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Afaq, S.; O'Hara, N.N.; Schemitsch, E.H.; Bzovsky, S.; Sprague, S.; Poolman, R.W.; ... ; FAITH & HEALTH Investigators

Arthroplasty Versus Internal Fixation for the Treatment of Undisplaced Femoral Neck Fractures: A Retrospective Cohort Study

Shaikh Afaq, MD,[a] Nathan N. O'Hara, MHA,[a] Emil H. Schemitsch, MD, FRCSC,[b] Sofia Bzovsky, MSc,[c] Sheila Sprague, PhD,[c,d] Rudolf W. Poolman, MD, PhD,[e] Frede Frihagen, MD, PhD, FRCSC,[f] Diane Heels-Ansdell, MSc,[d] Mohit Bhandari, MD, PhD, FRCSC,[c,d] Marc Swiontkowski, MD,[g] and Gerard P. Slobogean, MD, MPH[a] on behalf of the FAITH and HEALTH Investigators

Objective: To compare the 24-month risk of mortality between arthroplasty and internal fixation for undisplaced femoral neck fractures (FNFs).

Design: Retrospective cohort study.

Setting: Secondary data analysis of 2 multinational randomized controlled trials.

Participants: Patients aged 50 years or older with a FNF.

Intervention: Arthroplasty (n = 1441), including total hip arthroplasty and hemiarthroplasty, performed for a displaced FNF versus internal fixation (n = 734), including sliding hip screw or multiple cancellous screws, performed for an undisplaced FNF.

Main Outcome Measurement: The primary outcome was mortality within 24 months of injury. Secondary outcomes included reoperation and health-related quality of life.

Results: The 24-month mortality rate was 15.0% (n = 327). Arthroplasty was associated with a significant reduction in the odds

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From the [a]Department of Orthopaedics, R Adams Cowley Shock Trauma Center, University of Maryland School of Medicine, Baltimore, MD; [b]Department of Surgery, University of Western Ontario, London, ON, Canada; [c]Division of Orthopaedic Surgery, Department of Surgery, McMaster University, Hamilton, ON, Canada; [d]Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, ON, Canada; [e]Department of Orthopedic and Trauma Surgery, OLVG, Amsterdam and Leiden University Medical Center, Leiden, the Netherlands; [f]Division of Orthopaedic Surgery, Oslo University Hospital, Oslo, Norway; and [g]Department of Orthopaedic Surgery, University of Minnesota, Minneapolis, MN.

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Reprints: Gerard P. Slobogean, MD, MPH, Department of Orthopaedics, R Adams Cowley Shock Trauma Center, University of Maryland School of Medicine, 22 South Greene St, Baltimore, MD 21201 (e-mail: gslobogean@som.umaryland.edu).

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of mortality [adjusted odds ratio (aOR): 0.56, 95% confidence interval (CI): 0.44–0.72, $P < 0.01$] compared with treatment with internal fixation. 11.4% (n = 248) of the study patients required reoperation within 24 months of injury. The odds of reoperation were 59% lower with arthroplasty treatment than with internal fixation (aOR: 0.41, 95% CI: 0.32–0.55, $P < 0.01$). The 24-month SF-12 physical component scores were 2.7 points higher in arthroplasty patients compared with internal fixation patients (95% CI: 1.6–3.8, $P < 0.01$).

Conclusions: Our findings suggest arthroplasty for a FNF may reduce the risk of mortality and reoperation compared with internal fixation of undisplaced fractures. This finding is counter to many current surgical practices but consistent with a mounting body of evidence. Before widespread adoption of arthroplasty for undisplaced fractures, these results should be confirmed in a definitive comparative trial.

Key Words: arthroplasty, internal fixation, undisplaced femoral neck fracture

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

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BACKGROUND

Two decades ago, the optimal treatment of displaced femoral neck fractures (FNFs) was controversial.[1] A mounting body of evidence has since shifted clinical practice in favor of arthroplasty for displaced FNF management.[2,3] However, for undisplaced FNFs, internal fixation remains the preferred approach as a less invasive procedure with less expensive implants. A recent randomized trial comparing hemiarthroplasty with internal fixation in nondisplaced FNFs contested the current practice,[4] suggesting improved mobility and fewer major reoperations with hemiarthroplasty. This finding was consistent with another small trial and 2 recent retrospective cohort studies in minimally displaced FNF patients.[5–7]

Given the limited comparative data for the optimal treatment of undisplaced FNFs, we aimed to determine if arthroplasty in patients aged 50 years or older with displaced FNFs was associated with reduced mortality, fewer reoperations, and higher health-related quality of life compared with internal fixation for undisplaced FNFs in patients aged 50 years or older. We hypothesized that arthroplasty would decrease mortality, reduce reoperations, and increase health-related quality of life scores.[8] We also assessed the variation in treatment effect across various prefracture risk profiles. We hypothesized that the benefits of arthroplasty treatment would be greater in high-risk FNF patients.

METHODS

Study Design and Procedures

This retrospective cohort study combined data from the HEALTH and FAITH clinical trials.[9,10] The HEALTH trial was an international, expertise-based clinical trial conducted between 2013 and 2016 that enrolled 1495 participants from 80 centers. HEALTH participants were randomized to either total hip arthroplasty or hemiarthroplasty to treat a displaced FNF. The FAITH trial was also an international multicenter randomized clinical trial performed at 81 centers from 2008 through 2014. In FAITH, 1108 participants were randomized to either multiple cancellous screws or sliding hip screw fixation for the treatment of a low-energy FNF. Both trials were coordinated by McMaster University and were approved by the Ethics Committee at McMaster University and all participating centers.

Eligibility Criteria

We included participants aged 50 years or older with a low-energy fracture of the femoral neck. Eligible participants must have been able to ambulate either without assistance or assistance from an aid before the injury. Patients with rheumatoid arthritis, pathological fractures or severe osteoarthritis of the hip, other major injuries of the lower extremities, retained implant around the affected hip, infection around the hip, disorder of bone metabolism, and previous history of dementia were excluded. The FAITH trial included all FNFs amenable to surgical fixation but primarily included minimally displaced fractures, whereas HEALTH only included displaced fractures being treated with arthroplasty. All fractures were classified by each trial's Central Adjudication Committee using the Garden classification, and Garden I and II fractures were considered undisplaced.[11,12]

Because the target population for this study was undisplaced fractures, we excluded the displaced fracture patients from the FAITH trial. However, we included all patients from the HEALTH trial because the degree of fracture displacement has no effect on healing since the femoral head and neck is resected and should have no impact on the outcome after the arthroplasty procedure.

Study Treatments

Participants in the arthroplasty treatment group received either total hip arthroplasty or hemiarthroplasty as per the randomized allocation within the HEALTH trial. Treating surgeons had to meet a predefined threshold for surgical expertise in the procedures. Similarly, the internal fixation group comprised patients that were randomly assigned a sliding hip screw or multiple cancellous screws. The sliding hip screw was a single large-diameter, partly threaded screw affixed to the proximal femur with a side plate. Treatment with cancellous screws required a minimum of 2 threaded screws with a 6.5-mm diameter. Surgeons treating participants with internal fixation were required to have performed at least 25 hip fracture fixation procedures in their career, including at least 5 procedures in the year before the study treatment.

Study Outcomes

The primary end point was mortality within 24 months of injury. The secondary outcomes included reoperation within 24 months and health-related quality of life. Reoperation was defined as any operation subsequent to the initial procedure to promote fracture healing, relieve pain, treat infection, or improve function. Health-related quality of life was measured with the

12-item Short-Form General Health Survey (SF-12), which reports physical component summary (PCS) and mental component summary (MCS) scores on a scale of 0–100.[13] SF-12 scores were normalized to a population mean of 50, with higher scores implying greater health.

Statistical Analysis

Patient characteristics were described using counts with proportions and means with SDs, depending on the distribution of the data. Categorial data were compared between the treatment arms using χ^2 tests. Continuous variables were compared using *t* tests. To measure for potential confounding, we assessed for the distribution of covariates between the 2 surgical exposure groups and outcomes. If the covariates differed significantly between the exposure and outcome or resulted in a change in the effect measure of 10% or greater when added to the unadjusted model, they were included in the final adjusted analysis. Logistic regression models were used to determine the association of treatment with mortality and reoperation. All covariates listed under Table 1 were assessed for potential confounding. Using the above criteria, the final adjusted model for mortality included age and the American Society of Anesthesiologists (ASA) classification. ASA classification was the only confounder included in the reoperation model. The association between treatment and 24-month health-related quality of life scores was estimated using linear regression. Estimates for physical health quality of life included ASA classification, additional injuries, and preinjury back pain as confounders. Mental health quality of life estimates were conditioned on sex and preinjury depression as confounders.

To assess variations in the treatment effect on mortality across risk strata, we used the risk modeling approach described by Kent et al.[14] Briefly, we developed a risk prediction model for mortality omitting the treatment variable. The data-informed risk model included age, sex, ASA classification, prefracture functional status, cancer, and anemia or other blood diseases with a C-statistic of 0.76. Based on the risk model, the probability of mortality was assigned to each patient. We then binned the study sample into risk quartiles based on the probability of death. In each risk quartile, we calculated the association between treatment and mortality on a relative (odds ratio) and absolute scale (risk difference).

Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC) and R version 4.0.0 (Vienna, Austria). Missing covariate data were imputed using multiple imputations.[15]

RESULTS

Of the 2175 patients included in the study, 1441 were treated with arthroplasty, and 734 were treated with internal

TABLE 1. Patient Characteristics

Characteristic	Arthroplasty (n = 1441)	Internal Fixation (n = 734)	*P*
Age, y, mean (SD)	78.8 (8.4)	74.2 (11.9)	<0.01
Female, n (%)	1009 (70.1%)	488 (66.5%)	0.09
BMI, kg/m^2, mean (SD)	25.1 (4.8)	24.3 (4.5)	<0.01
Mechanism of injury, n (%)			<0.01
Fall from standing	1396 (97.2%)	711 (97.3%)	
Spontaneous fractures	30 (2.1%)	15 (2.1%)	
Fall from small height	11 (0.8%)	0 (0.0%)	
Others	0 (0.0%)	5 (0.7%)	
ASA classification, n (%)			<0.01
Class I–II	652 (45.3%)	414 (56.4%)	
Class III–IV	789 (54.8%)	320 (43.6%)	
Prefracture functional status, n (%)			0.95
Independent ambulator	1072 (74.4%)	547 (74.5%)	
Use of aid	369 (25.6%)	187 (25.5%)	
Prefracture living status, n (%)			0.22
Institutionalized	65 (4.5%)	42 (5.7%)	
Not institutionalized	1376 (95.5%)	692 (94.3%)	
Additional injuries, n (%)	61 (4.3%)	110 (15.0%)	<0.01
Hypertension, n (%)	877 (61.0%)	412 (56.4%)	0.04
Diabetes, n (%)	280 (19.5%)	116 (15.9%)	0.04
Back pain, n (%)	135 (9.4%)	163 (22.4%)	<0.01
Cancer, n (%)	145 (10.1%)	102 (14.0%)	<0.01
Anemia or other blood diseases, n (%)	103 (7.2%)	82 (11.3%)	<0.01
Ulcer, n (%)	116 (8.1%)	119 (16.3%)	<0.01
Depression, n (%)	154 (10.7%)	130 (17.8%)	<0.01

ASA, American Society of Anesthesiologists; BMI, body mass index.

TABLE 2. Study Outcomes

	Arthroplasty (n = 1441)	Internal Fixation (n = 734)	Crude OR (95% CI)	P	Adjusted OR (95% CI)	P
Mortality, n (%)	198 (13.7%)	129 (17.6%)	0.75 (0.59–0.95)	0.02	0.56 (0.44–0.73)	<0.01
Reoperation, n (%)	117 (8.1%)	131 (17.9%)	0.41 (0.31–0.53)	<0.01	0.41 (0.32–0.55)	<0.01

	Arthroplasty (n = 1006)	Internal Fixation (n = 490)	Crude Difference (95% CI)	P	Adjusted Difference (95% CI)	P
24-mo SF-12 PCS, mean (SD)	38.8 (9.9)	36.1 (9.9)	2.7 (1.7–3.8)	<0.01	2.7 (1.6–3.8)	<0.01
24-mo SF-12 MCS, mean (SD)	52.3 (10.6)	51.2 (14.5)	1.1 (−0.1–2.3)	0.07	0.9 (−0.3–2.0)	0.14

Only a subset of arthroplasty and internal fixation patients were administered the SF-12 survey as per the study protocols.
PCS, physical component summary; MCS, mental component summary.

fixation (Table 1). Patients in the arthroplasty group were older (78.8 vs. 74.2 years, $P < 0.01$) and more likely to have an ASA classification of 3–5 (54.8% vs. 43.6%, $P < 0.01$). We did not observe a significant difference in the proportion of patients requiring an aid before injury (25.6% vs. 25.5%, $P = 0.95$) or institutionalized before the fracture (4.5% vs. 5.7%, $P = 0.22$). The 24-month mortality rate was 15.0% (n = 327). Treatment with arthroplasty significantly reduced the odds of mortality [adjusted odds ratio (aOR): 0.56, 95% CI: 0.44–0.72, $P < 0.01$] compared with treatment with internal fixation (Table 2). 11.4% (n = 248) of the study patients required reoperation within 24 months of injury. The odds of reoperation were 59% lower with arthroplasty treatment than those with treatment by internal fixation (aOR: 0.41, 95% CI: 0.32–0.55, $P < 0.01$). The 24-month SF-12 physical component scores were 2.7 points higher in arthroplasty patients than those of internal fixation patients (95% CI: 1.6–3.8, $P < 0.01$). No difference in 24-month SF-12 mental component scores was observed between the 2 treatment groups (adjusted difference: 0.9, 95% CI: −0.3—2.0, $P = 0.14$).

The characteristics of the patients based on their mortality risk quartile are available in Table 3. The mean risk of mortality was 3.7% in the lowest risk quartile, 7.4% in the low-mid risk quartile, 16.0% in the mid-high risk quartile, and 33.1% in the high-risk quartile (Fig. 1). The point estimates for ORs and risk differences favored arthroplasty across the 4 risk quartiles. However, only significant differences were observed in the highest risk quartile with an OR of 0.54 [95% confidence interval (CI): 0.37–0.78] and a risk reduction of 14.1% (95% CI: 5.7%–22.6%).

DISCUSSION

The findings of our study suggest that arthroplasty reduced the risk of mortality and reoperation within 24 months after injury compared with internal fixation in undisplaced FNFs. Arthroplasty was also associated with a mild, yet statistically significant, improvement in overall physical health. The study treatment was not associated with a difference in overall mental health. We observed that arthroplasty provided the strongest protective effects against mortality in our high-risk strata patients.

Previous studies have suggested that arthroplasty is associated with lower reoperations when compared with internal fixation of minimally displaced fractures.[4–8] Consistent with the 2 previous trials and 2 previous observational analyses in this population,[4–7] we observed a similar magnitude of reduced odds of reoperation associated with arthroplasty. However, the survival benefits observed in our study contradict the 2 previous observational studies,[5,6] which suggested internal fixation was protective against mortality. In these studies, the effects of selection bias cannot be determined, and therefore, it is important to note that the prospective randomized trial comparing the arthroplasty and internal fixation treatments for mortality is consistent with our study results.[4] In the trial by Dolatowski et al,[4] mortality was

TABLE 3. Characteristic of Mortality Risk Quartiles

	Low Risk (1) (N = 544)	Low-Mid Risk (2) (N = 544)	Mid-High Risk (3) (N = 544)	High Risk (4) (N = 543)
Age, yrs, mean (SD)	67.2 (8.9)	77.1 (7.8)	80.9 (7.3)	83.8 (7.0)
Female, n (%)	449 (82.5%)	382 (70.2%)	362 (66.5%)	305 (56.2%)
ASA classification, n (%)				
Class I–II	505 (92.8%)	345 (63.4%)	177 (32.5%)	39 (7.2%)
Class III–IV	39 (7.2%)	199 (36.6%)	367 (67.5%)	504 (92.8%)
Prefracture functional status, n (%)				
Independent ambulator	538 (98.9%)	522 (96.0%)	407 (74.8%)	152 (28.0%)
Use of aid	6 (1.1%)	22 (4.0%)	137 (25.2%)	391 (72.0%)
Anemia or other blood diseases, n (%)	1 (0.2%)	11 (2.0%)	37 (6.8%)	137 (25.2%)
Cancer, n (%)	9 (1.7%)	32 (5.9%)	62 (11.4%)	146 (26.9%)

ASA, American Society of Anesthesiologists.

reported as a secondary outcome, and although the benefits of hemiarthroplasty were not statistically significant in their study ($P = 0.11$), the point estimate suggested a 60% relative risk reduction. Similarly, consistent with our SF-12 PCS results, the trial by Dolatowski et al observed a 10% benefit in health-related quality of life with hemiarthroplasty compared with internal fixation.[4]

There are several possible mechanisms for the observed benefits of arthroplasty in this patient population. Despite the more invasive procedure, a hip arthroplasty immediately creates a stable weight-bearing construct. This may contribute to less pain and earlier clinically significant mobilization, particularly because delayed mobilization has been previously demonstrated to lead to reduced function and lower survival in hip fracture patients.[16] Similarly, arthroplasty is associated with less reoperations than internal fixation, and this likely contributes to reduced mortality and improved clinical outcomes. In our study, this reduction in mortality was observed despite HEALTH participants remaining at a greater risk for mortality. These risk factors included older age and higher ASA prevalence. Therefore, although both clinical trials may have recruitment biases, such as HEALTH potentially recruiting a healthier population of displaced FNF patients suitable for randomization to total hip arthroplasty, the benefits of arthroplasty seem to still outweigh the difference in mortality risk factors.

To better understand potential participant recruitment biases between the trials and the substantial variation in risk of mortality in the pooled study population, we used a novel risk modeling approach to assess the heterogeneity of treatment effect (HTE).[14] HTE describes variation in the magnitude of treatment effect based on clinically relevant patient attributes (subgroups).[17] The risk modeling technique allowed us to account for an imbalance in baseline covariates between the treatment groups, assess the prognostic value of the observed variables, and estimate differences in treatment effects across clinically unique strata. Although all HTE treatment estimates favored arthroplasty, the most substantial mortality benefits were observed in the oldest, sickest patients.

With more than 2000 patients, our study is 3 times larger than the 4 previous studies combined.[4–7] We used data from 2 recent, high-quality, multinational, randomized trials.[9,10] The risk modeling technique for analyzing HTE represents an improvement over classic subgroup analysis, which is prone to low statistical power, multiplicity, and weak previous theory on relative effect modifiers and, therefore, susceptible to false-negative and false-positive findings. As patients have many attributes that simultaneously affect the study outcome, modeling their combined effects produced a more patient centered and clinically actionable estimate of treatment effects.

Despite the strengths of the study, there were some limitations. With regards to osteoporosis or smoking status, an important prognostic factor for both mortality and failure, only HEALTH had data for osteoporosis, whereas smoking status was collected only under FAITH. For this reason, we were unable to include these variables in our analysis. Furthermore, although the treatment decision for internal

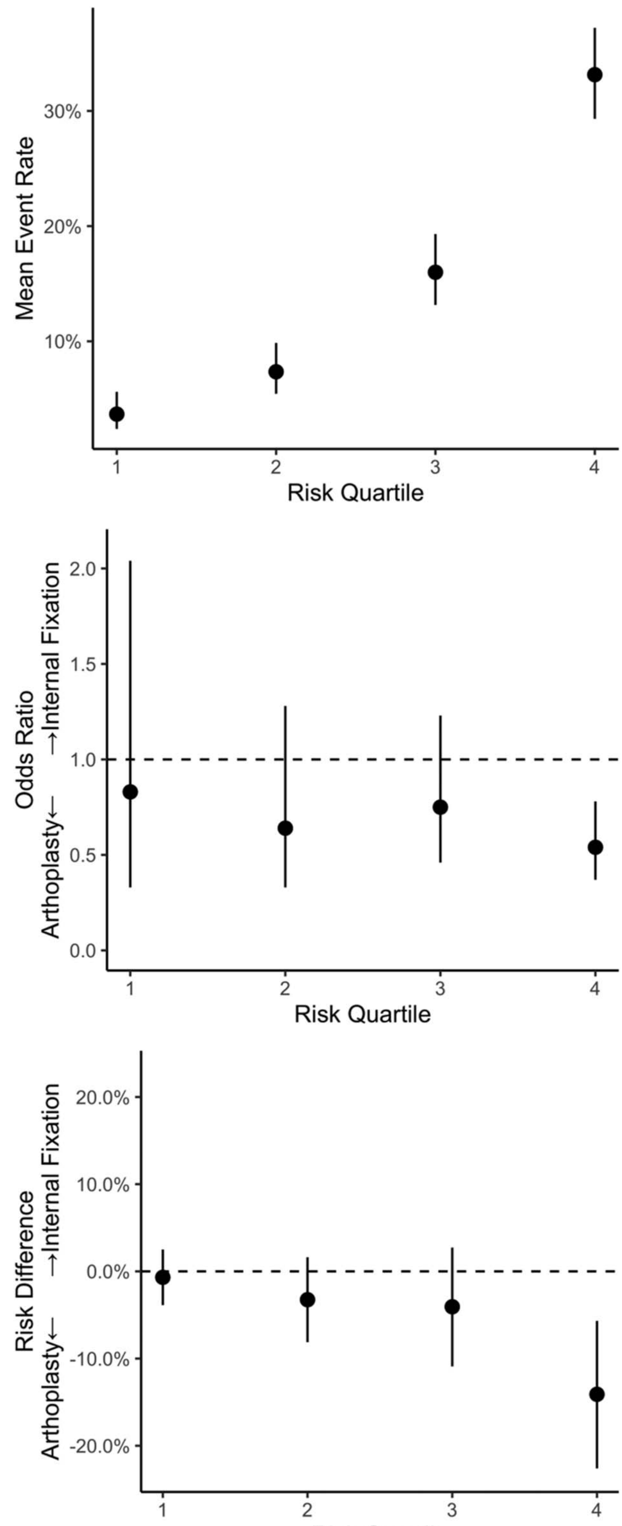

FIGURE 1. Association between treatment and mortality by risk quartile. The figure presented the mean risk of mortality with ranges by risk quartile (top), and the association between treatment and mortality by quartile based on observed odds ratios (middle) and risk differences (bottom).

fixation has traditionally been based on fracture displacement defined within the Garden classification (type I and II), more recent studies have highlighted the importance of also assessing the fracture alignment on the lateral hip radiograph. In certain fractures that seem minimally displaced on anteroposterior radiographs, large amounts of posterior angulation on the lateral view are highly predictive of internal fixation failure.[18] These previous findings suggest another layer of treatment decision complexity that favors widespread adoption of arthroplasty in this patient population.

Currently, the conventional treatment for an undisplaced or minimally displaced FNF is internal fixation. Arthroplasty has been typically disregarded in this fracture population given the invasive nature of the procedure, the cost of the implant, and the presumed good clinical results from internal fixation. As newer data continue to emerge, it becomes apparent that the results of internal fixation for undisplaced fractures are often poor and that hip arthroplasty reduces reoperations and potentially reduces mortality. Our results continue to challenge the prevailing practice of internal fixation for these fractures; however, definitive evidence from a large, appropriately powered trial remains warranted before a widespread practice change.

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