The FAITH and HEALTH Trials: Are We Studying Different Hip Fracture Patient Populations?

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Background: Over the past decade, 2 randomized controlled trials were performed to evaluate 2 surgical strategies (internal fixation and arthroplasty) for the treatment of low-energy femoral neck fractures in patients aged ≥50 years. We evaluated whether patient populations in both the FAITH and HEALTH trials had different baseline characteristics and compared the displaced femoral neck fracture cohort from the FAITH trial to HEALTH trial patients.

Methods: Patient demographics, medical comorbidities, and fracture characteristics from both trials were compared. FAITH trial patients with displaced fractures were then compared with HEALTH patients. T-tests and χ^2 tests were performed to compare differences for sex, age, osteoporosis status, and ASA class.

Results: The mean age of the 1079 FAITH trial patients was 72 versus 79 years for the 1441 HEALTH trial patients. HEALTH patients were older, mostly White, used more medication, and had more comorbidities than FAITH patients. Of the 1079 FAITH trial patients, 32% (346/1079) had displaced fractures. Their mean age was significantly lower than that of HEALTH patients (66 vs. 79 years; $P < 0.001$). HEALTH trial patients were significantly more

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likely to be female, have ASA classification Class III/IV/V, and carry a diagnosis of osteoporosis, as compared with the subgroup of FAITH patients with displaced femoral neck fractures ($P < 0.001$).

Conclusion: This study demonstrates significant differences between patients enrolled in the 2 trials. Although both studies focused on femoral neck fractures with similar enrollment criteria, patient populations differed. This sheds light on a noteworthy limitation of discordant patient enrollment into randomized trials, despite similar eligibility criteria.

Key Words: baseline characteristics, femoral neck fracture

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

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INTRODUCTION

Significant controversies exist regarding the ideal treatment of undisplaced and displaced femoral neck fractures in both the young and geriatric populations. In young patients, internal fixation is typically employed to preserve a healthy functional hip joint. Although arthroplasty outcomes are quite predictable and successful, revision surgery is occasionally needed due to issues such as component loosening, instability, adverse tissue reaction, periprosthetic fractures, and infections.[1] When hip arthroplasty is performed in young patients, the lifetime risk of revision is higher, and the poor success rates of those revisions are problematic.[2] In the elderly population, arthroplasty is the mainstay of treatment, especially in patients with displaced fractures. Intriguingly, recent studies suggest that in elderly patients, even undisplaced and minimally displaced fractures can have improved clinical outcomes with arthroplasty as compared with internal fixation.[3–5]

When considering both internal fixation and replacement, the ideal implant choice remains controversial. The FAITH trial randomized patients with both undisplaced and displaced femoral neck fractures to receive either cancellous screws or a sliding hip screw.[6] The HEALTH trial randomized patients with displaced femoral neck fractures to either a hemiarthroplasty or a total hip replacement.[7] Both studies enrolled patients aged 50 years and older with a low-energy fracture mechanism. Patient enrollment eligibility criteria of both studies are displayed in Table 1. However, the extent of similarity of patients who were actually enrolled in both studies is not known. The aim of this study was to evaluate whether the patient populations enrolled into both multicenter trials were different from one another in respect to demographics and medical comorbidities. Furthermore, we specifically compared the displaced femoral neck fractures that were treated with internal fixation in the FAITH trial with the HEALTH trial patients. We hypothesized that the 2 study populations would be similar.

METHODS

Baseline demographics and fracture characteristics of all enrolled patients from both the FAITH and HEALTH trials were compared. Factors included were age, sex, ethnicity,

TABLE 1. FAITH and HEALTH Trials Patient Enrollment Eligibility Criteria

FAITH Inclusion Criteria	HEALTH Inclusion Criteria
Adult men or women aged 50 years and older (with no upper age limit)	Adult men or women aged 50 years and older (with no upper age limit)
Fracture of the femoral neck confirmed with either AP or lateral hip radiographs, CT, MRI	Fracture of the femoral neck confirmed with either AP or lateral hip radiographs, CT, MRI
Operative treatment of displaced fractures within 4 days of presenting to the emergency room	Displaced fracture that is not, in the judgment of the attending surgeon, optimally managed by reduction and internal fixation
Operative treatment of undisplaced fractures within 7 days of presenting to the ER	Operative treatment within 3 days of the patient being medically cleared for surgery
Patient was ambulatory before fracture, although they may have used an aid such as a cane or a walker	Patient was ambulatory before fracture, although they may have used an aid such as a cane or a walker
Anticipated medical optimization for operative fixation of the hip	Anticipated medical optimization for arthroplasty of the hip
Provision of informed consent by patient or legal guardian	Provision of informed consent by patient or proxy
Low-energy fracture, in the judgment of the attending surgeon	Low-energy fracture (defined as a fall from standing height)
No other major trauma (defined as an injury severity score >16)	No other major trauma (defined as an injury severity score <17)
	Assurance that surgeons with expertise in both total hip arthroplasty and hemiarthroplasty were available to perform surgery
FAITH Exclusion Criteria	**HEALTH Exclusion Criteria**
Patients not suitable for internal fixation (ie, severe osteoarthritis, rheumatoid arthritis, or pathologic fracture)	Patient not suitable for hemiarthroplasty (eg, inflammatory arthritis, RA, pathologic fracture, or severe hip OA)
Associated major injuries of the lower extremity (ie, ipsilateral or contralateral fractures of the foot, ankle, tibia, fibula, knee, or femur; dislocations of the ankle, knee, or hip; or femoral head defects or fracture)	Associated major injuries of the lower extremity (ie, ipsilateral or contralateral fractures of the foot, ankle, tibia, fibula, knee, or femur; dislocations of the ankle, knee, or hip; or femoral head defects or fracture)
Retained implant around the affected hip	Retained implant around the affected hip
Infection around the hip (ie, soft tissue/bone)	Infection around the hip (soft tissue or bone)
Patients with disorders of known bone metabolism except osteoporosis (ie, Paget disease, renal osteodystrophy, osteomalacia)	Patients with a disorder of bone metabolism other than osteoporosis (ie, Paget disease, renal osteodystrophy, osteomalacia)
Patients with a history of frank dementia that would interfere with assessment of the primary outcome (ie, reoperation at 2 years)	Patients with a previous history of frank dementia that would interfere with assessment of the primary outcome (ie, secondary procedures at 2 years)
Likely problems, in the judgment of the investigators, with maintaining follow-up	Likely problems, in the judgment of the investigators, with maintaining follow-up
	Patients whose fracture occurred as a result of an act of violence

AP, anteroposterior; CT, computerized tomography; MRI, magnetic resonance imaging; OA, osteoarthritis; RA, rheumatoid arthritis.

body mass index (BMI), prefracture living status and functional status, medications, and major comorbidities. All patients enrolled in the HEALTH trial had a displaced femoral neck fracture (Garden III and IV).[8] The FAITH trial patients were divided using the Garden classification between undisplaced (Garden I and II) and displaced (Garden III and IV) fractures. The FAITH trial patients with displaced fractures were then separately compared with the HEALTH patients. To assess severity of fracture displacement in each trial, the numbers of patients with Garden III and IV fractures in each trial were also compared.

Statistical Analysis

Statistical analysis using *t*-tests and χ^2 tests were then used to compare the differences for the following factors using the a priori principle: sex, age, osteoporosis status, and American Society of Anesthesiologists (ASA) class. To avoid multiple comparisons, given the large numbers of variables collected in each study, the authors elected to statistically analyze only the 4 fundamental factors above. All tests were 2 tailed with alpha = 0.05. Continuous data were presented with means and SDs, and categorical data were presented as frequencies and proportions.

RESULTS

The mean age of the 1079 patients in the FAITH trial was 72 (SD, 12) years, as opposed to 79 (SD, 8) years for the 1441 patients in the HEALTH trial. The HEALTH patients were older, more often White and less ethnically diverse, used more medication, and had more comorbidities. Table 2 summarizes all the patient demographic comparisons between the FAITH and HEALTH trial participants.

The fracture characteristics of FAITH and HEALTH trial patients are summarized in Table 3. Of the 1079 patients in the FAITH trial, 32% (346/1079) of the patients had displaced fractures. Of these displaced fracture patients, 72% were classified as Garden 3, as opposed to 44% in the HEALTH trial. Tables 4 and 5 summarize the demographic and fracture characteristics of the displaced fracture patients from the FAITH trial as compared with the HEALTH trial patients.

Comparison of selected characteristics of displaced fracture patients in the FAITH and HEALTH trials found that the mean age of the HEALTH study patients was significantly higher than that of the patients in the FAITH study (79 vs. 66 years; $P < 0.001$). The HEALTH trial patients were significantly more likely to be female, have ASA classification Class III/IV/V, and have a known diagnosis of osteoporosis, as compared with the subgroup of FAITH patients with displaced femoral neck fractures ($P < 0.001$). Table 6 summarizes the subgroup comparisons.

DISCUSSION

Although the inclusion criteria for both the FAITH and HEALTH studies were very similar and included patients older than 50 years who sustained low-energy femoral neck fractures, this study critically evaluated the patients who were actually enrolled in both studies. Overall, the HEALTH patients were older, more often White and less ethnically diverse, used more medication, and had more comorbidities than the FAITH patients. When specifically comparing the patients with displaced fractures from the FAITH trial with those in the HEALTH study, we found that HEALTH study patients were significantly older, more often female, were ASA Class III/IV/V, and had osteoporosis. This demonstrates that there was unintentional discordant patient enrollment despite nearly identical inclusion and exclusion criteria. It is conceivable that surgeons were less likely to enroll unhealthy older patients with any fracture displacement in an internal fixation trial.

The importance of scrutinizing a trial's inclusion and exclusion criteria, as well as the subsequently enrolled study cohort cannot be overstated. Not appreciating the sometimes subtle exclusion of a specific patient population from a study can lead to findings that result in potentially unintended changes in surgical practice. For instance, a 2015 landmark study, Proximal Fracture of the Humerus Evaluation by Randomization (PROFHER), prospectively randomized displaced proximal humerus fracture patients aged 16 years and older between operative and nonoperative management.[9] They found that operative management provided no patient-reported clinical outcome benefit compared with nonoperative treatment. This has understandably led to greater interest in nonoperative management of displaced proximal humerus fractures. However, it is important to note that of the 1250 patients assessed for study eligibility, there were 1000 patients who were excluded using rationale such as "clear indication for surgery" and "other reasons." Having broad inclusion criteria, as well as exclusion criteria that give a surgeon the ability to not enroll patients based on their personal discretion can have unintentional consequences, such as often overlooked selection bias. In the FAITH trial, it was reported that 21% of patients required a revision within 24 months of their index surgery. Although a 21% revision rate is relatively acceptable for internal fixation in a geriatric femoral neck fracture cohort, it is easy to overlook that the study enrolled a disproportionate number of undisplaced fractures (68%; 733/1079). Overlooking that important point may result in misinterpreting the findings and concluding that internal fixation of all geriatric femoral neck fractures is successful in approximately 80% of patients. If a more representational geriatric femoral neck fracture population had been enrolled, it is likely that the revision rate would have been higher. One proposal would be to obtain a general consensus for standard study inclusion and exclusion criteria. Leaving enrollment criteria up to the investigator or surgeon enrolling the patient can oftentimes introduce unintended selection bias. Greater focus on this aspect of study design is needed.

Patients' age was highlighted to be a significant difference between the patients enrolled in both the HEALTH and FAITH studies. In a recent systematic review and meta-analysis of internal fixation versus arthroplasty for the treatment of nondisplaced femoral neck fractures in the elderly, patients' average age was approximately 80 years. The review concluded that when treating nondisplaced and minimally displaced femoral neck fractures in the elderly, hemiarthroplasty may reduce the relative risk of reoperation by 70% when compared with internal fixation. Nevertheless, the authors proposed that their results are most applicable to

TABLE 2. Patient Demographics in FAITH and HEALTH Trials

Characteristic	CS, n = 537	SHS, n = 542	THA, n = 718	HA, n = 723
Age, mean (SD)	n = 537	n = 542	n = 718	n = 722
	72.0 (12.3)	72.2 (12.0)	79.1 (8.3)	78.6 (8.6)
Age, n (%)	n = 535	n = 535	n = 718	n = 722
50–70 y	238 (44.5)	245 (45.8)	136 (18.9)	149 (20.6)
71–80 y	147 (27.5)	138 (25.8)	249 (34.7)	247 (34.2)
≥81 y	150 (28.0)	152 (28.4)	333 (46.4)	326 (45.1)
Sex, n (%)	n = 535	n = 535	n = 718	n = 722
Male	210 (39.3)	212 (39.6)	208 (29.0)	223 (30.9)
Female	325 (60.7)	323 (60.4)	510 (71.0)	499 (69.1)
Ethnicity, n (%)	n = 535	n = 533	n = 716	n = 721
Indigenous	3 (0.6)	1 (0.2)	2 (0.3)	1 (0.1)
South Asian	65 (12.1)	65 (12.2)	3 (0.4)	6 (0.8)
East Asian	4 (0.7)	6 (1.1)	7 (1.0)	7 (1.0)
Hispanic/Latino	1 (0.2)	3 (0.6)	7 (1.0)	6 (0.8)
White	444 (83.0)	436 (81.8)	683 (95.4)	684 (94.9)
Black	18 (3.4)	22 (4.1)	12 (1.7)	15 (2.1)
Middle Eastern	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.3)
BMI (kg/m^2), n (%)	n = 528	n = 530	n = 697	n = 705
Underweight <18.5	33 (6.3)	37 (7.0)	35 (5.0)	38 (5.4)
Normal weight 18.5–24.9	300 (56.8)	276 (52.1)	357 (51.2)	336 (47.7)
Overweight 25–29.9	148 (28.0)	159 (30.0)	217 (31.1)	243 (34.5)
Obese 30–39.9	47 (8.9)	58 (10.9)	77 (11.1)	83 (11.8)
Morbidly obese ≥40	0 (0.0)	0 (0.0)	11 (1.6)	5 (0.7)
Prefracture living status, n (%)	n = 537	n = 542	n = 718	n = 723
Institutionalized	31 (5.8)	30 (5.5)	30 (4.2)	27 (3.7)
Not institutionalized	506 (94.2)	512 (94.5)	688 (95.8)	696 (96.3)
Pre-fracture functional status, n (%)	n = 537	n = 542	n = 718	n = 723
Use of Aid	110 (20.5)	121 (22.3)	187 (26.0)	182 (25.2)
Independent ambulator	427 (79.5)	421 (77.7)	531 (74.0)	541 (74.8)
Current medications, n (%)	n = 534	n = 535	n = 715	n = 722
None	179 (33.5)	170 (31.8)	114 (15.9)	127 (17.6)
NSAIDs	64 (12.0)	86 (16.1)	91 (12.7)	90 (12.5)
Analgesics: opioid	69 (12.9)	58 (10.8)	63 (8.8)	55 (7.6)
Glucocorticoids	Not collected	Not collected	26 (3.6)	23 (3.2)
Anabolic steroid therapy	Not collected	Not collected	3 (0.4)	1 (0.1)
Hormone replacement therapy	Not collected	Not collected	30 (4.2)	34 (4.7)
Bisphosphonates	Not collected	Not collected	50 (7.0)	47 (6.5)
Other osteoporosis medications	73 (13.6)	67 (12.5)	28 (3.9)	15 (2.1)
Anti-hypertension medications	252 (47.1)	244 (45.6)	407 (56.9)	402 (55.7)
Pulmonary (respiratory system)	69 (12.9)	58 (10.8)	81 (11.3)	87 (12.1)
Medications				
General cardiac medications	167 (31.2)	167 (31.2)	296 (41.4)	278 (38.5)
Calcium	Not collected	Not collected	140 (19.6)	139 (19.3)
Calcitonin (mialcalcin)	Not collected	Not collected	2 (0.3)	1 (0.1)
Vitamin D	Not collected	Not collected	165 (23.1)	160 (22.2)
Prior surgery to affected hip, n (%)	N = 535	N = 535	N = 714	N = 722
	0 (0)	3 (0.6)	2 (0.3)	1 (0.1)
Major comorbidities, n (%)	N = 537	N = 542	N = 715	N = 722
Osteopenia	Not collected	Not collected	28 (3.9)	30 (4.2)
Osteoporosis	19 (3.5)	14 (2.6)	114 (15.9)	110 (15.2)
Lung disease	103 (19.2)	87 (16.1)	127 (17.8)	122 (16.9)
Diabetes	79 (14.7)	82 (15.1)	135 (18.9)	145 (20.1)
Ulcers or stomach disease	81 (15.1)	68 (12.5)	49 (6.9)	67 (9.3)
Kidney disease	58 (10.8)	34 (6.3)	71 (9.9)	67 (9.3)

TABLE 2. (*Continued*) Patient Demographics in FAITH and HEALTH Trials

Characteristic	CS, n = 537	SHS, n = 542	THA, n = 718	HA, n = 723
Anemia or other blood disease	55 (10.2)	40 (7.4)	48 (6.7)	55 (7.6)
Depression	92 (17.1)	76 (14.0)	70 (9.8)	84 (11.6)
Cancer	63 (11.7)	59 (10.9)	65 (9.1)	80 (11.1)
Osteoarthritis, degenerative arthritis	121 (22.5)	160 (29.5)	111 (15.5)	91 (12.6)
Back pain	104 (19.4)	106 (19.6)	64 (9.0)	71 (9.9)
Rheumatoid arthritis	26 (4.8)	6 (1.1)	13 (1.8)	21 (2.9)
Heart disease	157 (29.2)	156 (28.8)	247 (34.6)	249 (34.5)
High blood pressure	276 (51.4)	281 (51.8)	434 (60.7)	443 (61.4)

BMI, body mass index; CS, cancellous screws; HA, hemiarthroplasty; NSAIDS, nonsteroidal anti-inflammatory drugs; SHS, sliding hip screw; THA, total hip arthroplasty.

patients in their late 70s and 80s and may not be generalizable to younger patients.[5] Likewise, our study reveals that the overall results of both the FAITH and HEALTH trials might be applicable to dissimilar age groups. The significantly lower age in the FAITH group would suggest that surgeons are more likely to consider or attempt internal fixation of displaced femoral neck fractures in younger healthy male subjects.

The patients enrolled in the HEALTH trial were more often White and less ethnically diverse than the FAITH patient population. The lack of diversity in patient enrollment for orthopaedic studies should not go unnoticed. A systematic review of orthopaedic randomized controlled trials published from 2008 to 2011 highlighted this trend.[10] Few orthopaedic randomized controlled trials performed in the United States reported information on patients' race or ethnicity. Among trials that reported demographic race/ethnicity data, the inclusion of minority patients was considerably lower than would be anticipated on the basis of census demographics. Failure to represent racial diversity may result in decreased generalizability of study conclusions across different populations. Bias against patients with dementia was also recently recognized as a concern because patients with dementia and hip fractures often get excluded from clinical trials. In the FAITH study, a total of 1690 patients were excluded, 22.2% (375/1690) due to dementia or cognitive impairment. In the HEALTH study, 36%

TABLE 3. Fracture Characteristics in FAITH and HEALTH Trials

Characteristic	CS, n = 537	SHS, n = 542	THA, n = 718	HA, n = 723
Fractured hip, n (%)	n = 535	n = 535	n = 715	n = 722
Left	281 (52.5)	280 (52.3)	386 (54.0)	386 (53.5)
Right	254 (47.5)	255 (47.7)	329 (46.0)	336 (46.5)
Level of the fracture line, n (%)	n = 536	n = 535	n = 715	n = 722
Subcapital	351 (65.5)	331 (61.9)	434 (60.7)	456 (63.2)
Midcervical	154 (28.7)	159 (29.7)	251 (35.1)	230 (31.9)
Basal	31 (5.8)	45 (8.4)	30 (4.2)	36 (5.0)
Garden classification, n (%)	n = 537	n = 542	n = 715	n = 722
Garden I (undisplaced)	277 (51.7)	257 (48.0)	N/A	N/A
Garden II (undisplaced)	92 (17.2)	99 (18.5)	N/A	N/A
Garden III (displaced)	128 (23.9)	121 (22.6)	311 (43.5)	320 (44.3)
Garden IV (displaced)	39 (7.3)	58 (10.8)	404 (56.5)	402 (55.7)
Pauwels' classification, n (%)	n = 536	n = 535	n = 714	n = 721
Type I	59 (11.0)	59 (11.0)	70 (9.8)	47 (6.5)
Type II	394 (73.5)	398 (74.4)	404 (56.6)	367 (50.9)
Type III	83 (15.5)	78 (14.6)	240 (33.6)	307 (42.6)
Mechanism of injury, n (%)	n = 534	n = 533	n = 715	n = 722
Fall from standing	521 (97.6)	515 (96.7)	696 (97.3)	700 (97.0)
Spontaneous fracture	6 (1.1)	13 (2.4)	16 (2.2)	14 (1.9)
Fall from small height	Not collected	Not collected	3 (0.4)	8 (1.1)
Other low energy trauma	7 (1.3)	5 (0.9)	Not collected	Not collected
Additional fractures or injuries, n (%)	n = 535	n = 535	n = 714	n = 722
	72 (13.5)	67 (12.5)	61 (8.5)	60 (8.3)

CS, cancellous screws; HA, Hemi-arthroplasty; SHS, sliding hip screw; THA, total hip arthroplasty.

TABLE 4. Demographics of Displaced Fracture Patients in FAITH and HEALTH Trials

Characteristic	CS, n = 167	SHS, n = 179	THA, n = 718	HA, n = 723
Age, mean (SD)	n = 166	n = 179	n = 718	n = 722
	66.1 (11.5)	67.7 (11.1)	79.1 (8.3)	78.6 (8.6)
Age, n (%)	n = 166	n = 179	n = 718	n = 722
50–70 y	107 (64.1)	111 (62.0)	136 (18.9)	149 (20.6)
71–80 y	41 (24.6)	42 (23.5)	249 (34.7)	247 (34.2)
≥81 y	18 (10.8)	26 (14.5)	333 (46.4)	326 (45.1)
Sex, n (%)	n = 166	n = 179	n = 718	n = 722
Male	92 (55.1)	98 (54.7)	208 (29.0)	223 (30.9)
Female	74 (44.3)	81 (45.3)	510 (71.0)	499 (69.1)
Ethnicity, n (%)	n = 166	n = 179	n = 716	n = 721
Indigenous	2 (1.2)	1 (0.6)	2 (0.3)	1 (0.1)
South Asian	40 (24.0)	41 (22.9)	3 (0.4)	6 (0.8)
East Asian	1 (0.6)	1 (0.6)	7 (1.0)	7 (1.0)
Hispanic/Latino	1 (0.6)	0 (0.0)	7 (1.0)	6 (0.8)
White	120 (71.9)	133 (74.3)	683 (95.4)	684 (94.9)
Black	2 (1.2)	3 (1.7)	12 (1.7)	15 (2.1)
Middle Eastern	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.3)
BMI (kg/m^2), n (%)	n = 164	n = 174	n = 697	n = 705
Underweight <18.5	7 (4.2)	8 (4.5)	35 (5.0)	38 (5.4)
Normal weight 18.5–24.9	85 (50.9)	90 (50.3)	357 (51.2)	336 (47.7)
Overweight 25–29.9	54 (32.3)	60 (33.5)	217 (31.1)	243 (34.5)
Obese 30–39.9	16 (9.6)	14 (7.8)	77 (11.1)	83 (11.8)
Morbidly obese ≥40	2 (1.2)	2 (1.1)	11 (1.6)	5 (0.7)
Pre-fracture living status, n (%)	n = 167	n = 179	n = 718	n = 723
Institutionalized	5 (3.0)	12 (6.7)	30 (4.2)	27 (3.7)
Not institutionalized	162 (97.0)	167 (93.3)	688 (95.8)	696 (96.3)
Pre-fracture functional status, n (%)	n = 167	n = 179	n = 718	n = 723
Use of Aid	18 (10.8)	30 (16.8)	187 (26.0)	182 (25.2)
Independent Ambulator	149 (89.2)	149 (83.2)	531 (74.0)	541 (74.8)
Current medications, n (%)	n = 166	n = 179	n = 715	n = 722
None	87 (52.1)	78 (43.6)	114 (15.9)	127 (17.6)
NSAIDs	17 (10.2)	37 (20.7)	91 (12.7)	90 (12.5)
Analgesics: Opioid	6 (3.6)	9 (5.0)	63 (8.8)	55 (7.6)
Glucocorticoids	Not collected	Not collected	26 (3.6)	23 (3.2)
Anabolic steroid therapy	Not collected	Not collected	3 (0.4)	1 (0.1)
Hormone replacement therapy	Not collected	Not collected	30 (4.2)	34 (4.7)
Bisphosphonates	Not collected	Not collected	50 (7.0)	47 (6.5)
Other osteoporosis medications	12 (7.2)	15 (8.4)	28 (3.9)	15 (2.1)
Anti-hypertension medications	65 (38.9)	70 (39.1)	407 (56.9)	402 (55.7)
Pulmonary (respiratory system) Medications	16 (9.6)	16 (8.9)	81 (11.3)	87 (12.1)
General cardiac medications	29 (17.4)	40 (22.3)	296 (41.4)	278 (38.5)
Calcium	Not collected	Not collected	140 (19.6)	139 (19.3)
Calcitonin (mialcalcin)	Not collected	Not collected	2 (0.3)	1 (0.1)
Vitamin D	Not collected	Not collected	165 (23.1)	160 (22.2)
Prior surgery to Affected hip, n (%)	n = 166	n = 179	n = 714	n = 722
	0 (0.0)	1 (0.6)	2 (0.3)	1 (0.1)
Major comorbidities, n (%)	n = 166	n = 179	n = 715	n = 722
Osteopenia	Not collected	Not collected	28 (3.9)	30 (4.2)
Osteoporosis	5 (3.0)	10 (5.6)	114 (15.9)	110 (15.2)
Lung disease	24 (14.4)	15 (8.4)	127 (17.8)	122 (16.9)
Diabetes	24 (14.4)	17 (9.5)	135 (18.9)	145 (20.1)
Ulcers or stomach disease	9 (5.4)	13 (7.3)	49 (6.9)	67 (9.3)
Kidney disease	7 (4.2)	6 (3.4)	71 (9.9)	67 (9.3)

TABLE 4. (*Continued*) Demographics of Displaced Fracture Patients in FAITH and HEALTH Trials

Characteristic	CS, n = 167	SHS, n = 179	THA, n = 718	HA, n = 723
Anemia or other blood disease	4 (2.4)	6 (3.4)	48 (6.7)	55 (7.6)
Depression	12 (7.2)	11 (6.1)	70 (9.8)	84 (11.6)
Cancer	7 (4.2)	7 (3.9)	65 (9.1)	80 (11.1)
Osteoarthritis, degenerative arthritis	6 (3.6)	11 (6.1)	111 (15.5)	91 (12.6)
Back pain	9 (5.4)	8 (4.5)	64 (9.0)	71 (9.9)
Rheumatoid arthritis	5 (3.0)	1 (0.6)	13 (1.8)	21 (2.9)
Heart disease	28 (16.8)	31 (17.3)	247 (34.6)	249 (34.5)
High blood pressure	68 (40.7)	72 (40.2)	434 (60.7)	443 (61.4)

BMI, body mass index; CS, cancellous screws; HA, hemiarthroplasty; NSAIDS, nonsteroidal anti-inflammatory drugs; SHS, sliding hip screw; THA, total hip arthroplasty.

(207/575) of the excluded patients were not enrolled due to dementia/cognitive impairment.[11]

A limitation of this study is that not all demographic-, comorbidity-, and injury-related data between studies could be compared to avoid performing multiple comparisons. Therefore, there are likely other patient characteristics that may be significantly different between the studies that may not have been identified. Furthermore, the FAITH and HEALTH trials were never designed for intertrial comparisons. There were some differences in the eligibility criteria for each trial, and although similar data were collected, the 2 trials were not meant to be compared. Statistical differences between variables could therefore be misleading. Finally, we are unsure how prevalent discordant patient enrollment is between randomized trials evaluating the same injury in orthopaedics.

In conclusion, our study highlights the discrepancy in patient enrollment of 2 large multicenter prospective randomized control trials evaluating the surgical treatment of low-energy femoral neck fractures, despite using similar inclusion and exclusion criteria. The patients in the FAITH trial with displaced femoral neck fractures that were treated with internal fixation were younger, healthier male subjects with lower rates of osteoporosis compared with the HEALTH trial patients treated with arthroplasty. These limitations must be considered when selecting internal fixation or arthroplasty for low-energy hip fracture patients aged 50 years and older. This study highlights an opportunity to form greater investigator agreement on universal study inclusion and exclusion criteria. Leaving this at the discretion of each individual surgeon or investigator may introduce subtle enrollment bias, and greater

TABLE 5. Fracture Characteristics of Displaced Fracture Patients in FAITH and HEALTH Trials

Characteristic	CS, n = 167	SHS, n = 179	THA, n = 718	HA, n = 723
Fractured hip, n (%)	n = 167	n = 179	n = 715	n = 722
Left	91 (54.5)	103 (57.5)	386 (54.0)	386 (53.5)
Right	75 (44.9)	76 (42.5)	329 (46.0)	336 (46.5)
Level of the fracture line, n (%)	n = 167	n = 179	n = 715	n = 722
Subcapital	61 (36.5)	74 (41.3)	434 (60.7)	456 (63.2)
Midcervical	86 (51.5)	87 (48.6)	251 (35.1)	230 (31.9)
Basal	19 (11.4)	18 (10.1)	30 (4.2)	36 (5.0)
Garden classification, n (%)	n = 167	n = 179	n = 715	n = 722
Garden III (displaced)	128 (76.6)	121 (67.6)	311 (43.5)	320 (44.3)
Garden IV (displaced)	39 (23.4)	58 (32.4)	404 (56.5)	402 (55.7)
Pauwels' classification, n (%)	n = 167	n = 179	n = 714	n = 721
Type I	10 (6.0)	10 (5.6)	70 (9.8)	47 (6.5)
Type II	91 (54.5)	101 (56.4)	404 (56.6)	367 (50.9)
Type III	65 (38.9)	68 (38.0)	240 (33.6)	307 (42.6)
Mechanism of injury, n (%)	n = 167	n = 179	n = 715	n = 722
Fall from standing	162 (97.0)	170 (95.0)	696 (97.3)	700 (97.0)
Spontaneous fracture	1 (0.6)	6 (3.4)	16 (2.2)	14 (1.9)
Fall from small height	Not collected	Not collected	3 (0.4)	8 (1.1)
Other low energy trauma	3 (1.8)	3 (1.7)	Not collected	Not collected
Additional fractures or injuries, n (%)	n = 167	n = 179	n = 714	n = 722
	12 (7.2)	9 (5.0)	61 (8.5)	60 (8.3)

CS, cancellous screws; HA, hemiarthroplasty; SHS, sliding hip screw; THA, total hip arthroplasty.

TABLE 6. Comparison of Baseline Characteristics in FAITH and HEALTH Trial Displaced Fracture Patients

Characteristic	FAITH, n = 346	HEALTH, n = 1441	*P**
Age, mean (SD)	n = 346	n = 1440	<0.001
	66.9 (11.3)	78.8 (8.4)	
Sex, n (%)	n = 345	n = 1440	<0.001
Male	190 (54.9)	431 (29.9)	
Female	155 (44.8)	1009 (70.1)	
ASA classification, n (%)	n = 346	n = 1441	<0.001
Class I/II	274 (79.2)	652 (45.2)	
Class III/IV/V	72 (20.8)	789 (54.8)	
Osteoporosis, n (%)	n = 346	n = 1441	<0.001
	15 (4.3)	224 (15.6)	

*P-values calculated by t-tests and χ^2 tests.
ASA, American Society of Anesthesiologists.

focus on this aspect of study design is needed. A possible concern, however, would be that the narrower the study inclusion criteria, the less generalizable the results would be, especially when attempting to apply the clinical findings worldwide. Future work should be directed at the prevention of study enrollment selection bias by limiting the ability to exclude patients based on surgeon opinion, especially when treatment equipoise exists.

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