




# BMJ Open Total hip arthroplasty versus hemiarthroplasty for displaced femoral neck fracture: a protocol for an overview of systematic reviews

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## ABSTRACT

**Introduction** Hip arthroplasties for the treatment of displaced femoral neck fractures in adults can be total replacement or hemiarthroplasty. Despite the high prevalence of these fractures and large number of studies on the topic, the best choice of arthroplasty to be used remains unclear. The present study aims to overview the results of systematic reviews of randomised controlled trials (RCTs) comparing outcomes between total hip replacement and hemiarthroplasty for displaced femoral neck fractures in adults.

**Methods and analysis** Four electronic databases (Pubmed, Embase, Cochrane Library and Web of Science) and reference lists from previous reviews will be searched without language limitation. Eligible studies will be systematic reviews of RCT that compare total hip replacement and hemiarthroplasty for treatment of displaced femoral neck fractures in adults. Two reviewers will independently perform study selection, data extraction and quality assessment. Disagreements between reviewers will be resolved by a third reviewer. Comparisons of dichotomous data will report as the OR and 95% CI, and comparisons of functional and health-related quality of life outcomes are reported as the mean difference and 95% CI and as the risk difference, defined as the difference in the proportion achieving the minimum clinically important difference and 95% CI. As this overview will contribute to orthopaedic surgeons and health managers in better decision-making for the treatment of these fractures. The authors plan to complete the searches and analyses by 30 November 2021.

**Ethics and dissemination** Ethical approval was obtained at Federal University of Sao Paulo. Findings will be disseminated through peer-reviewed publication.

**PROSPERO registration number** CRD42021237885.

## INTRODUCTION

Due to the progressive population ageing, hip fractures are becoming highly prevalent worldwide. An epidemiological projection study points to a possible increase of these fractures by six times in the coming decades (from 700 000 fractures in 2013 to 4.5 million

## Strengths and limitations of this study

- This systematic review protocol follows the guidelines by the Cochrane Handbook of Overviews and Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.
- This overview of systematic reviews addresses a gap in a relevant topic of displaced femoral neck fractures.
- This review is limited to evidence from systematic reviews of randomised trials.
- Non-English electronic databases will not be searched. This limitation may cause language bias.
- There is the potential for a low and inconsistent quality in the reporting of some systematic reviews.

in 2050).<sup>1</sup> Therefore, geriatric hip fractures have become a public health issue. Displaced femoral neck fractures are commonly treated using either total hip arthroplasty (THA) or hemiarthroplasty. THA is a more complex procedure and is at a higher risk of future dislocation.<sup>2</sup> However, some randomised controlled trials (RCTs) have reported better functional outcomes and lowest rate of additional procedures after THA compared with hemiarthroplasty.<sup>3</sup> Some national guidelines recommend THA to patients with previous better functional condition who are most likely to take advantage from better well-functioning outcomes,<sup>4 5</sup> although these recommendations have not been implemented everywhere. For example, an international survey with general orthopaedic surgeons found that 73% prefer hemiarthroplasty.<sup>6</sup> There are clear institutional challenges to widespread THA, including availability of trained staff at all days.<sup>7</sup> The use of THA might also be affected by surgeons' skills and interpretation of the current literature.<sup>8 9</sup> The 'Hip fracture Evaluation with



Alternatives of Total Hip arthroplasty vs Hemiarthroplasty (HEALTH) trial<sup>10</sup> involved 1495 patients in 80 participating centres around 10 countries and aimed to collate hemiarthroplasty with THA in the population of adult patients with hip fracture that were independently mobile before lesion. The primary outcome was an unplanned secondary hip procedure within 24 months of operation. Judge *et al*<sup>11</sup> commented that although HEALTH is a huge and very relevant study, some aspects about their main outcomes must be carefully evaluated. First, the primary outcome was not function or quality of life because these are the principal advantages of THA versus hemiarthroplasty. It has been suggested that the more relevant outcomes in hip fracture patients are mortality, pain, daily living activities, mobility and health-related quality of life (HRQoL).<sup>12</sup> Second, the HEALTH authors concluded that the statistically significant functional benefit in favour of THA was not clinically important. However, the upper limit of the 99% CI for mean difference (MD) in EuroQoL-5D utility index score (0.11) was higher than the minimum clinically important difference that is often accepted for this outcome in the hip fracture population (0.08).<sup>13</sup> This points are relevant because HEALTH study was included in some systematic reviews published in 2020<sup>14–16</sup> and due to its large sample number it will probably have a significant impact on the analysis of the data in this overview.

Due to the relevance of the topic and the lack of an overview of the several published systematic reviews, we idealised the present study.

## METHODS AND ANALYSIS

### Types of studies and inclusion criteria

This is a secondary clinical study, an overview of systematic reviews. This study will follow the recommendations proposed by the Cochrane Handbook of Overviews<sup>17</sup> and Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.<sup>18</sup> Our study will include only systematic reviews with meta-analysis, comparing THA versus hemiarthroplasty for treatment of displaced femoral neck fracture in adults. Other studies in such narrative reviews or data from national hip arthroplasty register will be excluded. The clinical question was formulated according to PICOS strategy<sup>19</sup>:

Population: adults >50 years of age with displaced femoral neck fractures.

Intervention: THA.

Control: hemiarthroplasty

Outcomes: revision rate, mortality, quality of life, function, complications (infection, number of dislocations and periprosthetic fracture), cost effectiveness, hospital stay and surgical time.

Study (type of study): systematic reviews.

## Inclusion and exclusion criteria

### Study inclusion criteria

- ▶ Systematic reviews with meta-analysis of RCTs about THA versus hemiarthroplasty in adults with displaced femoral neck fractures.
- ▶ Systematic reviews with meta-analysis of RCTs about femoral neck fractures general treatment in at least one arm of the study evaluate THA versus hemiarthroplasty in adults with displaced fractures (only data of interest for the present study will be extracted).

### Exclusion criteria

- ▶ Non-systematic reviews (narrative reviews and synthesis from national arthroplasty register).
- ▶ Other studies design about femoral neck fractures treatment.

### Primary outcomes (critical)

The critical outcomes will be revision rate, function, HRQoL and mortality.

### Secondary outcomes (important)

The number of dislocations, periprosthetic fracture, periprosthetic joint infection, cost and operative time will be the secondary outcomes.

### Search methods and strategy

The search for articles will be carried out in four databases (Pubmed, Embase, Cochrane Library and Web of Science), without restriction of date or language (see online supplemental file). PROSPERO (International Prospective Register of Systematic Reviews) will be checked for on-going systematic reviews about the topic. A medical librarian expert and a discussion group will conduct effective search strategy. The search engine to be used for each library is described below.

#### Pubmed

(hip fractures(mesh) OR hip fracture\*(tw) OR femoral neck fractures(mesh) OR femoral neck fracture\*(tw) OR femur neck fracture\*(tw) OR femoral collum fracture\*(tw) OR femur collum fracture\*(tw) OR intracapsular hip fracture\*(tw) OR subcapital hip fracture\*(tw) OR intracapsular collum fracture\*(tw) OR subcapital collum fracture\*(tw) OR intracapsular neck fracture\*(tw) OR subcapital neck fracture\*(tw)) AND (arthroplasty(mesh) OR arthroplast\*(tw) OR hemiarthroplast\*(tw) OR hip replace\*(tw) OR hip prosth\*(tw)) AND random\*(tw) NOT (animals(mesh) NOT humans(mesh)).

#### Embase

('femur neck fracture'/syn OR (('femoral neck' OR 'femur neck' OR 'femoral collum' OR 'femur collum' OR 'intracapsular hip' OR 'subcapital hip' OR 'intracapsular collum' OR 'subcapital collum' OR 'intracapsular neck' OR 'subcapital neck') NEAR/3 fracture\*):ti,ab,de) AND ('hip arthroplasty'/syn OR hemiarthroplast\*:ti,ab,de OR (hip NEAR/3 (replace\* OR prosth\*)):ti,ab,de) AND random\*:ti,ab,de NOT (animal/de NOT human/de).

### Cochrane library

(hip fractures OR hip fracture OR femoral neck fractures OR femoral neck fracture OR femur neck fracture OR femoral collum fracture OR femur collum fracture OR intracapsular hip fracture OR subcapital hip fracture OR intracapsular collum fracture OR subcapital collum fracture OR intracapsular neck fracture OR subcapital neck fracture) AND (arthroplasty OR arthroplast OR hemiarthroplast OR hip replace OR hip prosthesis).

### Web of science

(hip fracture\* OR femoral neck fracture\* OR femur neck fracture\* OR femoral collum fracture\* OR femur collum fracture\* OR intracapsular hip fracture\* OR subcapital hip fracture\* OR intracapsular collum fracture\* OR subcapital collum fracture\* OR intracapsular neck fracture\* OR subcapital neck fracture\*) AND (arthroplast\* OR hemiarthroplast\* OR hip replace\* OR hip prosthesis\*) AND random\* NOT (animal\* NOT human\*).

If we need additional information about missing or not fully reported data in the included studies, the corresponding authors will be contacted directly by email.

### Data collection and analysis

Two reviewers will independently access the selected studies and the extracted data from these studies using institutional Google Workspace to facilitate collaboration among them during the selection process. Two authors will independently select and analyse the eligible studies for this systematic review through the title and abstract using the following criteria: (1) systematic reviews of RCTs and (2) comparative treatment between THA and hemiarthroplasty in adults with displaced femoral neck fractures in at least one arm of the study. Selected studies will be entirely reviewed for determining their eligibility, and any disagreement will be solved through discussion and when necessary will be judged by a senior author in an attempt to resolve a possible conflict. Technical appendix, statistical code and dataset will be available from the Google Drive link (falotico@unifesp.br).

### Assessment of methodological quality of included reviews

Systematic reviews will have the methodology evaluated by the tools AMSTAR-2<sup>20</sup> and ROBIS<sup>21</sup> to verify the quality of existing studies and carry out a critical analysis of the included literature. They are useful and widely used tools in evidence-based medicine and will allow the analysis to be grouped between studies of high risk and low risk of bias. The use of these instruments will allow for a critical analysis of the literature published on the topic.

The certainty of evidence for each included outcome will be rated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.<sup>22</sup> This tool will be applied to the assessments presented in the systematic reviews. In GRADE, recommendations can be strong or weak, in favour or against an intervention. Strong recommendations suggest that all or almost all persons would choose that intervention.

Weak recommendations imply that there is likely to be an important variation in the decision that informed persons are likely to make. The strength of recommendations is actionable: a weak recommendation indicates that engaging in a shared decision-making process is essential, while a strong recommendation suggests that it is not usually necessary to present both options. Recommendations are more likely to be weak rather than strong when the certainty in evidence is low, when there is a close balance between desirable and undesirable consequences, when there is substantial variation or uncertainty in patient values and preferences and when interventions require considerable resources. Disagreements will be solved by the analysis of a third reviewer after further analysis. The primary studies in the included systematic reviews will not directly be evaluated.

### Data extraction and handling

Only the data present in the systematic reviews will be evaluated and extraction will be performed by two reviewers using an appropriate customised extraction form (Microsoft Access/Excel, Excel V.16.34, 2020). A general table with the demographic data of the studies (author, year of publication and sample size) will be included. Reviewers will record details regarding eligible reviews: data will assess up to date range of the studies included in each review, population, intervention, comparison intervention, outcomes for which data were reported and systematic review limitations. The overlap of primary studies which are present in more than one systematic review included in this overview will be assessed according to the criteria of Pieper *et al*<sup>23</sup> and in case of overlap greater than 10% the studies will be added individually in the statistical analysis and not directly meta-analysed to avoid statistical bias of data superposition.

### Measures of treatment effect

The dichotomous data will be analysed with a relative risk and 95% CI. Continuous outcomes will be reported as an MD. If the systematic reviews measure the same outcomes using different instruments or different units of measurement, OR will be converted into standard MD (SMD) and effect size. The Cochrane Review Manager software (V.5.3, Copenhagen: the Nordic Cochrane Centre, the Cochrane Collaboration, 2014) will be used for statistical analyses, combining SMD using inverse variance methodology.

Selective publication of systematic reviews can lead to a false estimated effect and small numbers of patients and systematic reviews that included studies funded by industry are also factors that negatively influence publication bias, which can be analysed and clearly reported; funnel plots will be applied and less publications bias will be detected when systematic reviews were distributed around the best estimate of effect (HR).





## Data synthesis

Demographic data will summarise across systematic reviews as the pooled mean, weighted by sample size and the SD. A narrative summary of the data will be presented. Comparisons of dichotomous data will report as the OR and 95% CI, and comparisons of functional and HRQoL outcomes are reported as MD and 95% CI and as the risk difference, defined as the difference in the proportion achieving the minimally important difference and 95% CI. For all meta-analyses, the  $\chi^2$  test and the  $I^2$  statistic will be used to provide estimate of heterogeneity. If in any included outcome it is not possible to perform the statistical analysis, a descriptive summary of the data will be performed. If sufficient data will be available in the included systematic reviews, the patients will be categorised as below and above 80 years of age because this cut-off may clarify the best arthroplasty option in super-elderly population.

## Confidence in cumulative evidence

GRADE will be applied to the results reported in the included reviews to describe and rate the quality of evidence (QE) of each outcome and the strength of recommendations classifying them as high, moderate, low and very low.<sup>24 25</sup> The five categories (risk of bias, inconsistency, indirectness, imprecision and publication bias) can lower the GRADE approach; however, large effects, dose–response relationship and all plausible residual confounders or biases (would reduce a demonstrated effect or suggest a spurious effect if no effect was observed) can upgrade the QE.<sup>12</sup> Some critical and important outcomes for the GRADE approach were determined: revision rate, function, HRQoL and mortality.<sup>26</sup> These outcomes will be assessed individually and individual recommendation will be provided. Following this protocol publication, electronic search will be performed and the selected systematic reviews will be analysed. Once we get the results, we intend to publish this manuscript. Our intention is to have the manuscript ready by the early 2022. We expect to clarify the indications for the total hip replacement or hemiarthroplasty for treatment of displaced femoral neck fractures based on the best evidence available in published systematic reviews about this topic.

## ETHICS AND DISSEMINATION

The study has been approved by the Institutional Review Board of Universidade Federal de Sao Paulo (registry number: 6987100920). Findings will be disseminated through peer-reviewed publication after data extraction and analysis. The authors plan to complete the searches and analyses by 30 November 2021.

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