Is Total Hip Arthroplasty a Cost-Effective Option for Management of Displaced Femoral Neck Fractures? A Trial-Based Analysis of the HEALTH Study

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Background: Displaced femoral neck fractures are a significant source of morbidity and mortality and can be treated with either hemiarthroplasty (HA) or total hip arthroplasty (THA). Proponents of THA have argued THA offers lower risk of revision, with improved functional outcomes when compared to HA. To evaluate cost effectiveness of THA compared with HA, a trial-based economic analysis of the HEALTH study was undertaken.

Methods: Health care resource utilization (HRU) and health-related quality of life (HRQoL) data were collected postoperatively and costed using publicly available databases. Using EuroQol-5 Dimensions (EQ-5D) scores, we derived quality adjusted life years (QALYs). A 1.5% discount rate to both costs and QALYs was applied. Age analyses per age group were conducted. All costs are reported in 2019 Canadian dollars.

Results: When compared with HA, THA was not cost-effective for all patients with displaced femoral neck fractures (\$150,000/QALY gained). If decision makers were willing to spend \$50,000 or

\$100,000 to gain one QALY, the probability of THA being costeffective was 12.8% and 32.8%, respectively. In a subgroup of patients younger than 73 (first quartile), THA was both more effective and less costly. Otherwise, THA was more expensive and yielded marginal HRQoL gains.

Conclusions: Our results suggest that for most patients, THA is not a cost-effective treatment for displaced femoral neck fracture management versus HA. However, THA may be cost effective for younger patients. These patients experience more meaningful improvements in quality of life with less associated cost because of shorter hospital stay and fewer postoperative complications.

Key Words: economic evaluation, displaced femoral neck fracture, total hip arthroplasty, hemiarthroplasty

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

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INTRODUCTION

Hip fractures are the most common injury suffered by the elderly and contribute substantial morbidity to these patients, who often have multiple pre-existing comorbidities and are frail.¹ Moreover, the mortality associated with hip fractures approaches 25% for all patients.² The burden of these injuries—in both human and economic terms—is substantial. Up to 10 percent of patients with these injuries will require a secondary operation, thus multiplying the economic impact of these injuries.³ These revision surgeries range from 2 to 3 and half times more costly than the primary procedure.³

For displaced femoral neck fractures, both partial joint replacement of the hip (hemiarthroplasty, HA) and total joint replacement [total hip arthroplasty (THA)], are considered standard of care in the elderly.⁴ Those who have argued for HA suggest that it represents a less morbid, less expensive and noninferior treatment option to THA. Those who argue for THA believe it yields fewer reoperations, and affords better quality of life, similar to patients who receive THA for osteoarthritis.⁵

A recent meta-analysis suggested that THA for femoral neck fractures did meaningfully improve quality of life for patients while reducing unplanned reoperations.⁴ However, the meta-analysis was dependent on small, underpowered clinical trials with non-standardized adjudication of outcomes. Moreover, issues of confounding due to expertise bias were pervasive in all studies. Ultimately, even after multiple studies and meta-analyses,^{3,4,6} there remains uncertainty regarding the best treatment for displaced femoral neck fractures in the elderly.

To address this issue, a multi-national, multi-center expertise-based randomized controlled trial termed the Hip Fracture Evaluation With Alternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty (HEALTH) trial⁷ was performed. The HEALTH study did not find any clinically meaningful differences in either rate of unplanned reoperations or health utility when comparing THA to HA. At the same time that the main trial was undertaken, relevant health care utilization data was also collected to facilitate an economic evaluation to inform health care policy leaders and key stakeholders in this domain. In this study, we report on the results of these economic findings through a trial based economic analysis.

METHODS

Study Design and Participants

The study design and clinical results of the HEALTH trial are described elsewhere.⁷ Health care resource utilization and health-related quality of life [EuroQol Five-Dimension (EQ-5D)] information were collected during follow-up visits at 6, 12, 24, 38, and 52 weeks, and at 18 and 24 months.

Health Care Resource Utilization

A case report form was completed for each follow-up visit to collect information on health-related quality of life, secondary procedures, serious adverse events, physiotherapy visits and hospital readmissions. As the frequency of care was not captured for physiotherapy, we assumed that patients would use 7 physiotherapy visits.

The unit costs of secondary procedures were derived from a patient cost estimator from the Canadian Institute of Health Information.⁸ The patient cost estimator is an initiative which is informed by costing data submitted from all provinces across Canada, with the exception of Quebec. In addition, costs can be specified by province and by patient age. For the purpose of this analysis, all cost estimates were taken from the perspective of the Ontario health care system. Unit costs of implants were taken from costing inventory at Hamilton General Hospital in Hamilton, Ontario.

We assumed the hourly rate for provincially covered physiotherapy was \$120.⁹ Unit costs used in this economic evaluation are presented in **Supplemental Digital Content 1** (see **Appendix 1**, http://links.lww.com/JOT/B211). All costs are stated in 2019 Canadian dollars.

Health-Related Quality of Life and QALYs

Although both the Short Form-12 (SF-12) and the EQ-5D-5L questionnaires were collected in the HEALTH study, the economic results were derived from the EQ-5D, as this instrument most easily allows the calculation of a health utility score, necessary to calculate quality-adjusted life years (QALYs) and is validated for use in this population.¹⁰ QALYs combine quantity of life with health-related quality of life and are used in cost-utility analyses to compare outcomes between interventions.

The EQ-5D measures health-related quality of life in 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with 3 levels of scoring per attribute. Using a scoring algorithm, the individual responses to each of the domains are transformed into a health utility score where 0 represents death and 1 the best imaginable health state. The minimal important difference for the EQ-5D was set at 0.05.¹¹ QALYs were calculated for each intervention by weighting the utility scores by time spent in health states using an area under the curve approach.

Cost-Effectiveness Analyses

Utilizing a trial-based cost-effectiveness approach following good practice guidelines,^{12,13} use of THA versus HA was assessed in incremental cost per QALY gained. Overall costs and outcomes were first evaluated to determine if either strategy was dominant (both less costly and better quality of life). If neither strategy was found to be dominant, incremental cost-effectiveness ratios (ICERs) were estimated by calculating the difference in cost between THA and HA divided by the difference in their effect (ie, QALYs). Uncertainty regarding costs and effects due to sampling variability associated with the trial was measured using nonparametric bootstrapping techniques.¹⁴

The bootstrapping technique entails drawing a random sample from the original dataset (with replacement) and then calculating the mean costs and effects associated with each treatment group (ie, THA and HA). The sampling process was repeated 2000 times to create a sampling distribution and generate means, SEs, and 95% confidence intervals (CIs) for the incremental costs, incremental QALYs, and ICERs. Cost-

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	THA	HA	Difference	
	(N = 718)	(N = 723)		
	Mean (SE)	Mean (SE)	Mean (95% CI)	Р
Device	\$1789	\$925		
Initial procedure cost	\$16,756 (\$1220)	\$15,732 (\$840)	\$1024 (-\$1880 to \$3928)	0.10
Physiotherapy	\$592 (\$10.3)	\$596 (\$10.1)	\$4 (-\$23 to \$33)	0.74
Costs from adverse events	\$9469 (\$1100)	\$7933 (\$919)	\$1536 (-\$1274 to \$4346)	0.28
Costs from second procedures	\$4231 (\$1083)	\$2541 (\$526)	\$1690 (-\$666 to \$4047)	0.16
Payer perspective	\$32,851 (\$2368)	\$27,358 (\$1513)	\$5493 (-\$14 to \$11,000)	0.06

effectiveness acceptability curves (CEACs) were used to present the probability of THA to be cost effective at different willingness-to-pay thresholds (ie, \$50,000/QALY gained or \$100,000/QALY gained—2 commonly cited costeffectiveness thresholds) while taking into account the uncertainty associated with the trial data.¹⁵ Analyses were conducted from a public payer and societal perspective over a 2-year time horizon. Both costs and QALYs collected after one year were discounted at 1.5% per year, as per Canadian Agency for Drug and Technologies in Health (CADTH) guidelines, to indicate that either a single OALY or amount of cost was more valuable now than in one year's time.¹⁶

Sensitivity and Subgroup Analyses

Multiple sensitivity analyses were planned. First, we planned to assess the impact of change in discount rate, varying from 0% to 1.5% (base case) to 3%. In addition, we performed a sensitivity analysis evaluating the difference in ICERs using a multiple imputation model (base case) and list-case deletion. Moreover, a sensitivity analysis was planned to modify the cost of the technology (THA) by 30% in either direction, as recommended by CADTH.¹⁶ Finally, we performed a sensitivity analysis with changing mortality rates per group if mortality rates were found to be meaningfully different between THA and HA. We also performed a posthoc subgroup analysis by age quartile, hypothesizing that THA would be most cost effective for younger quartiles. This analysis mirrors a similar age stratified analysis performed for the main HEALTH trial.

RESULTS

Similar to the results of the clinical trial, there were no clinically meaningful differences between the 2 treatment groups in unplanned reoperation or health utility (Table 1).

The costs from the single payer perspective were estimated to be \$32,851 per patient (SE = \$2368) for THA and \$27,358 (SE = \$2781) for HA. The total number of QALYs estimated using the EQ-5D score over the two-year time horizon was 1.40 (SE = 0.02) for THA and 1.36 (SE = 0.019) for HA. The difference of 0.04 QALYs (95% CI: -0.01 to 0.11) was not significantly different. The resulting ICER of THA compared with HA for the treatment of patients

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with displaced femoral neck fractures was calculated at \$151,640/QALY gained (Fig. 1). Table 2 presents these results.

Our sensitivity analyses produced similar results. When either a 0% or 3% discount rate was applied to both costs and QALYs at one year, the ICERs did not meaningfully change. Finally, when comparing imputed to not imputed EQ-5D values, EQ-5D scores each decreased by 0.01 points for both THA and HA, yielding no change in the difference in EQ-5D scores. In addition, neither decreasing nor increasing the cost of THA by 30% yielded meaningful differences in ICERs, because implant costs only represented 10% of total costs per patient.

Finally, a subgroup analysis by age quartile was performed. For patients younger than 73 (first quartile), THA was both less expensive (-\$3693) and provided more health utility (0.10 QALYs). In contrast, for all other age quartiles, HA provided similar utility at a reduced cost (Table 3).

The CEACs curves presented in Fig. 2 indicate that when compared with HA, the probability of THA being cost-effective for treating operatively managed displaced femoral neck fractures was 12.8% and 32.8%, if decision makers



FIGURE 1. Cost-effectiveness plane. **Editor's Note**: A color image accompanies the online version of this article.

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	Cost Mean (95% CI)			QALYs Mean (95% CI)			ICER
	ТНА	НА	Δ Cost	ТНА	НА	Δ QALYs	\$/QALY Gained
All patients $(N = 1441)$	\$32,851 (\$5275-\$194,033)	\$27,358 (\$5211-\$144,953)	\$5493	1.40 (0–1.97)	1.36 (0–1.97)	0.04 (-0.01 to 0.09)	\$151,640

were willing to spend \$50,000 or \$100,000 to gain one QALY, respectively.

DISCUSSION

To the authors knowledge, this is the most up-to-date contemporary trial-based economic evaluation comparing THA versus HA in elderly patients with displaced femoral neck fractures. Previous studies have concluded, similar to our study, that THA is likely not a cost effective option in the majority of patients who suffer femoral neck fractures.^{17,18} Consistent with the results of the HEALTH trial and other systematic reviews, we did not observe any clinically significant differences in either reoperation or health-related quality of life by treatment group. Moreover, through a methodologically rigorous trial-based evaluation, we were able to assess whether or not THA was a cost-effective intervention and under what circumstances the treatment may be cost acceptable.

At both \$50,000 and \$100,000 willingness to pay thresholds, our cost effectiveness analysis revealed that compared with HA, THA is not likely to be a cost-effective intervention for all patients with displaced femoral neck fractures. Moreover, in no sensitivity analysis did THA represent a cost-effective intervention. However, in subgroup analysis, for patients younger than 73 (the youngest quartile), THA was a cost-effective intervention, because they received more QALYs for less estimated cost. In contrast, for all other age quartiles, THA was more expensive and did not provide more quality of life. Younger patients may be able to mobilize quicker with a THA as compared to the eldest cohort, reducing the comparative additional cost to HA. Moreover, younger patients may notice and appreciate the increased mobility offered from a THA, leading to higher health-related quality of life.

Although previous economic evaluations have been conducted comparing THA to HA, these were either performed using model approaches with significant assumptions or trial-based approaches using small trials.^{18,19} In a

recent meta-analysis including the HEALTH trial, the HEALTH trial contributed more than 50% of all patients to ever be evaluated in a randomized controlled trial comparing THA to HA.⁵ The dominance of this trial, in both sample size and methodologic rigor, necessitates that it be evaluated as a separate entity and through a single trial-based analysis.

Our study has a number of strengths and some limitations. As described above, the primary strength is that our evaluation is based on a multi-national, rigorously-conducted prospective randomized controlled trial which is the largest ever in its field. As is true of all trial-based analyses, using measured outcomes from patients rather than using modeling practices reduces the number of assumptions on both costs and utility. In addition, through using a standard discount rate, performing bootstrapping techniques for sampling uncertainty, and conducting multiple sensitivity analyses determined a priori, we have adhered to good practice guidelines for trial based economic evaluations.^{13,16} In addition, the use of CEACs easily illustrate the likelihood of THA to be cost-effective at given willingness to pay thresholds.

A notable limitation of our economic evaluation is that cost and health-related quality of life data were not available for all patients. Even though EQ-5D scores were absent for only approximately 8% of observations, relevant cost data such as medication use and return to work parameters were not collected throughout the trial. For missing health-related quality of life data, multiple imputation techniques were used to generate complete data sets, and subsequent sensitivity analyses were performed to generate confidence in these estimates. Regarding return to work, the mean age of patients enrolled in this trial was 79 years (± 8 years) and thus patients would be unlikely to be employed before their injury and to return to work, regardless of intervention.²⁰ Moreover, costing data, in particular for orthopedic secondary procedures, was often not sufficiently specific (eg, all revisions without infections were costed the same). However, the major cost driver for these events was length of stay during hospital readmission and, therefore, the severity of the event was more

TABLE 3. Subgroup Analysis of Cost Effectiveness by Age Quartile								
	Cost Mean			QALYs Mean				
	THA	HA	Δ Cost	ТНА	HA	Δ QALYs	ICER \$/QALY Gained	
Age <73	\$24,156	\$27,849	-\$3693	1.54	1.44	0.10	-\$38,175 (dominated)	
Age 73–79	\$42,441	\$26,500	\$15,941	1.48	1.45	0.03	\$574,220	
Age 80–84	\$32,709	\$21,947	\$10,762	1.31	1.32	-0.01	-\$789,066 (dominated)	
Age 85 and older	\$31,918	\$31,978	\$-60	1.28	1.22	0.06	-\$1072 (dominated)	

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FIGURE 2. Cost-effectiveness acceptability curves. **Editor's Note**: A color image accompanies the online version of this article.

accurately captured in costing analysis. Another limitation of this analysis is the 2-year duration of the HEALTH study. It is possible that with 2 years of follow-up, all possible costs and outcomes following surgery may not have been accounted for. In particular, it may take over 2 years for acetabular deterioration from a hemiarthroplasty to occur and to require revision. However, the best available data suggest that health outcomes following hip fractures take 2 years to stabilize (including rate of revision operations and functional outcomes).²¹

Our analysis provides further evidence as to the cost effectiveness of THA in the treatment of patients with displaced femoral neck fractures. We found no meaningful differences in health-related quality of life between THA and HA, whereas THA cost over \$5000 more per patient. However, for the youngest cohort of patients, THA was found to provide meaningful clinical benefit and at less cost. The cost effectiveness of THA for femoral neck fractures should be further evaluated prospectively and may justify reimbursement of the technology for this patient group. The results of this trial, although most applicable to the single payer health care system in Ontario, Canada, may be useful in informing health policy decisions internationally.

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REFERENCES

 Rapp K, Büchele G, Dreinhöfer K, et al. Epidemiology of hip fractures. Z Gerontol Geriatr. 2019;52:10–16.

- Veronese N, Maggi S. Epidemiology and social costs of hip fracture. *Injury*. 2018;49:1458–1460.
- Reeves RA, Schairer WW, Jevsevar DS. The national burden of periprosthetic hip fractures in the US: costs and risk factors for hospital readmission. *Hip Int.* 2019;29:550–557.
- Lewis DP, Wæver D, Thorninger R, et al. Hemiarthroplasty vs total hip arthroplasty for the management of displaced neck of femur fractures: a systematic review and meta-analysis. *J Arthroplasty*. 2019;34:1837–1843.e2.
- Ekthiari S, Gormly J, Axelrod D, et al. Total hip arthroplasty versus hemiarthroplasty for displaced femoral neck fracture: a systematic review and meta-analysis of randomized controlled trials. J Bone Joint Surg Am. 2020
- Carroll C, Stevenson M, Scope A, et al. Hemiarthroplasty and total hip arthroplasty for treating primary intracapsular fracture of the hip: a systematic review and cost-effectiveness analysis. In: *NIHR Health Technology Assessment Programme: Executive Summaries*. NIHR Journals Library; 2011;102(18),1638–1645.
- HEALTH Investigators, Bhandari M, Einhorn TA, Guyatt G, et al. Total hip arthroplasty or hemiarthroplasty for hip fracture. *N Engl J Med.* 2019; 381:2199–2208.
- Canadian Institute of Health Intitatives. *CIHI Patient Cost Estimator* [Internet]. 2020. Available at: https://www.cihi.ca/en/patient-costestimator. Accessed March 20, 2020.
- Province of Ontario. *Physiotherapy Reimbursement [Internet]*. 2019. Available at: http://www.health.gov.on.ca/en/pro/programs/physio/ physio_pro_doctors_nurses.aspx. Accessed March 20, 2020.
- Parsons N, Griffin XL, Achten J, et al. Outcome assessment after hip fracture: is EQ-5D the answer? *Bone Joint Res.* 2014;3:69–75.
- McClure NS, Al Sayah F, Xie F, et al. Instrument-defined estimates of the minimally important difference for EQ-5D-5L index scores. *Value Heal.* 2017;20:644–650.
- Ramsey SD, Willke RJ, Glick H, et al. Cost-effectiveness analysis alongside clinical trials II—an ISPOR good research practices task force report. *Value Heal*. 2015;18:161–172.
- Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS) statement. *BMJ*. 2013; 346:f1049–1055.
- Hunink MGM, Bult JR, De Vries J, et al. Uncertainty in decision models analyzing cost-effectiveness: the joint distribution of incremental costs and effectiveness evaluated with a nonparametric bootstrap method. *Med Decis Mak.* 1998;18:337–346.
- Woods B, Revill P, Sculpher M, et al. Country-level cost-effectiveness thresholds: initial estimates and the need for further research. *Value Heal*. 2016;19:929–935.
- Canadian Agency for Drugs and Technologies in Health. Guidelines for the Economic Evaluation of Health Technologies: Canada. 3rd ed. Ottawa, ON; 2006.
- Burgers PT, Hoogendoorn M, Van Woensel EAC, et al. Total medical costs of treating femoral neck fracture patients with hemi- or total hip arthroplasty: a cost analysis of a multicenter prospective study. *Osteoporos Int.* 2016;27:1999–2008.
- Slover J, Hoffman MV, Malchau H, et al. A cost-effectiveness analysis of the arthroplasty options for displaced femoral neck fractures in the active, healthy, elderly population. *J Arthroplasty.* 2009;24:854–860.
- Healy WL, Iorio R. Total hip arthroplasty: optimal treatment for displaced femoral neck fractures in elderly patients. *Clin Orthop Relat Res.* 2004;429:43–48.
- Statistics Canada. Labour Force Characteristics by Sex and Detailed Age Group, Annual, Inactive (X 1,000) [Internet]. 2019. Available at: https://www150.statcan. gc.ca/t1/tb11/en/tv.action?pid=1410001701. Accessed March 15, 2020.
- Ravikumar KJ, Marsh G. Internal fixation versus hemiarthroplasty versus total hip arthroplasty for displaced subcapital fractures of femur–13 year results of a prospective randomised study. *Injury*. 2000;31:793–797.

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