Study Summaries

FAITH Investigators and HEALTH Investigators

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SUPPLEMENT STUDY SUMMARIES

This supplement titled, "Outcomes After Hip Fractures: Secondary Analyses From the HEALTH and FAITH Trials" includes the manuscripts for 12 preplanned secondary analyses that use data from 2 large multicenter randomized controlled trials of older hip fracture patients. Please see below for a summary of each trial and their findings.

FAITH STUDY OVERVIEW

The FAITH (fracture fixation in the operative management of hip fractures) trial was a multicenter randomized controlled trial comparing the intervention of cancellous screws with a sliding hip screw in 1079 patients 50 years of age or older with a low energy displaced or undisplaced femoral neck fracture. Patients were enrolled from 81 clinical sites in the United States, Canada, Australia, the Netherlands, Norway, Germany, the United Kingdom, and India and 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 unplanned revision surgery within 24 months of femoral neck fracture to promote fracture healing, relieve pain, treat infection, or improve function. The secondary outcomes were to determine the impact of a sliding hip screw versus cancellous screws on health-related quality of life, functional outcomes, health state utilities, fracture healing, mortality, and other adverse events, such as avascular necrosis, nonunion, malunion, implant breakage or failure, and infection.[1] Unplanned revision surgery within 24 months did not differ by type of surgical fixation as follows: 107 of 542 patients (20%) in the sliding hip screw group versus 117 of 537 patients (22%) in the cancellous screws group (hazard ratio [HR] 0.83, 95% confidence interval [CI] 0.63–1.09; $P = 0.18$). Health-related quality of life, functional outcomes, health state utilities, fracture healing, and mortality also did not differ between groups ($P > 0.05$). Avascular necrosis was more common in the sliding hip screw group as compared to the cancellous screws group (HR 1.91, 1.06–3.44; $P = 0.0319$). However, no significant difference was found between the number of medically related adverse events between groups ($P = 0.82$).[2] The FAITH trial was registered on ClinicalTrials.gov (NCT00761813) and approved by the Hamilton Integrated Research Ethics Board (#06-402) as well as by all participating clinical sites' Research Ethics Boards/Institutional Review Boards. The protocol has been previously published[1] as well as the primary study results.[2]

HEALTH STUDY OVERVIEW

The HEALTH (hip fracture evaluations with alternatives of total hip arthroplasty vs. hemiarthroplasty) trial was a 1441-patient multicenter randomized controlled trial comparing the intervention of total hip arthroplasty with hemiarthroplasty in patients 50 years of age or older with low energy displaced femoral neck fractures. Patients were enrolled from 80 clinical sites in the United States, Canada, Australia, New Zealand, Finland, the Netherlands, Norway, Spain, the United Kingdom, and South Africa. The primary outcome was unplanned revision surgery within 24 months of the femoral neck fracture. Secondary outcomes included death, serious adverse events, hip-related complications, health-related quality of life, function, and overall health end points.[3] Unplanned revision surgery within 24 months did not differ between treatment groups as follows: 57 of 718 patients (7.9%) who had been randomly assigned to total hip arthroplasty versus 60 of 723 patients (8.3%) who had been randomly assigned to hemiarthroplasty (HR 0.95, 95% CI 0.64–1.40; $P = 0.79$). Hip instability or dislocation occurred in 34 patients (4.7%) assigned to total hip arthroplasty and 17 patients (2.4%) assigned to hemiarthroplasty (HR, 2.00; 99% CI, 0.97–4.09). Function, as measured with the

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total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score, pain score, stiffness score, and function score, modestly favored total hip arthroplasty over hemiarthroplasty. Death and serious adverse events were similar between groups ($P > 0.05$).[4] The trial was registered on ClinicalTrials.gov (NCT00556842) and approved by the Hamilton Integrated Research Ethics Board (#06-151) as well as by all participating clinical sites' Research Ethics Boards/Institutional Review Boards. The protocol has been previously published[3] as well as the primary study results.[4]

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REFERENCES

1. FAITH Investigators. Fixation using alternative implants for the treatment of hip fractures (FAITH): design and rationale for a multi-centre randomized trial comparing sliding hip screws and cancellous screws on revision surgery rates and quality of life in the treatment of f. *BMC Musculoskelet Disord.* 2014;15:219.
2. Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH) Investigators. Fracture fixation in the operative management of hip fractures (FAITH): an international, multicentre, randomised controlled trial. *Lancet* 2017;389:1519–1527.
3. Bhandari M, Devereaux PJ, Einhorn TA, et al. Hip fracture evaluation with alternatives of total hip arthroplasty versus hemiarthroplasty (HEALTH): protocol for a multicentre randomised trial. *BMJ Open* 2015;5:e006263.
4. HEALTH Investigators, Bhandari M, Einhorn TA, et al. Total hip arthroplasty or hemiarthroplasty for hip fracture. *N Engl J Med.* 2019;381:2199–2208.