Adequate levels of vitamin D are essential for maintaining general bone health because vitamin D regulates calcium and skeletal homeostasis. Previous research suggested that vitamin D supplementation may reduce the risk of osteoporosis, fractures, and falls and also may improve muscle strength in elderly patients after hip fracture. A large hip fracture trial was used to determine the proportion of patients who consistently used vitamin D after hip fracture surgery and to determine whether supplementation was associated with improved health-related quality of life and reduced reoperation rates. The FAITH study is a multicenter trial of elderly patients with femoral neck fracture treated with internal fixation. The current study asked a subset of patients included in the FAITH study about vitamin D supplementation and categorized them as consistent users, inconsistent users, or nonusers. This study also evaluated whether supplementation was associated with improved quality of life and reduced reoperation rates. The final analysis included 573 patients (mean age, 74.1 years; female, 66.3%; nondisplaced fractures, 72.4%). A total of 18.7% of participants reported no use of vitamin D, 35.6% reported inconsistent use, and 45.7% reported consistent use. Adjusted analysis found that consistent supplementation was associated with a 2.42 increase of the Short Form-12 physical component score 12 months postoperatively ($P = .033$). However, supplementation was not associated with reduced reoperation rates ($P = .386$). Despite guidelines recommending vitamin D supplementation, a low proportion of elderly patients with hip fracture use vitamin D consistently, suggesting a need for additional strategies to promote compliance. This study found that the use of vitamin D was associated with a statistically significant but not clinically significant improvement in health-related quality of life after hip fracture. Further research is needed to confirm these findings. [Orthopedics. 2017; 40(5):e868-e875.]
recent meta-analysis questioned the efficacy of vitamin D supplementation in preventing osteoporosis and fractures among healthy adults. However, the authors recommended vitamin D supplementation for individuals who are at risk for osteomalacia, which usually occurs in those with clinical risk factors, such as frailty, sunshine avoidance or deeply pigmented skin, and 25-hydroxyvitamin D levels of less than 25 nmol/L. A recent study found vitamin D deficiency among 73.0% of elderly patients immediately after a fracture. This finding suggests that elderly patients who have poor bone health may be at high risk for low-energy hip fractures.

Health Canada and the Endocrine Society recommended that those older than 50 years of age take 600 IU vitamin D daily, and the recommendation is 800 IU for adults older than 70 years; however, the number of individuals who follow these guidelines is not known. The recently completed FAITH trial (surgical randomized controlled trial in elderly patients with femoral neck fracture comparing sliding hip screws and cancellous screws) provided a unique opportunity to determine whether elderly patients with hip fracture are using vitamin D and to explore the association between vitamin D use and patient outcomes after hip fracture. The current study used data from this trial to determine the proportion of patients who consistently use vitamin D and to determine whether vitamin D supplementation is associated with improved physical function after injury and lower reoperation rates within 2 years of fracture.

**Materials and Methods**

**Overview of the FAITH Study**

The FAITH trial (NCT00761813) is a multicenter randomized controlled trial that compared cancellous screws vs sliding hip screws in patients older than 50 years who had femoral neck fracture. Patients were recruited from 81 clinical sites in 8 countries during a 6-year span. The primary objective of the FAITH trial was to assess the effect of sliding hip screws vs cancellous screw fixation on reoperation rates at 2 years in patients with femoral neck fracture. The secondary objective was to examine the effect of these treatments on health-related quality of life outcomes, nonoperatively treated fracture-related complications, time to fracture healing, and mortality. Patients were assessed clinically at 1, 2, and 10 weeks and at 6, 9, 12, 18, and 24 months after surgery. This trial was coordinated by the Centre for Evidence-Based Orthopaedics, McMaster University, Hamilton, Ontario, Canada, and was approved by the Hamilton Integrated Research Ethics Board as well as by the research ethics boards and institutional review boards at all participating clinical sites.

**Vitamin D Supplementation**

The FAITH trial did not require a specific vitamin D supplementation protocol after the fracture, but the protocol recommended that surgeons prescribe 1000 IU vitamin D daily to patients. A subset of patients in the FAITH study who enrolled after July 2009 were asked to indicate whether they were taking any medications from a list that included vitamin D. Based on their reported frequency of vitamin D supplementation in the first 6 months of follow-up, patients were categorized as either consistent users (3-4 of 4 visits), inconsistent users (1-2 of 4 visits), or nonusers (0 of 4 visits). Patients who attended at least 2 follow-up visits within 6 months and completed the trial were included in the final analysis.

**Physical Function**

Physical function was assessed with the Short Form-12 (SF-12) physical component score. The SF-12 is a health-related quality of life survey designed to measure functional health and well-being from the patient’s perspective. The SF-12 physical component score is a summary score that includes 4 domains related to physical health: physical functioning, role-physical, bodily pain, and general health. Scores range from 0 to 100, with 0 indicating the lowest level of physical function and 100 indicating the highest level. Previous studies showed that the SF-12 physical component score could discriminate between patients with healed vs unhealed fractures and demonstrated the responsiveness of the instrument to changes in patients with tibia fracture. The SF-12 physical component score was obtained at each follow-up visit with a self-administered or interview-administered format under the supervision of the research coordinator, either in the clinic or by telephone.

**Reoperation**

Reoperation within 2 years of initial surgery to promote fracture healing, relieve pain, treat infection, or improve function was considered a study outcome. Types of reoperation included implant removal, wound closure, bone graft, implant exchange, and soft tissue procedures. Reasons for reoperation included implant failure, infection, avascular necrosis, hip instability, hip dislocation, open wound, painful hardware, periprosthetic fracture, and nonunion. All reoperations were reviewed by a central adjudication committee of orthopedic trauma surgeons. This committee reviewed relevant case report forms and radiographs and confirmed that the reoperation met the criteria for a study event.

**Data Analysis**

Baseline patient characteristics were summarized with descriptive statistics. Categorical variables were summarized as counts and percentages. Continuous data were summarized as mean and standard deviation. Categorical baseline variables were compared across the 3 vitamin D compliance groups (consistent users, inconsistent users, and nonusers) with chi-square tests. Continuous baseline vari-
ables were compared across the 3 vitamin D compliance groups with analysis of variance. A linear regression model was used to compare the effect of consistent vitamin D supplementation on physical function 12 months after fracture, after adjustment for baseline SF-12 physical component score, patient sex, ASA classification, and fracture displacement. A logistic regression model was used to compare the effect of consistent vitamin D supplementation on reoperation within 2 years of surgery, after adjustment for SF-12 physical component score, patient sex, ASA classification, and fracture displacement. All statistical analysis was performed with JMP version 12 software (SAS Institute, Cary, North Carolina).

RESULTS

Patient Demographics

Of the 625 patients who were asked about vitamin D supplementation, 573 participated in at least 2 postoperative follow-up visits within the first 6 months after surgery and were included in the final analysis. Mean age of study participants was 74.1 years (±12.2 years), and most participants were female (66.3%) and had nondisplaced fractures (72.4%). Approximately 90% of the patients were enrolled at clinical sites in North America. Baseline SF-12 physical component score was 44.5 (±11.5), and baseline SF-12 mental component score was 54.5 (±10.8) (Table 1).

Vitamin D Supplementation

A total of 107 patients (18.7%) reported no use of vitamin D within the first 6 months after surgery, 204 (35.6%) reported inconsistent use, and 262 (45.7%) reported consistent use. No significant difference was found in age, fracture displacement, preinjury SF-12 physical component score, or preinjury SF-12 mental component score across the 3 vitamin D compliance groups. Men were less likely than women to use vitamin D 6 months after surgery (P=.025) (Table 1). A significant difference also was found in vitamin D compliance for patients categorized as ASA class 1 (P=.002) and ASA class 2 (P=.045) as well as for patients from the United States (P=.001) and Canada (P=.001).

Vitamin D and Physical Function

Consistent vitamin D supplementation had a significant positive effect on 12-month physical function scores in the unadjusted and adjusted generalized linear regression models. Adjusted analysis found that consistent vitamin D supplementation after fracture was associated with a 2.42 increase in 12-month SF-12 physical component score (P=.033) (Table 2).

Vitamin D and Reoperation

Unadjusted and adjusted analyses showed that vitamin D supplementation within 6 months of surgery was not

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### Table 1
Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All (n=573)</th>
<th>Consistent Vitamin D Use (n=262)</th>
<th>Inconsistent Vitamin D Use (n=204)</th>
<th>No Vitamin D Use (n=107)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>74.1 (12.2)</td>
<td>74.8 (12.2)</td>
<td>73.7 (12.1)</td>
<td>73.1 (12.1)</td>
<td>.394</td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>380 (66.3)</td>
<td>181 (69.1)</td>
<td>140 (68.6)</td>
<td>59 (55.1)</td>
<td>.025</td>
</tr>
<tr>
<td>Location, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>341 (59.5)</td>
<td>140 (53.4)</td>
<td>121 (59.3)</td>
<td>80 (74.8)</td>
<td>.001</td>
</tr>
<tr>
<td>Canada</td>
<td>167 (29.1)</td>
<td>92 (35.1)</td>
<td>59 (28.9)</td>
<td>16 (15.0)</td>
<td>.001</td>
</tr>
<tr>
<td>Australia</td>
<td>33 (5.8)</td>
<td>15 (5.7)</td>
<td>12 (5.9)</td>
<td>6 (5.6)</td>
<td>.995</td>
</tr>
<tr>
<td>Europe</td>
<td>19 (3.3)</td>
<td>11 (4.2)</td>
<td>8 (3.9)</td>
<td>0 (0.0)</td>
<td>.103</td>
</tr>
<tr>
<td>India</td>
<td>13 (2.3)</td>
<td>4 (1.5)</td>
<td>4 (2.0)</td>
<td>5 (4.7)</td>
<td>.171</td>
</tr>
<tr>
<td>American Society of Anesthesiologists classification, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>65 (11.3)</td>
<td>43 (16.4)</td>
<td>15 (7.4)</td>
<td>7 (6.5)</td>
<td>.002</td>
</tr>
<tr>
<td>2</td>
<td>237 (41.4)</td>
<td>96 (36.6)</td>
<td>98 (48.0)</td>
<td>43 (40.2)</td>
<td>.045</td>
</tr>
<tr>
<td>3</td>
<td>241 (42.1)</td>
<td>111 (42.4)</td>
<td>77 (37.7)</td>
<td>53 (49.5)</td>
<td>.134</td>
</tr>
<tr>
<td>4</td>
<td>30 (5.2)</td>
<td>12 (4.6)</td>
<td>14 (6.9)</td>
<td>4 (3.7)</td>
<td>.407</td>
</tr>
<tr>
<td>Displaced fracture, No. (%)</td>
<td>158 (27.6)</td>
<td>68 (26.0)</td>
<td>52 (25.5)</td>
<td>38 (35.5)</td>
<td>.125</td>
</tr>
<tr>
<td>Prefracture functional status, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Use of aid</td>
<td>146 (25.5)</td>
<td>69 (26.3)</td>
<td>55 (27.0)</td>
<td>22 (20.6)</td>
<td>.427</td>
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<tr>
<td>Short Form-12 physical component summary score, preinjury, mean (SD)</td>
<td>44.5 (11.5)</td>
<td>45.4 (11.0)</td>
<td>43.5 (12.5)</td>
<td>44.0 (10.9)</td>
<td>.255</td>
</tr>
<tr>
<td>Short Form-12 mental component summary score, preinjury, mean (SD)</td>
<td>54.5 (10.8)</td>
<td>54.6 (10.4)</td>
<td>54.2 (11.5)</td>
<td>55.0 (10.3)</td>
<td>.840</td>
</tr>
</tbody>
</table>
associated with a reduced risk of reoperation within 24 months postoperatively ($P=.386$) (Table 2).

**DISCUSSION**

Despite well-developed guidelines for vitamin D supplementation among the elderly population, the study found that a surprisingly low proportion of elderly patients with femoral neck fracture used vitamin D consistently. Specifically, 35.6% of patients did not report consistent vitamin D use after a fracture, and almost 18.7% of patients with fracture did not report using vitamin D. This finding suggests a gap in knowledge because it is evident that practice guidelines and recommendations are not being followed within a population that may be at risk.

Elderly patients who have a low-energy hip fracture, such as those included in the FAITH study, are typically frail and many have osteoporosis, as characterized by bone density 2.5 SD or more below the young adult mean.16 Previous research showed a high prevalence of vitamin D deficiency (serum 25-hydroxyvitamin D level <20 ng/mL) in patients with osteoporosis, even those receiving medical treatment for osteoporosis.16,17 Similarly, a recent systematic review found a high prevalence of vitamin D insufficiency, typically defined as serum 25-hydroxyvitamin D level of 21 to 29 ng/mL,10 after fractures in the elderly.10 These findings suggest that elderly patients with hip fracture may not be receiving the necessary vitamin D supplementation to maintain adequate bone health and may be at increased risk for osteomalacia, which is a metabolic bone disease characterized by incomplete mineralization of the bone matrix.18 In the Western world, vitamin D deficiency is considered the most prominent cause of osteomalacia.18 Further, the elderly patients included in the FAITH study may benefit from higher doses of vitamin D than the current guideline recommendations of 600 to 800 IU/d because those with osteoporosis may require large doses to increase and maintain serum levels.17

The importance of vitamin D supplementation in this elderly population with hip fracture and the current findings suggest the need to develop and evaluate educational programs targeted at both physicians and patients to improve vitamin D supplementation in these patients.

The high prevalence of vitamin D deficiency in patients with fracture has led to increased interest within the orthopedic community in the potential for vitamin D to improve outcomes after fracture.10 Femoral neck fractures are associated with high complication rates and poor functional outcomes, and these outcomes may be exacerbated by poor bone health caused by vitamin D deficiency.19,20 The current study found that vitamin D supplementation after fracture was associated with a 2.42 increase in the 12-month SF-12 physical component score. This finding was statistically significant but not clinically significant because the minimally clinically important difference is 4.0.21,22 In addition, in the current study, vitamin D supplementation was not associated with reduced risk of reoperation. This finding warrants further investigation to determine whether vitamin D supplementation can improve fracture healing outcomes within this patient group.

**Limitations**

This study is limited by its observational design. It is possible that the statistically significant increase in physical function seen among patients who complied with the recommendations for vitamin D supplementation was caused by other factors, such as compliance with overall recovery (eg, physical therapy, weight bearing). Data on vitamin D supplementation were based on patient self-reported data, and patients may have underreported or overreported their use of vitamin D. Additionally, the dose and route of vitamin D supplementation and serum levels were not collected as part of the FAITH trial, so the authors could not assess compliance with the current guidelines. This study was strengthened by its use of data from the FAITH trial, which was rigorous in its design and collected all data prospectively. Because vitamin D use was not strictly regulated as part of the trial, the results reflected actual vitamin D use after hip fracture for patients who were not enrolled in a clinical trial. The SF-12 is a reliable and valid tool that provides an accurate measure of physical health as an outcome, and all reoperations were verified by an independent central adjudication committee of practicing orthopedic surgeons.15 Finally, inclusion of patients from multiple clinical sites suggests the generalizability of the results.

**Conclusion**

The current study found that a surprisingly low proportion of elderly patients

<table>
<thead>
<tr>
<th>Consistent Vitamin D Use</th>
<th>Short Form-12 Physical Component Summary Score</th>
<th>Reoperation Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td><strong>Beta Coefficient</strong> (95% Confidence Interval)</td>
<td><strong>Odds Ratio</strong> (95% Confidence Interval)</td>
</tr>
<tr>
<td></td>
<td>2.77 (0.20-5.35)</td>
<td>1.01 (0.65-1.56)</td>
</tr>
<tr>
<td>Adjusted</td>
<td>2.42 (0.16-4.69)</td>
<td>0.80 (0.47-1.33)</td>
</tr>
</tbody>
</table>

*aEstimates adjusted for sex, American Society of Anesthesiologists classification, fracture displacement (binary), and preinjury Short Form-12 physical component summary score.*
with hip fracture consistently used vitamin D. This suggests that physician and patient education programs to improve vitamin D supplementation may need to be developed and evaluated to improve compliance within this high-risk patient group. Additionally, in this study, vitamin D supplementation was associated with improved physical function after femoral neck fracture in elderly patients. Further research is needed to confirm this finding, given the observational nature of the study.

REFERENCES


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