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Surgical and clinical efficacy of minimally invasive sacroiliac joint fusion surgery: a meta-analysis protocol

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ABSTRACT

Introduction Sacroiliac joint (SIJ) dysfunction has been shown to cause significant morbidity. Current treatment includes conservative management and surgical intervention. Previously published data reporting clinical and surgical outcomes reached conflicting conclusions. This protocol aims to conduct a meta-analysis to determine fusion rates and patient-reported outcomes of minimally invasive (MIS) SIJ fusions compared with conservative treatment.

Methods and analysis We drafted our protocol according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines. We will search PubMed, Embase and the Cochrane Library, supplemented by manual search when necessary. Two independent reviewers will screen for eligibility by title/abstract, then full text, arbitrated by a third reviewer if necessary. The two reviewers will carry out a risk of bias assessment using the Cochrane Collaboration Risk of Bias tool for randomised controlled trial and the Methodological Index for Non-Randomised Studies tool for observational cohort studies. A third reviewer will arbitrate any disagreement. We will perform data synthesis using Review Manager (RevMan for Windows, V.5.4.1, The Cochrane Collaboration, 2020) and Comprehensive Meta-Analysis (V.3.3.070). Meta-bias will be evaluated and confidence determined using the Grading of Recommendations, Assessment, Development and Evaluation guidelines.

Ethics and dissemination Ethical approval for this review will not be required as no patient data is being collected. The results of this study will be submitted for publication in peer-reviewed journals.

PROSPERO registration number CRD42021273481.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Methodological Index for Non-Randomised Studies will be used to evaluate the risk of bias of the cohort studies.
⇒ We will use Grading of Recommendations Assessment, Development and Evaluation to evaluate the strength of the recommendations.
⇒ This study will include cohort studies that have not been evaluated quantitatively in previous meta-analyses to mitigate the low number of randomised controlled trials evaluating fusion outcomes.
⇒ The cohort studies will be quantitatively analysed and pooled using the comprehensive meta-analysis software.

INTRODUCTION

Rationale

Back pain is one of the most common patient complaints worldwide.[1] In the USA alone, back pain affects 15%–45% of adults, causing significant morbidity.[2 3] Among this patient population, sacroiliac joint (SIJ) dysfunction has often been overlooked as a potential diagnosis.[4] Multiple reports showed that when axial loading or motion was exerted across the joint, long-term arthritis and pain ensued.[2 5 6] The reported incidence of SIJ dysfunction ranged from 10% to 30% and was often treated with conservative management.[3 5 7 8] This included pharmacologics, physical therapy and intra-articular injections; however, these therapies failed to demonstrate significant effectiveness, with only 50% of patients experiencing symptom relief.[9] Surgical intervention such as open SIJ fusion was initially described in the 1920s and had been associated with many reported complications.[10 11] Advances in technology and surgical technique enabled the increasing use of minimally invasive SIJ fusion, one of the most widely practiced neurosurgical procedures today.[12–15]

Evidence on the effectiveness of minimally invasive SIJ fusion techniques has been inconclusive.[3 7 8 16] Previous systematic reviews and meta-analyses covering publications up to 2016 reported favourable short-term clinical outcomes with significant improvement of symptoms. However, the long-term benefit of SIJ fusion remains unanswered. Currently, there is no standardised guideline for evaluating SIJ fusion.[17] Radiographic assessment using XR is inadequate due to difficulty in visualisation, while CT evaluation is not the standard of care, especially in asymptomatic patients.

Biomechanical studies using lumbar fixation models demonstrate that constant cyclic loading led to hardware loosening or failure.[18] Similarly, SIJ fixation outcome studies demonstrated loosening of the sacral hardware occurred in up to 45% of sacropelvic fixation patients with poor sacral bone quality.[19] Therefore, radiographic fusion is important in answering the long-term effectiveness of SI fixation. More recent literature reported fusion rates ranging from 13% to 100%.[3 8 16] Due to this increase in recent data, an updated evaluation and synthesis of the evidence is necessary.

Objective

We seek to conduct a meta-analysis evaluating the clinical and surgical efficacy of minimally invasive SIJ fusions compared with conservative treatment.

METHODS

This protocol has been registered on PROSPERO: International Prospective Register of Systematic Reviews: 2021 CRD42021273481. Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021273481

This meta-analysis will be performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol guidelines.

Eligibility criteria

We included only published randomised controlled trials (RCTs) comparing MIS SIJ fusion and open SIJ fusion or conservative treatment, prospective or retrospective observational comparative cohort studies when at least one cohort underwent MIS SIJ and case series (with >10 subjects) studies. Excluded studies were those in the paediatric population (<18 years in age), any study that is not available in the English language, studies that did not include or define our primary or secondary outcomes, studies that used only XR to evaluate fusion, study populations with non-degenerative pathology, studies with less than 6-month follow-up, as well as non-human subjects and cadaveric studies.

Information sources

The search will be performed using the PubMed, Embase and Cochrane Library and Central Register of Controlled Trials (CENTRAL) medical databases from 1 January 2000 to 29 July 2021. A handsearch of the references from key articles will be conducted. We will attempt to contact the original author for further clarification if necessary.

Search strategy

The following search strategy was in each of these medical databases: (Sacroiliac joint fusion OR sacroiliac joint arthrodesis OR minimally invasive sacroiliac joint fusion OR minimally invasive sacroiliac joint arthrodesis OR SIJ fusion OR SIJ arthrodesis OR MIS SIJ fusion OR MIS SIJ arthrodesis). Automated filters were applied to include specific periods and exclude non-English literature. Please refer to the online supplemental file 1 for our full search strategy.

Study records

Data management

Studies from the search will be imported into a citation and research management tool (Zotero V.5.0, centre for History and New Media at George Mason University: Fairfax, VA). Automated filters for duplicates will eliminate duplicate articles across multiple databases. The resulting articles will be imported into Covidence (Veritas Health Innovation. Melbourne, Australia), a systematic review production platform.

Selection process

During the initial selection, we will include any primary research (ie, no review articles) that mentions minimally invasive SIJ fusion. Automated duplicate filters will again be applied through Covidence. We will manually verify the results of the eliminated duplicate. The resulting articles in Covidence will be screened for eligibility by title and abstract by two independent authors (GA and RB) using covidence. A pilot screening will be conducted for the first five studies at each screening stage to ensure mutual agreement of inclusion and exclusion criteria among reviewers. Conflicts in screening judgments will be resolved by an arbitrator (ML).

Following, two independent reviewers (GA and RB) will access the full-text articles of the selected articles and upload them into Covidence to further evaluate the eligibility criteria. A pilot screening of the first five articles will be conducted by the reviewers above. Conflicts in eligibility determination will be resolved by an arbitrator (ML). Articles resulting from this step will undergo the data extraction process.

Data collection process

Two independent reviewers (GA and RB) will extract relevant data from the studies using a standardised template in covidence. Pertinent data items mentioned in the following section will guide the data collection process. We will conduct pilot testing with the form for the first five studies and modify the form if necessary. The consensus method will be used to solve disagreements. Conflicts in data extraction will be resolved by an arbitrator (ML).

Extraction will be blinded for authors, institutions and journals. We will attempt to contact the original author for further clarification if necessary.

Data items

Data extracted will include: year of publication, study design, number of participants, patients demographics including age, sex, body mass index; intervention types including conservative treatment and MIS implant type, biologics used, decortication use, method of assessing fusion (CT), use of fusion criteria interpreted by a separate independent reviewer or study author, the interval of follow-up, industry funding, perioperative outcomes including estimated blood loss, surgery length in minutes,

and hospital length of stay in days; and patient-reported outcomes.

Outcomes and prioritisation

The primary outcomes are fusion rates as determined using postoperative CT scans. We will define fusion as the visualisation of bridging trabecular bone across the joint.

Our secondary outcomes are patient-reported outcomes, including Visual Analogue Scales to assess pain intensity for low back and leg pain, Oswestry Disability Index for evaluation of patients' functional outcomes, as well as Short form-12 questionnaire Physical Component Score.

Risk of bias in individual studies

Two independent reviewers (GA and RB) will carry out the risk of bias assessment. A third reviewer (ML) will arbitrate any disagreement, and a resolution will be achieved by consensus. Study design labels such as RCT, cohort and case–control will not be used as a proxy for quality assessment. RCT will be evaluated using the Cochrane Collaboration Risk of Bias (RoB) tool by which risk of selection, performance, attrition, detection and selective outcome reporting biases will be assessed. Observational cohort studies will be evaluated by the Methodological Index for Non-Randomised Studies tool. Subgroup analysis and meta-regression based on methodological quality and Industry funding will be performed.

Data synthesis

Descriptive statistics will be performed using SPSS software (IBM. Released 2017. IBM SPSS Statistics for Windows, V.25.0). Data synthesis for RCT and observational cohort studies will be performed using Review Manager (RevMan for Windows, V.5.4.1, The Cochrane Collaboration, 2020) and Comprehensive Meta-Analysis (V.3.3.070), respectively.

The Mantel-Haenszel method using the random effects model will be used to calculate each study and the overall ORs for binary outcomes. Continuous outcomes will be provided as a difference in mean response if the studies have used the same units to report the data or as a standardised mean difference if studies have used different instruments to measure the same construct. For single cohort studies, since the fusion rate may be close to 1, logit transformation would be used to produce logit event rates and the 95% CI, then combined to give the pooled estimates. Heterogeneity will be evaluated using either Cochran's Q statistic or I^2 statistic, depending on the number of included studies. Homogeneity will be evaluated using the Breslow-Day test for homogeneity of ORs. These statistics will also be presented within forest plots. If significant heterogeneity is found, subgroup analyses and meta-regression will be considered for study-level confounders, including specific device, follow-up interval, fusion evaluation modality, radiographic evaluator and funding source. If the included studies do not allow subgroup analysis or meta-regression, we will include this point in our limitations section. Publication bias will be graphically assessed using a funnel plot to evaluate for overestimation of effect across the studies. Significance will be defined as $p<0.05$.

Metabias

Using Grading of Recommendations, Assessment, Development and Evaluations (GRADE), a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations, two independent reviewers (GA and RB) will analyse and screen for risk of bias, imprecision, inconsistency, indirectness, publication bias, large magnitude effect and dose–response gradient.

Confidence in cumulative evidence

GRADE will be used to evaluate the quality of evidence of each outcome and the strength of the recommendation as presented in our meta-analysis. The level of the evidence will be classified into high, moderate, low or very low according to the GRADE rating standards. The certainty will be evaluated for specific domains: study design, risk of bias, precision, consistency, directness, reporting bias, publication bias, the magnitude of effect and dose–response gradient. This grading is subjective. Therefore, the two authors will independently carry out the GRADE assessment with a third author as an arbitrator. We will rate the strength of evidence for each outcome and present our findings in a table format. Additionally, when heterogeneity is found or suspected, meta-regression is used to adjust for confounders at the metadata level controlling for differences across studies.

Ethics and dissemination

This is a review of the published literature with no patient data being collected; no ethical approval will be required. This review will be submitted to be presented at national conferences and published in recognised journals.

Patient and public involvement

No patients were involved.

Contributors All the authors contributed to the formulation and focus of the systematic review. GA and RB are the primary reviewers and were responsible for designing the study design of the protocol, search strategy and drafting the initial version of the protocol manuscript. ML will be the arbitrator. DT will guide the methodology and analyses. EY will provide editorial and writing support, and TMS will provide overall supervision. All of the authors reviewed and approved the final manuscript of this protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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