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Factors Associated with Revision Surgery Following Internal Fixation of Hip Fractures

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Abstract

Background—Femoral neck fractures are associated with high rates of revision surgery following management with internal fixation. Using data from the 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 post-surgery. 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, seven with hardware removal, and 14 with implant exchange. We used multivariable Cox proportional hazards analyses in our investigation.

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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 CS versus smokers treated with a SHS (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.

Level of Evidence—II

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 two 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 1,079 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 post-surgery. The primary outcome of the FAITH trial was revision surgery to promote healing, relieve pain, treat infection, or improve function over 24-months post-surgery.^{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), as well as 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 pre-identified factors (including levels) could be used in our analysis. We included 15 factors with 22 levels (Table 1) in our analysis. Since 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 seven 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 three 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, as this interaction was found to be significant in the FAITH primary paper. 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, North Carolina).

RESULTS

Participant Characteristics

815 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 low 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 pre-fracture 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 1,000 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.^{11,12,13,14} One systematic review containing nine tibia studies and eight other orthopaedic studies found that, overall, smoking had a negative effect on bone healing, in terms of delayed union, nonunion, 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 which 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 al. 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).⁹ This finding was similar to ours and may result from the increased amount of stress on the implant.

Additionally, the Gregersen et al. 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).⁹ Gregersen et al. defined poor reduction as fracture displacement greater than 5 mm, an anteroposterior Garden angle outside the interval of 160° to 175°, or a posterior or anterior angulation greater than 20°. ^{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 five 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. While there are radiologic predictors of failure, the absolute cut offs 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 Since arthroplasty involves partial or full replacement of a joint, while internal fixation involves joint preservation, they 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, while 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 pre-fracture (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. 1,079 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 seven post-surgery 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 While this study had several strengths, important limitations do exist. Although 1,079 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-value
Gender		
Female vs. 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 vs. Undisplaced	2.16 (1.44, 3.23)	0.0002
Pauwels Classification		
Type I vs. Type III	0.54 (0.26, 1.15)	0.11
Type III vs. Type II	2.13 (1.28, 3.57)	0.004
Quality of Implant Placement		
Unacceptable vs. Acceptable (Acceptable, n=776; Unacceptable, n=39)	2.70 (1.59, 4.55)	0.0002
Interaction: p-value=0.01		
Smoking status:		
Current vs. Other (non-smokers/previous smokers) for Cancellous screws	1.89 (1.10, 3.25)	0.021
Current vs. Other for Sliding hip screw	0.62 (0.32, 1.21)	0.16
Treatment:		
Cancellous screws vs. Sliding hip screw for Current smokers	2.94 (1.35, 6.25)	0.006
Sliding hip screw vs. Cancellous screws for Other (non-smokers/previous smokers)	1.05 (0.75, 1.47)	0.77
Age (Change in 10 years)	1.05 (0.87, 1.26)	0.62
ASA Classification		
Class II vs. Class I	0.76 (0.48, 1.2)	
Class III vs. Class I	0.84 (0.45, 1.55)	0.24
Class IV vs. Class I	0.22 (0.04, 1.1)	0.57
Class V vs. Class I	No data	0.06
Pre-fracture Living Setting		
Institutionalized vs. Not institutionalized	0.97 (0.33, 2.79)	0.95
Pre-Fracture Functional Status		
Using ambulatory aid vs. Independent ambulator	1.47 (0.92, 2.37)	0.11
Diabetes		
Yes vs. No	0.87 (0.54, 1.38)	0.55
Level of the Fracture Line		

Independent Variable	Hazard Ratio (95% Confidence Interval)	p-value
Midcervical vs Subcapital	0.73 (0.47, 1.14)	0.16
Basal vs Subcapital	0.55 (0.23, 1.30)	0.17
Type of Reduction		
None vs. Open	0.82 (0.32, 2.07)	0.67
Closed vs. Open	1.10 (0.43, 2.79)	0.85
Time from injury to surgery (days)	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-value
Age (Change in 10 years)	1.39 (1.05, 1.85)	0.020
Fracture Displacement Displaced vs. Undisplaced	2.91 (1.63, 5.18)	0.0003
Quality of Implant Placement Unacceptable vs. Acceptable	2.56 (1.11, 5.88)	0.027
Interaction: p-value=0.02		
Smoking status:		
Current vs. Other (non-smokers/previous smokers) for Cancellous screws	2.03 (0.91, 4.51)	0.12
Current vs. Other for Sliding hip screw	0.35 (0.10, 1.30)	0.08
Treatment:		
Sliding hip screw vs. Cancellous screws for Current smokers	0.09 (0.02, 0.37)	0.001
Sliding hip screw vs. Cancellous screws for Other (non-smokers/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
Pre-Fracture Functional Status Using ambulatory aid vs. 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-value
Gender		
Female vs Male	2.00 (1.32, 3.03)	0.001
Fracture Displacement		
Displaced vs. Undisplaced	2.31 (1.45, 3.69)	0.0005
Quality of Implant Placement		
Unacceptable vs. Acceptable (Acceptable, n=852; Unacceptable, n=42)	2.38 (1.32, 4.35)	0.0004
Age (Change in 10 years)	1.14 (0.94, 1.39)	0.17
Pre-Fracture Functional Status		
Using ambulatory aid vs. Independent ambulator	1.54 (0.96, 2.46)	0.07
Diabetes		
Yes vs. No	1.00 (0.60, 1.64)	0.99
Level of the Fracture Line		
Midcervical vs Subcapital	0.83 (0.54, 1.26)	0.37
Basal vs Subcapital	0.85 (0.34, 2.16)	0.73
Type of Reduction		
None vs. Open	1.3 (0.4, 4.21)	0.66
Closed vs. Open	1.71 (0.52, 5.59)	0.38
Time from injury to surgery (days)	0.99 (0.93, 1.06)	0.76
Interaction: p-value=0.07		
Smoking status:		
Current vs. Other (non-smokers/previous smokers) for Cancellous screws	1.39 (0.72, 2.69)	0.33
Current vs. Other for Sliding hip screw	0.58 (0.28, 1.21)	0.14
Treatment:		
Sliding hip screw vs. Cancellous screws for Current smokers	0.52 (0.22, 1.24)	0.14
Sliding hip screw vs. Cancellous screws for Other (non-smokers/previous smokers)	1.25 (0.86, 1.83)	0.25