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HIP

Is the use of bipolar hemiarthroplasty over monopolar hemiarthroplasty justified? A propensity score-weighted analysis of a multicentre randomized controlled trial

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Aims

Using data from the Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemiarthroplasty (HEALTH) trial, we sought to determine if a difference in functional outcomes exists between monopolar and bipolar hemiarthroplasty (HA).

Methods

This study is a secondary analysis of patients aged 50 years or older with a displaced femoral neck fracture who were enrolled in the HEALTH trial and underwent monopolar and bipolar HA. Scores from the Western Ontario and McMaster University Arthritis Index (WOMAC) and 12-Item Short Form Health Survey (SF-12) Physical Component Summary (PCS) and (MCS) were compared between the two HA groups using a propensity score-weighted analysis.

Results

Of 746 HAs performed in the HEALTH trial, 404 were bipolar prostheses and 342 were unipolar. After propensity score weighting, adequate balance between the bipolar and unipolar groups was obtained as shown by standardized mean differences less than 0.1 for each covariable. A total of 24 months after HA, the total WOMAC score and its subcomponents showed no statistically significant difference between the unipolar and bipolar groups. Similarly, no statistically significant difference was found in the PCS and MCS scores of the SF-12 questionnaire. In participants aged 70 years and younger, no difference was found in any of the functional outcomes.

Conclusion

From the results of this study, the use of bipolar HA over unipolar design does not provide superior functional outcomes at 24 months postoperatively. The theoretical advantage of reduced acetabular wear with bipolar designs does not appear to influence functional outcomes in the first two years postoperatively.

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Introduction

Hip hemiarthroplasty (HA) for treatment of displaced femoral neck fracture provides satisfactory and predictable results in the elderly population.[1] Despite a relative lack of evidence, bipolar hemiarthroplasty (BH) has been increasingly used over unipolar hemiarthroplasty (UH).[2] BH designs remain more expensive than UH, the two-articulation implant cost has been estimated at US$3,926, compared to US$2,869 for the unipolar design.[3] Considering rising healthcare costs, it is necessary to adopt an evidenced-based approach that is also cost-responsible. The driving argument for the use of bipolar designs is based on the theoretical benefit of reduced shear force at the prosthetic-joint surface interface,[4] and thus,

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Table I. Variability in the use of monopolar and bipolar hemiarthroplasties for treatment of displaced femoral neck fractures as part of the HEALTH trial.

	Hemiarthroplasty		
Variable	**Monopolar (n = 342)**	**Bipolar (n = 404)**	**Total (n = 746)**
Procedure performed by country, n (%)			
Canada	57 (16.7)	129 (31.9)	186 (24.9)
The Netherlands	104 (30.4)	4 (1)	108 (14.5)
USA	64 (18.7)	52 (12.9)	116 (15.5)
Australia	30 (8.8)	13 (3.2)	43 (5.8)
Norway	0 (0.0)	86 (21.3)	86 (11.5)
Spain	9 (2.6)	101 (25)	110 (14.7)
UK	50 (14.6)	16 (4.0)	66 (8.8)
Finland	24 (7)	0 (0.0)	24 (3.2)
New Zealand	4 (1.2)	0 (0.0)	4 (0.5)
South Africa	0 (0.0)	3 (0.7)	3 (0.4)
Procedure performed by province in Canada, n (%)	**n = 57**	**n = 129**	**n = 186**
Alberta	41 (71.9)	6 (1.5)	47 (6.3)
British Columbia	3 (5.3)	46 (11.4)	49 (6.6)
Newfoundland	0 (0)	6 (1.5)	6 (0.8)
Nova Scotia	0 (0)	6 (1.5)	6 (0.8)
Ontario	10 (17.5)	45 (11.1)	55 (7.4)
Quebec	3 (5.3)	20 (5.0)	23 (3.1)
Procedure performed by state in the USA, n (%)	**n = 64**	**n = 52**	**n = 116**
Arizona	8 (12.5)	0 (0.0)	8 (6.9)
California	0 (0)	2 (3.8)	2 (1.7)
Colorado	0 (0)	4 (7.7)	4 (3.4)
Indianapolis	3 (4.7)	7 (13.5)	10 (8.6)
Maryland	0 (0)	2 (3.8)	2 (1.7)
Massachusetts	12 (18.8)	2 (3.8)	14 (12.1)
Michigan	9 (14.1)	0 (0)	9 (7.8)
Minnesota	2 (3.1)	12 (23.1)	14 (12.1)
Mississippi	0 (0)	4 (7.7)	4 (3.4)
New Jersey	8 (12.5)	0 (0.0)	8 (6.9)
New York	11 (17.2)	0 (0)	11 (9.5)
North Carolina	4 (6.3)	3 (5.8)	7 (6)
Ohio	0 (0)	1 (1.9)	1 (0.9)
Pennsylvania	5 (7.8)	2 (3.8)	7 (6)
Texas	1 (1.6)	0 (0)	1 (0.9)
Utah	1 (1.6)	0 (0)	1 (0.9)
West Virginia	0 (0)	13 (25)	13 (11.2)
Femoral stem implant company, n (%)			
Stryker	110 (32.2)	197 (48.8)	307 (41.2)
DePuy	72 (21.1)	22 (5.4)	94 (12.6)
Smith & Nephew	56 (16.4)	38 (9.4)	94 (12.6)
Biomet	16 (4.7)	22 (5.4)	38 (5.1)
Zimmer	49 (14.3)	61 (15.1)	110 (14.7)
Other	39 (11.4)	64 (15.8)	103 (13.8)
Surgical approach, n (%)	**n = 341**		**n = 745**
Direct anterior and anteromedial	8 (2.3)	5 (1.2)	13 (1.7)
Anterolateral/lateral	259 (76)	264 (65.3)	523 (70.2)
Posterior/posterolateral	74 (21.7)	135 (33.4)	209 (28.1)
Mean length of procedure, mins (SD)	74.0 (43.9)	86.9 (41.2)	81.1 (42.9)
Who performed majority of procedure, n (%)			
Attending	208 (60.8)	226 (55.9)	434 (58.2)
Fellow	40 (11.7)	37 (9.2)	77 (10.3)
Resident	94 (27.5)	141 (34.9)	235 (31.5)

SD, standard deviation.

Table II. Baseline characteristics of covariates used in propensity score weighting for comparison of monopolar to bipolar hemiarthroplasty for WOMAC model.

Variable	Before propensity score weighting			After propensity score weighting		
	UH (n = 161)	BH (n = 197)	SMD	UH (n = 112)	BH (n = 163)	SMD
Mean age, yrs (SD)	78.4 (8)	78.2 (7.7)	-0.02	77.7 (8.1)	78.3 (7.9)	0.07
Male sex, %	28.0	24.4	-0.08	26.8	26.6	-0.004
Mean BMI, kg/m^2 (SD)	25.1 (4.6)	25 (4.5)	-0.03	25 (4.5)	25 (4.5)	-0.02
ASA classification III-IV, %	39.8	56.4	0.34	49.4	48.1	-0.03
Independent ambulation, %	21.7	19.8	-0.05	23.1	21.3	-0.04
Pre-fracture institutionalized living status, %	0.6	4.1	0.23	0.7	2.0	0.09
Treated for diabetes, %	10.6	18.8	0.23	15.1	15.9	0.02
Treated for kidney disease, %	3.7	5.1	0.07	3.5	4.5	0.05
Treated for heart disease, %	29.2	25.4	-0.09	24.6	25.9	0.03
Depression, %	11.2	18.8	0.21	16.2	14.9	-0.04
Treated for respiratory disease, %	13.7	9.6	-0.13	10.4	10.9	0.02
Surgical approach, %						
Direct anterior and anteromedial	1.9	1.5	-0.03	2.1	1.8	-0.02
Anterolateral/lateral	76.4	50.8	-0.55	61.4	62.4	0.02
Posterior/posterolateral	21.7	47.7	0.57	36.6	35.8	-0.02
Cemented femoral stem, %	62.7	72.1	0.20	66.5	67.5	0.02
Mean pre-injury WOMAC total (SD)	11.6 (15.2)	11.4 (15.2)	-0.01	11.6 (15.5)	11.4 (15.1)	-0.01
Mean pre-injury WOMAC Pain (SD)	1.7 (3.1)	1.5 (2.8)	-0.08	1.7 (2.9)	1.6 (2.9)	-0.03
Mean pre-injury WOMAC Stiffness (SD)	0.9 (1.3)	0.8 (1.3)	-0.08	0.9 (1.3)	0.8 (1.3)	-0.05
Mean pre-injury WOMAC Function (SD)	8.5 (11.2)	8.7 (11.7)	0.02	8.6 (11.7)	8.6 (11.3)	0.00
Mean propensity score (SD)	0.5 (0.2)	0.6 (0.2)	0.93	0.6 (0.2)	0.6 (0.2)	-0.003

ASA, American Society of Anesthesiologists; BH, bipolar hemiarthroplasty; SD, standard deviation; SMD, standardized mean difference; UH, monopolar hemiarthroplasty; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

improving function and decreasing pain from acetabular erosion. Meanwhile, data from national registries reports a low rate of 5% of revisions in Australia and 4.7% in Sweden due to acetabular erosion.[5]

Of the randomized controlled trials (RCTs) comparing functional outcomes after UH or BH published to date,[3,6-15] none have provided reliable evidence for the superiority of either design and are considered severely limited due to their small sample sizes and low number of events. Using data from the Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemiarthroplasty (HEALTH) trial (ClinicalTrials.gov NCT00556842),[16,17] we sought to determine if a difference exists between UH and BH. Using propensity score-weighted analysis, we aimed to circumvent the lack of large RCTs to assess the influence of HA designs on patients' functional outcomes within two years from the surgery.

Methods

HEALTH study overview. The HEALTH study was a multicentre RCT comparing the risk of revision surgery following THA or HA in a group of patients aged over 50 years presenting with an isolated, low-energy, displaced femoral neck fracture.[16,17] The population used for this study consisted of 746 patients who underwent HA for treatment of displaced femoral neck fracture. The UH group was defined as any participants who received a monopolar HA (n = 342), and the BH group was defined as any participants who received a bipolar HA (n = 404) for treatment of displaced femoral neck fracture. The 60patients who were treated with HA and underwent revision surgery within 24months of femoral neck fracture were not included in the analysis, considering that there no real differences in revision between the two groups and that little is known regarding the effect of revision surgery on functional outcomes (Supplementary table i). Participants were assessed clinically at one week, ten weeks, six, nine, 12, 18, and 24months postoperatively. The HEALTH trial was approved by the McMaster University Research Ethics Board (#06 to 151) and by the research ethics boards/institutional review boards of all participating clinical sites.

Comparison of UH and BH groups. Because the HEALTH trial randomized THA and HA, it was anticipated that the population receiving a BH would differ substantially from the population receiving a UH, a choice left at the discretion of the operating surgeon. To balance a comprehensive set of covariates among the BH and UH groups, an inverse probability weighting (IPTW) model was built to calculate propensity scores and generate a weighted cohort. Propensity scores were calculated using the WeightIt package in R.[18] IPTW creates groups that are otherwise similar when assessing the impact of a treatment or exposure.[19] Instead of matching treated and untreated

Table III. Baseline characteristics of covariates used in propensity score weighting for comparison of monopolar to bipolar hemiarthroplasty for SF-12 model.

Variable	Before propensity score weighting			After propensity score weighting		
	UH (n = 165)	BH (n = 207)	SMD	UH (n = 123)	BH (n = 179)	SMD
Mean age, yrs (SD)	78.6 (7.9)	78.4 (7.8)	-0.03	78.1 (8.2)	78.7 (7.9)	0.08
Male sex, %	28.5	24.6	-0.09	25.6	26.5	0.02
Mean BMI, kg/m^2 (SD)	25.1 (4.8)	24.9 (4.5)	-0.04	25.0 (4.5)	24.9 (4.5)	-0.02
ASA classification III-IV, %	40.6	57.5	0.34	50.3	50.7	0.01
Independent ambulation, %	21.2	20.8	-0.01	22.1	22.5	0.01
Pre-fracture institutionalized living status, %	0.6	3.9	0.22	0.9	2.4	0.10
Treated for diabetes, %	10.9	18.8	0.22	14.7	15.2	0.02
Treated for kidney disease, %	3.6	5.3	0.08	4.0	4.6	0.03
Treated for heart disease, %	29.7	25.1	-0.10	26.2	26.6	0.01
Depression, %	12.7	18.4	0.16	15.1	15.1	-0.001
Treated for respiratory disease, %	13.9	9.2	-0.15	10.7	11.1	0.01
Surgical approach, %						
Direct anterior and anteromedial	1.8	1.5	-0.03	2.0	1.7	-0.02
Anterolateral/lateral	77.0	52.2	-0.54	62.7	63.4	0.02
Posterior/posterolateral	21.2	46.4	0.55	35.4	35.0	-0.01
Cemented femoral stem, %	62.4	72.5	0.22	67.0	67.8	0.02
Mean pre-injury SF-12 PCS (SD)	45.4 (10.2)	46.5 (10.4)	0.12	45.6 (10.3)	45.9 (10.5)	0.03
Mean pre-injury SF-12 MCS (SD)	54.4 (8.8)	53.2 (9.4)	-0.13	54.3 (8.7)	53.9 (9.1)	-0.05
Mean propensity score (SD)	0.5 (0.2)	0.6 (0.2)	0.86	0.5 (0.2)	0.6 (0.2)	0.02

ASA, American Society of Anesthesiologists; BH, bipolar hemiarthroplasty; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12, 12-item Short Form Survey; SMD, standardized mean difference; UH, monopolar hemiarthroplasty.

individuals on a particular selection of confounders, the inverse probability treatment weighting approach uses the entire cohort and can include numerous confounding variables.[19] Every individual in the cohort is assigned a weight dependent on the probability of exposure to the treatment effect being explored and applying this weight to regression models lessens or eliminates the influence of confounders.[19] The following variables were controlled for in each comparison group: age, sex, BMI, American Society of Anesthesiologists classification (I-II vs III-IV), depression, prefracture living status, prefracture ambulatory status, surgical approach, type of femoral stem (cemented vs uncemented), and preinjury health-related quality of life (HRQoL) score. To ensure adequate balance of the two treatment groups, standardized mean differences (SMDs) of each covariate were calculated before and after IPTW. A SMD less or equal to 0.1 implies a negligible correlation and adequate balance between the groups and each covariate. Baseline variables regarding demographics and perioperative characteristics of the participants who received a BH or UH were presented as mean values and standard deviations (SDs) for continuous variables and as numbers and percentages for categorical variables.

Hip function assessment analysis. Hip function in the HEALTH trial was measured using the self-administered Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and 12-Item Short Form Health Survey (SF-12) questionnaires. SF-12 is a self-administered questionnaire, covering eight main health domains that make up the Physical Component Summary (PCS) and Mental Component Summary (MCS), with scores ranging separately from 0 (lowest level) to 100 (highest level).[20] WOMAC is a self-administered, 24-item questionnaire that assesses the three dimensions of pain, disability, and joint stiffness in knee and hip osteoarthritis.[21] The ranges for each dimension are 0 to 20 for pain, 0 to 8 for stiffness, and 0 to 68 for physical function, with a higher score indicating worse pain, stiffness, and functional limitations.

Statistical analysis. We performed three separate repeated measures model analyses with two levels (patient and time). The measure of HRQoL or hip function (either WOMAC, SF-12 PCS, or SF-12 MCS) was the dependent variable with patient entered as a random effect. BH versus UH was entered as a fixed effect as well as timing of the assessment (six, 12, and 24 months after surgery) and the propensity score weights. A threshold for minimally important difference (MID) was set at 7 points for the WOMAC and 4 points for the SF-12 based on previous literature.[22,23] Results were reported as adjusted mean differences (AMDs) with 99% confidence intervals (CIs). All tests were two-tailed and a p-value < 0.01 was considered statistically significant. All analyses were performed using R software version 4.0.2 (R Project for Statistical Computing, Austria). A subgroup analysis was also conducted for patients aged less than 70 years.

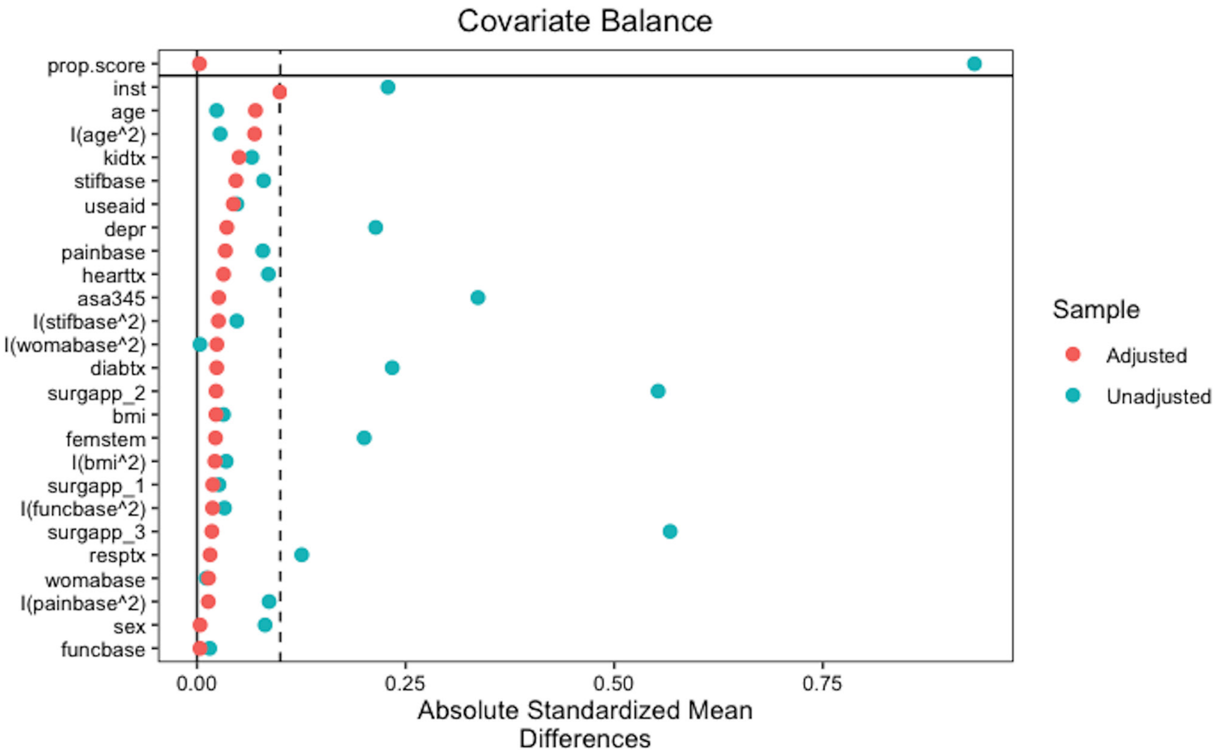

Fig. 1

Absolute standardized differences in unweighted and weighted samples for Western Ontario and McMaster Universities Osteoarthritis Index model.

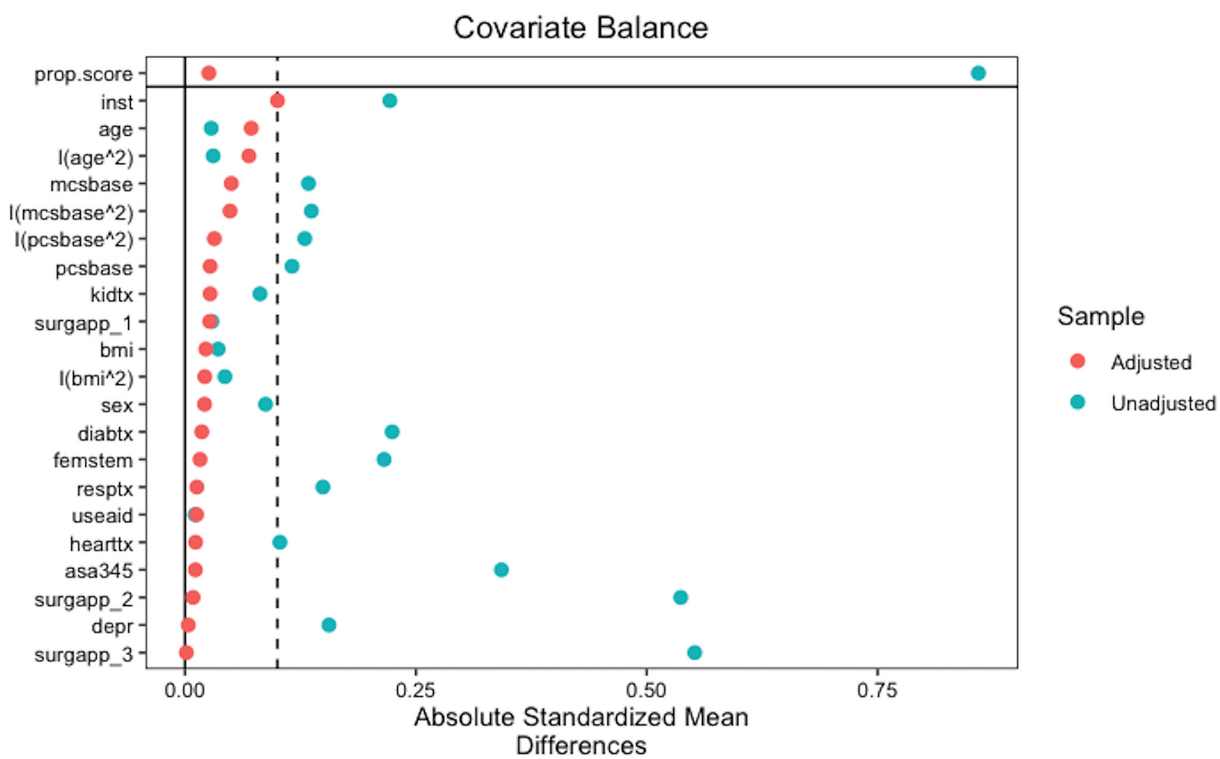

Fig. 2

Absolute standardized differences in unweighted and weighted for the 12-item Short-Form Health Survey model.

Results

Variability in the use of UH and BH for treatment of displaced

Table IV. Health-related quality of life scores comparing functional outcomes in patients who underwent bipolar hemiarthroplasty compared with monopolar hemiarthroplasty.

End point	Patients with data	Adjusted mean difference in score, bipolar hemiarthroplasty vs monopolar hemiarthroplasty (99% CI)*	p-value§
WOMAC†			
Total	1,635 observations among 352 participants	1.77 (-2.61 to 6.16)	0.296
Pain	1,635 observations among 352 participants	0.03 (-0.75 to 0.08)	0.910
Stiffness	1,635 observations among 352 participants	0.01 (-0.36 to 0.39)	0.927
Function	1,635 observations among 352 participants	1.64 (-1.78 to 5.06)	0.214
SF-12‡			
PCS	1,836 observations among 372 participants	-0.56 (-3.10 to 2.09)	0.612
MCS	1,836 observations among 372 participants	0.73 (-1.75 to 3.21)	0.447

*The mean difference was obtained from the multilevel model.
†Minimally important difference (MID) was set at 7 points.
‡MID was set at 4 points.
§Two-sided test.
CI, confidence interval; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12, 12-item Short-Form Health Survey; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index .

Table V. Health-related quality of life scores at 24 months comparing functional outcomes in patients aged≤ 70 years who underwent bipolar hemiarthroplasty compared with monopolar hemiarthroplasty.

End point	Patients with data	Adjusted mean difference in score, bipolar hemiarthroplasty vs monopolar hemiarthroplasty (99%CI)*	p-value§
WOMAC†			
Total	344 observations among 74 participants	4.24 (-5.48 to 13.95)	0.252
Pain	344 observations among 74 participants	1.09 (-0.76 to 2.94)	0.124
Stiffness	344 observations among 74 participants	0.44 (-0.48 to 1.36)	0.212
Function	344 observations among 74 participants	2.40 (-4.71 to 9.50)	0.376
SF-12‡			
PCS	361 observations among 76 participants	-1.23 (-7.11 to 4.65)	0.582
MCS	361 observations among 76 participants	-0.04 (-5.56 to 5.49)	0.987

*The mean difference was obtained from the multilevel model.
†Minimally important difference (MID) was set at 7 points.
‡MID was set at 4 points.
§Two-sided test.
CI, confidence interval; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12, 12-item Short-Form Health Survey (SF-12); WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

femoral neck fractures. From the 746 patients who underwent hemiarthroplasty for treatment of displaced femoral neck fracture as part of the HEALTH trial, a slightly higher number of participants received a BH (n = 404) compared to a UH (n = 342). Given that the surgeons were free to choose between UH and BH, the results reflect the trends in practice depending on the participating country. Among participating countries, Canada, Spain, and Norway used BH in the majority of participants, while the Netherlands and the UK used UH in most of their cases. The USA had a somewhat even use of BH and UH. In Canada, there was evidence of inter-provincial variation in the use of UH and BH, with Alberta using mostly UH, whereas British Columbia, Ontario, and Quebec used mostly BH (Table I).

BH versus UH

Tables II and III present baseline characteristics of covariates before and after applying IPTW, demonstrating adequate balance in all covariates for both WOMAC and SF-12 models. Figures 1 and 2 represent a summary of covariate balance before and after IPTW, demonstrating that balance was met within the set threshold of less than 0.1. Among all study participants, the WOMAC score and subcomponent scores along with SF-12 PCS and MCS scores were not statistically significantly different between receiving a UH and a BH 24 months postoperatively (Table IV). Similarly, for those aged under 70 years, presumed as more active, adjusted mean differences in scores for both models were not found to be statistically significant (Table V).

Discussion

This secondary analysis used data from the HEALTH trial to compare functional outcomes between modern modular UH and BH in a single, large study population representing independent and active elderly individuals. A subgroup analysis of participants aged under 70 years was additionally presented as many have advocated for the use of the two-articulation design in the younger and more active population. The type of hemiarthroplasty was not standardized in the HEALTH trial; here, we provide a propensity score-weighted analysis of a multicentre RCT to provide the latest evidence in the choice of hip hemiarthroplasty design for treatment of displaced femoral neck fracture in the elderly.

This paper adds to the evidence that the costly bipolar hemiarthroplasty design is unlikely to provide substantial functional benefits in comparison with unipolar designs, at least within the first two years postoperative. Patients aged under 70 years also did not benefit from a BH over a UH, at least within the first two years postoperatively. Bipolar prostheses were introduced with the theorical advantage of a lesser risk of dislocation and specifically, aiming to minimize and delay the need for a revision to a total hip arthroplasty in the younger and active elderly. The intraprosthetic motion between the inner and outer shell in bipolar heads could potentially shield the acetabulum from erosion and wear. Dong et al[24] combined six studies totalling 503 cases, and found an acetabular erosion rate five-times higher in UH compared to BH. Fillippo et al[25] combined 16 studies and found a statistically significant reduction in acetabular erosion in the bipolar group. However, the correlation of acetabular wear and functional outcomes is unclear.

Eight RCTs comparing UH to BH were published in the past ten years.[3,6-9,14,15,26] None had more than 60 patients per randomized group at final follow-up.[3,7-9,14,15,26] From those reporting HRQoL,[9,14,15,26] two reported significantly better EuroQol five-dimension index scores in the bipolar design group at two years postoperatively.[9,15] However, it remains difficult to confirm that the addition of inner bearing mobility could be responsible for such improvement in HRQoL at up to two years. Most importantly, the lack of superior function in either UH and BH groups are supported by five out of six RCTs who also could not substantiate improved functional outcomes at one or two years postoperatively for either type.[3,6,8,15,26] The longest follow-up to date is attributed to Kanto et al,[7] who reported no statistical difference in return to prefracture status of community ambulators between the two prosthetic designs at up to five years postoperatively. High heterogeneity, lack of standardized reporting, and absence of differentiation between prosthetic characteristics (i.e. use of cement) are severe limiting factors preventing meta-analyses to generate reliable evidence. Nevertheless, the most recent meta-analysis combining eight studies (cohort studies and RCTs) found no significant difference in HHS score at last follow-up between the use of UH and BH.[24]

The results of this study must be interpreted with caution since sample size calculations were only performed for the primary outcome in the original HEALTH study. The population from this study did not include individuals with cognitive dysfunction. Finally, cases with missing data and those needing a revision surgery were excluded, and the effect that those participants could have had on the results cannot be estimated.

In conclusion, despite the lack of evidence, more than half of participants included in this study were given a BH for treatment of femoral neck fracture. Our study suggests that BH does not confer superior function at two years postoperatively compared to a UH. Although the surgeon must use their clinical judgment in surgical decision-making, we urge physicians to choose wisely and consider the cost-effectiveness of their implant choice. Longer-term follow-up is required to confirm these findings.

Take home message

- Our study suggests that bipolar hemiarthroplasty does not confer superior function at two years postoperatively compared to a unipolar hemiarthroplasty in patients aged 50 years or older with a displaced femoral neck fracture.
- Although the surgeon must use their clinical judgment in surgical decision-making, we urge physicians to choose wisely and consider the cost-effectiveness of their implant choice. Longer-term follow-up is required to confirm these findings.

Supplementary material

Tables showing indications for revision surgery in the 60 participants who received a hemiarthroplasty, whether unipolar or bipolar; and a full list of HEALTH investigators.

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