

INPLASY PROTOCOL

To cite: Li et al. Should synovectomy be performed during total knee arthroplasty for knee osteoarthritis: A protocol for systematic review and meta-analysis. Inplasy protocol 2021100102. doi: 10.37766/inplasy2021.10.0102

Received: 27 October 2021

Published: 27 October 2021

Corresponding author:
Peimin Wang

drwpm@163.com

Author Affiliation:
1.The Affiliated Hospital of Nanjing University of Chinese Medicine 2.The Third People's Hospital of Kunshan.

Support: Suzhou Science&Technology Plan.

Review Stage at time of this submission: Data analysis - Completed but not published.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: The review question is should synovectomy be performed during total knee arthroplasty for knee osteoarthritis? Studies will be

Should synovectomy be performed during total knee arthroplasty for knee osteoarthritis: A protocol for systematic review and meta-analysis

Li, M¹; Shi, X²; Yin, S³; Zhang, L⁴; Wu, P⁵; Liao, T⁶; Jie, L⁷; Wang, P⁸.

Review question / Objective: The review question is should synovectomy be performed during total knee arthroplasty for knee osteoarthritis? Studies will be selected that met the following population, interventions, comparisons, outcomes, and study design (PICOS). 1. Participants - The population met the diagnostic criteria for primary KOA with initial TKA. 2 Interventions and Comparisons - The synovectomy group underwent TKA with synovectomy, and the synovial preservation group underwent TKA without synovectomy. 3 Outcomes - The outcome indicators included VAS scores, blood loss, operation time, transfusion rate, KSS clinical and functional scores, HSS scores, joint mobility, and adverse events. 4 Study designs. - The RCTs evaluating the efficacy and safety of synovectomy during TKA for patients with KOA will be included, regardless of blinding.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 October 2021 and was last updated on 27 October 2021 (registration number INPLASY2021100102).

selected that met the following population, interventions, comparisons, outcomes, and study design (PICOS). 1. Participants - The population met the diagnostic criteria for primary KOA with initial TKA. 2 Interventions and Comparisons - The

synovectomy group underwent TKA with synovectomy, and the synovial preservation group underwent TKA without synovectomy. 3 Outcomes - The outcome indicators included VAS scores, blood loss, operation time, transfusion rate, KSS clinical and functional scores, HSS scores, joint mobility, and adverse events. 4 Study designs. - The RCTs evaluating the efficacy and safety of synovectomy during TKA for patients with KOA will be included, regardless of blinding.

Rationale: Osteoarthritis is a common and disabling disease that currently affects 250 million people worldwide, and it is a significant personal, medical and socioeconomic burden. Total knee arthroplasty (TKA) is an effective treatment for end-stage knee osteoarthritis (KOA). The overall satisfaction of TKA patients is high, but approximately 20% of patients are still dissatisfied with their results after surgery. Postoperative pain, infection, swelling, metallosis, and recurrent bleeding are the main causes of dissatisfaction. Synovectomy is frequently recommended or mentioned in the management of postoperative complications. Synovial inflammation is correlated with postoperative complications. On the one hand, surgical provocation of synovial tissue can cause inflammation, congestion, hyperplasia, and exudation; on the other hand, polyethylene abrasion and granulogenesis can lead to a synovial phagocytic cascade response, causing synovial proliferation, hypertrophy, and subsequent impingement, resulting in pain, swelling, or bleeding, thus prompting the clinician to wonder whether synovectomy be performed in KOA patients undergoing initial TKA. Some researchers have suggested that synovectomy increases blood loss and operation time and has no beneficial effect on postoperative pain or function; thus, the synovium should be preserved as much as possible. Some studies have pointed out that synovectomy reduces sensory innervation of synovial tissue and reduces pain. Other studies have indicated that preoperative synovitis scores are negatively correlated with postoperative pain scores, to say that a

milder preoperative synovitis can cause more postoperative pain. The reduction of postoperative pain is the key to achieving rapid recovery and improving patient satisfaction. However, there are no authoritative guidelines on whether to perform synovectomy in TKA, which mainly depends on the surgeon's intraoperative assessment of synovial health and surgical preference. Therefore, the question is raised concerning whether synovectomy is necessary in TKA. This question is very interesting and meaningful. Previous meta-analyses have reported the clinical outcomes of synovectomy in TKA, but there are some limitations, such as a small number of included studies, few outcome indicators, a short follow-up time, and a lack of RCT studies with a large sample size. An increasing number of clinical studies are emerging, and there is a need to re-evaluate the clinical outcomes of synovectomy performed in TKA and the scientific validity of the current RCT study design. Further consideration of the need for preoperative synovial inflammation assessment as a basis for intraoperative synovectomy is needed.

Condition being studied: Some researchers have suggested that synovectomy increases blood loss and operation time and has no beneficial effect on postoperative pain or function; thus, the synovium should be preserved as much as possible. Some studies have pointed out that synovectomy reduces sensory innervation of synovial tissue and reduces pain. Other studies have indicated that preoperative synovitis scores are negatively correlated with postoperative pain scores, to say that a milder preoperative synovitis can cause more postoperative pain. However, there are no authoritative guidelines on whether to perform synovectomy in TKA, which mainly depends on the surgeon's intraoperative assessment of synovial health and surgical preference. Therefore, the question is raised concerning whether synovectomy is necessary in TKA. Previous meta-analyses have reported the clinical outcomes of synovectomy in TKA, but there are some limitations, such as a small number of

included studies, few outcome indicators, a short follow-up time, and a lack of RCT studies with a large sample size. An increasing number of clinical studies are emerging, and there is a need to re-evaluate the clinical outcomes of synovectomy performed in TKA and the scientific validity of the current RCT study design. Further consideration of the need for preoperative synovial inflammation assessment as a basis for intraoperative synovectomy is needed.

METHODS

Search strategy: We will search synovectomy during TKA for end-stage KOA patients in PubMed, EMBASE, Web of Science, the Cochrane Library, the China National Knowledge Infrastructure (CNKI), the Chinese Scientific Journals Database, the Wanfang database, and the Chinese Biomedicine Database (CBM). We will also search for RCTs that are unpublished, including the International Clinical Trials Registry Platform, the NIH Clinical Trails, and the Chinese Clinical Register.

Participant or population: The population met the diagnostic criteria for primary KOA with initial TKA.

Intervention: The synovectomy group underwent TKA with synovectomy, and the synovial preservation group underwent TKA without synovectomy.

Comparator: The outcome indicators included VAS scores, blood loss, operation time, transfusion rate, KSS clinical and functional scores, HSS scores, joint mobility, and adverse events.

Study designs to be included: The RCTs evaluating the efficacy and safety of synovectomy during TKA for patients with KOA will be included, regardless of blinding.

Eligibility criteria: Studies that met the following population, interventions, comparisons, outcomes, and study design (PICOS) were selected: (1) the population met the diagnostic criteria for primary knee

osteoarthritis with initial unilateral TKA; (2) the synovectomy group underwent TKA with synovectomy; (3) the synovial preservation group underwent TKA without synovectomy; (4) outcome indicators included VAS scores, blood loss, operation time, transfusion rate, KSS clinical and functional scores, HSS scores, joint mobility, and adverse events; (5) clinical randomized controlled trials.

Information sources: Studies that met the following population, interventions, comparisons, outcomes, and study design (PICOS) were selected: (1) the population met the diagnostic criteria for primary knee osteoarthritis with initial unilateral TKA; (2) the synovectomy group underwent TKA with synovectomy; (3) the synovial preservation group underwent TKA without synovectomy; (4) outcome indicators included VAS scores, blood loss, operation time, transfusion rate, KSS clinical and functional scores, HSS scores, joint mobility, and adverse events; (5) clinical randomized controlled trials. The exclusion criteria were as follows: (1) research on nonprimary knee osteoarthritis; (2) duplicate studies; (3) review articles; (4) literature with inappropriate statistical methods and missing data; (5) basic research literature; (6) animal studies; (7) genetic studies; and (8) grey literature. We will search synovectomy during TKA for end-stage KOA patients in PubMed, EMBASE, Web of Science, the Cochrane Library, the China National Knowledge Infrastructure (CNKI), the Chinese Scientific Journals Database, the Wanfang database, and the Chinese Biomedicine Database (CBM). We will also search for RCTs that are unpublished, including the International Clinical Trials Registry Platform, the NIH Clinical Trails, and the Chinese Clinical Register.

Main outcome(s): The outcome indicators included VAS scores, blood loss, operation time, transfusion rate, KSS clinical and functional scores, HSS scores, joint mobility.

Additional outcome(s): The adverse events will be also recorded.

Data management: NoteExpress Version 3.2 will be used for literatures management. At first, duplicate documents will be deleted by software. Then 2 reviewers will remove irrelevant articles independently by screening the titles and abstracts. If there is any uncertainty, we will obtain and read full texts. All the reasons for excluding studies will be recorded. The eligible references will be retrieved and inserted into the NoteExpress. Two reviewers will independently retrieve and extract the data.

Quality assessment / Risk of bias analysis: According to the risk of bias assessment tool provided by Cochrane Reviewer's Handbook 5.2, two evaluators will assess the risk of bias independently, which included random sequence generation, allocation, concealment, blinding assessment, incomplete outcome data, reporting bias, and other biases. The risk of bias will be graded as low bias or unclear or high bias.

Strategy of data synthesis: Review Manager software (RevMan Version 5.3) will be used to combine and calculate the outcomes. The results of the selected studies will be pooled for meta-analysis when two or more results are available. Continuous data will be entered as the means and standard deviations, and dichotomous outcomes are entered as the number of events. Continuous outcomes will be expressed as weighted mean differences (WMDs) and 95% confidence intervals (CIs). Dichotomous data will be stated as relative ratios (RRs) and 95% CIs.

Subgroup analysis: The subgroup analysis will be carried out to explore possible reasons of the heterogeneity.

Sensitivity analysis: The sensitivity analyses will be performed by removing the studies with high risk of bias in order to evaluate the stability of the results. To further confirm the stability of the above results, we excluded relevant studies sequentially for each outcome.

Language: The search language was limited to English and Chinese.

Country(ies) involved: China.

Keywords: Knee Osteoarthritis(KOA); total knee arthroplasty(TKA); synovectomy; pain; Meta-analysis.

Contributions of each author:

Author 1 - Mingchao Li - The author participated in the conceptualization, designed the study, and drafted the original manuscript.

Email: 20195053@njucm.edu.cn

Author 2 - Xiaoqing Shi - The author participated in the conceptualization, provided statistical expertise, and Writing-review.

Email: 20203019@njucm.edu.cn

Author 3 - Songjiang Yin - The author provided statistical expertise.

Email: 260303@njucm.edu.cn

Author 4 - Li Zhang - The author provided methodology, data curation, and approved the final manuscript.

Email: 20193018@njucm.edu.cn

Author 5 - Peng Wu - The author provided methodology, data curation, and approved the final manuscript.

Email: 20183052@njucm.edu.cn

Author 6 - Taiyang Liao - The author provided data curation and approved the final manuscript.

Email: 20190058@njucm.edu.cn

Author 7 - Lishi Jie - The author provided data curation and approved the final manuscript.

Email: 20200087@njucm.edu.cn

Author 8 - Peimin Wang - The corresponding author, provided supervision, project administration, funding acquisition, and writing-review & editing.

Email: wangpeimin@njucm.edu.cn