INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Can locked fibula nail replace plate fixation for treatment of acute ankle fracture? A protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **We seek to conduct a meta-analysis of relevant studies to evaluate and compare functional outcomes and complication rates between locked fibula intramedullary nail fixation and plate fixation for treatment of ankle fractures.**
Condition being studied: **Ankle fractures, with an incidence rate of 4.22/10, 000 person-years in the United States, are one of the most common lower extremity fractures. Currently, the standard surgical treatment approaches for unstable ankle fractures involves open reduction and internal fixation (ORIF) with plates and screws. However, ORIF has resulted in little efficacy during treatment of fractures since the 1960s, while plate and screw fixation has also been associated with several complications. Previous studies have shown that closed reduction and internal fixation (CRIF) with fibula intramedullary nail (IMN) has achieved satisfactory efficacy in treatment of ankle fractures, and is associated with low complication rates. Additionally, a systematic review showed that a locked intramedullary nail (LIMN) device provides better stability and rotation control, thereby reducing the risk of nail migration and loss of fixation, compared to unlocked nails. Therefore, a meta-analysis is imperative to provide evidence on whether LIMN can replace PF for treatment of ankle fractures, owing to an increase in related studies that have been published in recent years.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 July 2022 and was last updated on 20 July 2022 (registration number INPLASY202270094).

INTRODUCTION

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Condition being studied: Ankle fractures, with an incidence rate of 4.22/10, 000 person-years in the United States, are one of the most common lower extremity fractures. Currently, the standard surgical treatment approaches for unstable ankle fractures involves open reduction and internal fixation (ORIF) with plates and screws. However, ORIF has resulted in little efficacy during treatment of fractures since the 1960s, while plate and screw fixation has also been associated with several complications. Previous studies have shown that closed reduction and internal fixation (CRIF) with fibula intramedullary nail (IMN) has achieved satisfactory efficacy in treatment of ankle fractures, and is associated with low complication rates. Additionally, a systematic review showed that a locked intramedullary nail (LIMN) device provides better stability and rotation control, thereby reducing the risk of nail migration and loss of fixation, compared to unlocked nails. Therefore, a meta-analysis is imperative to provide evidence on whether LIMN can replace PF for treatment of ankle fractures, owing to an increase in related studies that have been published in recent years.

METHODS

Search strategy: We will conduct a comprehensive literature search in PubMed, Cochrane Library, EMBASE and Web of Science databases, from their inception dates to August 15, 2021. Search terms will include keywords; "ankle", "malleolus", "fibula", "fracture", "intramedullary fixation" and "nail". A similar search strategy will be applied to the other electronic databases. In addition, we will manually examine reference lists of previously published systematic reviews on intramedullary fixation of ankle fracture for additional pertinent studies.

Participant or population: We will recruit participants diagnosed with acute closed ankle fractures, irrespective of their country, ethnicity, sex, occupation and mechanism of injury.

Intervention: All patients in the experimental group will receive fixation with intramedullary locked fibular nail, whereas those in the control group will receive open reduction and internal fixation with plate.

Comparator: Open reduction and internal fixation with plate.

Study designs to be included: We will include Randomized Controlled Trials (RCTs) that are published in English.

Eligibility criteria: Review articles, case reports, experimental studies, expert experience, animal studies and conference abstracts will be excluded.

Information sources: We will conduct a comprehensive literature search in PubMed, Cochrane Library, EMBASE and Web of Science databases. In addition, we will manually examine reference lists of previously published systematic reviews on intramedullary fixation of ankle fracture for additional pertinent studies.

Main outcome(s): Primary outcomes will include Olerud and Molander Scores (OMAS) and the rate of complications, and will be used to assess postoperative function and risk of surgery.

Additional outcome(s): The American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score, surgery time and malreduction rates will be defined as secondary outcomes.

Data management: The following data will be extracted: first author name, year of publication, country of origin, study design, sample size, age, fracture type, implant type, outcome measures and follow-up duration. Any differences in opinion between the researchers will be resolved through a group discussion or consultation with a third reviewer. In cases where relevant data has not been reported, we will contact the corresponding author via email or other means to obtain missing data. The Preferred Report items for the System Review and Meta-analysis

(PRISMA) flow diagram will be filled out after the screening study is completed to provide specific information.

Quality assessment / Risk of bias analysis: Two independent investigators (W.-X.G., and F.W.) will independently evaluate quality of the included studies, then apply the risk-of-bias tool of the Cochrane Collaboration for Randomized Controlled Trials (RCTs) to assess the methodological quality. The 7 items used to evaluate bias in each trial included the randomization sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessments, incomplete outcome data, selective reporting, and other biases, such as the baseline characteristics between different groups. The level of evidence will be examined according to the guidelines of the Oxford Centre for Evidence-based Medicine Levels of Evidence.

Strategy of data synthesis: All meta-analyses will be conducted using the Review Manager (RevMan) software version 5.4 (Cochrane Collaboration). The mean difference (MD) will be used as the effect analysis statistic for continuous variables, while the risk ratio (RR) will be used as the effect analysis statistic for categorical variables. We will also calculate 95% confidence interval (CI) for each statistic, and summarize statistical heterogeneity among summary data using the I2 statistic. Cases with I2≤50% will not be considered to have significant heterogeneity, thus a fixed-effects model will be applied for meta-analysis. In cases where there is statistical heterogeneity among studies, we will further analyze the source of heterogeneity. A random-effects model will be used to pool the data, after excluding the obvious source of clinical heterogeneity, and in cases where obvious clinical heterogeneity exists, the researchers will perform subgroup, sensitivity or only descriptive analyses. Study-specific and pooled estimates will be graphically presented using forest plots, and P <0.05 considered statistically significant.

Subgroup analysis: When significant clinical heterogeneity is observed, we will perform subgroup analysis based on fracture classification, patients' age and follow-up periods, to identify the source of heterogeneity.

Sensitivity analysis: To evaluate robustness of the results, we will perform sensitivity analysis by excluding studies with low quality.

Country(ies) involved: China.

Keywords: ankle fracture, fibula nail, plate fixation, protocol.

Contributions of each author:

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