International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Management of leiomyomata with radiofrequency ablation

INPLASY202380123
doi: 10.37766/inplasy2023.8.0123
Received: 30 August 2023
Published: 30 August 2023

Chen, I[1]; Choudhry, AJ[2]; Kowalczewski, E[3].

Corresponding author:
Abdul Choudhry

abchoudhry@ohri.ca

Author Affiliation:
The Ottawa Hospital Research Institute.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380123

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 August 2023 and was last updated on 30 August 2023.

INTRODUCTION

Review question / Objective P - In patients with symptomatic leiomyomata. I - Had radiofrequency ablation. C - Compared with no treatment or other treatment. O - Result in changes in leiomyoma volume, symptoms, and quality of life?

Rationale Radiofrequency ablation is typically performed in a medical facility, and typically in an operating room. We will include studies describing radiofrequency ablation for leiomyomata in any setting.

Condition being studied Uterine leiomyoma are common benign tumors of the uterus that can cause heavy menstrual bleeding and pelvic pressure and pain.

METHODS

Search strategy Based on the preliminary search findings a comprehensive search strategy is being developed to search electronic databases (PubMed/MEDLINE, Embase, MEDLINE EPub & InProcess, CINAHL & Cochrane Central Register of Controlled Trials) using pertinent keywords primarily using MeSH (Medical subject headings) terms covering uterine leiomyoma/fibroid, radiofrequency ablation and clinical trials/cohort studies with an objective to maximize sensitivity of search strategy.

Participant or population Patients with symptomatic uterine leiomyomata.

Intervention Radiofrequency ablation using any approach. Some approaches described in the literature include laparoscopic, transvaginal, and transcervical. Some use ultrasound or other radiologic guidance while performing the procedure, while some do not.

Comparator For all studies, including single arm studies, pre- post- data will be collected and compared.

Study designs to be included Published peer-reviewed full text manuscripts that pertain to the PICO question of this review.We will include randomized controlled trials, prospective and retrospective cohort studies, and case series with >10 participants.

Eligibility criteria Patients with symptomatic uterine leiomyomata.

Information sources MEDLINE, Embase, MEDLINE EPub & InProcess, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL). Inception to Jun 30, 2023. No language restrictions.

Main outcome(s) Fibroid or uterine size, often measured as volume or fibroid diameter. Bleeding symptoms. Abdominal pressure and pain symptoms. Quality of life measures. Operative time. Length of hospital stay. Post-operative recovery. Procedural complications. Pregnancy or obstetrical outcomes.

Additional outcome(s) Not applicable.

Data management Two independent reviewers will perform title and abstract screen, as well as full text review for eligibility. Thereafter, they will perform data extraction, using a structured data extraction tool. Discrepancies will be resolved through discussion with a third reviewer available if needed to resolve any conflicts.

Quality assessment / Risk of bias analysis Two independent reviewers will perform assessment for risk of bias. The Cochrane Risk of Bias tool will be used for randomized controlled trials. The National Heart, Lung, and Blood Institute [(NHLBI]) Quality Assessment Tool will be used for other study types.

Strategy of data synthesis A random-effects model will be used for meta-analysis where appropriate. Meta-analysis will be performed if there are at least 3 studies available for the outcome. Post-procedure outcomes may be meta-analyzed according to time following procedure as reported in the study.

Subgroup analysis Subgroup analysis will be performed according to the approach to RFA ablation (eg. Laparoscopic, transvaginal/cervical). Where possible, subgroup analysis can also be performed according to fibroid characteristics.

Sensitivity analysis We will conduct sensitivity analyses where there were sufficient trials included, in order to determine whether the conclusions were robust (i.e. whether conclusions would have differed if the inclusion of trials was restricted to those with low risk of bias).
We will perform this sensitivity analysis for the primary outcomes only.
We will perform a sensitivity analysis comparing outcomes based on random-effects model.

Language restriction No language restriction.

Country(ies) involved Canada.

Other relevant information Not applicable.

Keywords fibroids; leiomyoma; uterine; laparoscopy; transvaginal; radiofrequency ablation.

Dissemination plans Presentation at scientific conferences in gynecology and dissemination through peer-reviewed journal article(s).

Contributions of each author
Author 1 - Innie Chen - design of review, third reviewer to resolve conflicts, manuscript preparation.
Email: ichen@toh.ca
Author 2 - Abdul Choudhry - design of review, screening of studies, risk of bias assessment, data extraction, manuscript preparation.
Email: abchoudhry@ohri.ca
Author 3 - Emilie Kowalczewski - screening of studies, risk of bias assessment, data extraction, data analysis, manuscript preparation.
Email: ekowalczewski@ohri.ca