INPLASY PROTOCOL

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None declared.

External fixation versus intramedullary nailing for the treatment of open tibial shaft fractures: a meta-analysis of randomized controlled trials

Chen, Z[1].

Review question / Objective: **To compare external fixation (EF) with intramedullary nailing (IMN) to determine which strategy was optimal for the treatment of open tibial shaft fractures.**
Condition being studied: **Open fractures of the tibial diaphysis are high-energy trauma that are often involved with severe bone and soft-tissue injure, which are reported to be related with the high incidence of complications such as infection and nonunion. Delays or missteps in treatment can lead to long-term disability or even life-threatening conditions. Generally, standard strategy should include early use of antibiotics, surgical wound debridement, early soft-tissue coverage, and fractures stabilization. The first three items are widely accepted in the treatment of open tibial shaft fractures. To date, however, there is still no consensus regarding fractures stabilization with external fixation (EF) versus intramedullary nailing (IMN).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 January 2023 and was last updated on 19 January 2023 (registration number INPLASY202310061).

INTRODUCTION

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METHODS

Participant or population: Patients with open tibial fractures.

Intervention: Treatment methods.

Comparator: Exteral fixation group versus intramedullary nailing group.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The RCTs that report the comparative outcomes of EF versus IMN for the treatment of open tibial fractures were included in the current analysis.

Information sources: The PubMed, EMBASE, and Cochrane Library databases.

Main outcome(s): Incidence of deep infection, incidence of malunion, and incidence of nonunion.

Additional outcome(s): incidence of superficial infection, incidence of delayed union, incidence of fixation failure, and time to union.

Quality assessment / Risk of bias analysis: The Cochrane risk-of-bias criteria was used for the assessment of bias.

Strategy of data synthesis: For continuous variables, mean differences (MD) with 95% confidence intervals (CI) were calculated using the inverse variance method. For dichotomous variables, risk ratios (RR) with a 95% CI were calculated using the Mantel–Haenszel analysis method. Heterogeneity was assessed using the Chi2 and I2 tests, with I2 more than 50% indicating substantial heterogeneity. For variables presenting with substantial heterogeneity, sensitivity analysis (sequentially excluding individual studies) was performed to assess the heterogeneity and robustness of the pooled results.

Subgroup analysis: For primary results, subgroup analysis by study-level characteristics was conducted by stratifying studies according to severity of open fractures (Gustilo-Anderson I/II/IIIA vs Gustilo-Anderson IIIB). Furthermore, subgroup analyses within fractures grade Gustilo-Anderson I/II/IIIA were also performed by stratifying studies according to types of EFs (plane EF vs ring EF), and types of IMNs (unreamed IMN vs reamed IMN). Chi2 test was undertaken to test for subgroup interactions.

Sensitivity analysis: For variables presenting with substantial heterogeneity, sensitivity analysis (sequentially excluding individual studies) was performed to assess the heterogeneity and robustness of the pooled results.

Country(ies) involved: China (West China Hospital, Sichuan University).

Keywords: Open tibial fractures; External fixation; Intramedullary nailing; Randomized controlled trials; Meta-analysis.

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