INPLASY PROTOCOL

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None declared.

Comparison of 4 tibial fixation devices in anterior cruciate ligament reconstruction: result from a network meta-analysis

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Review question / Objective: **The preferred treatment for anterior cruciate ligament injury is applying autologous hamstringreconstruction. In clinical practice, there have been many studies on the fixation of ligaments at the femoral end, and a consensus has been nearly reached, but there are few studies on the selection of tibial fixation devices. This meta-analysis mainly studies and evaluates four current mainstream fixation methods: Bioabsorbable screw (BS), Cortical button (CB), Metal screw (MS) and Sheathed screw (SS).**

Condition being studied: **What we studied was the performance of the hamstring tendon autograft and reconstruction on the tibial side of patients with anterior cruciate ligament injury using 4 different fixation methods (Bioabsorbable screw (BS), Cortical button (CB), Metal screw (MS) and Sheathed screw (SS).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 November 2022 and was last updated on 18 November 2022 (registration number INPLASY2022110087).

INTRODUCTION

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METHODS

Participant or population: Patients with anterior cruciate ligament injury who underwent autologous hamstring reconstruction on the tibial side according to different fixation methods (BS, CB, MS, and SS).

Intervention: Autologous hamstring tendon reconstruction was performed on the anterior cruciate ligament injury patients, and four different tendon fixation methods (BS, CB, MS, and SS) were used on the tibial side.The inclusion criteria were: (1) studies compliance with level of evidence I or II; (2) studies of ACLR using hamstring autograft; (3) studies that compared at least two tibial fixation devices; (4) studies related to primary surgery。The exclusion criteria were: (1) cadaver studies; (2) animal studies; (3) biomechanical studies; (4) radiological studies.

Comparator: Four different tendon fixation methods were used on the tibial side, which would be used to make a comparison：Bioabsorbable screw (BS), Cortical button (CB), Metal screw (MS) and Sheathed screw (SS).The inclusion criteria were: (1) studies compliance with level of evidence I or II; (2) studies of ACLR using hamstring autograft; (3) studies that compared at least two tibial fixation devices; (4) studies related to primary surgery。The exclusion criteria were: (1) cadaver studies; (2) animal studies; (3) biomechanical studies; (4) radiological studies.

Study designs to be included: After the articles are screened strictly according to the inclusion and exclusion criteria, the researches meeting the requirements are selected, and then the data of the articles are reviewed and entered by professional personnel.Treatment effects were assessed as mean differences and 95% credibility interval (CI) for continuous data, or as odds ratios (ORs) and 95% confidence intervals for categorical data. Via Markov chain Monte Carlo methods with ADDIS version 1.16.7, a random-effects model combined with Bayesian framework was created for measurement of study outcomes. The non-informativ.

Eligibility criteria: The inclusion criteria were: (1) studies compliance with level of evidence I or II; (2) studies of ACLR using hamstring autograft; (3) studies that compared at least two tibial fixation devices; (4) studies related to primary surgery;The exclusion criteria were: (1) cadaver studies; (2) animal studies; (3) biomechanical studies; (4) radiological studies; (5) computer studies;The outcome included the Graft failure, IKDC (International Knee Documentation Committee) score A or B, Lachman test, Pivot-shift test, IKDC score, KT-1000 SSDs, Tegner score and Lysholm score.Through STATA、R and Origin software to achieve the data calculation and presentation.

Information sources: Cochrane Library, Embase and PubMed were searched to identify researchers on tibia fixation in ACLR, published between 1983 and September 10, 2022. Search terms were as below: (anterior cruciate ligament AND (reconstruction OR transplant) AND tibia AND fixation).

Main outcome(s): The outcome included the Graft failure, IKDC (International Knee Documentation Committee) score A or B, Lachman test, Pivot-shift test, IKDC score, KT-1000 SSDs, Tegner score and Lysholm score.

Quality assessment / Risk of bias analysis: The risk of bias will be independently

analyzed and assessed by two authors and adjudicated by an experienced third author, using the Cochrane Collaboration's tool which contains sequence generation, allocation concealment, blinding, incomplete outcome data. The final statistics will be presented by STATA software.

Strategy of data synthesis: Each of the screened articles will be checked in detail and recorded with the following content and data: (1) study features (author, publication year, journal, country, study design, level of evidence); (2) patient features (age, gender, sample size, follow-up time, number of lost to follow-up, time from injury to surgery; (3) features of interventions and comparators (tibial and femoral fixation device, tibial and femoral tunnel position, graft type, drilling technique);(4) outcome measures shown above. All data collection and collation involving scores and outcomes will be taken from the latest follow-up record. Treatment efects will beexpressed as mean diferences and 95% credibility intervals (CI) for continuous data, or as odds ratios (ORs) and 95% confdence intervals for categorical data. For each outcome measure, a random-efects model within a Bayesian framework will be established using Markov chain Monte Carlo methods with ADDIS version 1.16.7. The non-informative prior distributions will be set, normal likelihood distributions will be assumed, and four Markov chains will be run to judge convergence with a burn-in phase of 5000 iterations and a sampling phase of the posterior distribution of 50, 000 iterations. A thin-out function saving only every 10th sample from the posterior distribution will be used to prevent autocorrelation. Through STATA、R and Origin software to achieve the data calculation and presentation.

Subgroup analysis: For the selected studies, 2010 will be demarcated as the age of publication, and subgroup analysis will be conducted for the studies before and after 2010, to determine whether the age of publication has any influence on the results. For the selected studies, 2 years of postoperative observation will be defined as the length of treatment, and subgroup analysis will be conducted for observation and follow-up studies within 2 years and more than 2 years after surgery. The effect size will be combined for each subgroup, and meta-regression analysis will be performed for more than two variables.

Sensitivity analysis: If it is found that the degree of heterogeneity is moderate and the combined results show edge effects, the random effects model is used to evaluate whether the combined results of the fixed effects model are stable. At this time, R software was used to draw relevant forest maps and make data statistics. It is necessary to carefully eliminate relevant literature.

Country(ies) involved: China.

Keywords: Anterior cruciate ligament reconstruction, Autograft, Hamstring, Tibial fixation, Network meta-analysis.

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