Efficacy of four hollow nail rhombic fixation for the treatment of patients with femoral neck fractures: A protocol of systematic review and meta-analysis

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Abstract

Background : This study aims to assess the efficacy of four hollow nail rhombic fixation (FHNRF) for the treatment of patients with femoral neck fractures (FNF).

Methods : A literature search in MEDLINE, Scopus, Web of Science, EMBASE, Cochrane Library, ProQuest, Thesis and Dissertation Catalog, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge Infrastructure will be performed from inception through February 29, 2020. This study will not apply limitations to the language and publication date. All potential randomized controlled trials (RCTs) that identify the efficacy and safety of FHNRF for the treatment of patients with FNF. Two contributors will separately examine searched records, extract essential data, and assess study quality using Cochrane risk of bias tool. Any opposition between two authors will be settled by a third contributor. We will employ RevMan 5.3 software for statistical analysis.

Discussion : This study will summarize high quality RCTs to assess the efficacy and safety of FHNRF for the treatment of patients with FNF. It will help to determine whether or not FHNRF is effective and safety for the treatment of patients with FNF. Systematic review registration CRD42020168378.

Background

Femoral neck fractures (FNF) is a common injury in the emergency visits, especially in elderly population [1–3]. It is estimated that the incidence of hip factures is approximately 6 million by 2050 worldwide [4–5], and FNF accounts for about 50% of all hip fractures [6–7]. It is associated with impaired mobility, loss of function, mortality and morbidity [8–11]. The optimal management of FNF is surgery [12].

Studies suggested that four hollow nail rhombic fixation (FHNRF) can be utilized for the treatment of FNF [13–20]. However, no systematic review is published on investigating the efficacy and safety of FHNRF for the treatment of FNF. This study aims to determine the efficacy and safety of FHNRF in the treatment of FNF by assessing the quality of the available evidence. The specific question addressed by this study: is FHNRF effective and safe in the treatment of patients with FNF?

Methods And Analysis

Study registration

This study has been registered on PROSPERO (CRD42020168378). We have reported it following the guideline of Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol statement [21–22].

Eligibility criteria for study selection

Types of study

All randomized controlled trials (RCTs) that appraised the efficacy and safety of FHNRF for the treatment of patients with FNF will be included. We will exclude all other studies, such as laboratory studies, case report, case series, review, and non-clinical trial.

Types of participant

All patients who were diagnosed with FNF will be included, in spite of their characteristics, and duration and severity of FNF.

Types of intervention

Interventions

All patients in the interventional group received FHNRF as their therapy.

Comparators

Studies comparing any other treatments, such as partial hip replacement, and total hip replacement will be included in this study.

Types of outcome measurement

The primary outcome is pain intensity, which has been assessed by any relevant pain scales, such as Visual Analogue Scale.

The secondary outcomes are stiffness and physical function (as examined by any associated index, such as Western Ontario and McMaster Universities Osteoarthritis Index); and quality of life (as assessed by any related scales, such as 36-Item Short Form Health Survey), and adverse events.

Literature search

We will systematically and comprehensively conduct searches in MEDLINE, Scopus, Web of Science, EMBASE, Cochrane Library, ProQuest, Thesis and Dissertation Catalog, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge Infrastructure from inception through February 29, 2020 with no restrictions to language and publication date. We will consider all potential RCTs that explored the efficacy and safety of FHNRF for the treatment of patients with FNF. The full search strategy

for MEDLINE is displayed (table 1), and we will adapt similar search strategies for other electronic databases.

We will identify other sources to avoid losing potential studies, such as dissertations/thesis, conference proceedings and reference lists of included RCTs.

Study selection

Two examiners will independently evaluate the titles and abstracts of the found literatures during the searches for potential inclusion. All irrelevant and duplicated studies will be removed. Potential relevant articles will be carefully read in full by the same two examiners. The articles that meet all eligibility criteria will be included. Different views will be discussed in consensus conferences with the help of a third examiner. The results of study selection will be presented in a flow diagram.

Data extraction and management

Two examiners will independently extract data from eligible studies. The extracted information includes trial setting, trial characteristics (e.g. first author, time of publication, et el), research design, details of intervention and comparator, eligibility criteria, outcomes, patient characteristics (e.g. sample size, sex, age, co-morbidities, et al), results, conclusion and conflict of interest. Any discrepancies will be solved through discussion with a third examiner.

Missing data dealing with

If there is unclear or missing data, primary authors will be contacted to request it by email or telephone. In case of unavailable data, we will analyze present data using an intention-to-treat analysis.

Risk of bias assessment

Two examiners will separately identify risk of bias for each eligible study using Cochrane Risk of Bias Tool. It assesses risk of bias through 7 aspects and each one is graded as low, unclear or high risk of bias. Opposite opinions will be arbitrated by a third examiner through discussion.

Statistical analysis

Data synthesis

We will place RevMan 5.3 software to analyze extracted data, and carry out a meta-analysis whenever it is possible. We will estimate the pooled treatment effects of dichotomous data as risk ratio and 95% confidence intervals (CIs), and those of continuous data as weighted mean difference or standardized mean difference and 95% CIs. We will check statistical heterogeneity across RCTs by I^2 test. $I^2 \leq 50\%$ exerts little statistical heterogeneity, and a fixed-effects model will be applied. $I^2 > 50\%$ indicates distinct heterogeneity, and a random-effects model will be employed. A subgroup analysis will be conducted to test possible reasons of apparent heterogeneity. If there is still evident heterogeneity after subgroup analysis, we will conduct a narrative summary.

Subgroup analysis

We will carry out a subgroup analysis to explore the sources of obvious heterogeneity based on the different types of study and patient characteristics, interventions and comparators, and outcomes.

Sensitivity analysis

We will perform a sensitivity analysis to test the robustness of study findings based on the methodological weaknesses and missing data.

Publication bias

We will conduct a funnel plot and Egger's test to investigate the publication biases when more than 10 RCTs are included.

Grading quality of evidence

Two examiners will separately appraise the quality of evidence for major outcomes by Grading of Recommendations Assessment, Development, and Evaluation System approach [23–24]. Any conflicts will be cleared up by discussion with a third examiner, and a final consensus will be reached.

Dissemination

We will publish this study via a peer-reviewed journal.

Discussion

FNF is a common disorder in the elderly population, which often brings very poor quality of life in patients with FNF. Currently, FHNRF approach is used for the treatment of patients with FNF. In spite of the clinical and experimental support, the efficacy and safety of FHNRF for FNF have not been fully validated and

evaluated. In addition, no systematic review and meta-analysis regarding it has been done. Therefore, this study aims to evaluate the efficacy and safety of FHNRF for the treatment of patients with FNF. Its findings may supply evidence for the reference of clinical practice and health-related policy maker.

Abbreviations

FHNRF, four hollow nail rhombic fixation; FNF, femoral neck fractures; RCTs, randomized controlled trials; CIs, confidence intervals.

Declarations

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and material: Data sharing is not applicable to this article as no datasets were generated or analyzed during the current protocol

Competing interests: Not applicable.

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*Authors' contributions:*QHJ and YBL conceived the study. ZXR and YFY contributed with the clinical background and expertise. QHJ, YX, JM, and YBL contributed with the analytical plan and the bias assessment approach. ZXR and YFY performed the literature search plan. QHJ, YX, JM, YFY, and YBL drafted the protocol. All authors revised the protocol and approved the final version. YBL supervised the study

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Table

Table 1 Search strategy utilized for MEDLINE database

Number	Search terms
1	femoral neck fractures
2	hip fractures
3	femoral head
4	femoral neck
5	femoral neck junction
6	Or 1-5
7	four hollow nail
8	rhombic fixation
9	nail fixation
10	fracture fixation
11	Or 7-10
12	random
13	randomly
14	blind
15	control
16	comparator
17	controlled trial
18	clinical trial
19	study
20	Or 12-19
21	6 and 11 and 20

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