INPLASY PROTOCOL

To cite: Liu et al. High-intensity focused ultrasound ablation versus surgical interventions for the treatment of symptomatic uterine fibroids: a systematic review and meta-analysis. Inplasy protocol 202080012. doi: 10.37766/inplasy2020.8.0012

Received: 04 August 2020

Published: 04 August 2020

Corresponding author:
Lu Liu

1318245760@qq.co

Author Affiliation:
Shenzhen University

Support: **None.**

Review Stage at time of this submission: **Data extraction.**

Conflicts of interest:
None.

High-intensity focused ultrasound ablation versus surgical interventions for the treatment of symptomatic uterine fibroids: a systematic review and meta-analysis

Liu, L[1]; Wang, T[2]; Lei, B[3].

Review question / Objective: **Non-invasive treatments such as high-intensity focused ultrasound (HIFU) have been developed as an effective and safe option in managing uterine fibroids. The purpose of this meta-analysis is to compare the effectiveness and safety of HIFU with surgical interventions for the treatment of symptomatic uterine fibroids in women according to the studies available in current literature.**
Condition being studied: **Uterine fibroids are the most common benign gynaecological tumours in women of childbearing age, with a prevalence of 20–25%. Conventional therapy comprises hysterectomy and myomectomy. Highintensity focused ultrasound ablation (HIFU) is a noninvasive technique that causes instant coagulative necrosis in a well circumscribed area a few mm in diameter, and can be performed under either magnetic resonance imaging (MRI) guidance or ultrasound guidance. Some studies have found HIFU to be safe and effective in managing uterine fibroids. However, scientifically valid comparisons with surgery method treatments have not been reported.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 August 2020 and was last updated on 04 August 2020 (registration number INPLASY202080012).

INTRODUCTION

Review question / Objective: **Non-invasive treatments such as high-intensity focused ultrasound (HIFU) have been developed as an effective and safe option in managing uterine fibroids. The purpose of this meta-analysis is to compare the effectiveness and safety of HIFU with surgical interventions for the treatment of symptomatic uterine fibroids in women according to the studies available in current literature.**

Condition being studied: **Uterine fibroids are the most common benign gynaecological tumours in women of childbearing age, with a prevalence of 20–**

25%. Conventional therapy comprises hysterectomy and myomectomy. Highintensity focused ultrasound ablation (HIFU) is a noninvasive technique that causes instant coagulative necrosis in a well circumscribed area a few mm in diameter, and can be performed under either magnetic resonance imaging (MRI) guidance or ultrasound guidance. Some studies have found HIFU to be safe and effective in managing uterine fibroids. However, scientifically valid comparisons with surgery method treatments have not been reported.

METHODS

Participant or population: We considered all studies published in English, of any study design, that compared the effectiveness and safety of HIFU with surgical interventions in patients with symptomatic uterine fibroids.

Intervention: The patients of intervention group must be treated by high-intensity focused ultrasound (HIFU) guided by ultrasound or magnetic resonance.The mechanism of HIFU treatment is to focus ultrasound wave, with its good ability of tissue penetration, on the target tumour, which leads to an instant temperature rise to 70– 100°C, causing coagulative necrosis of tumour tissues.

Comparator: The patients of control group must be treated by surgery methods including hysterectomy, open myomectomy, laparoscopic myomectomy and hysteroscopic myomectomy.

Study designs to be included: The patients of control group must be treated by surgery methods including hysterectomy, open myomectomy, laparoscopic myomectomy and hysteroscopic myomectomy.

Eligibility criteria: We considered all studies published in English, of any study design, that compared the effectiveness and safety of HIFU with surgical interventions in patients with symptomatic uterine fibroids.

Information sources: We conducted a literature search for studies in PubMed, EMBASE, Web of Science, Cochrane Library, Google Scholar and ClinicalTrials.gov from January 2000 to July 2020.

Main outcome(s): (1)The improvement of fibroid-related symptoms that will be assessed by a validated disease-specific questionnaire named the Uterine Fibroid Symptom and Quality of Life (UFS-QoL); (2) time spend in hospital; (3) time to return to work; (4) complications and adverse events:Complications were recorded and graded using the guidelines of the Society of Interventional Radiology, which classifies the severity of complications as: no therapy required or no consequence (grade A); minimal therapy required or no consequence, including overnight admission for observation only (grade B); therapy required, including minor hospitalisation of <48 hours (grade C); major therapy required, including unplanned increases in the level of care, or prolonged hospitalisation for at least 48 hours (grade D); permanent adverse sequelae (grade E); and death (grade F). Grades A and B were considered to be minor; grades C to F were considered to be major;(5) re-intervention rate:defined as patients undergoing additional MR-HIFU sessions or other interventions because of fibroid-related symptoms during the follow-up period;(4) symptom improvement;(5) symptom recurrence; (6) pregnancy outcomes.

Quality assessment / Risk of bias analysis: Risk of bias of RCT will be assessed according to the Cochrane Collaboration's tool for assessing risk of bias. The following characteristics will be evaluated: (1) Randomization; (2) Allocation concealment; (3) Blinding; (4) Incomplete outcome data; (5) Selective reporting.(6) Other sources of bias. Non-RCT will be assessed according to Methodological Index for Non-randomized Studies. The following characteristics will be evaluated: (1) A clearly stated aim; (2) Inclusion of consecutive patients; (3) Prospective collection of data; (4) Endpoints

appropriate to the aim of the study; (5) Unbiased assessment of the study endpoint; (6) Follow-up period appropriate to the aim of the study; (7) Loss to follow up less than 5%; (8) Prospective calculation of the study size; (9) An adequate control group; (10) Contemporary groups; (11) Baseline equivalence of groups; (12) Adequate statistical analyses.

Strategy of data synthesis: Risk of bias of RCT will be assessed according to the Cochrane Collaboration's tool for assessing risk of bias. The following characteristics will be evaluated: (1) Randomization; (2) Allocation concealment; (3) Blinding; (4) Incomplete outcome data; (5) Selective reporting.(6) Other sources of bias. Non-RCT will be assessed according to Methodological Index for Non-randomized Studies. The following characteristics will be evaluated: (1) A clearly stated aim; (2) Inclusion of consecutive patients; (3) Prospective collection of data; (4) Endpoints appropriate to the aim of the study; (5) Unbiased assessment of the study endpoint; (6) Follow-up period appropriate to the aim of the study; (7) Loss to follow up less than 5%; (8) Prospective calculation of the study size; (9) An adequate control group; (10) Contemporary groups; (11) Baseline equivalence of groups; (12) Adequate statistical analyses.

Subgroup analysis: Heterogeneity between studies reflects variance from individual studies and may be attributable to differences in study population, location, study design, analysis methods or other characteristics. We test the heterogeneity of intervention effects among studies using the I^2 statistic and its 95% CI (I^2 values >50% were indicative of significant heterogeneity). We use a fixed-effect model if there was no substantial or considerable heterogeneity, and used a random-effect model if there was a significant heterogeneity. If I^2 values demonstrate significant heterogeneity, the subgroup analyses will be performed according to the types of surgery (hysterectomy or uterus-sparing surgery).

Sensibility analysis: If I^2 values demonstrate significant heterogeneity, the sensitivity analysis will be considered to be performed.

Country(ies) involved: China.

Keywords: uterine fibroids; high-intensity focused ultrasound; hysterectomy; myomectomy; meta-analysis.

Contributions of each author:
Author 1 - Lu Liu.
Author 2 - Tianfu Wang.
Author 3 - Baiying Lei.