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Total Hip Arthroplasty or Hemiarthroplasty for Hip Fracture

The HEALTH Investigators*

ABSTRACT

BACKGROUND

Globally, hip fractures are among the top 10 causes of disability in adults. For displaced femoral neck fractures, there remains uncertainty regarding the effect of a total hip arthroplasty as compared with hemiarthroplasty.

METHODS

We randomly assigned 1495 patients who were 50 years of age or older and had a displaced femoral neck fracture to undergo either total hip arthroplasty or hemiarthroplasty. All enrolled patients had been able to ambulate without the assistance of another person before the fracture occurred. The trial was conducted in 80 centers in 10 countries. The primary end point was a secondary hip procedure within 24 months of follow-up. Secondary end points included death, serious adverse events, hip-related complications, health-related quality of life, function, and overall health end points.

RESULTS

The primary end point occurred in 57 of 718 patients (7.9%) who were randomly assigned to total hip arthroplasty and 60 of 723 patients (8.3%) who were randomly assigned to hemiarthroplasty (hazard ratio, 0.95; 95% confidence interval [CI], 0.64 to 1.40; P=0.79). Hip instability or dislocation occurred in 34 patients (4.7%) assigned to total hip arthroplasty and 17 patients (2.4%) assigned to hemiarthroplasty (hazard ratio, 2.00; 99% CI, 0.97 to 4.09). Function, as measured with the total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score, pain score, stiffness score, and function score, modestly favored total hip arthroplasty over hemiarthroplasty. Mortality was similar in the two treatment groups (14.3% among the patients assigned to total hip arthroplasty and 13.1% among those assigned to hemiarthroplasty, P=0.48). Serious adverse events occurred in 300 patients (41.8%) assigned to total hip arthroplasty and in 265 patients (36.7%) assigned to hemiarthroplasty.

CONCLUSIONS

Among independently ambulating patients with displaced femoral neck fractures, the incidence of secondary procedures did not differ significantly between patients who were randomly assigned to undergo total hip arthroplasty and those who were assigned to undergo hemiarthroplasty, and total hip arthroplasty provided a clinically unimportant improvement over hemiarthroplasty in function and quality of life over 24 months. (Funded by the Canadian Institutes of Health Research and others; ClinicalTrials.gov number, NCT00556842.)

The members of the writing committee (Mohit Bhandari, M.D., Ph.D. [cochair], Thomas A. Einhorn, M.D., Gordon Guyatt, M.D., Emil H. Schemitsch, M.D., Robert D. Zura, M.D., Sheila Sprague, Ph.D., Frede Frihagen, M.D., Ph.D., Ernesto Guerra-Farfán, M.D., Ydo V. Kleinlugtenbelt, M.D., Ph.D., Rudolf W. Poolman, M.D., Ph.D., Amar Rangan, Ch.M., F.R.C.S., Sofia Bzovsky, M.Sc., Diane Heels-Ansdell, M.Sc., Lehana Thabane, Ph.D., Stephen D. Walter, Ph.D., and P.J. Devereaux, M.D., Ph.D. [cochair]) assume responsibility for the overall content and integrity of this article. The affiliations of the members of the writing committee are listed in the Appendix. Address reprint requests to Dr. Bhandari at the Division of Orthopaedic Surgery, McMaster University, 293 Wellington Street N., Suite 110, Hamilton, ON L8L 8E7, Canada, or at bhandam@mcmaster.ca.

*A complete list of members of the Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty (HEALTH) Investigators is provided in the Supplementary Appendix, available at NEJM.org.

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A Quick Take is available at NEJM.org

Patients with a hip fracture are at substantial risk for death, health complications, and reduced quality of life.[1-4] Despite the high frequency of the injury, the way in which displaced femoral neck fractures in elderly patients should be managed surgically remains uncertain.[2] Options include hemiarthroplasty, which involves replacing the femoral head with a prosthesis, or total hip arthroplasty, which involves replacement of both the femoral head and the acetabulum with prostheses. Advocates of total hip arthroplasty perceive benefits with regard to patient function and quality of life as compared with hemiarthroplasty. There are concerns, however, that total hip arthroplasty has greater associated surgical morbidity than hemiarthroplasty and may increase the risk of dislocation, which often leads to a secondary procedure to reduce or revise the prosthesis.[1] Meta-analyses of studies involving patients with a displaced hip fracture have suggested that total hip arthroplasty results in fewer reoperations and substantially better function than hemiarthroplasty.[4-6]

We performed the Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty (HEALTH) trial, an expertise-based randomized, controlled trial involving patients with a displaced femoral neck hip fracture, to examine the effect that total hip arthroplasty, as compared with hemiarthroplasty, has on the risk of a secondary hip procedure.

Methods

Trial Design

Our trial was an international, expertise-based, randomized, controlled trial. Details of the trial objectives and design have been published previously.[7] The protocol is available with the full text of this article at NEJM.org. Additional information about the eligibility criteria, interventions, follow-up, outcome definitions, and statistical analysis are provided in Section S2 in the Supplementary Appendix, available at NEJM.org.

Trial Oversight

The trial was funded by the Canadian Institutes of Health Research, the National Institutes of Health, and others. The funding sources had no role in the design or conduct of the trial; the collection, management, analysis, or interpretation of the data; or the preparation, review, or approval of the manuscript for submission. The Methods Center, located at McMaster University, coordinated the trial and was responsible for randomization, maintenance, validation, data analysis, and trial-center coordination. Boston Medical Center and New York University assisted in the coordination of trial sites in the United States. The steering committee, chaired by the principal investigators, designed the trial and the prespecified statistical analysis plan. The members of the steering committee (listed in Section S1) vouch for the completeness and accuracy of the data and for adherence of the trial to the protocol.

Patients

We enrolled patients at 80 participating sites in Canada, the United States, Spain, the United Kingdom, the Netherlands, Norway, Finland, Australia, New Zealand, and South Africa. To be eligible for participation, patients had to be 50 years of age or older, had to have a low-energy displaced fracture of the femoral neck that was planned to be treated with surgery, and had to have been able to ambulate without the assistance of another person before the hip fracture occurred.

Procedures

Patients were assigned to undergo either total hip arthroplasty or hemiarthroplasty. Minimization was used within each center to ensure prognostic balance between the treatment groups with regard to age, prefracture living setting, prefracture functional status, and American Society for Anesthesiologists (ASA) physical status.[2,8,9]

Surgeons, patients, end-point adjudicators, and research coordinators who assessed patient end points were aware of the assigned treatment groups. The data analyst remained unaware of the treatment groups throughout the trial and while performing analyses.

To facilitate the expertise-based trial design,[10] we set expertise thresholds for surgeons' participation. Among the 523 participating surgeons, 277 of 283 (97.9%) of those who performed total hip arthroplasty and 369 of 381 (96.9%) of those who performed hemiarthroplasty met thresholds for surgical expertise. Patients underwent assessment at 1 week, 10 weeks, and 6, 9, 12, 18, and 24 months after surgery, either in person or by telephone.

END POINTS

The primary end point was any unplanned secondary hip procedure within 24 months after the initial surgery. The procedures included closed and open reductions of a hip dislocation, open reduction of a fracture, full or partial implant exchange, implant removal, implant adjustment, soft-tissue procedure, excision of heterotopic ossification, insertion of an antibiotic spacer, and other events as determined by an independent central adjudication committee. Secondary end points included death, serious adverse events, hip-related complications, health-related quality of life, function, and overall health measures. Assessments of function and quality of life included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score (range, 0 to 96, with higher scores indicating worse pain, stiffness, and function; the minimal clinically important difference calculated in different studies ranges from 9 to 22), pain score (range, 0 to 20), stiffness score (range, 0 to 8), and function score (range, 0 to 68)[11-14]; the European Quality of Life–5 Dimensions (EQ-5D) utility index score and visual analogue scale; the 12-Item Short Form General Health Survey (SF-12) physical and mental component summary scores; and Timed Up and Go (TUG) scores.

The central adjudication committee reviewed secondary procedures to confirm the type of and reason for the procedure, as well as to confirm key secondary end points (death and hip-related complications). Separate independent data and safety monitoring boards coordinated by the National Institutes of Health and Canadian Institutes of Health Research monitored trial safety and reviewed all serious adverse events.

STATISTICAL ANALYSIS

In 2006, during the initial vanguard phase of the trial, which had the primary goal of assessing feasibility, the definitive trial was conceived as a noninferiority trial with an anticipated sample of 2500 patients. However, during the transition phase to the definitive trial (358 patients), we made the strategic decision to switch to a more feasible superiority design.

The planned sample size was 1434 patients (717 patients per treatment group), calculated under the assumption of a 5% risk of the primary end point in the hemiarthroplasty group at 1 year and a 45% lower relative risk of the primary end point at 2 years in the hemiarthroplasty group than in the total hip arthroplasty group. Our sample-size calculation reflected the proposed approach to the primary analysis, which used the proportional-hazards model.[15] The sample size was based on a two-sided test with an alpha of 0.05 and included adjustment for surgeon-level effects and for the expectation that 7.6% of patients would cross over from their randomly assigned group.

Analyses included patients in the groups to which they had been randomly assigned. Data for a given patient were censored at 24 months of follow-up or at the time of the last follow-up for patients who were lost to follow-up. The primary analysis was conducted with a proportional-hazards model and a competing-risk framework (with death as the competing risk), with the percentage of patients with a primary end-point event, analyzed in a time-to-event analysis, as the outcome. The independent variable was the procedure (total hip arthroplasty or hemiarthroplasty), and the age, prefracture living setting, prefracture functional status, and ASA status were used as covariates. For our competing-risk analyses, we reported marginal estimates and used the method described by Zhou et al. to account for clustering of data according to surgeon.[16] We report the treatment effects as hazard ratios with 95% confidence intervals. Kaplan–Meier curves were constructed for the primary end point.

Cox proportional-hazards modeling was used to estimate the relative effect of total hip arthroplasty as compared with hemiarthroplasty on time to death and serious adverse events. Proportional-hazards modeling with a competing-risk analysis (with death as the competing risk) was used to provide a marginal estimate of the relative effect of total hip arthroplasty as compared with hemiarthroplasty on the time to hip-related complications. We used multilevel models to estimate the effect of total hip arthroplasty as compared with hemiarthroplasty on quality of life, function, and mobility. In our multilevel analyses, we used joint modeling to account for death, using the method described by Rizopoulos.[17] We analyzed the TUG as a dichotomous end point. For our multilevel analyses of quality of life, function, and mobility, all available data were used, with no imputation performed. The models did not require that a pa-

tient have end-point scores at all follow-up visits. We chose alpha levels of 0.05 and 0.01 for the primary and secondary end points, respectively. All tests were two-sided, and no adjustments were made for multiple testing.

Before unblinding, we prespecified four subgroup analyses that were conducted to investigate possible effect modification according to age, prefracture living setting, prefracture functional status, and ASA status. The primary end point was the dependent variable for these analyses. Because these were exploratory analyses, we did not make any adjustment for multiple testing within our subgroup analyses. We also performed multiple sensitivity analyses.

We first interpreted the results on the basis of a blinded review of the results of our primary analysis.[18] The randomization code was then broken, the correct interpretation was chosen, and the manuscript was written. All analyses were performed with SAS, version 9.4 (SAS Institute), and R, version 3.6.0 (R Project for Statistical Computing).

RESULTS

PATIENTS

From January 2009 through May 2017, we randomly assigned 1495 patients to undergo total hip arthroplasty (749 patients) or hemiarthroplasty (746 patients). The final 24-month assessments were completed in May 2019. Of the 1495 patients who underwent randomization, 1441 were included in the final analyses. Of the 1243 patients who were alive at 24 months, 1058 (85.1%) had 24-month follow-up data available for the analysis of the primary end point. (Details regarding patient flow and the reasons for exclusion are provided in Fig. S1 and Tables S1 and S2.)

The majority of patients were female (70.1%), 70 years of age or older (80.2%), and able to ambulate without the aid of an assistive device before their fracture (74.4%), and the injury in the majority of the patients was a subcapital femoral neck fracture (61.9%). The baseline characteristics were similar in the two treatment groups (Table 1 and Tables S3 through S5).

SURGICAL CARE AND ADHERENCE TO THE ASSIGNED INTERVENTION

A total of 54 patients (7.5%) who had originally been assigned to total hip arthroplasty received hemiarthroplasty, and 21 (2.9%) who had originally been assigned to hemiarthroplasty received total hip arthroplasty (P<0.001). The frequency of crossing over did not vary substantially according to country. (Details regarding the patients who crossed over and of surgical and postoperative care are provided in Tables S6 through S10.)

PRIMARY END POINT

A secondary hip procedure within 24 months of follow-up occurred in 57 of 718 patients (7.9%) who had been randomly assigned to total hip arthroplasty and in 60 of 723 patients (8.3%) who had been randomly assigned to hemiarthroplasty (hazard ratio, 0.95; 95% confidence interval [CI], 0.64 to 1.40; P=0.79) (Fig. 1 and Table 2). The Kaplan–Meier curves show that the assumption of proportional hazards for the primary end point was not met — that is, the hazard ratio for the relative effects of the two interventions changed substantially over time. Post hoc analyses elucidated the nature of this change in effect over time: the risk of a secondary hip procedure up to 1 year was higher in the total hip arthroplasty group than in the hemiarthroplasty group (hazard ratio, 1.23; 95% CI, 0.82 to 1.86; P=0.32); after 1 year and up to 2 years, the risk was higher in the hemiarthroplasty group than in the total hip arthroplasty group (hazard ratio, 0.23; 95% CI, 0.08 to 0.69; P=0.01) (Table S11). In light of the finding of a non–proportional-hazards function, we conducted a prespecified analysis of the interaction between time and treatment. We found that the log of the hazard ratio decreased by 0.097 each month (95% CI, 0.031 to 0.162; P=0.004), which was also inconsistent with the plot of the estimated log of the hazard ratio over time (Fig. S2).

Sensitivity analyses of various assumptions regarding the risk of the primary end point in patients who were lost to follow-up showed no significant difference between the treatment groups. All other sensitivity analyses showed results similar to those in the primary analysis. Hip dislocations that were treated with open or closed reduction were the most common secondary procedure in the total hip arthroplasty group (33 of 57 procedures), and implant revisions were the most common secondary procedure in the hemiarthroplasty group (36 of 60 procedures). Subgroup analyses did not show any effect modification. (Details regarding the sensitivity and subgroup analyses are provided in Tables S12, S13, and S15.)

Table 1. Patient Demographic Characteristics.*

Characteristic	Total Hip Arthroplasty (N=718)	Hemiarthroplasty (N=723)
Age — yr†	79.1±8.3	78.6±8.6
Age — no./total no. (%)		
50 to 70 yr	136/718 (18.9)	149/722 (20.6)
71 to 80 yr	249/718 (34.7)	247/722 (34.2)
≥81 yr	333/718 (46.4)	326/722 (45.2)
Sex — no./total no. (%)		
Male	208/718 (29.0)	223/722 (30.9)
Female	510/718 (71.0)	499/722 (69.1)
Race or ethnic group — no./total no. (%)‡		
Native or aboriginal	2/716 (0.3)	1/721 (0.1)
South Asian	3/716 (0.4)	6/721 (0.8)
East Asian	7/716 (1.0)	7/721 (1.0)
Hispanic or Latino	7/716 (1.0)	6/721 (0.8)
White	683/716 (95.4)	684/721 (94.9)
Black	12/716 (1.7)	15/721 (2.1)
Middle Eastern	2/716 (0.3)	2/721 (0.3)
Body-mass index — no./total no. (%)§		
Underweight, <18.5	35/697 (5.0)	38/705 (5.4)
Normal weight, 18.5–24.9	357/697 (51.2)	336/705 (47.7)
Overweight, 25–29.9	217/697 (31.1)	243/705 (34.5)
Obese, 30–39.9	77/697 (11.0)	83/705 (11.8)
Morbidly obese, ≥40	11/697 (1.6)	5/705 (0.7)
Prefracture living status — no./total no. (%)		
Institutionalized	30/718 (4.2)	27/723 (3.7)
Not institutionalized	688/718 (95.8)	696/723 (96.3)
Prefracture functional status — no./total no. (%)		
Uses assistive device for ambulation	187/718 (26.0)	182/723 (25.2)
Able to ambulate without assistive device	531/718 (74.0)	541/723 (74.8)
Previous surgery to affected hip — no./total no. (%)	2/714 (0.3)	1/722 (0.1)
Major coexisting conditions — no./total no. (%)		
Osteopenia	28/715 (3.9)	30/722 (4.2)
Osteoporosis	114/715 (15.9)	110/722 (15.2)
Lung disease	127/715 (17.8)	122/722 (16.9)
Diabetes	135/715 (18.9)	145/722 (20.1)
Ulcers or stomach disease	49/715 (6.9)	67/722 (9.3)
Kidney disease	71/715 (9.9)	67/722 (9.3)
Anemia or other blood disease	48/715 (6.7)	55/722 (7.6)
Depression	70/715 (9.8)	84/722 (11.6)
Cancer	65/715 (9.1)	80/722 (11.1)
Osteoarthritis, degenerative arthritis	111/715 (15.5)	91/722 (12.6)
Back pain	64/715 (9.0)	71/722 (9.8)
Rheumatoid arthritis	13/715 (1.8)	21/722 (2.9)
Heart disease	247/715 (34.5)	249/722 (34.5)
High blood pressure	434/715 (60.7)	443/722 (61.4)

* Plus–minus values are means ±SD. Percentages may not total 100 because of rounding.
† Data were missing for one patient in the hemiarthroplasty group.
‡ Race and ethnic group were reported by the patients.
§ Body-mass index is the weight in kilograms divided by the square of the height in meters.

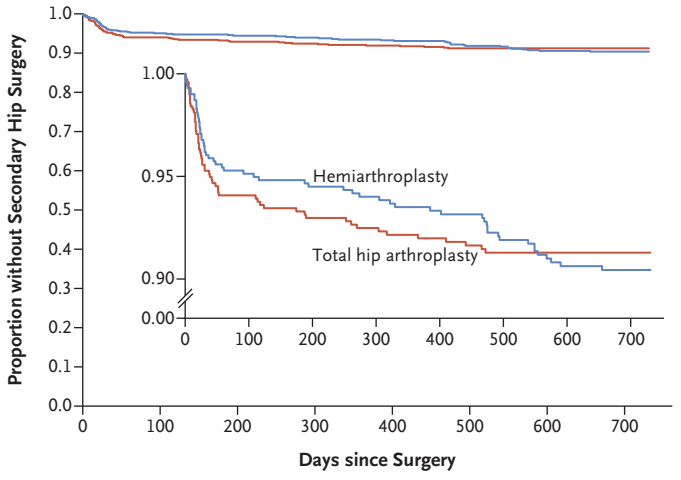

Figure 1. Kaplan–Meier Curves for the Primary End Point.

The primary end point was any unplanned secondary hip procedure within 24 months after the initial surgery. The inset shows the same data on an expanded y axis.

SECONDARY END POINTS

Over 24 months, 198 of 1441 patients (13.7%) died. Mortality did not differ significantly between the treatment groups (14.3% in the total hip arthroplasty group and 13.1% in the hemiarthroplasty group, P=0.48) (Table 2). Serious adverse events occurred in 300 of 718 patients (41.8%) in the total hip arthroplasty group and in 265 of 723 patients (36.7%) in the hemiarthroplasty group (hazard ratio, 1.16; 99% CI, 0.90 to 1.51) (Table 3). Overall, hip-related complications were more frequent with total hip arthroplasty (Table 2). Hip instability or dislocation occurred in 34 patients (4.7%) who were assigned to total hip arthroplasty and 17 patients (2.4%) who were assigned to hemiarthroplasty (hazard ratio, 2.00; 99% CI, 0.97 to 4.09).

Over 24 months, the functional assessment tests and quality-of-life questionnaires were completed by 943 to 1141 patients (depending on the test) at one or more follow-up visits (Table 4). Patients who underwent total hip arthroplasty had superior function as measured by the WOMAC total score (mean difference, −6.37; 99% CI, −9.18 to −3.56), WOMAC pain score (mean difference, −0.93; 99% CI, −1.42 to −0.44), WOMAC stiffness score (mean difference, −0.44; 99% CI, −0.65 to −0.23), and WOMAC function score (mean difference, −4.97; 99% CI, −7.11 to −2.83). These differences between the treatment groups fell below the threshold for a minimal clinically important difference for WOMAC (range, 9 to 22 points). EQ-5D visual analogue scale scores, the 12-Item Short Form General Health Survey (SF-12) physical and mental component summary scores, and TUG scores did not differ significantly between the treatment groups during follow-up (Table 4). The characteristics of the patients who did and those who did not have data included in analyses of health-related quality of life, function, or overall health end points are shown in Table S14.

DISCUSSION

Among patients with displaced fractures of the femoral neck, we found that the type of arthroplasty had no significant influence on the risk of unplanned secondary hip procedures over 24 months. Functional end points favored total hip arthroplasty over hemiarthroplasty during the 24-month period. Patients who underwent total hip arthroplasty had a slightly higher incidence of serious adverse events.

Strengths of our trial included the concealed randomization, expertise-based design,[10] independent adjudication of primary end-point events, and safeguards against interpretation bias.[18] Nearly all participating surgeons (97.8%) met thresholds for surgical expertise.

Our trial had certain limitations. Patients and end-point assessors were unblinded in the assessments of function, which left a possibility of bias. The percentage loss to follow-up was 14.9% for the analysis of our primary end point. Baseline characteristics of patients who were lost to follow-up were similar to those of patients we followed. Sensitivity analyses in which patients in the total hip arthroplasty group who were lost to follow-up were assumed to have had a risk of a primary event that was up to 4 times as high as the risk among those with complete follow-up did not alter our principal findings. Data on function during follow-up were incomplete; 82.9% of patients completed at least one follow-up questionnaire over 24 months, with complete data from follow-up questionnaires available for 46.8% of patients at 12 months and for 42.1% of patients at 24 months. We did not use imputation to handle missing data; however, our analysis model did not require that a patient have end-point scores at all follow-up visits, and it performs well as compared with other approaches for han-

Table 2. Trial End Points.

End Point	Total Hip Arthroplasty (N=718)	Hemiarthroplasty (N=723)	Hazard Ratio (95% or 99% CI)*	P Value†
	number (percent)			
Primary end point: unplanned secondary procedure	57 (7.9)	60 (8.3)	0.95 (0.64–1.40)‡	0.79
Components of primary end point§				
Closed reduction of hip dislocation	29 (4.0)	12 (1.7)		
Open reduction of hip dislocation	4 (0.6)	2 (0.3)		
Open reduction of fracture	5 (0.7)	8 (1.1)		
Soft-tissue procedure	15 (2.1)	15 (2.1)		
Insertion of antibiotic spacer	3 (0.4)	3 (0.4)		
Full implant exchange	7 (1.0)	18 (2.5)		
Partial implant exchange	19 (2.6)	18 (2.5)		
Implant adjustment: reorientation of stem	0	2 (0.3)		
Implant adjustment: reorientation of acetabulum component	2 (0.3)	0		
Implant removal with no replacement	3 (0.4)	3 (0.4)		
Excision heterotopic ossification	0	0		
Supplementary fixation	3 (0.4)	1 (0.1)		
Other	1 (0.1)	3 (0.4)		
Secondary end points				
Death	103 (14.3)	95 (13.1)	1.10 (0.77–1.58)	0.48
Serious adverse event¶	300 (41.8)	265 (36.7)	1.16 (0.90–1.51)	0.13
Any hip-related complication‖	132 (18.4)	118 (16.3)	1.13 (0.81–1.57)	
Periprosthetic fracture	38 (5.3)	35 (4.8)	1.08 (0.61–1.88)	
Hip instability or dislocation**	34 (4.7)	17 (2.4)	2.00 (0.97–4.09)	
Superficial surgical-site infection	9 (1.3)	6 (0.8)		
Deep surgical-site infection	17 (2.4)	16 (2.2)		
Another wound-healing problem	6 (0.8)	5 (0.7)		
Another soft-tissue procedure	11 (1.5)	11 (1.5)		
Clinically important heterotopic ossification††	29 (4.0)	24 (3.3)	1.19 (0.62–2.30)	
Abductor failure	1 (0.1)	3 (0.4)		
Implant failure: loosening or subsidence	5 (0.7)	5 (0.7)		
Implant failure: breakage	1 (0.1)	0		
Pain	6 (0.8)	12 (1.7)		
Neurovascular injury: technical error	2 (0.3)	1 (0.1)		
Other	7 (1.0)	13 (1.8)		

* The hazard ratio is for total hip arthroplasty as compared with hemiarthroplasty; the 95% confidence interval (CI) is given for the primary end point, and 99% confidence intervals are given for the secondary end points. Proportional-hazards regressions were performed only for hip-related complications for which at least 50 events occurred.

† P values are from regression models of subdistribution hazards.

‡ The proportional-hazards assumption was violated, and analyses of year 1 as compared with year 2 followed a post hoc analysis guided by the Kaplan–Meier curve.

§ The numbers for the individual components add up to more than the total number of patients with the primary end point because some patients had more than one event.

¶ The marginal estimate for the competing-risk analysis is shown in the table; the conditional estimate for serious adverse events was a hazard ratio of 1.19 (99% CI, 0.94 to 1.50; P=0.06).

‖ The numbers for specific hip-related complications add up to more than the overall total number of patients with hip-related complications because some patients had more than one event.

** One patient in the total hip arthroplasty group and three patients in the hemiarthroplasty group who had hip instability or dislocation were not treated operatively for this complication.

†† Clinically important heterotopic ossification was defined as class 3 or higher according to the Brooker classification.

Table 3. Serious Adverse Events.

End Point	Total Hip Arthroplasty (N=718)	Hemiarthroplasty (N=723)	P Value*
	number (percent)		
Any serious adverse event†	300 (41.8)	265 (36.7)	0.13
Hip fracture–related serious adverse event	59 (8.2)	57 (7.9)	0.85
Neurologic serious adverse event	28 (3.9)	26 (3.6)	0.78
Respiratory serious adverse event	42 (5.8)	37 (5.1)	0.56
Cardiac serious adverse event	51 (7.1)	49 (6.8)	0.84
Renal serious adverse event	23 (3.2)	22 (3.0)	0.88
Vascular serious adverse event	22 (3.1)	16 (2.2)	0.33
Other serious adverse event	201 (28.0)	177 (24.5)	0.14
Non–trial-related fracture‡	50 (7.0)	37 (5.1)	
Non–trial-related dislocation‡	2 (0.3)	0	
Other non–trial-related injury‡	10 (1.4)	14 (1.9)	
Cellulitis	2 (0.3)	2 (0.3)	
Death	103 (14.3)	95 (13.1)	
Multiorgan failure	1 (0.1)	2 (0.3)	
Osteoporosis, new or worsening	0	1 (0.1)	
Sepsis	9 (1.3)	8 (1.1)	
Reported by site as "other"	66 (9.2)	60 (8.3)	

* All P values were calculated with Fisher's exact test with the exception of "any serious adverse event," for which the P value was calculated with the Cox model.
† The numbers for individual serious adverse events add up to more than the total because some patients had more than one type of serious adverse event.
‡ The determination of whether an injury was related to the trial was made by the attending surgeon.

dling missing patient data.[19] The follow-up period in our trial may have been insufficient for understanding longer-term end points.

Our results differ from those of published meta-analyses reporting that the risk of reoperation associated with total hip arthroplasty is 34 to 43% lower than with hemiarthroplasty.[4-6] This difference may, in part, be the consequence of longer follow-up periods in these meta-analyses (ranging from 1 to 13 years) or potential differences in our eligibility criteria.[4-6]

Our inclusion of patients who could ambulate independently before the fracture occurred (i.e., patients who did not require the assistance of another person to ambulate) is consistent with previous trials.[6] Although the use of assistive devices was balanced between the treatment groups, we did not record the type of assistive device or the specific ambulatory capacity of the patients. Data on 17,985 femoral neck fractures over a period of 16 years from the Australian Joint Registry suggest that modern hemiarthroplasty and total hip arthroplasty have similar incidences of revision over 10 years (hazard ratio, 1.13; 95% CI, 0.95 to 1.33; P=0.16).[20] A large multicenter trial involving 298 patients with femoral neck fractures in Scotland showed no significant difference in the incidence of secondary hip procedures at 2 years (hazard ratio, 0.81; 95% CI, 0.24 to 2.81; P=0.74).[21] Our subgroup analyses did not show any effect modification according to patient age, the use of assistive devices for ambulation, ASA status, or living status at the time of fracture. The larger number of events in the hemiarthroplasty group during the second year is in keeping with the possibility of more events being associated with that procedure over the long term.

A meta-analysis reported significantly fewer complications with total hip arthroplasty than with hemiarthroplasty (relative risk, 0.75; 95% CI, 0.60 to 0.94; P<0.05).[4] In our trial, the incidence

of serious adverse events was slightly higher in the total hip arthroplasty group than in the hemiarthroplasty group. Serious adverse events were not driven by a specific type of complication; rather, total hip arthroplasty broadly led to more cardiac, renal, vascular, neurologic, and respiratory events than hemiarthroplasty. The incidence of dislocation after total hip arthroplasty in our trial was high (4.7%). Pooled estimates from randomized, controlled trials suggest a risk of dislocation after total hip arthroplasty that is more than 2.5 times as great as that associated with hemiarthroplasty (9% vs. 3%; relative risk, 2.53; 95% CI, 1.05 to 6.10).[5]

Although limited comparative data are available, total hip arthroplasty has consistently been associated with better function and quality of life than hemiarthroplasty in previous studies.[4-6] Our findings showed slightly but significantly lower WOMAC scores (indicating better function) in the total hip arthroplasty group, as well as trends that favored total hip arthroplasty in EQ-5D, SF-12 scores, and TUG test times. However, the differences in WOMAC scores were deemed clinically unimportant on the basis of the thresholds for the minimal clinically important difference.[12,13]

The American Academy of Orthopaedic Surgeons and National Institute for Health and Care Excellence guidelines recommend total hip arthroplasty in all patients with displaced femoral neck fractures who are able to ambulate independently.[22,23] Our findings suggest that the advantages of total hip arthroplasty may not be compelling. The limited advantages of total hip arthroplasty, as well as the possible higher risk of complications, may be particularly important in regions of the world where total hip arthroplasty is not easily accessible or is cost-prohibitive.

In our trial, the incidence of secondary procedures after 2 years did not differ significantly between the total hip arthroplasty group and the hemiarthroplasty group. Total hip arthroplasty was associated with modestly better function over 24 months but with a slightly higher incidence of serious adverse events than hemiarthroplasty among independently ambulating patients with displaced femoral neck fractures.

Table 4. Health-Related Quality of Life, Function, and Overall Health End Points.

End Point	Patients with Data (N=1441)	Mean Difference in Score at 24 Mo, Total Hip Arthroplasty vs. Hemiarthroplasty (99% CI)*
	no. (%)	
WOMAC total score†	943 (65.4)	–6.37 (–9.18 to –3.56)
WOMAC pain score†	990 (68.7)	–0.93 (–1.42 to –0.44)
WOMAC stiffness score†	987 (68.5)	–0.44 (–0.65 to –0.23)
WOMAC function score†	947 (65.7)	–4.97 (–7.11 to –2.83)
EQ-5D utility index score‡	1141 (79.2)	0.04 (–0.03 to 0.11)
EQ-5D VAS score‡	1111 (77.1)	0.72 (–2.02 to 3.46)
SF-12 PCS§	1006 (69.8)	1.41 (–0.33 to 3.14)
SF-12 MCS§	1006 (69.8)	1.34 (–0.38 to 3.05)
		Odds Ratio (99% CI)
TUG¶	1268 (88.0)	0.72 (0.38 to 1.36)

* The mean difference was obtained from the multilevel model.
† Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total scores range from 0 to 96, with higher scores indicating worse pain, stiffness, and function; it is the sum of the pain score (range, 0 to 20), stiffness score (range, 0 to 8), and function score (range, 0 to 68). For the total score, the minimal clinically important difference calculated in different studies ranges from 9 to 22.
‡ The European Quality of Life–5 Dimensions (EQ-5D) measures quality of life in five dimensions; utility scores range from –0.109 to 1, with higher scores indicating better states of health. Scores on the EQ-5D visual analogue scale (VAS) range from 0 to 100, with higher scores indicating better states of health.
§ The 12-Item Short Form General Health Survey (SF-12) measures health-related quality of life and includes a physical composite score (PCS) and a mental composite score (MCS). Each composite score ranges from 0 to 100, with higher scores indicating better states of health.
¶ Timed Up and Go (TUG) results were dichotomized, with patients who took more than 12 seconds to complete the test or were unable to complete the test compared with patients who took 12 seconds or less to complete the test. The odds ratio (total hip arthroplasty vs. hemiarthroplasty) is for completing the test in more than 12 seconds or not being able to complete the test and was obtained from the multilevel model.

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APPENDIX

The affiliations of the members of the writing committee are as follows: the Division of Orthopaedic Surgery, Department of Surgery (M.B., S.S., S.B.), the Department of Health Research Methods, Evidence, and Impact (M.B., G.G., S.S., D.H.-A., L.T., S.D.W., P.J.D.), the Department of Medicine (G.G., P.J.D.), and the Population Health Research Institute (P.J.D.), McMaster University, Hamilton, and the Department of Surgery, University of Western Ontario, London (E.H.S.) — all in Ontario, Canada; the Department of Orthopedic Surgery, New York University Langone Medical Center, New York (T.A.E.); the Department of Orthopedic Surgery, Louisiana State University Health Sciences Center, New Orleans (R.D.Z.); the Division of Orthopedic Surgery, Oslo University Hospital, Oslo (F.F.); the Department of Traumatology, Orthopedic Surgery, and Emergency, Hospital Vall d'Hebrón, Barcelona (E.G.-F.); the Department of Orthopedic and Trauma Surgery, Deventer Ziekenhuis, Deventer (Y.V.K.), and the Department of Orthopedic Surgery, OLVG, Amsterdam (R.W.P.) — both in the Netherlands; and the Department of Orthopaedic Surgery, James Cook University Hospital, Middlesbrough, the Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, and the Department of Health Sciences, University of York, York — all in the United Kingdom (A.R.).

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