

INPLASY PROTOCOL

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Corresponding author:
Jialei Zhang

470200949@qq.com

Author Affiliation:
Clinical Medical College of
Yangzhou University

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Conflicts of interest:
None.

Comparison of suture-button versus syndesmotic screw in the treatment of distal tibiofibular syndesmosis injury: a meta-analysis

Xu, K¹; Zhang, J²

ABSTRACT

Review Question: Whether suture-button (SB) device can achieve better clinical outcomes and decrease the risk of complications compared with syndesmotic screw (SS).

Condition being studied: Syndesmotic injuries arise in approximately 13% of all patients with ankle fractures which are commonly seen in pronation and external rotation injuries, and in approximately 20% of ankle fractures requiring operative fixation. As persistent ankle pain, functional disability, and early osteoarthritis are potential problems related to misdiagnosed or inadequate treatment of syndesmotic injuries, thus, it is essential to acquire accuracy and maintenance of syndesmotic reduction when treating ankle fractures with concomitant syndesmotic injuries.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 March 2020 and was last updated on 31 March 2020 (registration number INPLASY202030021).

INTRODUCTION

Objectives / Review question: Whether suture-button (SB) device can achieve better clinical outcomes and decrease the risk of complications compared with syndesmotic screw (SS).

Condition being studied: Syndesmotic injuries arise in approximately 13% of all patients with ankle fractures which are commonly seen in pronation and external rotation injuries, and in approximately 20% of ankle fractures requiring operative

fixation. As persistent ankle pain, functional disability, and early osteoarthritis are potential problems related to misdiagnosed or inadequate treatment of syndesmotic injuries, thus, it is essential to acquire accuracy and maintenance of syndesmotic reduction when treating ankle fractures with concomitant syndesmotic injuries.

METHODS

Participant or population: The patient with distal tibiofibular syndesmosis injury.

Intervention: Treatment with suture-button.

Comparator: Treatment with syndesmotic screw.

Study designs to be included: (1) Studies compared SB and SS techniques. (2) Clinical or radiographic outcomes were not limited to pool. (3) Studies published in English.

Eligibility criteria: (1) duplicate publication. (2) Studies with insufficient data. (3) Studies not published in English. (4) Conference, case report, or cadaver studies.

Information sources: Embase, Medline, Web of Science, Cochrane databases were searched to retrieve related studies updated on February 2020.

Main outcome(s): The rate of malreduction.

Additional outcome(s): Joint range of motion measured with DF and PF, postoperative radiographic parameters of the tibiofibular syndesmosis, implant failure, implant removal, implant irritation and other complications (infection, osteoarthritis, damage to neurovascular structures and so on).

Data management: The following information were respectively extracted from each of the included studies by two investigators. The basic data of demographics were extracted from the studies: author, year of publication,

country, the number of patients, age, type of SB usage or cortical screw usage, the time of follow-up, whether to remove screws routinely, and the outcomes of our research including AOFAS, OMA, EQ-5D, FADI, joint range of motion measured with DF and PF, postoperative radiographic parameters of the tibiofibular syndesmosis (MCS, TCS, and TFO), malreduction, implant failure, implant removal, implant irritation and other complications (infection, osteoarthritis, damage to neurovascular structures and so on) When disagreement existed, it was resolved by consulting another investigator.

Quality assessment / Risk of bias analysis: The quality of the non-RCTs studies was assessed according to the Downs and Black[16] and the Newcastle-Ottawa Scale (NOS) [17] quality assessment method. A total NOS score was 9* and if the NOS score was over 6*, it would be considered as higher quality research. A higher score was recognized as better quality research. The 12-item scale was used to assess the quality of the RCTs[18]. Each item was scored "Yes", "Unclear", or "No". If a trial with a score of more than 7 "Yes" was considered high quality, more than 4 but no more than 7 was considered moderate quality, and no more than 4 was considered low quality. Any different opinions were resolved by a third reviewer.

Strategy of data synthesis: Statistical heterogeneity of data was evaluated by using Cochran's Q statistic. If statistical Q statistic ($P < 0.10$) was considered to be significant heterogeneous among studies, a random-effects model was performed, if not, a fixed-effects model was used. If the heterogeneity of a parameter was over 85%, the meta-analysis was not performed. The results of continuous data were applied to the mean difference with 95% confidence interval (CI). For dichotomous data, the Odd ratio (OR) was calculated using the Mantel-Haenszel method, mean difference and standardized mean difference were considered statistically significant at the $P < 0.05$ level. Data analysis was carried out by using Review Manager 5.3. Sensitivity analysis was

performed to assess the accuracy of our results through the exclusion of eligible studies once time.

Subgroup analysis: Randomized control trials and no randomized control trials.

Sensibility analysis: One study was individual deleted each time to observe its influence on the pooled MD or OR.

Countries involved: Norway, Canada, Germany, Turkey, Korea, Finland, Netherland, Ireland, America..

Keywords: Syndesmosis, Ankle, Suture-button, TightRope, Screw; Meta-analysis.