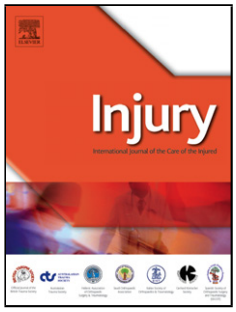

Title: Unipolar versus bipolar hemiarthroplasty for displaced femoral neck fractures: A pooled analysis of 30250 participants data

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PII: S0020-1383(19)30335-3
DOI: https://doi.org/10.1016/j.injury.2019.06.004
Reference: JINJ 8194

To appear in: *Injury, Int. J. Care Injured*

Received date: 2 January 2019
Revised date: 13 March 2019
Accepted date: 2 June 2019

Please cite this article as: Imam MA, Shehata M, Abdallah AR, Ahmed H, Kader N, Ernstbrunner L, Narvani A, Kambouroglou G, Mcnamara I, Sallam AA, Unipolar versus bipolar hemiarthroplasty for displaced femoral neck fractures: A pooled analysis of 30250 participants data, *Injury* (2019), https://doi.org/10.1016/j.injury.2019.06.004

Unipolar versus bipolar hemiarthroplasty for displaced femoral neck fractures: A pooled analysis of 30250 participants data

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Highlights

- Bipolar hemiarthroplasty is associated with greater range of motion and less acetabular erosion than unipolar hemiarthroplasty.

- The operative time was longer during bipolar hemiarthroplasty compared to unipolar hemiarthroplasty.
- No significant difference in hip function using Harris hip score, mortality, surgical, and medical outcomes is evident.

ABSTRACT

Purpose: To assess the clinical outcomes of unipolar versus bipolar hemiarthroplasty for displaced intracapsular femoral neck fractures in older patients and to report whether bipolar implants yield better long-term functional results.

Methods: We searched PubMed, Scopus, EBSCO, and Cochrane Library for relevant randomized clinical trials (RCTs) and observational studies, comparing unipolar and bipolar hemiarthroplasty. Data was extracted from eligible studies and pooled as relative risk (RR) or mean difference (MD) with corresponding 95% confidence intervals (CI) using RevMan software for Windows.

Results: A total of 30 studies were included (13 RCTs and 17 observational studies). Analyses included 30250 patients with a mean age of 79 years and mean follow-up time of 24.6 months. The overall pooled estimates showed that bipolar was superior to unipolar hemiarthroplasty in terms of hip function, range of motion and reoperation rate, but at the expense of longer operative time. In the longer term the unipolar group had higher rates of acetabular erosion compared to the to the bipolar group. There was no significant difference in terms of hip pain, implant related complications, intraoperative blood loss, mortality, six-minute walk times, medical outcomes, and hospital stay and subsequently cost.

Conclusions: Bipolar hemiarthroplasty is associated with better range of motion, lower rates of acetabular erosion and lower reoperation rates compared to the unipolar hemiarthroplasty but at the expense of longer operative time. Both were similar in terms of

mortality, and surgical or medical outcomes. Future large studies are recommended to compare both methods regarding the quality of life.

keywords: Unipolar; Bipolar; Hemiarthroplasty; hip; reoperation; acetabular erosion

INTRODUCTION

Displaced intra-articular femoral neck fractures are commonly encountered in geriatric population secondary to senile osteoporosis [1,2]. The purported advantages of HA include earlier mobility, lower reoperation rates and better functional outcomes at 1 year [3].

A substantial difference of opinion exists on the choice between unipolar and bipolar designs. The hypothetical advantage of the bipolar design over the unipolar one is the reduction of acetabular erosion attributed to motion occurring within the components rather than at the acetabular implant interface [4]. Therefore, it is hypothesized that bipolar implants yield improved long-term functional results with reduced complications [5]. However, evidence supporting this theory is scarce within the literature.

The purpose of this meta-analysis is to assess the clinical outcomes and surgical complications of unipolar versus bipolar hemiarthroplasty for femoral neck fractures in older patients.

MATERIALS AND METHODS

All steps of this systematic review were performed in a strict accordance with the Cochrane handbook of systematic reviews and meta-analysis [6,7]. Additionally, the preferred reporting

items for systematic reviews and meta-analyses (PRISMA statement guidelines) were followed the during drafting of the manuscript [8].

Literature search strategy

We searched PubMed, Scopus, EBSCO, Cochrane library, and web of science for articles published before May 1, 2017, using the following keywords: hemiarthroplasty, arthroplasty, displaced femoral neck fractures, hip fractures, hip prosthesis, hip replacement, unipolar, monopolar, bipolar. We also checked the clinical trial registry (Clinicaltrials.gov) for additional ongoing and unpublished studies. The reference lists of relevant reviews and articles were further scanned for additional relevant studies.

Eligibility criteria

Randomized clinical trials (RCTs) and observational studies that compared bipolar (BH) versus unipolar hemiarthroplasty (UH) in management of elderly patients with femoral neck fractures were included in our meta-analysis.

We excluded non-English articles, reviews, case reports, duplicate references, and studies that included patients with immature skeleton, delayed union, nonunion, previous surgery, or pathological fractures.

Selection process

Three authors independently applied the selection criteria. Eligibility screening was conducted in two steps, a) titles and abstract screening for matching the inclusion criteria, and b) full text screening of eligibility for meta-analysis. Disagreements were resolved upon the result of discussion.

Outcomes of interest

We included studies reporting at least one of the following outcomes: hip function postoperatively using modified Harris Hip Score [9,10], hip pain, reoperation rate, operative details (operative duration and intraoperative blood loss), mortality, implant related complications (e.g. periprosthetic fractures, dislocations of prosthesis, loosening of prosthesis and wound infection), quality of life, range of motion (flexion, adduction, abduction, internal rotation, and external rotation), 6-minute walk test, acetabular erosion, medical complications (e.g. pulmonary embolism, cardiac arrest, myocardial infarction, acute heart failure and deep venous thrombosis), length of hospital stay, and cost.

Data Extraction

Two reviewers independently extracted and tabulated data on first author, publication year, study design, number of participants in each group, mean age, gender, type of intervention, study period, follow up period and relevant outcomes data. Another reviewer resolved disagreements, and reasons of exclusion were recorded.

Risk of bias assessment

For clinical trials, two review authors independently used the Cochrane risk of bias (ROB) assessment tool, clearly described in (chapter 8.5) of the Cochrane handbook of systematic reviews of interventions 5.1.0 [6]. For observational studies, we used the Newcastle Ottawa scale (NOS) for assessing the quality of observational studies [11].

Each included study was assessed based on reporting of three essential domains: a) selection of the study subjects, b) comparability of groups on demographic characteristics and important potential confounders, and c) ascertainment of the prespecified outcome

(exposure/treatment). To assess the risk of bias across included studies, we compared the reported outcomes between all studies to exclude selective reporting of outcomes.

Dealing with missing data

In cases of missing standard deviation (SD) data, SD was calculated from the corresponding standard error or confidence interval according to Altman [12].

Data analysis

For dichotomous data, we calculated relative risks (RR) and 95% confidence intervals (CI) for each outcome. For continuous data, we calculated mean difference (MD) and 95% confidence intervals (CI) for each outcome. The statistics analysis was conducted with Review Manager version 5.3 and Comprehensive meta-analysis software for windows. An alpha level of <0.05 was considered statistically significant.

Assessment of Heterogeneity

We tested for heterogeneity among included studies by the Chi-Square test and I-square tests. A *p* value of >0.1 and *I*-square value of <50% were considered as no statistical heterogeneity. We performed the meta-analysis using a fixed-effect model if no significant heterogeneity was present (*I2*<50 %; *p*>0.1). Otherwise we adopted the random effect model.

Sensitivity analysis

To resolve detected statistical heterogeneity, we performed sensitivity analysis excluding one study in each scenario.

Publication bias

To investigate the possibility of publication bias, we used the Egger's test [13] and the funnel plot method. In case of significant publication bias, the trim and fill method were used for correction and the effect estimate was recalculated accordingly.

RESULTS

Demographics and characteristics

Our search yielded 174 unique citations. Thirty studies were selected for inclusion in our meta-analysis, of which 13 were RCTs and 17 were observational studies (Fig. 1). The 30 included studies (table 1) included a total of 30250 participants with a mean age of 79 years and mean follow up 24.6 months. 15190 patients underwent bipolar HA and 15060 underwent unipolar HA. Both groups had similar characteristics (table 2).

Quality of evidence

All RCTs were at low risk of bias regarding selective reporting and incomplete outcome data. Eight out of 13 RCTs achieved adequate random sequence generation, four trials described allocation concealment and eight kept unbroken blinding (Fig. 2a). Observational studies achieved a mean of 7 out of 9 points on the NOS indicating a moderate quality (fig. 2b).

Outcomes (table 3)

Ten studies (7 RCTs [5,14-19] and 4 observational studies [20-23]) reported data on postoperative hip function using Harris Hip score (HHS). The pooled estimate (figure 3) showed initial better score at 1 and 2 years (MD=2.30, 95% [0.14, 4.47], P=0.04; MD=2.68, 95% CI [0.98, 4.37], P=0.002, respectively) and then no significant difference between the BH and UH groups at four years' follow-up (MD=0.67, 95% CI [-3.29, 4.63], P=0.74; MD=2.61, 95% CI [-3.80, 9.02], P=0.42, respectively). .

Table 1: Summary of the included studies

No.	Authors	Publication year	Study type	Study size	Mean duration of follow-up	Outcome measures
1.	Abdelkhalek et al. [19]	2011	RCT	50	4.4 (2-6) years	Hip function, pain and ROM, Prosthesis migration, subsidence, loosening and dislocation LLD, acetabular erosion, conversion to THR. limping, infection, DVT
2.	Ayhan et al. [21]	2013	Observational	144	Minimum 1 year	Quality of life, mortality, hip function, acetabular erosion, infection, DVT
3.	Azhar MM [24]	2015	Observational	44	2.3 (1-3) years	Hip function, fracture of implant, dislocation of implant, acetabular erosion, acetabulum protusia, loosening, calcar resorption and osteolysis, hip pain, infection, sciatic nerve injury
4.	Balan et al. [14]	2016	RCT	68	One year	Hip function, sciatic nerve palsy, stem subsidence, peri-prosthetic fracture, pneumonia, superficial infection and dislocation
5.	Biščević and Smrke [23]	2005	Observational	694	3.8 (2-8.6) years	Hip function, hip pain, limping, ROM
6.	Calder et al. [5]	1996	RCT	250	1.7 (1-3) years	Hip function, hip pain, limping, mortality, infection, dislocation, acetabular erosion, satisfaction, return to preinjury status
7.	Cornell et al. [15]	1998	RCT	48	6 months	Hip function, ROM, prosthetic dislocation, 6-minute walk test, get up and go
8.	Davison et al. [25]	2001	RCT	280	Minimum 2 years	Hip function, mortality, morbidity, revision surgery, satisfaction, return to preinjury status, acetabular erosion, subsidence, loosening, head migration
9.	Enocson et al. [26]	2011	Observational	830	3.1 (0–9.1) years	Reoperation rate, dislocation, deep infection, periprosthetic fracture, acetabular erosion
10.	Grosso et al. [27]	2016	Observational	686	Minimum 2 years	acetabular erosion, loosening, periprosthetic fracture, dislocation, revision surgery
11.	Hudson et al. [2]	1998	Observational	367	8 years	Revision, mortality, surgical complications

12.	Inngul et al. [16]	2013	RCT	120	4 years	Quality of life, hip function, acetabular erosion
13.	Jain et al. [20]	2016	Observational	39	3 years	Hip function, mortality, complications, length of stay, dislocation, loosening, foot drop
14.	Jeffcote et al. [28]	2010	RCT	52	2 years	Head migration, hip function, 6-minute walk test, mortality, complications
15.	Kanto et al. [29]	2014	RCT	175	8 years	Hip function, mortality, acetabular erosion, dislocation (implant and patient survival)
16.	Kenzora et al. [30]	1998	Observational	270	Minimum 2 years	Hip function, length of hospital stay, medical complications, quality of life, dislocation, infection, revision surgery
17.	Leonardsson et al [31]	2012	Observational	23,509	1.5 year	Reoperation, dislocation, infection, periprosthetic fracture
18.	Lin et al. [32]	2012	Observational	120	5 years	Hip pain, dislocation, infection, comorbidities, mortality
19.	Malhotraet al. [33]	1995	RCT	68	9-47 months	Hip pain, ROM, limping, dislocation, infection, acetabular erosion, subsidence, revision surgery
20.	Marcus,et al. [34]	1992	Observational	173	22 (12-46) months	Hip pain, function, mortality, complications, dislocation, intra-operative femoral fractures, acetabular erosion, reoperation
21.	Mishra et al. [35]	2013	RCT	40	1 year	Hip pain, function, ROM, acetabular erosion, complications, LLD, mortality
22.	Ong et al. [36]	2002	Observational	281	Minimum 3 years	Hip pain, function, return to preinjury status, ADL, dislocation, medical and wound complications, revision surgery
23.	Paton and Hirst [37]	1989	Observational	171	6 months – 4 years	Dislocation
24.	Raia et al. [38]	2003	RCT	115	1 year	Quality of life, hip function, blood loss, length of hospital stay, mortality rate, number of dislocations, postoperative complications, or ambulatory status
25.	Sabnis and Brenkel [4]	2011	Observational	707	4 months	Complications, ability to walk, use of aid, mortality, pain
26.	Somashekar et al. [17]	2013	RCT	41	1 year	Hip function, ROM, painful hip, posterior dislocation, periprosthetic fracture, acetabular erosion

27.	Stoffel et al. [18]	2013	RCT	261	1 year	Hip function, hip, pain, ROM, 6-minute-walk test, length of stay, infection, DVT, comorbidities
28.	Wathne et al. [39]	1995	Observational	140	Minimum 1 year	Hip function, hip pain, comorbidities, length of stay, postoperative complications, mortality rate, revision surgery
29.	Yamagata et al. [22]	1987	Observational	1001	2-10 years	Hip function, hip pain, loosening, acetabular erosion, reoperation rate
30.	Ng et al. [40]	2015	Observational	193	4 years	Hip pain, hip function, acetabular erosion, component migration, revision surgery, rates of postoperative complications, satisfaction

RCT: randomized clinical trial, LLD: limb length discrepancy, DVT: deep venous thrombosis, THR: total hip replacement, ROM: range of motion, ADL: activities of daily living

Table 2: Demographic data of the studies groups

Variable	**UH group**		**BH group**	
	Observational studies	RCTs	Observational studies	RCTs
Number of patients	14182	878	14451	739
Age, years (mean, range)	79.6 (55-85)	77.8 (55-85)	78.5 (55-85)	80.7 (55-85)
Male/Female	5082/9100	270/608	4336/10115	289/450
Delay in surgery, days	3.4 (2-9)	2.9 (2-9)	3.6 (2-9)	3.1 (2-9)
Follow-up period, months	24.2 (6-72)	25.4 (6-72)	25.1 (6-72)	24.1 (6-72)

UH: Unipolar hemiarthroplasty, BH: Bipolar hemiarthroplasty, RCTs: Randomized clinical trial

Hip pain data was available for eight studies (3 RCTs [17,19,25] and 5 observational studies [4,24,32,36,39]). The pooled risk ratio (figure 4a) showed no significant difference between the BH and UH groups in terms of postoperative hip pain (RR=0.90, 95% CI [0.61, 1.33], P=0.60). High heterogeneity was observed between these studies (I2=75%, P=0.0002), therefore, the random effect model was conducted. Sensitivity analysis was consistent with the previous analysis (figure 4b), and indicated no significant difference (RR=0.86, 95% CI[0.71, 1.05], P=0.15), with low heterogeneity (I2=21%, P=0.27).

Eight studies (3 RCTs [25,29,38] and 5 observational studies [2,26,27,31,34]) contributed to the calculation of the summary estimate for reoperation rate. Under the fixed effect model, the pooled risk ratio (figure 5) favored the BH group over the UH group in terms of reoperation rate (RR=1.32, 95% CI [1.17, 1.50], P<0.00001). No significant heterogeneity was observed (I2=18%, P=0.29).

Four studies (2 RCTs [16,29] and 2 observational studies [22,32]) reported operative time. The pooled mean difference (figure 6) showed significantly higher operative time with the BH group (MD=7.77 min, 95% CI [4,00, 11.55], P<0.0001). The studies were consistent in terms of statistical heterogeneity (I2=0%, P=0.46) and fixed effects model was conducted.

The mean difference of intraoperative blood loss (figure 7) was pooled for four studies (2 RCTs [16,29] and 2 observational studies [22,39]) and showed no significant difference between the two compared groups (MD=24.00 ml, 95% CI [-17.06, 65.06], P=0.25). No substantial heterogeneity was observed (I2=24%, P=0.27).

Four studies (1 RCT [29] and 3 observational studies [36,39,40]) provided data on perioperative mortality. The pooled risk ratio (figure 8) showed no significant difference between the BH

and the UH groups in perioperative mortality (RR=1.17, 95% CI [0.88, 1.56], P=0.28). Pooled studies were homogenous (I2=0%, P=0.73).

Four studies (2 RCTs [5,25] and 2 observational studies [21,34]) provided data for mortality at 6 months postoperatively. The pooled estimate did not favor either of the two groups (RR=1.00, 95% CI [0.73, 1.35], P=0.98). Pooled studies were homogenous (I2=0%, P=0.46).

Eight studies (5 RCTs [5,17,25,28,38] and 3 observational studies [2,21,39]) compared BH and UH in terms of mortality at one year follow up. The pooled estimate showed no significant difference between the BH and UH group for this parameter (RR=1.03, 95% CI [0.87, 1.22], P=0.75). No evidence of heterogeneity was observed (I2=0%, P=0.85).

Pooled estimates from four studies (2 RCTs [14,17] and 2 observational studies [20,27]) did not favor either of BH or UH in terms of periprosthetic fractures (RR=0.58, 95% CI [0.18, 1.83], P=0.35). Pooled studies were homogenous (I2=0%, P=0.9) (figure 9).

Dislocations of prosthesis data was available for 19 studies (10 RCTs [5,14-19,25,29,38] and 9 observational studies [20,26,27,32,34,36,37,39,40]). The pooled RR (figure 9) revealed no significant difference between the two compared groups in terms of dislocation of prosthesis (RR=0.87, 95% CI [0.59, 1.27], P=0.47). No heterogeneity was observed among the pooled studies (I2=0%, P=0.73). Egger's test showed no evidence of publication bias, P=0.42.

Two observational studies reported data on loosening of prosthesis [24,27]. The pooled estimate (figure 9) showed no significant difference between the two compared groups (RR=0.74, [0.20, 2.82], P=0.66), with no evidence of heterogeneity (I2=0%, P=0.85).

Wound infection data was provided by 13 studies (8 RCTs [5,14,16-18,25,28,38] and 5 observational studies [20,24,34,36,40]). The combined RR did not favor either of the two groups in terms of wound infection (RR=1.02, 95% CI [0.61, 1.70], P=0.94). No heterogeneity was observed among the pooled studies (I2=0%, 0.98) (figure 9). Egger's test showed no evidence of publication bias, P=0.81.

Two RCTs reported on quality of life. Inngual et al. [16] showed that the BH group has significantly higher quality of life over the UH group at 48 months' follow up using EQ-5D [16]. Whilst, Raia et el. showed no significant difference between the two groups at one-year follow up using SF-36 [38].

The total estimate from four studies (3 RCTs [18,19,35] and 2 observational studies [22,23]) showed that the BH group was associated with better range of motion than the UH group (RR=2.48, 95% CI [1.14, 3.82], P=0.0003). Whilst subgroup analysis according to the type of motion showed no significant difference in flexion, abduction, adduction, external or internal rotation. High heterogeneity was observed so the random effect model was conducted (figure 10).

The pooled RR from two RCTs [15,18] did not favor either of the two compared groups in terms of six-minute walk test (RR=-18.59, 95% CI [-62.87, 25.70], P=0.41). High heterogeneity was observed (I2=84%, P=0.01), therefore, the random effect model was conducted (figure 11).

Seven studies (5 RCTs [5,16,19,25,33] and 2 observational studies [26,31]) reported data on acetabular erosion. The pooled RR (figure 12) showed significantly higher acetabular erosion with the UH group compared to the BH group at four months' follow-up (RR=0.32,

95% CI [0.11, 0.93], P=0.04), at one year (RR=0.23, [0.06, 0.89], P=0.03) and at two years (RR=0.39, 95% CI [0.23, 0.67], P=0.0006). At 4 years, however, there was no significant difference between the two compared groups (RR=0.54, 95% CI [0.24, 1.20], P=0.13).

Five studies (3 RCTs [16,29,38] and 2 observational studies [34,40]) reported on the number of patients who experienced pulmonary embolism postoperatively. The pooled RR (figure 13) did not favor either of the two groups in terms of pulmonary embolism (RR=0.92, 95% CI [0.38, 2.22], P=0.85). There was no evidence of heterogeneity among pooled studies (I2=0%, P=0.95).

Seven studies (3 RCTs [16,18,29] and 4 observational studies [20,22,34,40]) reported the results of cardiac complications. The pooled estimate (figure 13) was comparable across the BH and UH groups (RR=0.75, 95% CI [0.48, 1.16], P=0.19). No heterogeneity was observed among these studies (I2=13%, P=0.33).

The combined RR from five studies (3 RCTs [15,16,18] and 2 observational studies) showed no significant difference between the two compared groups in terms of deep venous thrombosis (RR=1.26, 95% CI [0.54, 2.90], P=0.59). The pooled studies were homogenous (I2=0%, P=0.82) (figure 13).

Hospital stay data was reported by eight studies (5 RCTs [5,15,18,25,38] and 3 observational studies [22,32,39]). The pooled mean difference (figure 14a) showed no significant difference between the BH and the UH groups in terms of hospital stay (MD=-1.34 days, 95% CI [-3.76, 1.07], P=0.28). High heterogeneity was observed among pooled studies (I2=93%, P<0.00001), therefore, a random effect model was conducted. Further sensitivity analysis was performed after one observational study was excluded. The sensitivity analysis

revealed no significant difference (MD=0.14 days, 95% CI [-0.45, 0.72], P=0.64) with low heterogeneity (I2=5%, P=0.39) (figure 14b).

Two RCTs [15,30] assessed the cost of the prostheses used and revealed that the bipolar implants were more expensive than the unipolar implants.

Table 3: Outcomes of meta-analysis

Outcomes	**Effect size (RR or MD)**	**95% CI**	**P value**	**Heterogeneity**
Postoperative hip function at 2 years	2.68	0.98 to 4.37	0.002	I2=0%, p=0.62
Hip pain	0.90	0.61 to 1.33	0.60	I2=75%, P=0.0002
Reoperation rate	1.32	1.17 to 1.50	P<0.00001	I2=18%, P=0.29
Operative time	7.77 min	4,00 to 11.55	P<0.0001	I2=0%, P=0.46
Intra-operative blood loss	24.00 ml	-17.06 to 65.06	P=0.25	I2=24%, P=0.27
Perioperative mortality	1.17	0.88 to 1.56	P=0.28	I2=0%, P=0.73
Mortality at 6 months postoperative	1.00	0.73 to 1.35	P=0.98	I2=0%, P=0.46
Mortality at 1 year postoperative	1.03	0.87 to 1.22	P=0.75	I2=0%, P=0.85
Periprosthetic fractures	0.58	0.18 to 1.83	P=0.35	I2=0%, P=0.9
Dislocations of prosthesis	0.87	0.59 to 1.27	P=0.47	I2=0%, P=0.73
Loosening of prosthesis	0.74	0.20 to 2.82	P=0.66	I2=0%, P=0.85
Wound infection	1.02	0.61 to 1.70	P=0.94	I2=0%, P=0.98
Range of motion	2.48	1.14 to 3.82	P=0.0003	I2=96%, p<0.00001
Six-minute walk	-18.59	-62.87 to 25.70	P=0.41	I2=84%, P=0.01
Acetabular erosion at 4m	0.32	0.11 to 0.93	P=0.04	I2=0%, P=0.80
Acetabular erosion at 1 year	0.23	0.06 to 0.89	P=0.03	I2=0%, P=0.85
Acetabular erosion at 2 years	0.39	0.23 to 0.67	P=0.0006	I2=0%, P=0.93
Acetabular erosion at 4 years	0.54	0.24 to 1.20	P=0.13	I2=0%, P=0.70
Pulmonary embolism	0.92	0.38 to 2.22	P=0.85	I2=0%, P=0.95
Cardiac complications	0.75	0.48 to 1.16	P=0.19	I2=13%, P=0.33
Deep venous thrombosis	1.26	0.54 to 2.90	P=0.59	I2=0%, P=0.82
Hospital stay	-0.39	-0.65 to -0.13	p=0.28	I2=93%, P<0.00001

Sensitivity analysis

Sensitivity analysis was conducted to check for the effect of individual studies on the summary of effect size. None of the included studies could influence the summary effect estimates when removed from the analysis [6]. Moreover, heterogeneity was resolved by performing sensitivity analysis. Consistency of the effect size, despite removal of the high risk of bias, confirms that the effect estimates obtained from our analysis are statistically robust. the overall effect estimate did not change significantly for the outcomes hip pain and hospital stay

DISCUSSION

More than two thirds of all days spent in hospital for a fracture are owed to hip fractures [41]. The choice of treatment and outcome assessment in elderly patients is contentious because of their limited life expectancy. This makes early satisfaction as important as long-term outcomes [5]. With an annual mortality of 30% and associated substantial impairment of independence and quality of life, the treatment goal for hip fractures is to return to pre-injury mobility status as early as possible [41,42].

Treatment options for femoral neck fractures in elderly active patients include ORIF, hemiarthroplasty and total hip replacement. In a multicenter randomized controlled trial that compared all these methods of treatment, the authors concluded that arthroplasty is more clinically effective and cost-effective than reduction and fixation. Additionally, they supported the possibility of better long-term results with primary total hip replacement [43]. Although some authors indicated better function with the total hip replacement [43,44], others stated no short-term significant differences between both modalities [45]. Therefore,

hemiarthroplasty is still considered as the treatment of choice [46-48]. Whether unipolar or bipolar hemiarthroplasty should be preferred is unknown. Several RCTs and observational studies comparing unipolar versus bipolar hemiarthroplasty reported on outcomes after hip hemiarthroplasty [2,4,5,14-29,31,32,34-41]. There is no evidence supporting the choice between unipolar or bipolar femoral head prosthetic replacement. To rectify this, we pooled, in a meta-analysis, the results of 30 studies including 13 RCTs and 17 observational studies comparing unipolar and bipolar hemiarthroplasty in a total of 30250 patients [2,4,5,14-29,31,32,34-41].

The most important finding of our meta-analysis is that bipolar hemiarthroplasty provides better range of motion than unipolar hemiarthroplasty. Another main finding is that the reoperation rate and acetabular erosion are less frequent than with unipolar hemiarthroplasty. Although these results might favor implantation of bipolar hemiarthroplasty for femoral neck fractures in the elderly, data about quality of life in such patients is still missing.

Several prospective, randomized studies have been published to compare functional outcomes of patients receiving either unipolar or bipolar hemiarthroplasty. Functional results in several of these studies observed similar results. Calder et al. published a prospective RCT comparing unipolar Thomson prosthesis with bipolar Monk prosthesis in patients over 80 years. At the 2-year follow-up interval the only statistically significant difference found was that patients with unipolar prostheses were more likely to return to their preinjury functional state than patients with bipolar prostheses [5]. Davison et al. compared unipolar hemiarthroplasty, bipolar hemiarthroplasty and internal fixation with compression hip screws in patients between 65 and 79 years. They found no difference in

functional outcomes between unipolar and bipolar prostheses [25]. Cornell et al. published a 48-patient series in which the same femoral stem was used in all patients with the only difference being the prosthesis head design. Patients with bipolar prostheses did better on walking tests and had better range of motion at 6 months but the patient-oriented hip scores did not differ at 6 months between the unipolar and bipolar groups [15]. Raia et al. compared the efficacy of unipolar versus bipolar hemiarthroplasty in elderly patients with displaced femoral neck fractures in terms of quality of life and functional outcomes. They found no difference between the groups when estimating blood loss, length of hospital stays, mortality rate, number of dislocations, postoperative complications or ambulatory status at 1 year in their 115 patient series [38].

Although it was not assessed in our analysis, the surgical approach may influence the postoperative hip range of motion and function. Several studies favored the anterolateral over the posterior approach as it preserves that posterior hip stabilizers and subsequently has a lower risk of dislocation than the posterior approach, a finding that matches previous studies [17,26,31,49].

While several RCTs have failed to present convincing data on differences in clinical outcome between the unipolar and the bipolar designs, the overall pooled estimates of our meta-analysis provided better hip range of motion with the bipolar prosthesis. Therefore, in the active and independent elderly population, bipolar hemiarthroplasty might be the preferred option over unipolar hemiarthroplasty.

The bipolar design has a theoretical advantage of less wear on acetabular cartilage. It has therefore been proposed as a more suitable alternative for more active patients with a longer

life expectancy [4,48]. However, the polyethylene cover of the inner surface of the bipolar head may run the risk of polyethylene wear causing synovitis and loosening of the stem [26]. Baker et al. introduced a grading system for acetabular erosion as judged from radiographs ranging from 0 (no erosion) to 3 (acetabular protrusion) [50]. They reported acetabular erosion in an RCT after three years in 21 of 32 patients (66%) operated upon using a unipolar cemented HA. Thirteen of the 21 patients had only a grade 1 erosion. The same grading system was used in an RCT by Hedbeck et al. including 60 patients with Exeter bipolar HAs showing only 14% erosion (all grade 1) after four years [51]. In another RCT by Enocson et al. of 120 patients allocated to treatment groups using either Exeter uni- or bipolar hemiarthroplasty the authors reported significantly less erosion in the bipolar (5%) group compared to the unipolar (20%) group after one year [26]. Moreover, there was a trend towards worse hip function and a lower quality of life (EQ-5D) among patients with acetabular erosion compared to those without. Our pooled results confirm these findings as acetabular erosion was more frequent in the unipolar group. These results indicate that the bipolar design may be advantageous for patients with a long-life expectancy as predicted preoperatively by Carlson comorbidity index scoring system [52].

Medical costs continue to increase and have been a subject of great interest over the past several years. The economic burden of caring for hip fracture patients is enormous and now contributes to a substantial percent of health care resources. The cost of caring for patients with hip fractures in the United States exceeds $8.7 billion; it is estimated that it will increase to more than $16 billion annually by 2040 [53]. Bipolar hemiarthroplasty is associated with longer operative time, although no significance in surgical or medical outcome was proved compared to unipolar HA. From an economical point of view, costs

may be higher with the bipolar hemiarthroplasty. However, given the difference in outcomes, bipolar hemiarthroplasty may be more cost-effective when considering the reoperation rate and hip function is superior. Unfortunately, evidence proving the cost effectiveness comparing both implant types is missing.

The reoperation rate comparing uni- and bipolar prosthesis is controversial. Inngul et al. found no difference in reoperation rates between uni- and bipolar patients [16]. This is in line with a previous study from the same institution on 830 Exeter HA patients with a median follow-up time of three years, where no difference in reoperation rate found between unipolar and bipolar HAs [26]. In contrast, Leonardsson et al. reported significantly higher risk for reoperation in bipolar HAs compared to unipolar ones in patients from the Swedish hip arthroplasty register including all HAs performed in Sweden between 2005 and 2010 [31]. The causes of reoperation in their study were dislocation, infection or periprosthetic fractures. A lower risk of reoperation due to acetabular erosion was shown in the bipolar than the unipolar hemiarthroplasty patients. Our pooled results are the opposite of these findings as the reoperation rate, dislocation, infection and periprosthetic fractures in bipolar HA were inferior compared to unipolar hip arthroplasty. An explanation could be that the risk of these complications generally increases in hemiarthroplasty procedures performed after failed internal fixation, in patients younger than 75 years and when uncemented stems were used or the posterior hip stabilizers were disturbed through a posterior hip approach [17,31].

Comparing the mortality of our pooled results, no difference was observed between both types of hemiarthroplasties. High mortality rates are directly proportionate to number of recurrent dislocations and preoperative comorbidities [26,54].

Limitations and strengths

A comprehensive database search and a rigorous screening process permitted us to concentrate on the studies that suited our eligibility criteria and appropriate to the research question. A strength of our study was the large sample size (30,250 patients) so that data could be generalized. This is due to the inclusion of both observational studies and RCTs. Some of our results showed significant heterogeneity which was best resolved using subgroup and sensitivity analyses. The Cochrane Collaboration tool was utilized to assess the risk of bias of the included RCTs. For observational studies, the Newcastle Ottawa scale was applied. The results of this study are subjected to limitations inherent to any meta-analysis based on data pooling from different trials with heterogenous study protocol, definitions for efficacy and safety outcomes, and different baseline patient characteristic. Only published data were utilized.

CONCLUSIONS

Bipolar hemiarthroplasty is associated with longer operative time, greater range of motion and less acetabular erosion than unipolar hemiarthroplasty. However, no significant difference in hip function using Harris hip score, mortality, surgical, and medical outcomes is evident. Future large studies are recommended to compare both methods in terms of quality of life.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

Conflict of Interest: The authors declare that they have no conflict of interest.
Funding: There is no funding source.
Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

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FIGURE LEGENDS

Fig. 1. PRISMA Flow diagram of articles selection process

Fig. 2. ***a.*** Risk of bias summary of randomized clinical trials, ***b.*** Risk of bias summary of observational studies

Fig. 3. Forest plot of postoperative hip function

Fig. 4. ***a.*** Forest plot of postoperative hip pain, ***b.*** Sensitivity analysis of hip pain

Fig. 5. Forest plot of reoperation rate

Fig. 6. Forest plot of operative duration

Fig. 7. Forest plot of intra-operative blood loss

Fig. 8. Forest plot of perioperative mortality and mortality at 6 months and one year after surgery

Fig. 9. Forest plot of implant-related complications

Fig. 10. Forest plot of postoperative hip range of motion

Fig. 11. Forest plot of postoperative six-minute-walk test

Fig. 12. Forest plot of postoperative acetabular erosion

Fig. 13. Forest plot of postoperative medical outcomes

Fig. 14. ***a.*** Forest plot of length of hospital stay, ***b.*** Sensitivity analysis of length of hospital stay

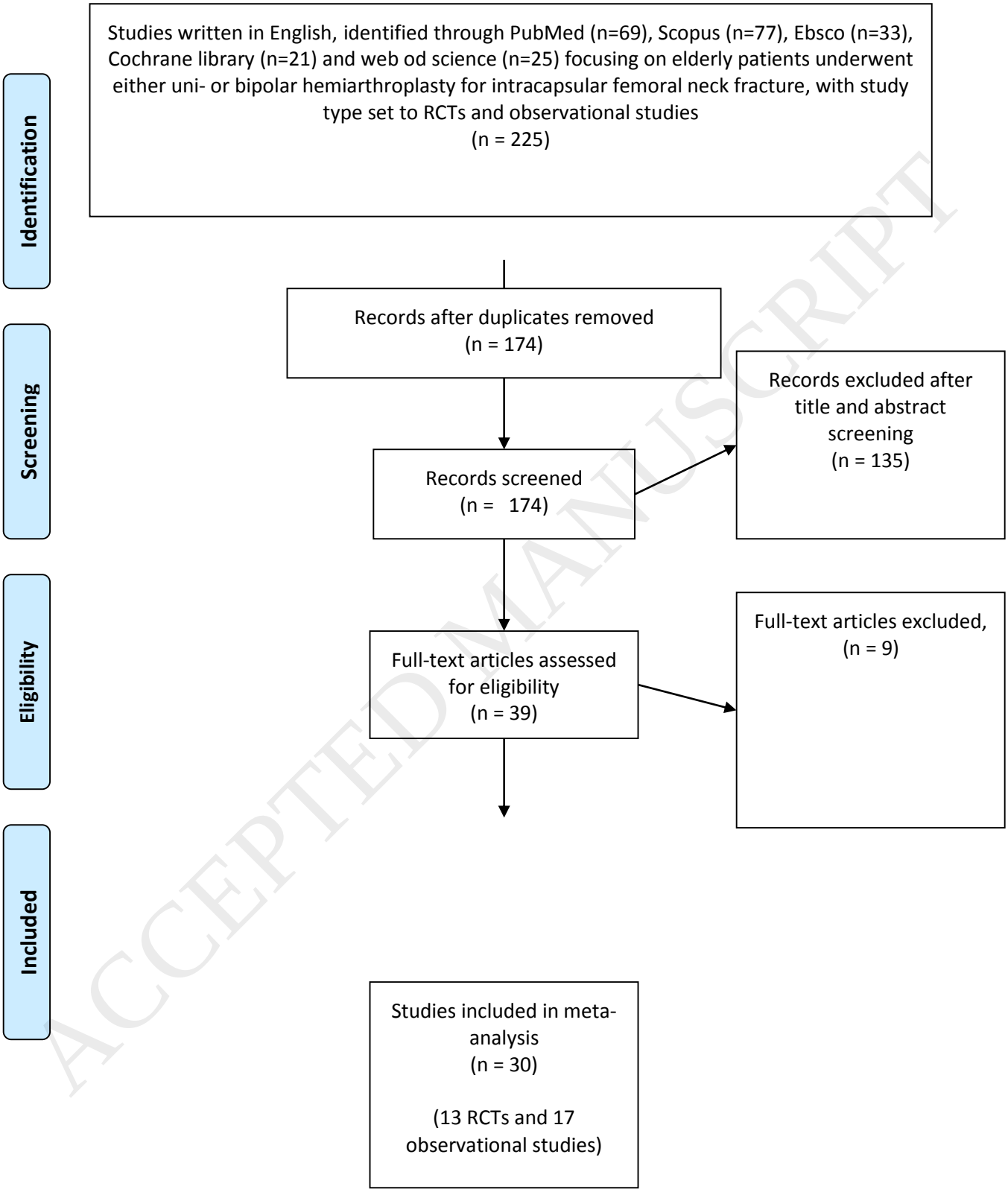
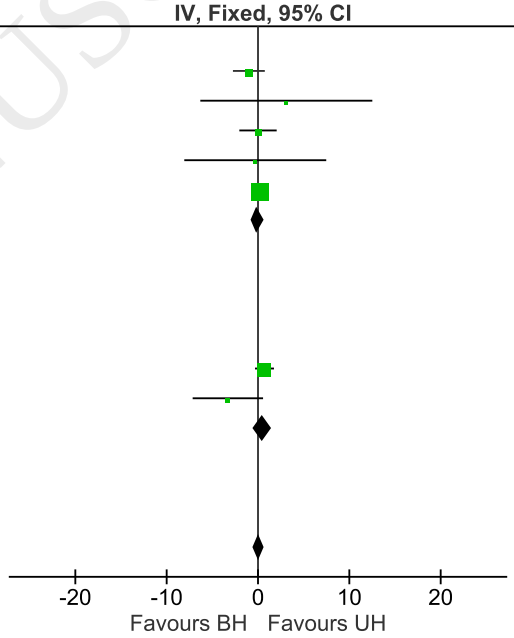


Figure 1. PRISMA (Preferred Reporting Items for Systematic of Reviews and Meta-analyses) flow diagram of articles selection process.

Study or Subgroup	BH Mean	BH SD	BH Total	UH Mean	UH SD	UH Total	Weight	Mean Difference IV, Fixed, 95% CI
1.6.1 RCTs								
Calder 1996	17	6.67	118	18	7.41	132	11.3%	-1.00 [-2.75, 0.75]
Cornell 1998	13.4	19.3	33	10.3	13.3	15	0.4%	3.10 [-6.32, 12.52]
Davison 2001	15	5.9	97	15	8.1	90	8.2%	0.00 [-2.04, 2.04]
Raia 2003	5.2	19.7	55	5.5	22.8	60	0.6%	-0.30 [-8.07, 7.47]
Stoffel 2013	8	1.8	133	7.8	4.7	128	45.4%	0.20 [-0.67, 1.07]
Subtotal (95% CI)			**436**			**425**	**65.8%**	**-0.02 [-0.74, 0.70]**
Heterogeneity: Chi² = 1.88, df = 4 (P = 0.76); I² = 0%								
Test for overall effect: Z = 0.05 (P = 0.96)								
1.6.2 Observational studies								
Lin 2012	10.1	2.78	58	9.39	3.02	62	31.9%	0.71 [-0.33, 1.75]
Wathne 1995	21.1	8.4	92	24.4	12.2	48	2.3%	-3.30 [-7.15, 0.55]
Subtotal (95% CI)			**150**			**110**	**34.2%**	**0.44 [-0.56, 1.44]**
Heterogeneity: Chi² = 3.88, df = 1 (P = 0.05); I² = 74%								
Test for overall effect: Z = 0.86 (P = 0.39)								
Total (95% CI)			**586**			**535**	**100.0%**	**0.14 [-0.45, 0.72]**
Heterogeneity: Chi² = 6.29, df = 6 (P = 0.39); I² = 5%								
Test for overall effect: Z = 0.46 (P = 0.64)								
Test for subgroup differences: Chi² = 0.53, df = 1 (P = 0.47), I² = 0%								



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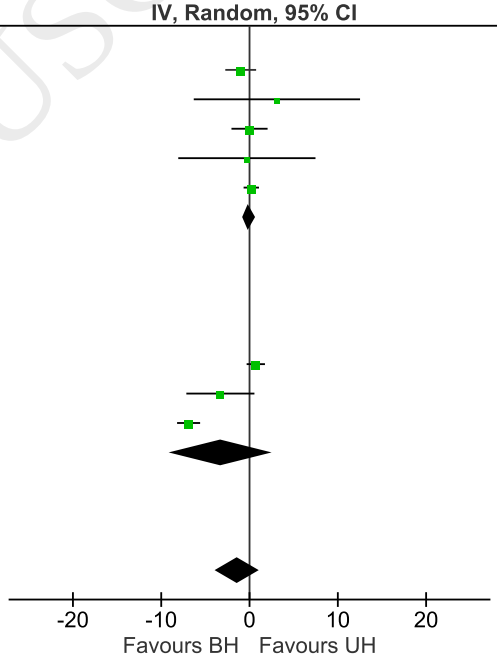
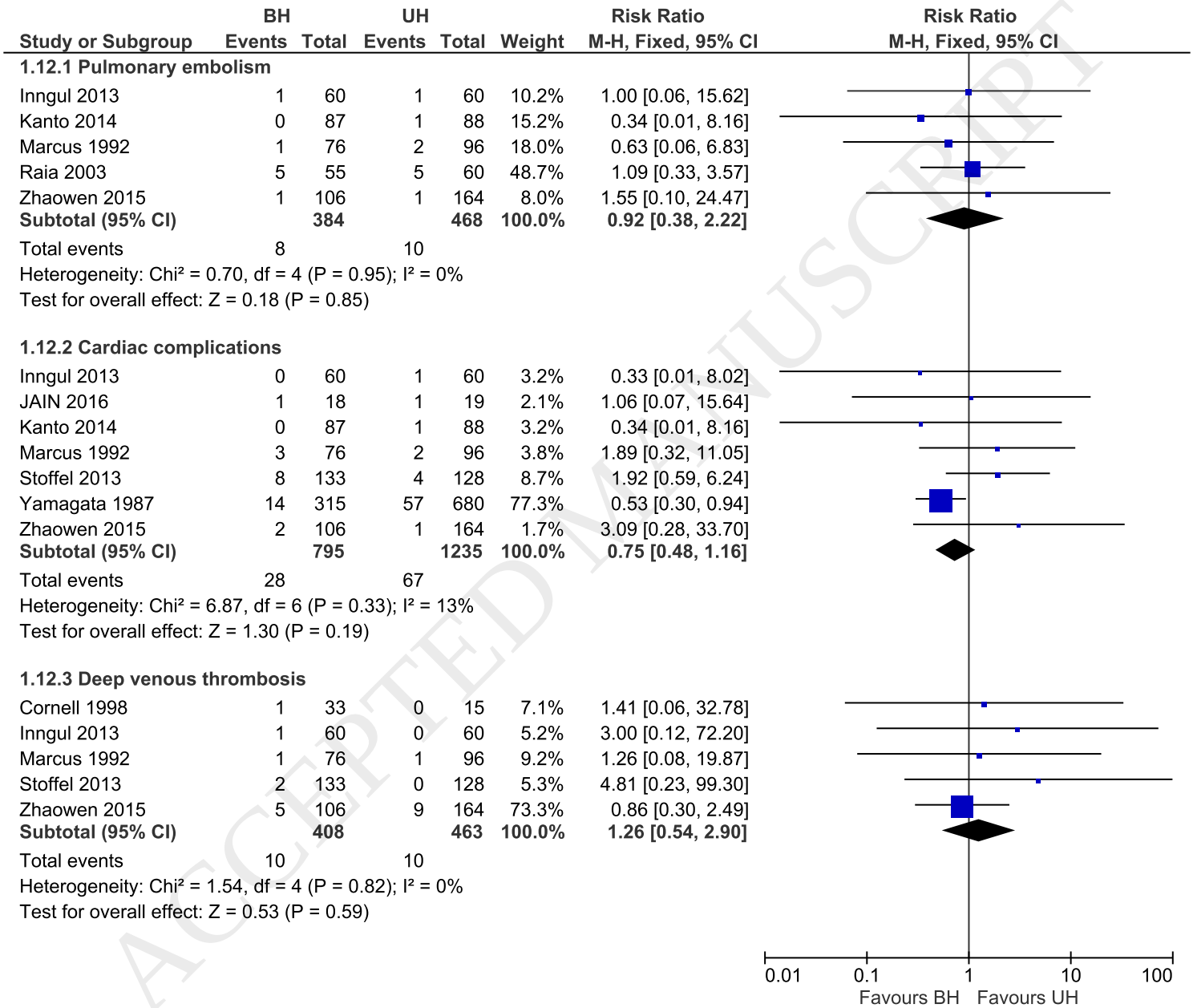
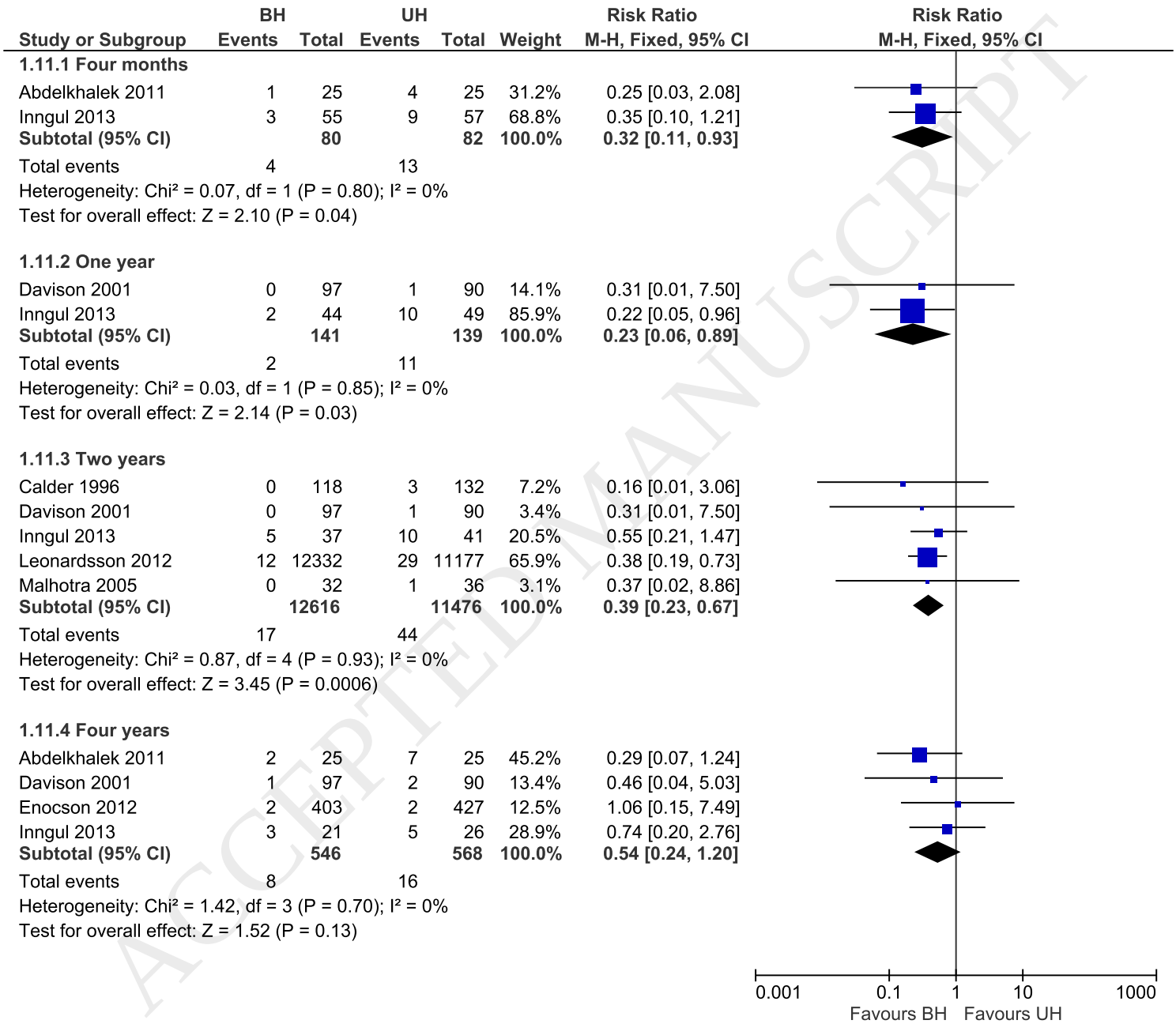
Cornell 1998	13.4	19.3	33	10.3	13.3	15	4.7%	3.10 [-6.32, 12.52]
Davison 2001	15	5.9	97	15	8.1	90	14.7%	0.00 [-2.04, 2.04]
Raia 2003	5.2	19.7	55	5.5	22.8	60	6.1%	-0.30 [-8.07, 7.47]
Stoffel 2013	8	1.8	133	7.8	4.7	128	16.1%	0.20 [-0.67, 1.07]
Subtotal (95% CI)			**436**			**425**	**56.7%**	**-0.02 [-0.74, 0.70]**
Heterogeneity: Tau² = 0.00; Chi² = 1.88, df = 4 (P = 0.76); I² = 0%								
Test for overall effect: Z = 0.05 (P = 0.96)								
1.6.2 Observational studies								
Lin 2012	10.1	2.78	58	9.39	3.02	62	16.0%	0.71 [-0.33, 1.75]
Wathne 1995	21.1	8.4	92	24.4	12.2	48	11.6%	-3.30 [-7.15, 0.55]
Yamagata 1987	17.5	8.4	315	24.4	12.2	680	15.7%	-6.90 [-8.20, -5.60]
Subtotal (95% CI)			**465**			**790**	**43.3%**	**-3.15 [-8.96, 2.66]**
Heterogeneity: Tau² = 24.93; Chi² = 80.35, df = 2 (P < 0.00001); I² = 98%								
Test for overall effect: Z = 1.06 (P = 0.29)								
Total (95% CI)			**901**			**1215**	**100.0%**	**-1.34 [-3.76, 1.07]**
Heterogeneity: Tau² = 9.22; Chi² = 99.36, df = 7 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 1.09 (P = 0.28)								
Test for subgroup differences: Chi² = 1.10, df = 1 (P = 0.29), I² = 9.0%								



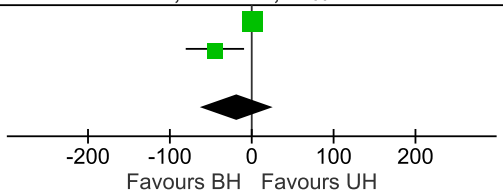


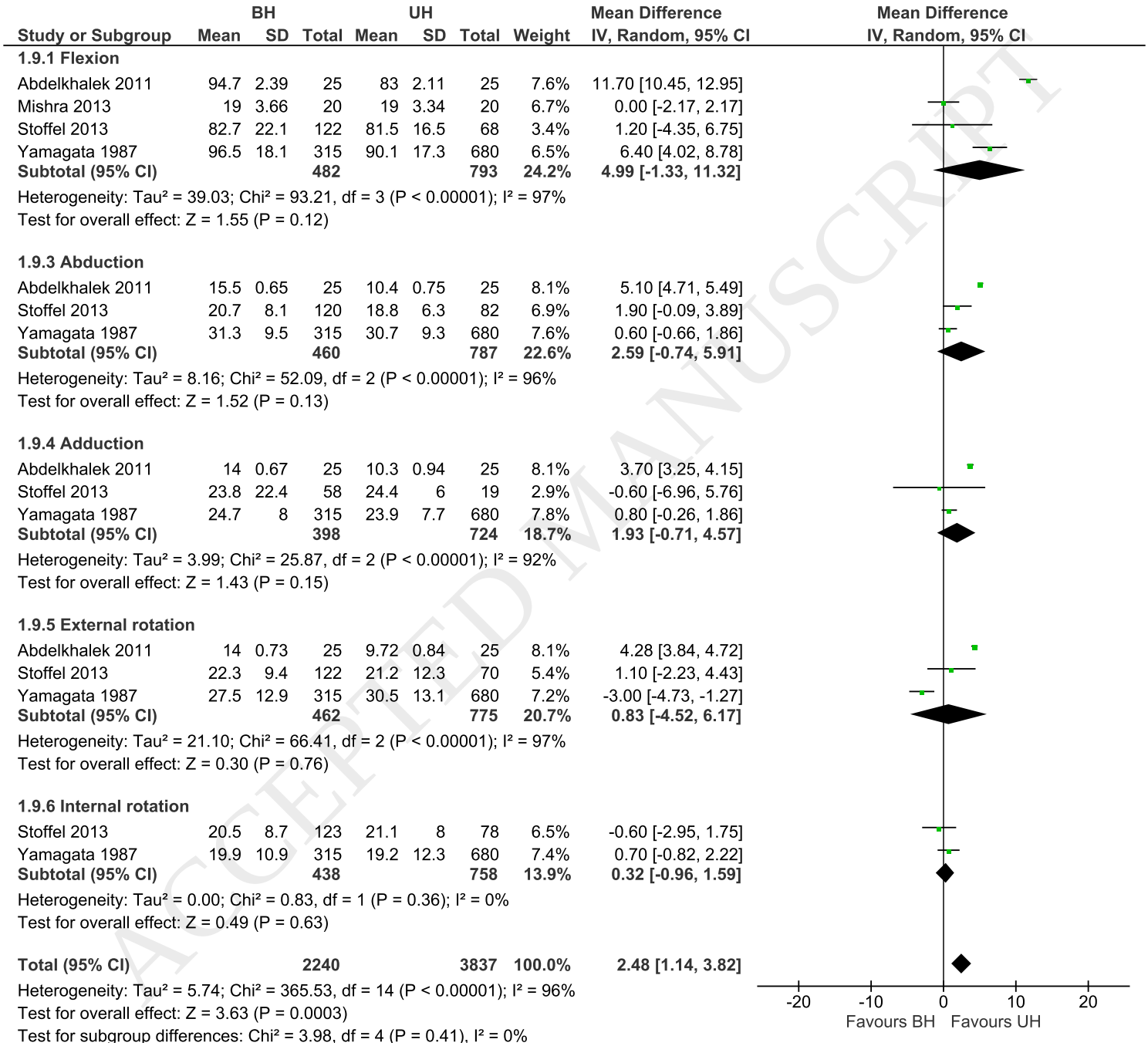


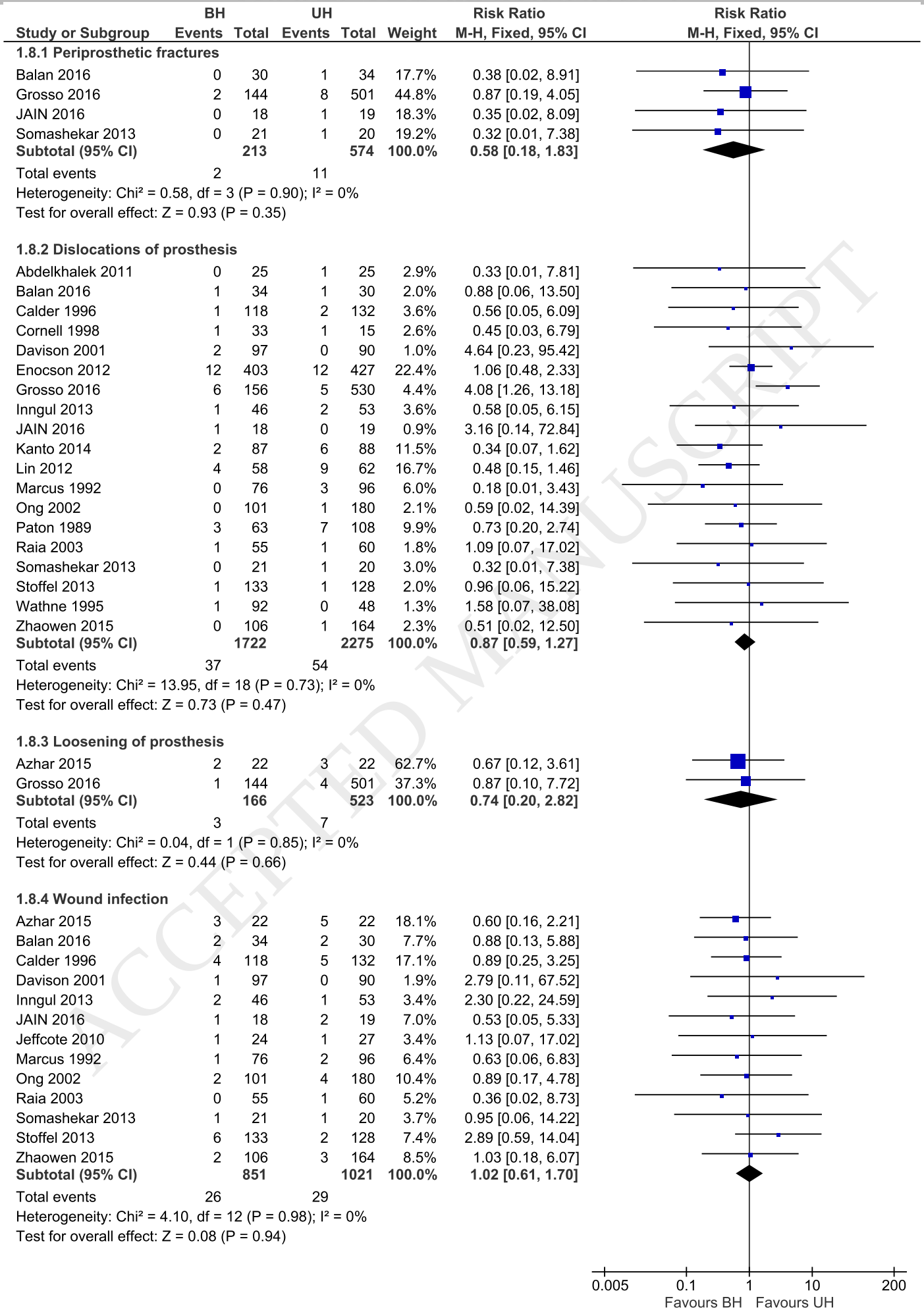
Study or Subgroup	BH Mean	BH SD	BH Total	UH Mean	UH SD	UH Total	Weight	Mean Difference IV, Random, 95% CI
Cornell 1998	2.67	14.8	33	1.93	0.8	15	57.7%	0.74 [-4.33, 5.81]
Stoffel 2013	138	126	94	183	122	92	42.3%	-45.00 [-80.64, -9.36]
Total (95% CI)			**127**			**107**	**100.0%**	**-18.59 [-62.87, 25.70]**

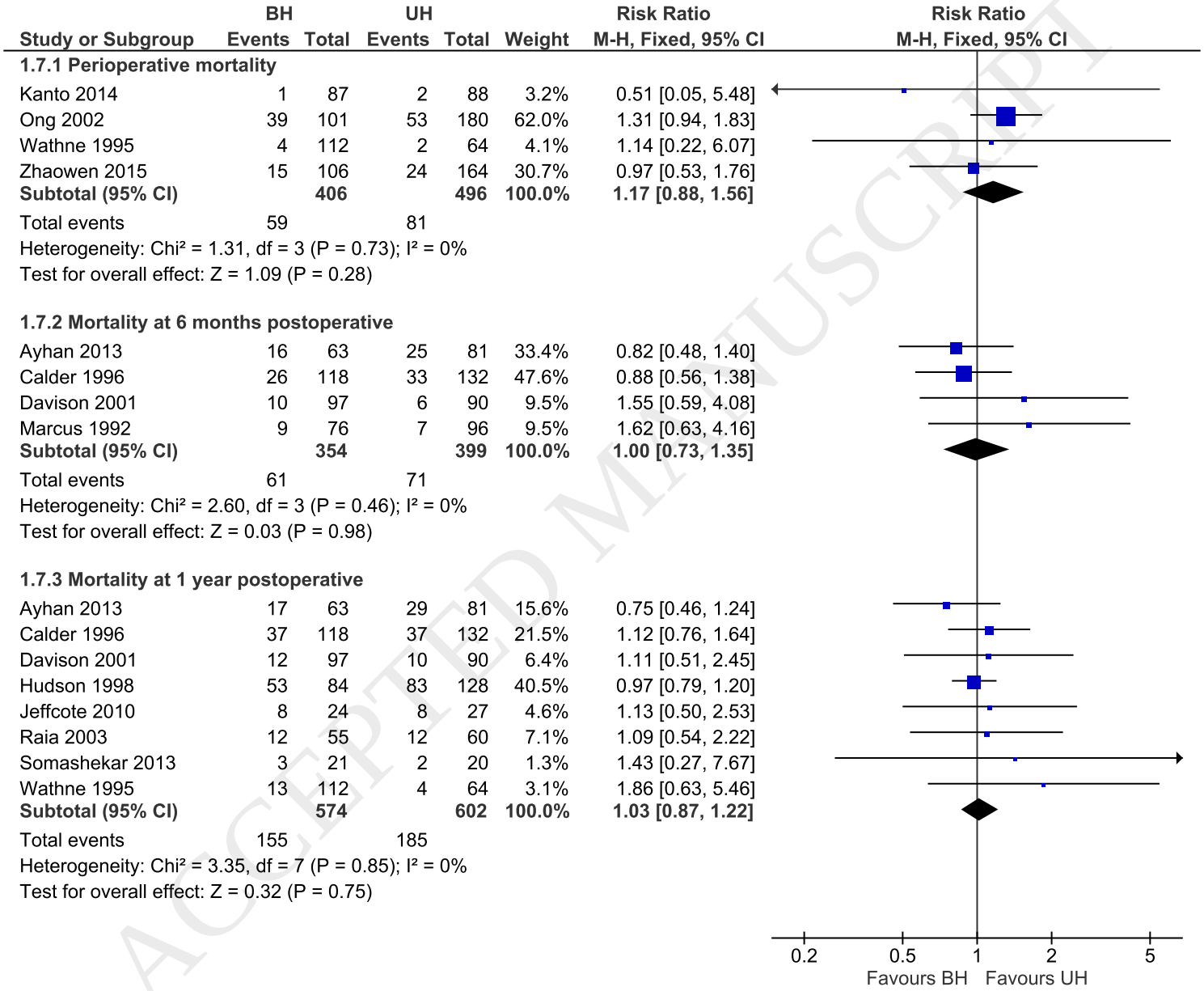
Heterogeneity: Tau² = 877.40; Chi² = 6.20, df = 1 (P = 0.01); I² = 84%

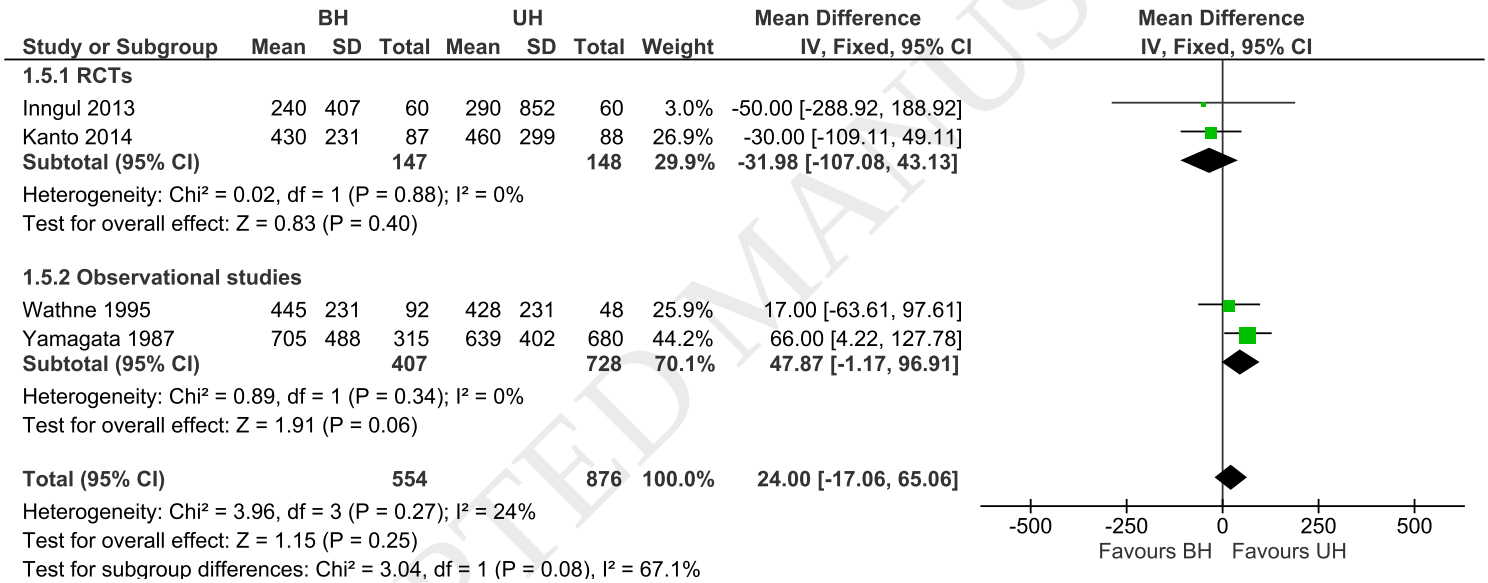
Test for overall effect: Z = 0.82 (P = 0.41)

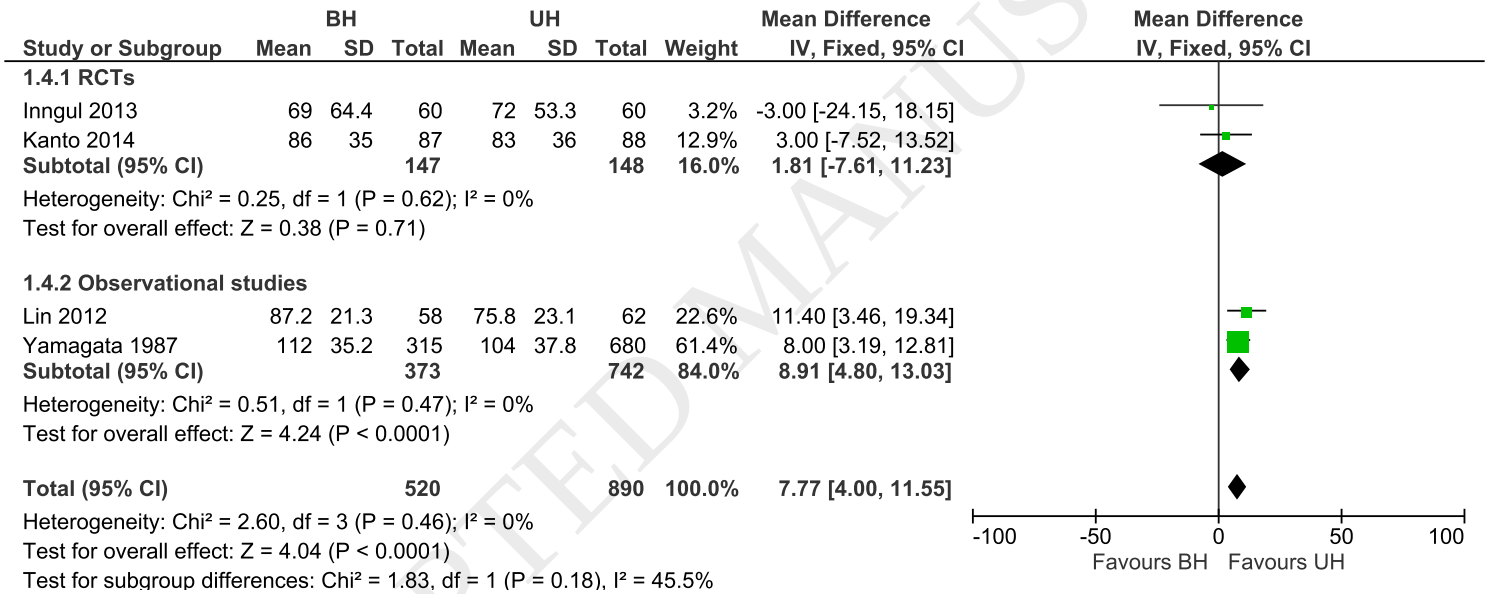




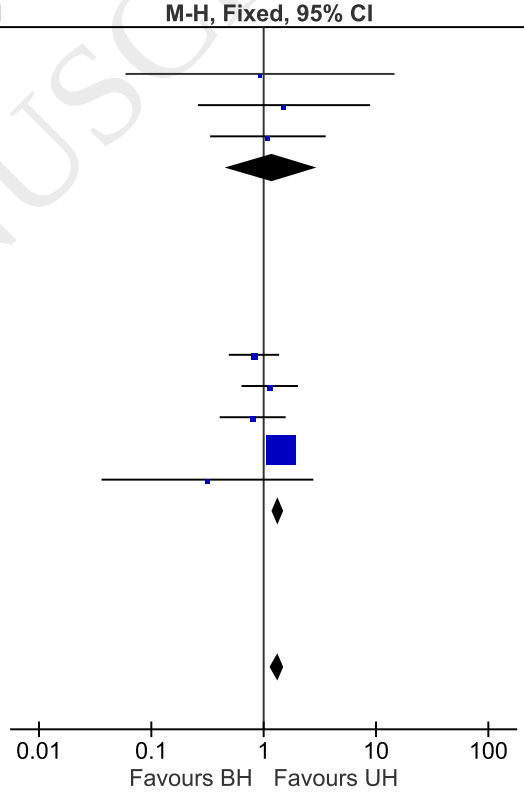




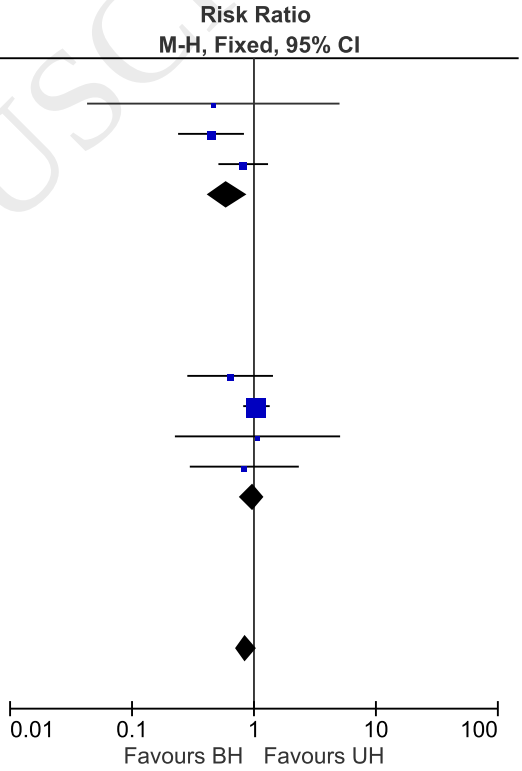




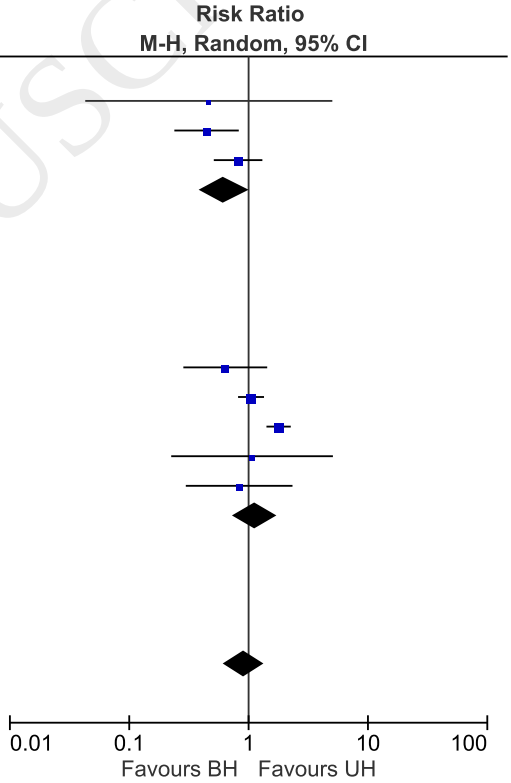
Study or Subgroup	BH Events	BH Total	UH Events	UH Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.3.1 RCTs						
Davison 2001	1	97	1	90	0.2%	0.93 [0.06, 14.61]
Kanto 2014	3	87	2	88	0.5%	1.52 [0.26, 8.86]
Raia 2003	5	55	5	60	1.1%	1.09 [0.33, 3.57]
Subtotal (95% CI)		**239**		**238**	**1.8%**	**1.18 [0.47, 2.97]**
Total events	9		8			
Heterogeneity: Chi² = 0.12, df = 2 (P = 0.94); I² = 0%						
Test for overall effect: Z = 0.35 (P = 0.73)						
1.3.2 Observational studies						
Enocson 2012	24	403	31	427	6.8%	0.82 [0.49, 1.37]
Grosso 2016	14	156	42	530	4.3%	1.13 [0.64, 2.02]
Hudson 1998	11	84	21	128	3.8%	0.80 [0.41, 1.57]
Leonardsson 2012	541	12332	347	11177	82.5%	1.41 [1.24, 1.61]
Marcus 1992	1	76	4	96	0.8%	0.32 [0.04, 2.77]
Subtotal (95% CI)		**13051**		**12358**	**98.2%**	**1.33 [1.17, 1.50]**
Total events	591		445			
Heterogeneity: Chi² = 8.36, df = 4 (P = 0.08); I² = 52%						
Test for overall effect: Z = 4.53 (P < 0.00001)						
Total (95% CI)		**13290**		**12596**	**100.0%**	**1.32 [1.17, 1.50]**
Total events	600		453			
Heterogeneity: Chi² = 8.55, df = 7 (P = 0.29); I² = 18%						
Test for overall effect: Z = 4.54 (P < 0.00001)						
Test for subgroup differences: Chi² = 0.06, df = 1 (P = 0.80), I² = 0%						



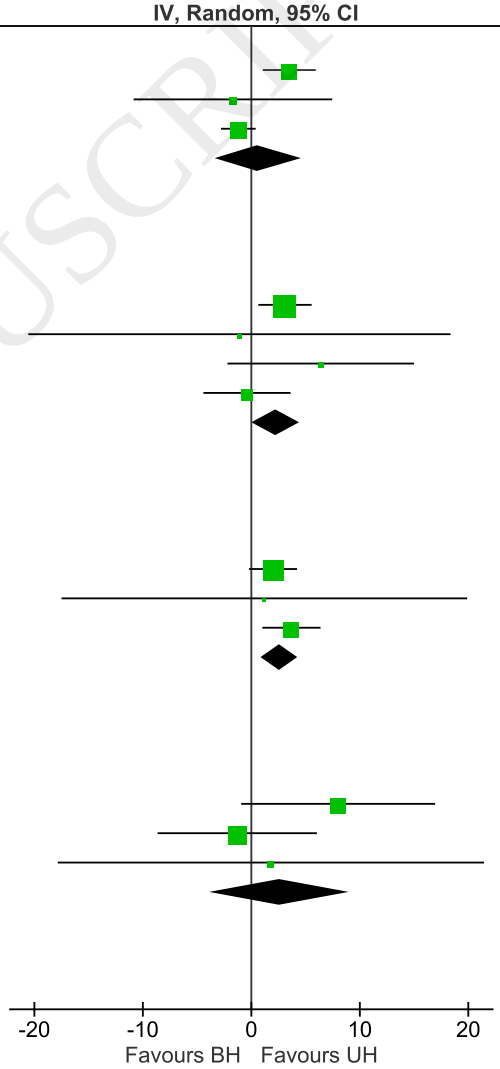
Study or Subgroup	BH Events	BH Total	UH Events	UH Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
1.2.1 RCTs							
Davison 2001	1	97	2	90	1.8%	0.46 [0.04, 5.03]	2001
Abdelkhalek 2011	8	25	18	25	15.5%	0.44 [0.24, 0.83]	2011
Somashekar 2013	12	21	14	20	12.3%	0.82 [0.51, 1.30]	2013
Subtotal (95% CI)		**143**		**135**	**29.6%**	**0.60 [0.41, 0.88]**	
Total events	21		34				
Heterogeneity: Chi² = 2.59, df = 2 (P = 0.27); I² = 23%							
Test for overall effect: Z = 2.62 (P = 0.009)							
1.2.2 Observational studies							
Wathne 1995	11	92	9	48	10.2%	0.64 [0.28, 1.43]	1995
Ong 2002	50	101	85	180	52.6%	1.05 [0.82, 1.35]	2002
Lin 2012	3	58	3	62	2.5%	1.07 [0.22, 5.09]	2012
Azhar 2015	5	22	6	22	5.2%	0.83 [0.30, 2.33]	2015
Subtotal (95% CI)		**273**		**312**	**70.4%**	**0.97 [0.77, 1.23]**	
Total events	69		103				
Heterogeneity: Chi² = 1.49, df = 3 (P = 0.69); I² = 0%							
Test for overall effect: Z = 0.22 (P = 0.83)							
Total (95% CI)		**416**		**447**	**100.0%**	**0.86 [0.71, 1.05]**	
Total events	90		137				
Heterogeneity: Chi² = 7.63, df = 6 (P = 0.27); I² = 21%							
Test for overall effect: Z = 1.45 (P = 0.15)							
Test for subgroup differences: Chi² = 4.47, df = 1 (P = 0.03), I² = 77.6%							



Study or Subgroup	BH Events	BH Total	UH Events	UH Total	Weight	Risk Ratio M-H, Random, 95% CI	Year
1.2.1 RCTs							
Davison 2001	1	97	2	90	2.4%	0.46 [0.04, 5.03]	2001
Abdelkhalek 2011	8	25	18	25	14.3%	0.44 [0.24, 0.83]	2011
Somashekar 2013	12	21	14	20	16.9%	0.82 [0.51, 1.30]	2013
Subtotal (95% CI)		**143**		**135**	**33.7%**	**0.63 [0.39, 1.00]**	
Total events	21		34				
Heterogeneity: Tau² = 0.04; Chi² = 2.59, df = 2 (P = 0.27); I² = 23%							
Test for overall effect: Z = 1.95 (P = 0.05)							
1.2.2 Observational studies							
Wathne 1995	11	92	9	48	11.5%	0.64 [0.28, 1.43]	1995
Ong 2002	50	101	85	180	20.4%	1.05 [0.82, 1.35]	2002
Sabnis 2011	105	274	93	433	20.7%	1.78 [1.41, 2.26]	2011
Lin 2012	3	58	3	62	4.9%	1.07 [0.22, 5.09]	2012
Azhar 2015	5	22	6	22	8.8%	0.83 [0.30, 2.33]	2015
Subtotal (95% CI)		**547**		**745**	**66.3%**	**1.13 [0.75, 1.72]**	
Total events	174		196				
Heterogeneity: Tau² = 0.12; Chi² = 13.60, df = 4 (P = 0.009); I² = 71%							
Test for overall effect: Z = 0.59 (P = 0.56)							
Total (95% CI)		**690**		**880**	**100.0%**	**0.90 [0.61, 1.33]**	
Total events	195		230				
Heterogeneity: Tau² = 0.18; Chi² = 28.09, df = 7 (P = 0.0002); I² = 75%							
Test for overall effect: Z = 0.52 (P = 0.60)							
Test for subgroup differences: Chi² = 3.41, df = 1 (P = 0.06), I² = 70.7%							



Study or Subgroup	BH Mean	BH SD	BH Total	UH Mean	UH SD	UH Total	Weight	Mean Difference IV, Random, 95% CI
1.1.2 Postoperative hip function at 6 months								
Balan 2016	85.6	4.3	34	82.1	5.5	30	41.2%	3.50 [1.06, 5.94]
Cornell 1998	63.2	15	33	64.9	15	15	13.5%	-1.70 [-10.85, 7.45]
JAIN 2016	75.8	2.37	18	77	2.59	19	45.3%	-1.20 [-2.80, 0.40]
Subtotal (95% CI)			**85**			**64**	**100.0%**	**0.67 [-3.29, 4.63]**
Heterogeneity: Tau² = 8.35; Chi² = 10.13, df = 2 (P = 0.006); I² = 80%								
Test for overall effect: Z = 0.33 (P = 0.74)								
1.1.3 Postoperative hip function at 1 year								
Balan 2016	89.6	3.82	34	86.5	5.86	30	65.4%	3.10 [0.64, 5.56]
Inngul 2013	77.7	49.6	46	78.8	48.9	53	1.2%	-1.10 [-20.56, 18.36]
Somashekar 2013	86.2	12.2	21	79.8	15.6	20	6.2%	6.40 [-2.20, 15.00]
Stoffel 2013	58.9	14.9	129	59.3	17.4	122	27.2%	-0.40 [-4.42, 3.62]
Subtotal (95% CI)			**230**			**225**	**100.0%**	**2.30 [0.14, 4.47]**
Heterogeneity: Tau² = 0.29; Chi² = 3.13, df = 3 (P = 0.37); I² = 4%								
Test for overall effect: Z = 2.09 (P = 0.04)								
1.1.4 Postoperative hip function at 2 years								
Calder 1996	72	8.9	118	70	8.9	132	59.0%	2.00 [-0.21, 4.21]
Inngul 2013	77.8	37	44	76.6	51.9	45	0.8%	1.20 [-17.49, 19.89]
Yamagata 1987	81.3	20.3	315	77.6	19.5	680	40.2%	3.70 [1.02, 6.38]
Subtotal (95% CI)			**477**			**857**	**100.0%**	**2.68 [0.98, 4.37]**
Heterogeneity: Tau² = 0.00; Chi² = 0.94, df = 2 (P = 0.62); I² = 0%								
Test for overall effect: Z = 3.09 (P = 0.002)								
1.1.5 Postoperative hip function at 4 years								
Abdelkhalek 2011	92.3	5.2	25	84.3	22.2	25	38.7%	8.00 [-0.94, 16.94]
Ayhan 2013	83.5	13.8	20	84.8	9.5	20	51.3%	-1.30 [-8.64, 6.04]
Inngul 2013	77.6	29.6	29	75.8	45.9	30	10.0%	1.80 [-17.84, 21.44]
Subtotal (95% CI)			**74**			**75**	**100.0%**	**2.61 [-3.80, 9.02]**
Heterogeneity: Tau² = 6.82; Chi² = 2.49, df = 2 (P = 0.29); I² = 20%								
Test for overall effect: Z = 0.80 (P = 0.42)								



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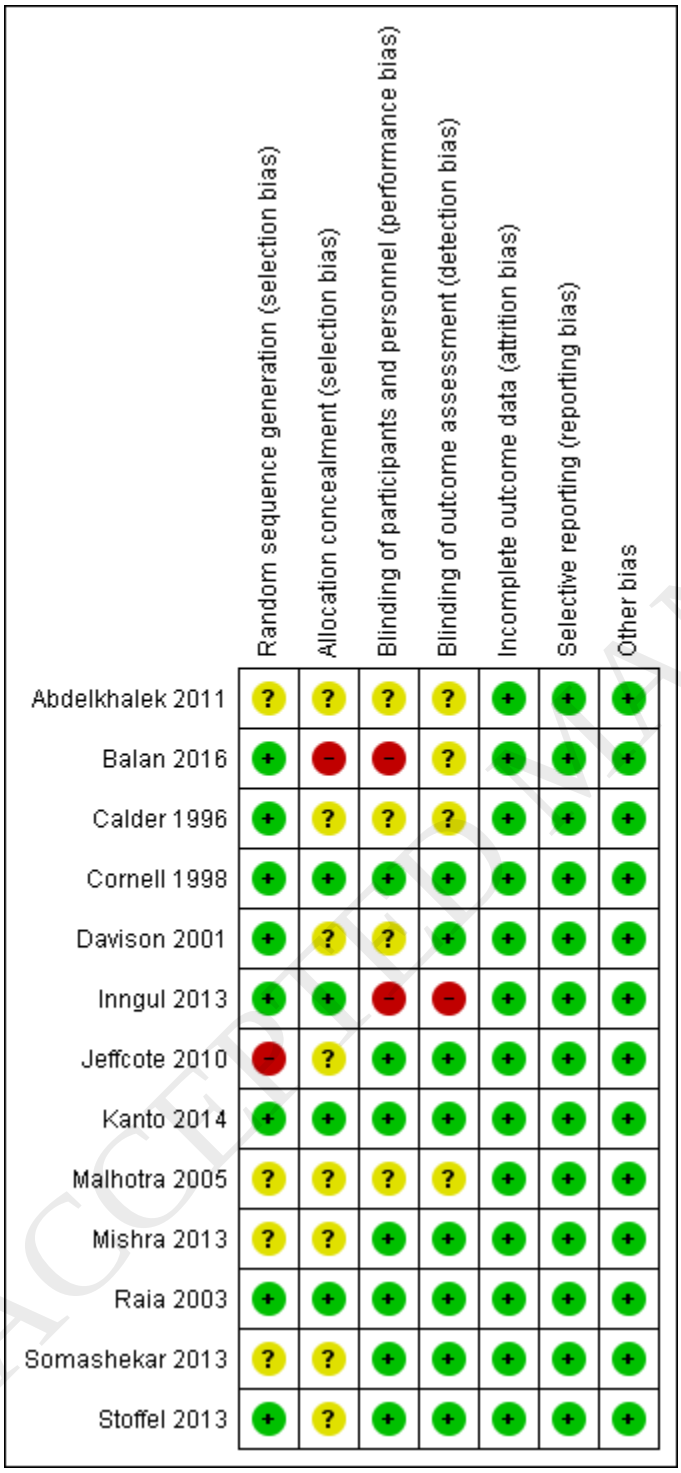

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