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Factors Associated With Revision Surgery After Internal Fixation of Hip Fractures

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Abstract

Background: Femoral neck fractures are associated with high rates of revision surgery after management with internal fixation. Using data from the Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH) trial evaluating methods of internal fixation in patients with femoral neck fractures, we investigated associations between baseline and surgical factors and the need for revision surgery to promote healing, relieve pain, treat infection or improve function over 24 months postsurgery. Additionally, we investigated factors associated with (1) hardware removal and (2) implant exchange from cancellous screws (CS) or sliding hip screw (SHS) to total hip arthroplasty, hemiarthroplasty, or another internal fixation device.

Methods: We identified 15 potential factors a priori that may be associated with revision surgery, 7 with hardware removal, and 14 with implant exchange. We used multivariable Cox proportional hazards analyses in our investigation.

Results: Factors associated with increased risk of revision surgery included: female sex, [hazard ratio (HR) 1.79, 95% confidence interval (CI) 1.25–2.50; P = 0.001], higher body mass index (for every 5-point increase) (HR 1.19, 95% CI 1.02–1.39; P = 0.027), displaced fracture (HR 2.16, 95% CI 1.44–3.23; P , 0.001), unacceptable quality of implant placement (HR 2.70, 95% CI 1.59–4.55; P , 0.001), and smokers treated with cancellous screws versus smokers treated with a sliding hip screw (HR 2.94, 95% CI 1.35–6.25; P = 0.006). Additionally, for every 10-year decrease in age, participants experienced an average increased risk of 39% for hardware removal.

Conclusions: Results of this study may inform future research by identifying high-risk patients who may be better treated with arthroplasty and may benefit from adjuncts to care (HR 1.39, 95% CI 1.05–1.85; P = 0.020).

Introduction

Hip fractures in elderly adults are common, affecting approximately 1.6 million individuals worldwide each year and resulting in a significant amount of morbidity and mortality.1,2 Fractures of the femoral neck generally necessitate surgical management with either internal fixation or arthroplasty and there exists controversy surrounding which of these 2 treatment options is optimal in elderly patients.3 Typically, most displaced fractures of the femoral neck are treated with arthroplasty, but there exists evidence to suggest that internal fixation is better suited for treating undisplaced fractures.4 In addition, internal fixation does offer some advantages over arthroplasty, including less surgical trauma, allowing the patient to retain their own femoral head, and a marginal reduction in mortality and morbidity in very frail patients.5 Regardless of treatment option, fractures of the femoral neck are associated with high rates of complications, including nonunion, delayed union, shortening, infection, and avascular necrosis.3 Our recently completed Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH) trial found a high revision surgery rate of 20.8%, which was actually lower than a previously conducted meta-analysis.6 Revision surgery prolongs patients' recovery time, is associated with higher rates of complications, and reduces patients' health-related quality of life. Identifying factors that are associated with revision surgery, and precisely which type of revision surgery, can aid surgeons in making treatment decisions and optimizing the care of hip fracture patients.

The recently completed FAITH randomized controlled trial evaluated the effectiveness of internal fixation with a sliding hip screw (SHS) versus cancellous screws (CS) in patients with a femoral neck fracture.7 The primary outcome of this trial was the rate of revision surgery to promote fracture healing, relieve pain, treat infection, or improve function within 24 months of fracture.7 Our primary aim was to identify factors associated with an increased risk of revision surgery, as defined above, for patients enrolled in the FAITH trial. Our secondary aims were to determine factors associated with an increased risk of surgery for hardware removal, defined as the removal of CS or SHS, and surgery for implant exchange, defined as the conversion of CS or SHS to total hip arthroplasty (THA), hemiarthroplasty (HA), or another internal fixation device.

Materials and Methods

FAITH Study Overview

The FAITH trial (Clinical Trials Identification Number: NCT00761813) enrolled 1079 patients with a low-energy femoral neck fracture requiring fracture fixation from 81 clinical sites in the United States, Canada, Australia, the Netherlands, Norway, Germany, the United Kingdom, and India. Patients were assessed clinically at 1 and 10 weeks and 6, 9, 12, 18, and 24-months postsurgery. The primary outcome of the FAITH trial was revision surgery to promote healing, relieve pain, treat infection, or improve function over 24-months postsurgery.7,8 All revision surgeries were reviewed by a Central Adjudication Committee. The trial protocol and results have been previously published.7,8 The trial was approved by the Hamilton Integrated Research Ethics Board (#06-402) and by all participating clinical sites' Research Ethics Boards/Institutional Review Boards.

Selection of Factors

Based on biologic rationale and previous literature,[9] a priori we identified 22 potential factors that may be associated with revision surgery, from the baseline data, fracture characteristics, and surgical data collected as part of the FAITH trial (Table 1).[7] When selecting factors for each analysis, we ensured that there were at least 10 events for each factor to avoid having an overfitted or unstable model.[10] Of note, we had intended to include quality of reduction within the models; however, less than 10 patients had unacceptable quality of reduction. Therefore, this factor was not included in the models. The number of factors included was based on the primary outcome of the FAITH trial, revision surgery. As 224 participants had a revision surgery to promote healing, relieve pain, treat infection or improve function over 24-months post-surgery, all 22 preidentified factors (including levels) could be used in our analysis. We included 15 factors with 22 levels (Table 1) in our analysis. Because logistic and Cox models require at least 10 events per covariate to produce stable estimates,[10] the minimum number participants required to support the analysis of 22 factors would be 220 participants. As 74 participants underwent hardware removal surgery, we selected 7 factors that might be associated with hardware removal in our model (Table 2). Finally, 150 participants had implant exchange surgery. Therefore, we selected 14 factors to be included in this model (Table 3). For every factor in each of our 3 models, we proposed a priori a hypothesized effect and rationale for revision surgery, hardware removal, and implant exchange, respectively.

Data Analysis

We used multivariable Cox proportional hazards regression stratified by center analyses to investigate the association between our selected factors and increased risk of revision surgery, hardware removal, and implant exchange. An interaction term between the randomized treatment and smoking status was added to all models because this interaction was found to be significant in the FAITH primary paper.7 All FAITH patients with complete data for all selected factors were included in the analysis. Results were reported as adjusted hazard ratios (HR), 95% confidence intervals (CIs), and associated P-values. All tests were 2-tailed with alpha = 0.05. We tested the assumption of proportional hazards for all independent variables. We performed all analyses using SAS software (version 9.4: SAS Institute, Cary, NC).

Results

Participant Characteristics

Eight hundred fifteen patients enrolled in the FAITH trial had complete prognostic and follow-up data for the 15 selected factors and were included in the revision surgery model (mean age: 73.4 years; 64% female). Complete data were available for 894 (mean age: 73.4 years; 64% female) and 823 (mean age: 73.6 years; 64% female) patients to perform the analyses investigating factors associated with hardware removal and implant exchange, respectively. Of the patients included in this analysis, 191 patients had revision surgeries to promote fracture healing, relieve pain, treat infection, or improve function. Within this subset, there were 70 hardware removal surgeries and 143 implant exchange surgeries (92 conversions to THA, 44 conversions to HA, and 9 IF exchanges).

Factors Associated With Revision Surgery

Female sex (HR 1.79, 95% CI 1.25–2.50; P = 0.001), displaced fracture (HR 2.16, 95% CI 1.44–3.23; P , 0.001), and a fracture configuration corresponding to a Pauwels type III as compared to type II (HR 2.13, 95% CI 1.28–3.57; P = 0.004) were associated with a higher risk of revision surgery (Table 1). Unacceptable quality of implant placement, which was adjudicated by the Central Adjudication Committee and was defined in the FAITH trial as evidence of prominent screws (at the lateral femoral cortex), screw penetration, and lag screw being too high on immediate post-operative radiographs, was also found to be associated with a higher risk of revision surgery (HR 2.70, 95% CI 1.59–4.55; P , 0.001). Lastly, we found that for every 5-point increase in body mass index (BMI), participants experienced an average increased risk of 19% for revision surgery (HR 1.19, 95% CI 1.02–1.39; P = 0.027) during the 24-month follow-up period. Additionally, we found that being treated with CS (compared to SHS) increased the risk of revision surgery in patients who were smokers (HR 2.94, 95% CI 1.35–6.25; P = 0.006). No other factors were significantly associated with revision surgery (P . 0.05).

Factors Associated With Hardware Removal

Having a displaced fracture (HR 2.91, 95% CI 1.63–5.18; P , 0.001) and unacceptable quality of implant placement (HR 2.56, 95% CI 1.11–5.88; P = 0.027) were associated with an increased risk of hardware removal (Table 2). We found that for every 10-year decrease in age, participants experienced an average increased risk of 39% for hardware removal (HR 1.39, 95% CI 1.05–1.85; P = 0.020) during the 24-month follow-up period. Additionally, we found that being treated with CS compared to a SHS was associated with an increased risk of hardware removal; however, the treatment effect was significantly higher in non-smokers/prior smokers (HR 0.53, 95% CI 0.29–0.96; P = 0.040) compared to current smokers (HR 0.09, 95% CI 0.02–0.37; P = 0.001). BMI and prefracture functional status were not associated with hardware removal (P< 0.05).

Factors Associated With Implant Exchange

Factors associated with an increased risk of implant exchange included: female sex (HR 2.00, 95% CI 1.32–3.03; P = 0.001), displaced fracture (HR 2.31, 95% CI 1.45–3.69; P 0.001), and unacceptable quality of implant placement (HR 2.38, 95% CI 1.32–4.35; P , 0.001) (Table 3). No other factors were significantly associated with implant exchange (P< 0.05).

Discussion

Using data from the FAITH trial, we investigated factors associated with revision surgery, hardware removal, and implant exchange in patients over the age of 50 with a low-energy femoral neck fracture.7 To date, there have been a limited number of studies that have enrolled large numbers of femoral neck fracture patients treated with internal fixation across multiple centers and countries. Assessing nearly 1000 participants provided us with greater precision in our secondary analyses for determining the factors associated with overall revision surgery, hardware removal, and implant exchange surgery.

In the FAITH primary paper, the interaction between randomized treatment and smoking status was found to be statistically significant. When this interaction term was added to the overall revision surgery model and the hardware removal model, a SHS was found to be beneficial in smokers (compared to CS). The existing literature concerning the risk of revision surgery in smokers following internal fixation of a femoral neck fracture is currently lacking. At this time, only one other published study has evaluated factors associated with revision surgery for femoral neck fractures, but this study did not assess whether smoking was a factor.9 However, there is fracture healing literature that suggests that smoking can have a negative effect on bone healing.11–14 One systematic review containing 9 tibia studies and 8 other orthopaedic studies found that, overall, smoking had a negative effect on bone healing, in terms of delayed union, non-union, and other complications.11 Another systematic review found similar findings that smoking significantly increased the risk of nonunion of fractures overall [odds ratio (OR) 2.32; 95% CI 1.76–3.06; P , 0.001], tibial fractures (OR 2.16; 95% CI 1.55–3.01; P < 0.001), and open fractures (OR 1.95; 95% CI 1.3–2.9; P , 0.001).12

Additionally, a recently published prospective, multicentre, cohort study evaluating the treatment of acute tibial plateau fractures with open reduction and internal fixation found that current smoking was an independent risk factor for the development of surgical site infection (OR 5.68; 95% CI 1.56–20.66; P = 0.009).13 Smoking is also known to have a negative impact on bone density that impacts post-surgical fracture mechanical stability.15 Our finding that smokers receiving a SHS will have better outcomes needs to be confirmed through future research conducted on this topic.

Patients with a type III Pauwels fracture compared to type II were found to be at a significantly higher risk of revision surgery in the current study. However, those with a type III Pauwels fracture were not found to be at a higher risk of revision surgery compared to patients with a type I Pauwels fracture. This may have been due to a smaller proportion of patients with fractures classified as type I (n = 93) or type III (n = 107) compared to type II (n = 615). Although some evidence suggests that Pauwels classification may not be highly reliable, it is still widely used to classify femoral neck fractures.16

The Gregersen et al9 trial found that underweight elderly individuals (BMI ,19) had a lower risk of revision surgery compared to elderly individuals with a BMI $ 19 (HR 0.33, 95% CI 0.11–0.95; P = 0.040). This finding was similar to ours and may result from the increased amount of stress on the implant. Additionally, the Gregersen et al9 trial found that a higher risk of revision surgery was associated with living at home independently compared to living in a nursing home (HR 2.67; 95% CI 1.35–5.31; P = 0.005) and with poor quality of fracture reduction in displaced fractures (HR 1.95; 95% CI: 1.02–3.72; P = 0.040). Gregersen et al defined poor reduction as fracture displacement greater than 5 mm, an anteroposterior Garden angle outside the interval of 160–175 degrees, or a posterior or anterior angulation greater than 20 degrees.9,17 This finding was consistent with an earlier study which found that poor reduction led to a higher risk of treatment failure following internal fixation of displaced fractures of the femoral neck.18 Due to a low number of participants with an unacceptable reduction, we did not include this factor in our models. Review of the quality of fracture reduction by a Central Adjudication Committee in the FAITH trial found that only 5 participants had unacceptable reduction. Radiographs of the hip fracture were examined by the Central Adjudication Committee for approximation of the displaced fracture fragments and overall fracture alignment. The Adjudication Committee assessed the quality of reduction. Although there are radiologic predictors of failure, the absolute cutoffs for acceptable and unacceptable reductions are not known. Therefore, the Central Adjudication Committee erred on the side of acceptable, except in cases where there was gross malreduction, which rarely occurred.

To ensure that all conversion surgeries were captured, our implant exchange model included conversion to THA, HA, or another internal fixation device.19 Arthroplasty involves partial or full replacement of a joint, whereas internal fixation involves joint preservation. Therefore, the two procedures are very different clinically. For this reason, we repeated the implant exchange analysis removing the 9 patients who underwent implant exchange to another internal fixation device. Typically, implant exchanges mostly involve THA and HA procedures, whereas implant exchanges to another internal fixation device are less common. We found similar results to our original analysis where female sex (P = 0.001), displaced fracture (P = 0.0003), and unacceptable quality of implant placement (P = 0.006) were associated with an increased risk of CS or SHS conversion to THA or HA. Unlike in the original analysis, using an ambulatory aid prefracture (P = 0.04) was also found to be associated with an increased risk of CS or SHS conversion to THA or HA.

Our study has numerous notable strengths. A total of 1079 patients from 81 clinical sites in the United States, Canada, Australia, the Netherlands, Norway, Germany, the United Kingdom, and India were included in the FAITH trial. The large sample size and diversity of the participants included in the trial increases the external validity and generalizability of our research findings from this analysis. The 7 postsurgery follow-up visits across a 24-month period allowed for frequent and long-term assessment of participant outcomes and all revision surgery events were centrally adjudicated. Additionally, the use of a multivariable Cox proportional hazards regression for our analysis was advantageous, as this type of model helps control for numerous potentially confounding variables when the sample size is large enough.20 Although this study had several strengths, important limitations do exist. Although 1079 patients were included in the primary analysis of the FAITH trial, it was not possible to include them all in this analysis, due to missing data. Also, it may be possible that not all factors associated with revision surgery were collected as part of the FAITH trial. Bone density determination is one important factor in this regard. Only variables collected as part of the FAITH trial could be used in our analysis.

Identifying factors associated with revision surgery will help to optimize the care of hip fracture patients. Understanding which patients are at risk for revision surgery, and specifically which type of revision surgery, can let surgeons communicate these risks to patients when explaining treatment options and prognosis. Additionally, the variables identified in our analysis may allow for surgeons to consider alternate care options, such as joint replacement, for patients who are at higher risk of revision surgery. Finally, the results of this study may also inform future research by identifying high-risk patients who may benefit from novel interventions and adjuncts to care.

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TABLE 1. Factors Associated With Revision Surgery (n = 815; 191 Events)

Independent Variable	Hazard Ratio (95% confidence interval)	*P*
Gender		
Female versus Male	1.79 (1.25–2.50)	0.001
Body mass index (Change in 5 points)	1.19 (1.02–1.39)	0.027
Fracture displacement		
Displaced versus undisplaced	2.16 (1.44–3.23)	0.0002
Pauwels classification		
Type I versus type III	0.54 (0.26–1.15)	0.11
Type III versus type II	2.13 (1.28–3.57)	0.004
Quality of implant placement		
Unacceptable versus acceptable; (Acceptable, n = 776; Unacceptable, n = 39)	2.70 (1.59–4.55)	0.0002
Interaction		0.01
Smoking status		
Current versus other (nonsmokers/previous smokers) for Cancellous screws	1.89 (1.10–3.25)	0.021
Current versus other for sliding hip screw	0.62 (0.32–1.21)	0.16
Treatment		
Cancellous screws versus sliding hip screw for current smokers	2.94 (1.35–6.25)	0.006
Sliding hip screw versus cancellous screws for other (nonsmokers/previous smokers)	1.05 (0.75–1.47)	0.77
Age (Change in 10 y)	1.05 (0.87–1.26)	0.62
ASA Classification		
Class II versus class I	0.76 (0.48–1.2)	0.24
Class III versus class I	0.84 (0.45–1.55)	0.57
Class IV versus class I	0.22 (0.04–1.1)	0.06
Class V versus class I	No data	
Pre-fracture living setting		
Institutionalized versus Not institutionalized	0.97 (0.33–2.79)	0.95
Prefracture functional status		
Using ambulatory aid versus independent ambulator	1.47 (0.92–2.37)	0.11
Diabetes		
Yes versus No	0.87 (0.54–1.38)	0.55
Level of the fracture line		
Midcervical versus subcapital	0.73 (0.47–1.14)	0.16
Basal versus subcapital	0.55 (0.23–1.30)	0.17
Type of reduction		
None versus open	0.82 (0.32–2.07)	0.67
Closed versus open	1.10 (0.43–2.79)	0.85
Time from injury to surgery (d)	1 (0.95–1.06)	0.88

TABLE 2. Factors Associated With Hardware Removal (n = 894; 70 Events)

Variable	Hazard Ratio (95% confidence interval)	*P*
Age (Change in 10 y)	1.39 (1.05–1.85)	0.020
Fracture displacement		
Displaced versus undisplaced	2.91 (1.63–5.18)	0.0003
Quality of implant placement		
Unacceptable versus acceptable	2.56 (1.11–5.88)	0.027
Interaction		0.02
Smoking status		
Current versus other (nonsmokers/ previous smokers) for cancellous screws	2.03 (0.91–4.51)	0.12
Current versus other for sliding hip screw	0.35 (0.10–1.30)	0.08
Treatment		
Sliding hip screw versus cancellous screws for current smokers	0.09 (0.02–0.37)	0.001
Sliding hip screw versus cancellous screws for other (nonsmokers/ previous smokers)	0.53 (0.29–0.96)	0.04
Body mass index (Change in 5 points)	1.03 (0.75–1.41)	0.86
Prefracture functional status		
Using ambulatory aid versus independent ambulator	0.62 (0.21–1.83)	0.39

TABLE 3. Factors Associated With Implant Exchange (n = 823; 143 Events)

Variable	Hazard Ratio (95% confidence interval)	*P*
Gender		
Female versus male	2.00 (1.32–3.03)	0.001
Fracture displacement		
Displaced versus undisplaced	2.31 (1.45–3.69)	0.0005
Quality of implant placement: unacceptable versus acceptable. (acceptable, n = 852; unacceptable, n = 42)	2.38 (1.32–4.35)	0.0004
Age (change in 10 y)	1.14 (0.94–1.39)	0.17
Prefracture functional status		
Using ambulatory aid versus independent ambulator	1.54 (0.96–2.46)	0.07
Diabetes		
Yes versus no	1.00 (0.60–1.64)	0.99
Level of the fracture line		
Midcervical versus subcapital	0.83 (0.54–1.26)	0.37
Basal versus subcapital	0.85 (0.34–2.16)	0.73
Type of reduction		
None versus open	1.3 (0.4–4.21)	0.66
Closed versus open	1.71 (0.52–5.59)	0.38
Time from injury to surgery (d)	0.99 (0.93–1.06)	0.76
Interaction		0.07
Smoking status		
Current versus other (nonsmokers/previous smokers) for cancellous screws	1.39 (0.72–2.69)	0.33
Current versus other for sliding hip screw	0.58 (0.28–1.21)	0.14
Treatment		
Sliding hip screw versus cancellous screws for current smokers	0.52 (0.22–1.24)	0.14
Sliding hip screw versus cancellous screws for other (nonsmokers/previous smokers)	1.25 (0.86–1.83)	0.25