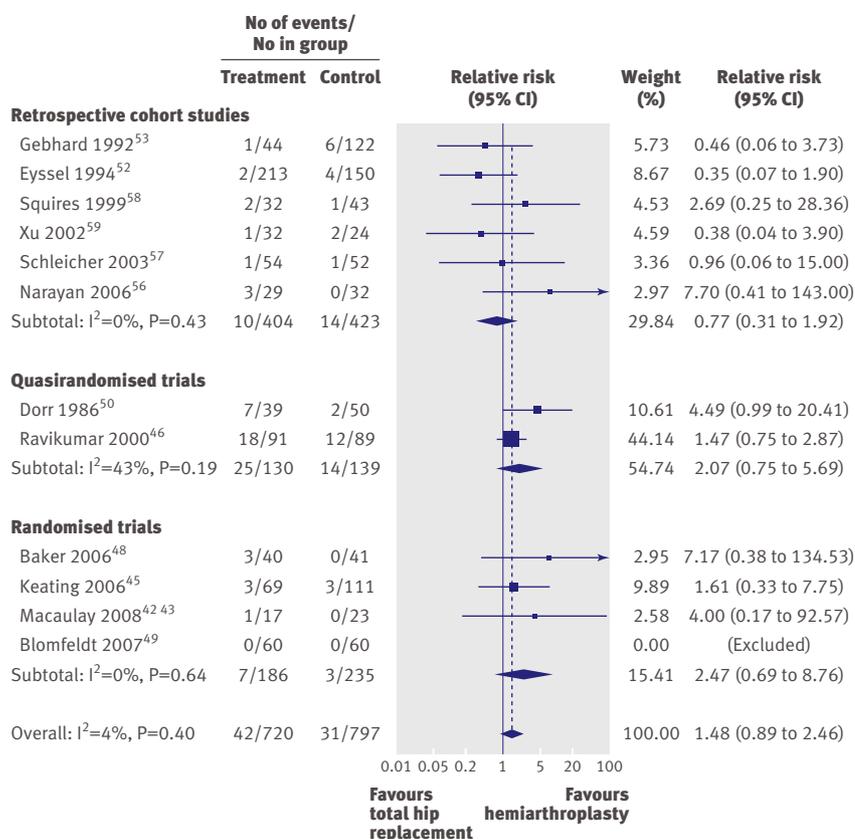


Fig 3 | Random effects meta-analysis comparing relative risk of dislocation after total hip arthroplasty and hemiarthroplasty for displaced intracapsular hip fractures

standardised mean difference. In general, higher scores indicate better function—for example, the Harris hip score, the short form 36 (SF-36) physical component score, or the European quality of life instrument 5D (EQ-5D) visual analogue scale. We reversed the polarity of inverse scores (those producing higher values with poorer function, such as the Oxford hip score³⁰) by subtracting the maximum possible score from the observed score. In case authors provided ranges instead of standard deviations of means, we approximated the standard deviation by the rule of thumb range divided by 4.

To account for variability within and between studies we used the DerSimonian-Laird random effects approach to aggregate data.³¹ We assessed heterogeneity by using the I² statistic,³² with values more than 50% suggesting substantial variability between studies. Publication bias was evaluated by funnel plot asymmetry and Egger's linear regression test.³³ We assumed the presence of publication bias if the intercept of the regression line was significantly (P<0.1) away from the null.

We carried out stratified analyses for differences between the results from randomised trials and retrospective cohort studies and further differentiated between randomised trials with and without proper concealment of treatment allocation. To examine the impact of individual patient and study criteria we planned the following additional two way sensitivity

analyses a priori: balanced patient profile given published information on personal details, comorbidity and ambulation (yes or no); inclusion of mobile and oriented patients only (yes or heterogeneous sample/unclear); cementation of stems in the hemiarthroplasty group (100% or <100%, or unclear); follow-up interval less than or more than 24 months; intention to treat analysis specified (yes or no); specification of surgeon grades in the study (yes or no); less than 5% loss to follow-up (yes or no, or not specified); and postoperative care specified (yes or no). We compared treatment effects between independent subgroups using the test for interaction proposed by Altman and Bland,³⁴ providing both P values and ratios of relative risks with 95% confidence intervals. For all calculations we used Stata 10.0 statistical software, incorporating the updated metan meta-analysis package.³⁵

RESULTS

The electronic search strategy revealed 3821 papers, 160 of which were potentially relevant to the analysis. An additional search of the reference lists yielded 42 citations not covered by the electronic search. A shortlist of 24 papers was compiled from the set of 202 full text articles retrieved. At this stage, the reviewers omitted another nine manuscripts. Two studies, one of which was published in German and later duplicated in English, included patients with trochanteric fractures only, as did a study from Belgium.³⁶⁻³⁸

Another two studies enrolled patients with femoral neck and trochanteric fractures but did not provide sufficient information to enable separate analyses on both factors.^{39,40} One study that compared primary joint replacement with internal fixation did not distinguish between subgroups who had undergone hemiarthroplasty and total hip arthroplasty.⁴¹

Two randomised trials were reported in duplicate.⁴²⁻⁴⁵ The related publications were assessed for overlapping and unique information relevant to this review. Finally, one study represented the 13 year follow-up of patients enrolled in an earlier randomised trial but had different authors.^{46,47}

For studies available in duplicate, references to the most recent publication were provided. This left 15 original reports (fig 1) of four randomised trials, three quasirandomised trials, and eight retrospective cohort studies, enrolling a total of 1890 patients.

Study characteristics

Tables 1-3 summarise the key characteristics of the included studies, and table 4 the criteria of methodological quality. In seven studies (n=776) patients were randomly allocated to hemiarthroplasty or to total hip arthroplasty.^{43 45 46 48-51} Concealed randomisation (sealed envelopes or a central automated telephone system) was guaranteed by four trials, all of which met most other quality criteria.^{43 45 48 49} In the remaining studies, patients were assigned to one of the procedures by admission numbers,⁵⁰ day of the week,⁴⁶ or in a fixed, alternating sequence.⁵¹ Only one study stated blinded outcome assessment.⁵¹

Table 4 | Methodological quality of included studies

Study	Concealment of allocation	Entry criteria specified	Intention to treat analysis	Intervention groups characterised	Surgeon grade specified	Postoperative care	Outcome measures defined	Outcome assessor blinded	Follow-up period of ≥ 1 year	Missing information on <5% of patients
Baker 2006 ⁴⁸	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes
Keating 2006 ⁴⁵	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Blomfeldt 2007 ⁴⁹	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Macaulay 2008 ^{42 43}	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No
Dorr 1986 ⁵⁰	No	Yes	No	Yes	No	Yes	Yes	No	Yes	Yes
Ravikumar 2000 ⁴⁶	No	Yes	No	No	Yes	Yes	Yes	No	Yes	No
Mouzopoulos 2008 ⁵¹	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
Gebhard 1992 ⁵³	No	No	No	No	No	No	Yes	No	Yes	No
Eyssel 1994 ⁵²	No	No	No	Yes	Yes	Yes	Yes	No	No	No
Levi 1996 ⁵⁵	No	No	No	No	Yes	Yes	Yes	No	No	No
Squires 1999 ⁵⁸	No	Yes	No	Yes	Yes	No	Yes	No	Yes	Yes
Xu 2002 ⁵⁹	No	No	No	No	No	No	No	No	Yes	No
Schleicher 2003 ⁵⁷	No	No	No	Yes	No	No	Yes	No	Yes	Yes
Healy 2004 ⁵⁴	No	No	No	No	No	No	Yes	No	Yes	Yes
Narayan 2006 ⁵⁶	No	Yes	No	No	No	Yes	Yes	No	Yes	No

Experimental evidence was supplemented by data from eight retrospective cohort studies (n=1114) of low methodological quality.⁵²⁻⁵⁹ The number of fulfilled quality criteria ranged from one to seven of a maximum 12. However, two of these observational studies together included 584 patients, or one third of the entire sample of participants.^{52,55}

Most studies showed balanced patient baseline characteristics (n=12), included mobile and oriented patients only (n=10), attempted a minimum follow-up of more than 24 months (n=12), and specified postoperative care (n=9). Loss to follow-up was less than 5% in seven of the 15 studies, and hemiarthroplasty stems were cemented in six. Information on intention to treat analysis was provided in four studies: either all the patients were analysed according to the allocated intervention,^{45 49} or the paper confirmed that all patients had undergone the assigned procedure.^{43 51}

According to seven studies,^{43 45 48 49 52 57 59} total hip replacement lengthened the duration of surgery by an average of 11 minutes (95% confidence interval 4 to 19 minutes). Heterogeneity was significant for the reported lengths of surgery (I²=71%, P=0.002).

Reoperation rates

The seven randomised trials and seven of eight retrospective cohort studies, totalling 1669 patients and 123 events, provided data on reoperation rates. Overall, primary total hip arthroplasty was associated with a lower risk of subsequent reoperation compared with hemiarthroplasty (fig 2). The pooled relative risk was 0.57 (95% confidence interval 0.34 to 0.96), equalling a risk difference of 4.4% (95% confidence interval 0.2% to 8.5%) in favour of total hip replacement. Heterogeneity across studies was low (I²=27%, P=0.16). Publication bias was not evident (intercept 0.79, P=0.36).

Table 5 shows the influence of the study design and other prespecified variables on relative risks of reoperation. Studies with follow-up intervals of two years or longer were associated with bigger treatment effects in favour of total hip replacement (ratio of relative risks 0.44, 95% confidence interval 0.15 to 1.26, test for interaction, P=0.13). Treatment effects were comparable between retrospective cohort and experimental studies (1.26, 0.42 to 3.79, test for interaction, P=0.67) but seemed to be overestimated by studies with

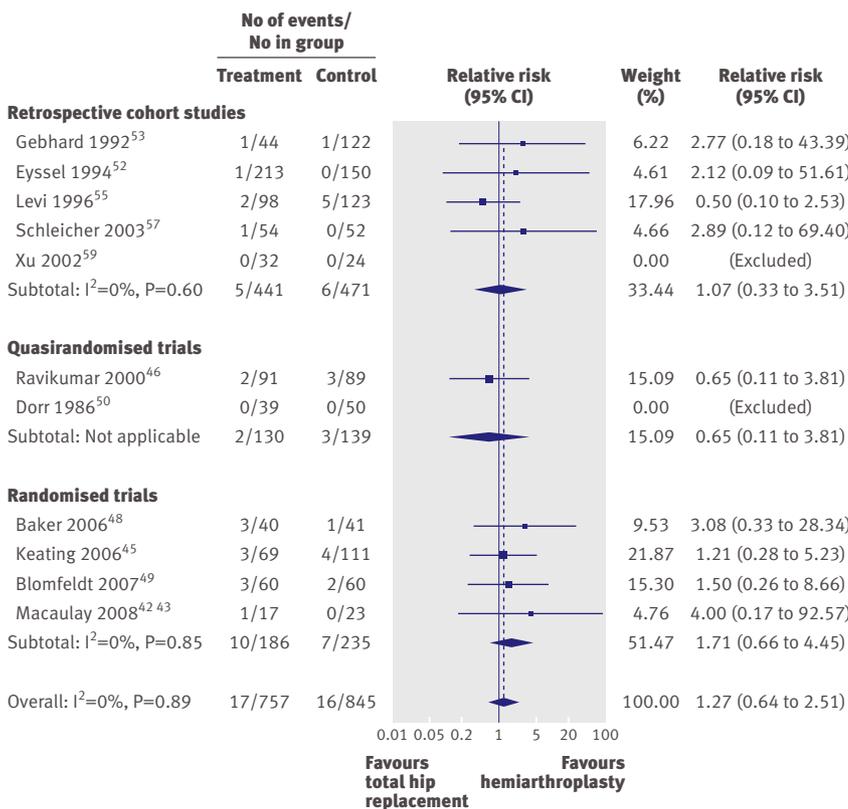
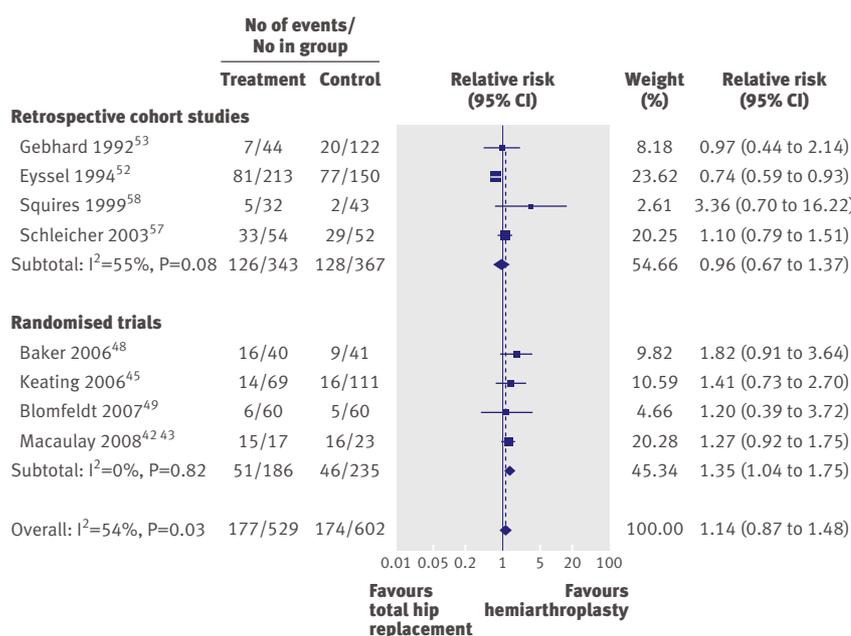


Fig 4 | Random effects meta-analysis comparing relative risk of deep infections after total hip arthroplasty and hemiarthroplasty for displaced intracapsular hip fractures

Table 5 | Sensitivity analysis showing influence of prespecified variables on relative risks of reoperation

Variables	No of trials/ No of patients	Relative risk (95% CI)	Relative risk ratio (95% CI)	z	P value*
Design:					
Randomised or quasirandomised	7/776	0.63 (0.29 to 1.40)	1.26 (0.42 to 3.79)	0.42	0.67
Retrospective cohort	7/893	0.50 (0.23 to 1.08)			
Concealment:					
Appropriate	4/421	1.08 (0.39 to 3.03)	2.59 (0.83 to 8.07)	1.65	0.10
Unclear	10/1248	0.41 (0.25 to 0.68)			
Baseline characteristics:					
Balanced	12/1240	0.55 (0.30 to 1.01)	0.98 (0.15 to 6.09)	-0.01	0.99
Unbalanced	2/429	0.56 (0.10 to 3.15)			
Patient sample:					
Oriented and ambulatory	10/1201	0.75 (0.41 to 1.38)	2.80 (1.09 to 7.22)	2.14	0.03
Mixed	4/468	0.27 (0.13 to 0.56)			
Hemiarthroplasty type:					
All cemented stems	6/866	0.88 (0.44 to 1.73)	2.35 (0.95 to 5.82)	1.86	0.06
Mixed	8/803	0.37 (0.20 to 0.68)			
Follow-up:					
≥2 years	12/1186	0.47 (0.26 to 0.86)	0.44 (0.15 to 1.26)	-1.51	0.13
<2 years	2/483	1.05 (0.45 to 2.45)			
Surgeon grade:					
Specified	7/1039	0.59 (0.26 to 1.33)	1.13 (0.35 to 3.57)	0.21	0.83
Not specified	7/630	0.52 (0.23 to 1.21)			
Intention to treat:					
Respected	4/426	1.32 (0.60 to 2.90)	3.26 (1.27 to 8.33)	2.47	0.01
Not specified	10/1243	0.40 (0.24 to 0.67)			
Losses to follow-up					
<5%	7/737	0.60 (0.28 to 1.30)	1.17 (0.39 to 3.48)	0.29	0.77
Not specified	7/932	0.51 (0.24 to 1.11)			
Postoperative care					
Specified	8/1036	0.54 (0.30 to 0.96)	0.98 (0.28 to 3.37)	-0.02	0.98
Not specified	6/633	0.55 (0.18 to 1.64)			

*Derived from test of interaction.³⁴**Fig 5** | Random effects meta-analysis comparing relative risk of general complications after total hip arthroplasty and hemiarthroplasty for displaced intracapsular hip fractures

inadequate or unclear concealment of allocation (2.59, 0.83 to 8.07, test for interaction, P=0.10).

The observed benefit in reoperation rates with total hip replacement mitigated in studies that had enrolled only oriented and ambulatory patients, used only cemented stems for hemiarthroplasty, and respected the intention to treat principle (table 5).

Local and general complications

Dislocation rates were reported in 12 studies (1517 patients, 73 events). Effect sizes were homogeneous (I²=4%, P=0.40) and publication bias was not evident (intercept 1.43, P=0.24). The pooled analysis (fig 3) showed no significant difference in the risk for dislocation between total hip arthroplasty and hemiarthroplasty (relative risk 1.48, 95% confidence interval 0.89 to 2.46, risk difference 1.0%, 95% confidence interval -1.2% to 3.2%). A tendency was, however, noted towards a higher risk for dislocation after total hip arthroplasty among randomised and quasirandomised trials. This trend was most pronounced in studies with balanced patient baseline profiles and follow-up intervals of two or more years (table 6).

Table 6 | Sensitivity analysis showing influence of prespecified variables on relative risks of dislocation

Variables	No of trials/ No of patients	Relative risk (95% CI)	Relative risk ratio (95% CI)	z	P value*
Design:					
Randomised or quasirandomised	6/690	1.87 (1.08 to 3.25)	2.43 (0.83 to 7.10)	1.63	0.10
Retrospective cohort	6/827	0.77 (0.30 to 1.92)			
Concealment:					
Appropriate	4/421	2.46 (0.69 to 8.76)	1.88 (0.44 to 7.93)	0.87	0.39
Unclear	8/1096	1.30 (0.66 to 2.57)			
Baseline characteristics:					
Balanced	11/1154	1.67 (1.02 to 2.73)	4.75 (0.82 to 27.57)	1.74	0.08
Unbalanced	1/363	0.35 (0.06 to 1.89)			
Patient sample:					
Oriented and ambulatory	9/1115	1.99 (0.93 to 4.27)	1.74 (0.61 to 4.92)	1.05	0.29
Mixed	3/402	1.14 (0.56 to 2.32)			
Hemiarthroplasty type:					
All cemented stems	5/800	0.91 (0.27 to 3.02)	0.52 (0.14 to 1.95)	-0.95	0.34
Mixed	7/717	1.73 (1.01 to 2.97)			
Follow-up:					
≥2 years	10/1034	1.67 (1.02 to 2.73)	4.75 (0.82 to 27.48)	1.74	0.08
<2 years	2/483	0.35 (0.06 to 1.89)			
Surgeon grade:					
Specified	7/1039	1.43 (0.83 to 2.47)	0.97 (0.25 to 3.63)	0.00	1.00
Not specified	5/478	1.47 (0.44 to 4.91)			
Intention to treat:					
Respected	3/340	1.93 (0.47 to 7.87)	1.36 (0.28 to 6.46)	0.39	0.70
Not specified	9/1177	1.41 (0.72 to 2.75)			
Losses to follow-up					
<5%	6/651	2.67 (1.10 to 6.49)	2.56 (0.78 to 8.37)	1.57	0.12
Not specified	6/866	1.04 (0.47 to 2.26)			
Postoperative care					
Specified	7/950	1.58 (0.63 to 3.93)	1.15 (0.30 to 4.39)	0.21	0.83
Not specified	5/567	1.36 (0.51 to 3.63)			

*Derived from test of interaction.³⁴

Deep infections occurred in 33 of 1264 patients enrolled in 11 studies. There was no heterogeneity ($I^2=0\%$, $P=0.89$) but evidence of funnel plot asymmetry (intercept 2.81, $P=0.027$) for this end point. The pooled relative risk of infection after total hip arthroplasty compared with hemiarthroplasty was 1.27 (95% confidence interval 0.64 to 2.51), translating into a risk difference of 0.4% (95% confidence interval -0.7% to 1.6%). Results were virtually similar among experimental, quasiexperimental, and retrospective cohort studies (fig 4). Also, no substantial interaction was noted between all investigated subgroups for this end point (table 7).

General complications were observed slightly more often after total hip arthroplasty than after hemiarthroplasty (relative risk 1.14, 95% confidence interval 0.87 to 1.48, risk difference 3.7%, 95% confidence interval -3.7% to 11.1%). This trend was consistently observed in randomised trials (fig 5) as well as in studies with balanced patient baseline profiles and follow-up intervals of two or more years (table 8). Results were prone to publication bias (intercept 4.09, $P=0.033$).

One year mortality

Nine studies (1023 patients, 178 events) provided data on one year mortality. There was no evidence of heterogeneity ($I^2=0\%$, $P=0.85$) and publication bias (intercept 0.22, $P=0.76$). Altogether, mortality did not differ between patients undergoing total hip arthroplasty and hemiarthroplasty (relative risk 0.92, 95% confidence interval 0.70 to 1.21, risk difference 1.4%, 95% confidence interval -2.6% to 5.4%). Notable benefits were observed in randomised trials (fig 6); however, the test for interaction did not reveal significant differences between subgroups (table 9).

Function and health related quality of life

The Harris hip score was used for outcome assessment in three randomised trials and in 246 patients, with follow-up intervals ranging from 12 to 48 months.^{43,49,51} This score contains the subscales pain, function, deformity, and range of motion, and may achieve values from 0 to 100 points, with higher scores indicating better function.⁶⁰ Total hip replacement was consistently associated with better function in all studies ($I^2=4\%$,

Table 7 | Sensitivity analysis showing influence of prespecified variables on relative risks of deep infection

Variables	No of trials/ No of patients	Relative risk (95% CI)	Relative risk ratio (95% CI)	z	P value*
Design:					
Randomised or quasirandomised	6/690	1.37 (0.59 to 3.18)	1.28 (0.29 to 5.47)	0.33	0.74
Retrospective cohort	5/912	1.07 (0.32 to 3.51)			
Concealment:					
Appropriate	4/421	1.71 (0.65 to 4.44)	1.86 (0.47 to 7.34)	0.89	0.38
Unclear	7/1181	0.91 (0.34 to 2.46)			
Baseline characteristics:					
Balanced	9/1018	1.52 (0.69 to 3.31)	2.25 (0.43 to 11.63)	0.97	0.33
Unbalanced	2/584	0.67 (0.15 to 2.85)			
Patient sample:					
Oriented and ambulatory	7/979	1.81 (0.75 to 4.36)	2.48 (0.61 to 10.11)	1.27	0.20
Mixed	4/623	0.72 (0.24 to 2.17)			
Hemiarthroplasty type:					
All cemented stems	5/800	1.61 (0.61 to 4.19)	1.64 (0.41 to 6.47)	0.71	0.48
Mixed	6/802	0.98 (0.36 to 2.62)			
Follow-up:					
≥2 years	8/898	1.52 (0.63 to 3.64)	1.63 (0.39 to 6.74)	0.69	0.49
<2 years	3/704	0.93 (0.30 to 2.83)			
Surgeon grade:					
Specified	7/1185	1.14 (0.55 to 2.37)	0.40 (0.04 to 3.67)	-0.80	0.42
Not specified	4/417	2.82 (0.35 to 22.5)			
Intention to treat:					
Respected	3/340	1.49 (0.51 to 4.31)	1.33 (0.33 to 5.36)	0.41	0.68
Not specified	8/1262	1.12 (0.45 to 2.75)			
Losses to follow-up:					
<5%	5/576	1.65 (0.63 to 4.31)	1.74 (0.44 to 6.87)	0.79	0.43
Not specified	6/1026	0.95 (0.35 to 2.54)			
Postoperative care:					
Specified	7/1110	1.02 (0.43 to 2.44)	0.57 (0.13 to 2.35)	-0.78	0.44
Not specified	4/492	1.79 (0.58 to 5.50)			

*Derived from test of interaction.³⁴

P=0.35) (fig 7), and without evidence of publication bias (intercept -0.18, P=0.95). The weighted mean difference in favour of total hip replacement was 5.4 (95% confidence interval 2.7 to 8.2).

Another trial⁴⁵ had utilised the hip rating questionnaire, an instrument consisting of the four subscales arthritis, pain, walking, and daily function. Scores may range from 16 to 100 points.⁶¹ At final follow-up after 24 months, the weighted mean difference was 6.1 (95% confidence interval 0.4 to 11.8) in favour of total hip replacement.

The Oxford hip score was used for functional outcome measurement in another trial.⁴⁸ This score ranges from 12 to 60 points, with higher values indicating poorer function.⁶² After three years of follow-up, hip function after total hip arthroplasty was rated slightly better than after hemiarthroplasty, by 3.5 points (95% confidence interval -0.7 to 7.7 points).

The standardised mean difference from all trials was estimated at 0.42 (95% confidence interval 0.24 to 0.61), indicating a medium functional benefit of total hip replacement.⁶³

SF-36 physical component scores were available from two trials totalling 121 patients,^{43,48} with no differences between total hip arthroplasty and hemiarthroplasty (weighted mean difference 1.9, 95% confidence interval -2.2 to 6.0). Another trial had used EQ-5D utility scores, which were rated significantly better in the total hip arthroplasty group compared with the hemiarthroplasty group after two years of follow-up (mean difference 0.16, 95% confidence interval 0.05 to 0.27).⁴⁵

DISCUSSION

The purpose of this review was to provide additional insight into the options for treating intracapsular hip fractures, focusing on the role of total hip replacement now that there is a significant body of evidence indicating that older patients treated with arthroplasty of all types have fewer complication rates and better health outcomes than those treated with internal fixation. Total hip arthroplasty compared with hemiarthroplasty was found to be beneficial for reoperation rates and functional outcomes. It is unclear whether patients

Table 8 | Sensitivity analysis showing influence of prespecified variables on relative risks of general complications

Variables	No of trials/ No of patients	Relative risk (95% CI)	Relative risk ratio (95% CI)	z	P value*
Design:					
Randomised or quasirandomised	4/421	1.35 (1.04 to 1.75)	1.41 (0.91 to 2.19)	1.54	0.12
Retrospective cohort	4/710	0.95 (0.67 to 1.36)			
Concealment:					
Appropriate	4/421	1.35 (1.04 to 1.75)	1.41 (0.91 to 2.19)	1.54	0.12
Unclear	4/710	0.95 (0.67 to 1.36)			
Baseline characteristics:					
Balanced	7/768	1.24 (1.02 to 1.51)	1.68 (1.24 to 2.27)	3.37	<0.01
Unbalanced	1/363	0.74 (0.58 to 0.93)			
Patient sample:					
Oriented and ambulatory	7/965	1.16 (0.86 to 1.56)	1.20 (0.51 to 2.78)	0.43	0.67
Mixed	1/166	0.97 (0.44 to 2.13)			
Hemiarthroplasty type:					
All cemented stems	4/744	1.14 (0.68 to 1.93)	0.96 (0.55 to 1.70)	-0.11	0.92
Mixed	4/387	1.18 (0.95 to 1.47)			
Follow-up:					
≥2 years	6/648	1.24 (1.02 to 1.51)	1.65 (1.22 to 2.23)	3.27	<0.01
<2 years	2/483	0.75 (0.60 to 0.94)			
Surgeon grade:					
Specified	6/859	1.22 (0.83 to 1.80)	1.13 (0.69 to 1.85)	0.52	0.60
Not specified	2/272	1.07 (0.79 to 1.45)			
Intention to treat:					
Respected	3/340	1.28 (0.97 to 1.70)	1.18 (0.73 to 1.89)	0.70	0.48
Not specified	5/791	1.08 (0.74 to 1.58)			
Losses to follow-up:					
<5%	5/562	1.26 (0.97 to 1.63)	1.31 (0.79 to 2.18)	1.07	0.28
Not specified	3/569	0.95 (0.62 to 1.48)			
Postoperative care:					
Specified	3/564	1.09 (0.56 to 2.11)	0.90 (0.45 to 1.80)	-0.28	0.78
Not specified	5/567	1.20 (0.98 to 1.48)			

*Derived from test of interaction.³⁴

undergoing total hip replacement may also benefit from a small survival advantage after one year. The potential advantages must be traded off against a possible higher risk of dislocation and general complications, higher invasiveness, and longer theatre times.

Strengths and weaknesses of this review

This is the first review to compile all available head to head investigations of total hip arthroplasty compared with hemiarthroplasty for femoral neck fractures. By including both experimental and non-experimental studies, the sample size and robustness of estimates was enhanced compared with previous reviews. Yet, the number of available studies was small, and with an overall sample size of fewer than 2000 patients our results do not allow for conclusive statements on the effectiveness of total hip arthroplasty and hemiarthroplasty for treating femoral neck fractures.

Some might argue about the inclusion of retrospective cohort studies because of their inherent risk of bias. However, such studies enrolled a significant number of patients and, despite methodological limitations, ignoring this source of data might have affected the

external validity of our findings. The researchers were diligent about extracting as much information as possible from the available papers. We tried to control our computations for confounding, carried out various sensitivity analyses, and explored the interaction between subgroups.

There is no doubt that only randomisation creates biologically similar patient cohorts, in which unknown confounders are equally distributed, and allows for inferences on causal relations between exposure and outcome. It might be assumed that in non-randomised studies, patients with poorer prognosis were more likely to undergo the faster, less invasive procedure of hemiarthroplasty, thereby introducing selection and differential indication bias.

Although the published information on patient profiles was limited in quantity and quality, participants enrolled in the retrospective cohort studies were not entirely different from those enrolled in the randomised trials. This is not surprising, since the typical patient presenting with a femoral neck fracture to an emergency department in an industrial country (thus being a potential candidate for a clinical study) is a

Table 9 Sensitivity analysis showing influence of prespecified variables on relative risks of one year mortality

Variables	No of trials/No of patients	Relative risk (95% CI)	Relative risk ratio (95% CI)	z	P value*
Design:					
Randomised or quasirandomised	6/695	0.8 (0.56 to 1.14)	0.71 (0.41 to 1.24)	-1.19	0.24
Retrospective cohort	3/328	1.11 (0.73 to 1.71)			
Concealment:					
Appropriate	3/340	0.67 (0.29 to 1.50)	0.70 (0.29 to 1.65)	-0.81	0.42
Unclear	6/683	0.95 (0.71 to 1.27)			
Baseline characteristics:					
Balanced	9/1023	0.91 (0.69 to 1.20)	—	—	—
Unbalanced	0	—	—	—	—
Patient sample:					
Oriented and ambulatory	6/621	0.88 (0.57 to 1.37)	0.94 (0.53 to 1.66)	-0.20	0.84
Mixed	3/402	0.93 (0.66 to 1.32)			
Hemiarthroplasty type:					
All cemented stems	3/356	0.84 (0.40 to 1.77)	0.90 (0.40 to 2.02)	-0.24	0.81
Mixed	6/667	0.93 (0.69 to 1.24)			
Follow-up:					
≥2 years	8/903	0.90 (0.68 to 1.19)	0.67 (0.15 to 2.98)	-0.51	0.61
<2 years	1/120	1.33 (0.31 to 5.70)			
Surgeon grade:					
Specified	4/520	0.79 (0.51 to 1.22)	0.79 (0.45 to 1.37)	-0.83	0.41
Not specified	5/503	1.01 (0.70 to 1.43)			
Intention to treat:					
Respected	4/426	0.72 (0.42 to 1.23)	0.72 (0.38 to 1.34)	-1.02	0.31
Not specified	5/597	1 (0.72 to 1.37)			
Losses to follow-up:					
<5%	5/581	0.93 (0.59 to 1.47)	1.03 (0.58 to 1.82)	0.12	0.90
Not specified	4/442	0.90 (0.64 to 1.27)			
Postoperative care:					
Specified	5/531	0.87 (0.60 to 1.26)	0.90 (0.49 to 1.65)	-0.32	0.75
Not specified	4/492	0.96 (0.59 to 1.54)			

*Derived from test of interaction.³⁴

woman in her mid-70s with osteoporosis, cardiovascular comorbidity, and associated drugs. The available information did not support the thesis that different treatment assignment in non-randomised studies was mainly based on preoperative risk assessment. Although we do not discount this, we suspect that in these studies surgeons' preferences, as well as disposability of teams, hardware, and theatre time slots, contributed to the decision to implant a total hip or a bipolar prosthesis. This does, however, resemble clinical reality.

We noted further interesting patterns of treatment effects that may be useful for planning future trials. Random assignment to interventions in itself had little influence on the reported reoperation rates. In fact, the observed advantage with total hip replacement disappeared with adequate concealment of allocation, which may be an important surrogate of higher methodological quality. Other features such as the recruitment of physically and mentally fit patients and routine cementation of stems in the hemiarthroplasty control group mitigated (but still did not exclude) favourable reoperation risks after total hip arthroplasty.

Upcoming trial protocols should respect these important variables that may distort effect sizes. They must also aim for minimum follow-up intervals of two years to confirm or refute potential gains of total hip arthroplasty over hemiarthroplasty in the fracture scenario.

It is noteworthy that, although derived from a small subset of studies, the findings of better hip function after total hip replacement were highly consistent. A reliable trade-off of the possible benefits and harms with total hip replacement also requires large scale data on health related quality of life.

Other studies

A recent meta-analysis of randomised trials identified three studies,⁶⁴ all included in this review.^{45,46,50} The meta-analysis reported similar findings to this review, with higher reoperation rates and a trend for lower dislocation rates with hemiarthroplasty. Patients who had undergone total hip replacement were more likely to become mobile and less likely to require a second analgesic at 1, 2, 4, and 13 years, although this was not statistically significant at any assessment time. The greater proportion of mobile patients who had

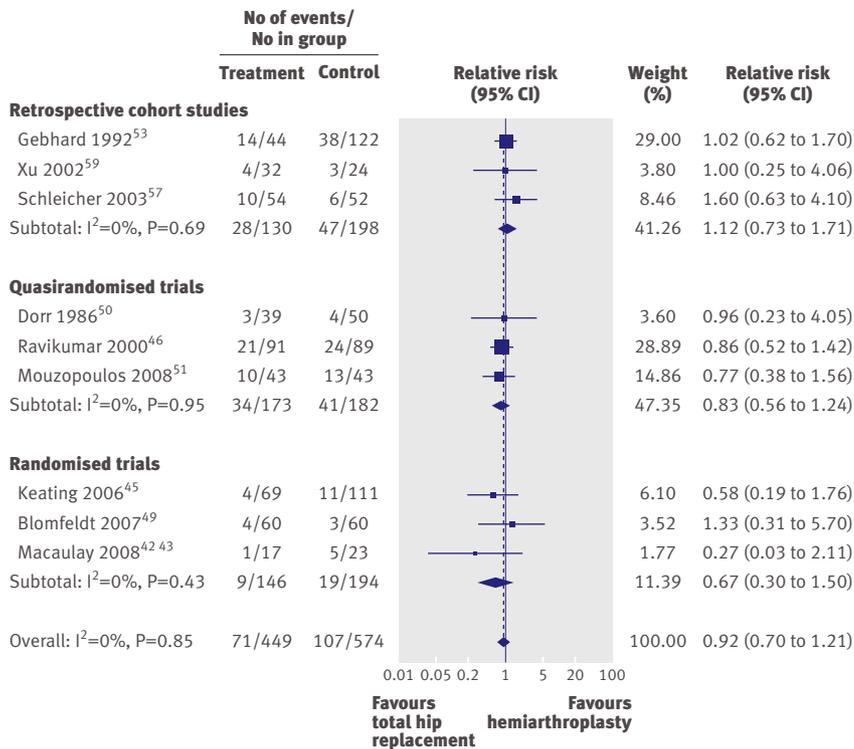


Fig 6 | Random effects meta-analysis comparing relative risk of one year mortality after total hip arthroplasty and hemiarthroplasty for displaced intracapsular hip fractures

undergone total hip replacement seems to correspond to the better hip function found with total hip replacement in this review. An earlier Cochrane review²⁸ that compared cemented and cementless arthroplasty and internal fixation also carried out a meta-analysis of total hip arthroplasty compared with hemiarthroplasty based on three studies used in this review.^{45 47 50} The Cochrane review found no significant differences between the interventions, although there was a trend for higher dislocation rates and lower reoperation rates with total hip replacement. Also, total hip arthroplasty was found to take about 20 minutes longer than hemiarthroplasty.

Meaning of our review

The optimal treatment strategy for hip fractures matters to healthcare professionals, policy makers, and payers of healthcare services, and should avoid costly reoperations, secondary hospital admissions, loss of independence, and physical disability. The noted 43% relative or 4% absolute reduction in the risk of reoperation with total hip arthroplasty is clinically important, given reported baseline risks of revision with hemiarthroplasty ranging from 6% to 18%.^{21 23} It must be kept in mind, however, that this is an aggregated effect mainly driven by data from trials with inadequate concealment. In contrast, total hip replacement was associated with a 48% relative or 1% absolute increase in the risk of dislocation. Avoiding further major surgical procedures is particularly relevant to patients with hip fractures, who are generally older and less healthy than the general population.

Considering the upper and lower confidence limits, it is possible that the reduction in the risk of reoperation may be smaller than the theoretical increase in the risk of dislocation. Under these circumstances, total hip replacement may still be the dominant treatment strategy, as dislocation can be managed on an outpatient basis and is a less serious event than reoperation. Also, the direct costs for a bipolar head in hemiarthroplasty may exceed those for a cemented polyethylene cup in total hip arthroplasty.

In this review, total hip replacement was not associated with a higher risk of deep infections, and a slightly higher risk of general complications did not result in higher mortality. Thus the procedure may be considered effective and safe in patients with intracapsular hip fractures, and a reasonable alternative to hemiarthroplasty.

We believe that the consistently better functional outcome ratings after total hip replacement are the most relevant findings of this review. However, the observed mean difference of 5.4 points in the total Harris hip score remains difficult to interpret, since no minimal important difference has currently been defined for this widely used outcome measure. The standardised mean difference derived from all five studies that had used at least one validated disease specific questionnaire was 0.42, suggesting a medium treatment effect.⁶³

Unanswered questions and future research

The results from this review cannot be considered conclusive owing to various interactions between strata. Furthermore, the improvement in function and health outcomes with total hip replacement was modest and only reported by a small number of studies. Therefore large scale clinical research to study the potential effects of total hip replacement on mobility and regain of independent living after displaced fractures of the femoral neck is merited. The quantitative findings from this review may allow for a better planning of those trials, selection of trial end points, and sample size estimation.

Patients are currently being recruited to the Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty trial, an initiative of the International Hip Fracture Research Collaborative. With a target sample size of 2500 patients for this study, the results from this trial, expected to be published in 2011, may allow for more conclusive inferences on this matter, but still must be interpreted in the light of current best evidence and the prior probability of effectiveness with either type of joint replacement. Additionally, a formal health economic analysis would be useful for providing greater clarity in decision making.

Patients with greater levels of activity treated with hemiarthroplasty may induce osteoarthritis more rapidly than in less active patients and, as they are likely to have a higher life expectancy, will be exposed to the risk of acetabular erosion for a longer period. Factors contributing to dislocation rates may be the

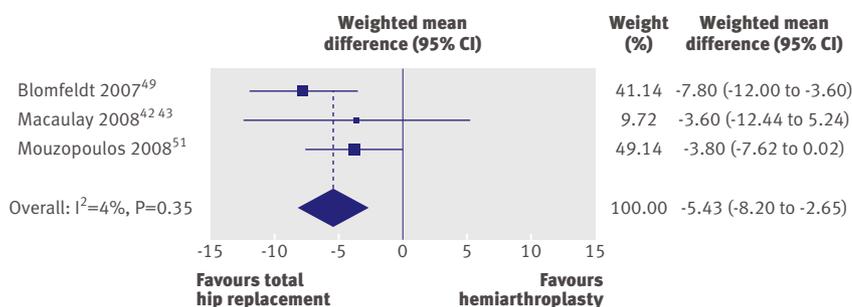


Fig 7 | Random effects meta-analysis comparing weighted mean differences of Harris hip scores after total hip arthroplasty and hemiarthroplasty for displaced intracapsular hip fractures

surgical approach and the size of the prosthetic head. A multivariable analysis of dislocation after primary total hip replacement for all diagnoses found that a posterolateral approach and a smaller prosthetic head were associated with a higher rate of dislocation.⁶⁵ Apart from choosing the optimal hardware, improving the surgical access route may help to reduce complications with this common procedure.

Conclusion

Although this review was limited to a small number of randomised controlled trials and retrospective cohort studies, some evidence suggested that patients treated with total hip arthroplasty for intracapsular hip fractures may have better outcomes than those treated with hemiarthroplasty.

The data currently available, however, do not yet allow for definitive conclusions about the scale and existence of some of the identified treatment effects, owing to varying interactions between subgroups, particularly those concerning random allocation of patients. Considering that a more frequent use of total hip replacement in oriented and mobile patients with displaced intracapsular hip fractures may be appropriate and save costs in the long run, an adequately powered trial is urgently needed to dispel these remaining doubts of the benefit to risk ratio with total hip replacement in the fracture setting.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Arthroplasty is associated with lower reoperation rates and better function than internal fixation for patients with displaced intracapsular hip fractures

Total hip arthroplasty may be associated with better function than hemiarthroplasty in this setting and may also avoid secondary conversion surgery

A sample of randomised trials comparing both interventions was included in a recent systematic review, but an overview of the entire body of evidence is lacking

WHAT THIS STUDY ADDS

Data from 15 studies suggest that total hip arthroplasty is associated with lower reoperation rates and slightly better functional outcomes than hemiarthroplasty

Advantages with total hip arthroplasty must be traded off against a slightly higher risk of dislocations and general complications

Large well designed clinical trials comparing the two interventions are required before a definitive conclusion on their risk-benefit ratio can be reached

Contributors: CH conceived the study. CH and MW did the first data analyses, and DS did the final analyses. CH wrote the first draft of the protocol and the paper. CH, MW, and DS wrote the final draft of the paper and did the literature searches. All authors contributed to extracting and interpreting data and to revising the protocol and manuscript. CH and DS are the guarantors.

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Ethical approval: Not required.

Data sharing: The technical appendix, and datasets extracted from individual papers and meta-analyses are available from the corresponding author at chopley@its.jnj.com.

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