

High-intensity focused ultrasound ablation versus surgical resection for treating abdominal wall endometriosis: a systematic review and meta-analysis

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Abstract

Background Abdominal wall endometriosis (AWE) is the most common type of extrapelvic endometriosis in women of reproductive age, and several studies have compared high-intensity focused ultrasound (HIFU) ablation with surgical resection in the management of AWE; however, the results are controversial. **Objective** To compare the efficiency and safety of HIFU ablation with surgery in the treatment of AWE. **Search strategy** Literature on surgery versus HIFU ablation for treating AWE was identified using the PubMed, Embase, Web of Science, China National Knowledge Infrastructure, WANFANG Database and the Cochrane Library databases. **Selection Criteria** Full-text manuscripts comparing HIFU ablation and surgery for treating AWE were included. **Data collection and analysis** Two independent reviewers reviewed and extracted data from the articles, and the risk of bias was assessed according to the Cochrane Handbook for Systematic Reviews of Interventions. Data analysis was performed using RevMan 5.4. **Main results** We included 7 studies involving 405 patients. Compared with the surgery group, the immediate posttreatment visual analogue scale (VAS) score was lower in the HIFU group (mean difference [MD] -1.58, 95% CI -2.56 to -0.59), the length of hospitalization was shorter in the HIFU group (MD -1.95 days, 95% CI -2.43 to -1.48), and the incidence of adverse events was lower in the HIFU group (relative risk 0.32, 95% CI 0.15 to 0.65). There was no significant difference in the symptom recurrence rate, VAS score at the 3-, 6- and 12-month follow-ups, or treatment time between the two groups. **Conclusions** Compared with surgery, immediate postoperative VAS scores were lower, hospitalization times were shorter, and the risk of adverse events were lower in patients receiving HIFU ablation treatment for AWE.

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Running title: HIFU ablation vs surgical resection for abdominal wall endometriosis

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To compare the efficiency and safety of HIFU ablation with surgery in the treatment of AWE.

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Literature on surgery versus HIFU ablation for treating AWE was identified using the PubMed, Embase, Web of Science, China National Knowledge Infrastructure, WANFANG Database and the Cochrane Library databases.

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Two independent reviewers reviewed and extracted data from the articles, and the risk of bias was assessed according to the Cochrane Handbook for Systematic Reviews of Interventions. Data analysis was performed using RevMan 5.4.

Main results

We included 7 studies involving 405 patients. Compared with the surgery group, the immediate posttreatment visual analogue scale (VAS) score was lower in the HIFU group (mean difference [MD] -1.58, 95% CI -2.56 to -0.59), the length of hospitalization was shorter in the HIFU group (MD -1.95 days, 95% CI -2.43 to -1.48), and the incidence of adverse events was lower in the HIFU group (relative risk 0.32, 95% CI 0.15 to 0.65). There was no significant difference in the symptom recurrence rate, VAS score at the 3-, 6- and 12-month follow-ups, or treatment time between the two groups.

Conclusions

Compared with surgery, immediate postoperative VAS scores were lower, hospitalization times were shorter, and the risk of adverse events were lower in patients receiving HIFU ablation treatment for AWE.

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Key words: Abdominal wall endometriosis; High-intensity focused ultrasound; Surgery

1 Introduction

Abdominal wall endometriosis (AWE) refers to the presence of endometrium-like tissue within the abdominal wall and is the most common type of extrapelvic endometriosis in women of reproductive age [1]. The estimated prevalence of AWE is 0.03%-1% [2]. Typical presentations of AWE are periodic progressively worsening pain and a gradually enlarging palpable mass within the abdominal wall. These symptoms affect the physical, mental and social well-being of patients [3].

Surgical excision of the AWE mass is considered the first-line treatment for AWE [4]. Previous studies have reported a success rate of > 95% and a recurrence rate of < 5% with wide local surgical excision of the AWE mass [5]; nevertheless, wide local surgical excision may potentially lead to muscle and fascia defects, which increase the risk of postoperative complications, such as poor wound healing and hernia[5,6]. High-intensity focused ultrasound (HIFU) ablation, which is a noninvasive approach widely used to treat uterine myoma, adenomyosis, and placenta accreta, has been applied in the treatment of AWE in the past decade. The results of several studies suggest that HIFU ablation is an effective and safe treatment for AWE, with low

complication and recurrence rates [7-9]. However, studies comparing the effectiveness of surgery versus HIFU ablation in the treatment of AWE have yielded controversial results [10-14].

The aim of our study was to compare the efficiency and safety of surgery versus HIFU ablation in the treatment of AWE.

2 Materials

2.1 Data sources and search strategy

The study protocol for this systematic review was registered in advance on PROSPERO (registration No. CRD42022342170). We performed an extensive electronic database search in the PubMed, Embase, Web of Science, China National Knowledge Infrastructure (CNKI), WANFANG Database and the Cochrane Library databases to identify research articles published between January 2010 and July 2022 that examined the effect of surgical excision versus HIFU ablation in reproductive age women. The search terms were used as free text and MeSH expressions as follows: (high-intensity focused ultrasound ablation OR HIFU OR ablation) AND (abdominal wall endometriosis OR caesarean scar endometriosis OR AWE) AND (excision OR surgery OR resection).

2.2 Inclusion criteria

We selected studies that compared HIFU ablation versus surgery for treating AWE in the same setting. Repeated studies were excluded from the analysis. Single-arm studies other than comparative reports were excluded. Furthermore, abstracts, reviews, commentaries, case reports, or conference articles were also excluded. Finally, studies that reported at least one outcome measure of interest as follows were eligible.

2.3 Main outcome measures

The primary outcome measures of interest were: (1) Improvement of symptoms (pain scores and size of the lesions were used to assess this outcome measure). The VAS was used to assess the severity of AWE symptoms, and a higher score was indicative of more severe symptoms; (2) Intraoperative condition (intraoperative blood loss, time of operation and the incidence of mesh implantation); (3) Recovery (the length of hospital stay and the postoperative length of hospital stay); (4) Adverse events (defined as skin burns, intestinal injury, fever, infection, anaesthesia-related complications, complications of the urinary system, and complications of the digestive system); (5) Symptom recurrence; (6) Reintervention rate (requirements for a new therapy owing to symptomatic recurrence).

2.4 Study selection and data quality assessment

We employed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines in our analysis [15,16]. First, the titles and abstracts of the articles were screened. Second, we collected all relevant articles for full-text assessment. In addition, we scrutinized the references of the included articles and some reviews to search for more relevant articles. Two authors independently performed the search and reviewed all publications found relevant to this study. We resolved any disagreements about inclusion or analysis by consensus or mediation by a third reviewer.

2.5 Bias assessment

The risk of bias was assessed using the approach recommended by the Cochrane Handbook for Systematic Reviews of Interventions[17]. The following characteristics for each article were assessed: (1) allocation concealment; (2) random sequence generation; (3) blinding of outcome assessment; (4) blinding of personnel and participants; (5) selective reporting; (6) incomplete outcome data; and (7) other bias.

2.6 Data extraction and analysis

Two investigators independently extracted data from the articles. We generated descriptive tables for population and study characteristics for all eligible studies to prepare for quantitative analysis. For each eligible study, we recorded study characteristics such as the first author, publication year, study design, duration of

follow-up, sample size, and outcome measures. The size of the lesions, VAS score, mean age and BMI were also recorded as characteristics of the patients.

Analysis was performed with RevMan 5.4 (Cochrane collaboration). We synthesized the relative risk (RR) with a 95% confidence interval (CI) for dichotomous data and mean difference (MD) with a 95% CI for continuous data. The mean values were calculated using the median, sample size, and interquartile ranges if they were not described [18,19]. The I^2 value was used to evaluate the heterogeneity between the included articles. An I^2 statistic with a value greater than 50% indicated substantial heterogeneity between studies. To account for substantial heterogeneity, we used random-effects models [20].

3 Results

3.1 Data search results

The search flow results of our systematic review are described in the study selection process (Appendix S1). After removing 20 duplicate records, the titles and abstracts of 57 records were screened. We excluded 48 records by reading the abstracts, of which 16 studies included only one treatment group without a comparison group and 32 studies were reviews, commentaries and case reports. Of the 9 full-text articles assessed for eligibility, 2 were excluded for reporting overlapping data. Finally, 7 studies met the selection criteria and were included in the meta-analysis [12-14,21-24].

3.2 Characteristics of the included studies

A total of 7 articles involving 405 women were included, 148 (37%) of whom underwent HIFU and 257 (63%) of whom underwent surgery. Table 1 summarizes the details on the author, time of publication, study design, follow-up time, interventions, and outcome measures. Table 2 summarizes the characteristics of the patients before treatment.

3.3 Risk of bias assessment

All articles were cohort studies, indicating a high risk of selection bias. All patients were fully informed regarding the therapies they received, so none of the studies included blinded patients. The risk of bias for each article is shown in Fig. 1.

3.4 Synthesis of results

Table 3 shows the details of the synthesized results to compare the effectiveness and safety between HIFU and surgery. Fig. 3-5 show the forest plots for the outcome measures.

3.5 Pain score

Four studies included data concerning pain score at baseline in the HIFU and surgery groups. Four studies included a total of 81 and 94 women in the HIFU and surgery groups, respectively. The MD before interventions between the two groups was not significantly different, with an estimated value of 0.17 (95% CI, -0.19 to 0.52). Heterogeneity among the studies was low ($I^2=0\%$, $p=0.37$) (Fig. 2A). The mean pain scores after HIFU or surgery decreased significantly at the postoperation follow-up compared with baseline in both groups. The pain scores immediately after management were higher in the HIFU group than in the surgery group, with an overall MD of -1.58 (95% CI, -2.56 to -0.59, $p=0.002$, $I^2=58\%$) (Fig. 2B). There was no statistically significant difference in pain scores at the 3-, 6- and 12-month follow-ups between the two groups, with overall MDs of -0.01 (95% CI, -0.30 to 0.28, $p=0.94$, $I^2=0\%$) (Fig. 2C), 0.04 (95% CI, -0.18 to 0.27, $p=0.70$, $I^2=0\%$) (Fig. 2D) and -0.08 (95% CI, -0.35 to 0.19, $p=0.56$, $I^2=0\%$) (Fig. 2E), respectively.

3.6 Recovery

Compared to the surgery group, the length of hospital stay was significantly shorter in the HIFU group, with an overall MD of -2.00 (95% CI, -2.44 to -1.56, $p=0.002$, $I^2=35\%$) (Fig. 3). The mean length of hospital stay ranged from 4.07 to 5.25 days and from 6.33 to 8.37 days, respectively.

3.7 Adverse events

The incidence of adverse events was lower in the HIFU group than in the surgery group, with an overall RR of 0.32 (95% CI, 0.15 to 0.65, $p=0.002$, $I^2=35\%$) (Fig. 4). Among the included studies, the incidence of adverse events ranged from 0 to 15.38% in the HIFU group and from 0 to 47.06% in the surgery group. However, the inclusion criteria for patients varied across different studies, which might have affected the accuracy of the results.

3.8 Symptom recurrence rate

Compared to the women in the surgery group, those in the HIFU group had a lower symptom recurrence rate, but the results did not reach statistical significance, with an overall RR of 0.95 (95% CI, 0.41 to 2.23, $p=0.91$, $I^2=0\%$) (Fig. 5). The symptom recurrence rate ranged from 0 to 12% in the HIFU group and from 0 to 17.2% in the surgery group.

4 Discussion

4.1 Main Findings

This systematic review and meta-analysis demonstrated that there were lower immediate postoperative VAS scores, shorter hospitalization times and a lower risk of adverse events in HIFU ablation treatment for AWE than in surgical treatment for AWE.

4.2 Strengths and Limitations

To our knowledge, this is the first meta-analysis that compares the clinical outcomes of HIFU with surgical interventions for treating AWE. However, there are also some limitations to this study: (1) Although we included literature from the widest search possible, the number of included articles was limited, possibly due to the rare use of HIFU ablation in AWE; (2) All studies included were cohort studies with a high risk of bias in at least 2 domains; (3) All studies were retrospective without a clear method to identify cases.

4.3 Interpretation

AWE, a rare disease with variable presentation, results in pain and reduced quality of life [25]. Surgical resection of the AWE mass is currently the first-line treatment option; however, several studies have examined HIFU ablation as a noninvasive treatment approach. One study focused on the efficiency of HIFU and revealed that HIFU is safe and effective for treating AWE [10,26]; nevertheless, these studies are limited by the lack of a surgical resection comparison group. The current meta-analysis compared the efficiency and safety of HIFU ablation with surgery for managing AWE and found that noninvasive HIFU ablation appears to be beneficial for treating AWE, with fewer adverse events and a more rapid recovery.

Pain scores were evaluated before and after treatment using the VAS, which has been demonstrated to be reliable for assessing therapy effectiveness. We compared the decrease in pain score from baseline to the time of follow-up between the HIFU and surgery groups, as the baseline pain scores in each group varied across studies. The results showed that the changes in pain scores immediately after management were significantly higher in the HIFU groups than in the surgery group. Surgical removal includes wide local excision, which causes more damage and more severe pain than HIFU [3]. Moreover, pain in the immediate postoperative period can negatively affect patient quality of recovery, prolong hospital stay, and increase the risk of developing persistent pain [27]. However, the relief of periodic pain between the HIFU and surgery groups was not significantly different at the 3-, 6- and 12-month follow-up periods. This demonstrates that HIFU ablation is as effective as surgery regarding symptom relief.

Furthermore, the largest diameter of an AWE lesion after treatment, as assessed by ultrasound, was clearly more noticeable in the surgery group than in the HIFU group. This is because the AWE lesion was destroyed in the HIFU group, whereas the lesion was removed in the surgery group. HIFU ablation uses targeted ultrasonic energy to instantaneously heat tissue, resulting in coagulative necrosis and dysfunction of the ectopic endometrium. A previous study found that, as necrotic tissue is slowly absorbed, ultrasound imaging shows a gradual reduction in HIFU ablation lesions, along with no obvious blood signal during follow-up[28].

HIFU ablation not only relieves abdominal cyclic pain and shrinks the lesion but also serves as a minimally invasive treatment option for patients. Compared with surgery, HIFU does not cause intraoperative blood loss or abdominal wall defects. Wide local excision with 1 cm margins via laparotomy is currently accepted as the optimal treatment for AWE[29]. However, these lesions often leave fascial defects much larger than the original mass due to fibrosis causing fascial retraction around the lesion[30]. For larger abdominal wall defects, reconstruction with mesh should be considered to lessen tissue tension and prevent hernia formation. In this meta-analysis, all the included studies showed that the patients in the HIFU group had a significantly shorter duration of hospital stay than those in the surgery group. The reason may be that, as a noninvasive treatment approach, HIFU enables the patient to avoid surgery (thereby avoiding surgery-related complications), reduces the volume of lesions significantly without incision, and leads to faster recovery to usual activities.

We found that differences in adverse events incidence between the HIFU and surgery groups was not statistically significant. Most adverse events were minor and self-limiting during follow-up. The main adverse events were intestinal injury, pain at the treatment area, skin burns along the acoustic path, and injury of the urinary tract mucosa in the HIFU group and haemorrhage, infection, pneumonia, irritation sign of the bladder, and urinary retention in the surgery group. A previous study showed that after HIFU treatment, no severe complications occurred, except for one patient who had a first-degree skin burn, during a 48-month follow-up period[31]. The incidence of adverse events in different studies varied, and one of the reasons is that there is no consensus on the definition of adverse events.

Horton et al. [24] reported a recurrence rate of 4.3% among 445 patients after surgery in a systematic review. Most studies in the meta-analysis of Horton et al were single-arm trials, whereas all studies in our meta-analysis were comparative studies. Our study showed that there was no statistically significant difference in the recurrence rate between the HIFU and surgery groups. The symptom recurrence rate ranged from 0 to 12% and from 0 to 17.2% in the surgery and HIFU groups, respectively, during the 6-48 months of follow-up. X Zhu et al.[14] reported that there was recurrence of AWE in one patient after HIFU treatment a year later, ultimately requiring wide surgical excision. Z Lin et al. showed that there was no recurrence in either group during a 12-month follow-up. However, L Zhao et al. implied that the recurrence rate was high (12% and 17.2% in the surgery and HIFU groups, respectively) during a 30-month follow-up. Recurrence rates across studies varied, possibly due to the following factors: (1) Studies had different lengths of follow-up time, ranging from 6 to 48 months; (2) The surgeons in each study were different; (3) The depth of lesion invasion for each patient was different. In the HIFU groups, if the lesion was deeper and closer to the parietal peritoneum, to avoid intestinal injury, lower energy exposure was used, preventing the complete destruction of the lesion.

4.4 Conclusions

Compared with surgery, HIFU ablation treatment for AWE is associated with lower immediate postoperative VAS scores, shorter hospitalization times and lower risks of adverse events. There are comparable rates of symptom recurrence and postoperative pain relief between both treatment approaches for AWE.

Author contributions: Dr. Lingbing Qiu contributed to data collection, data analysis and interpretation, and manuscript drafting. Dr. Jinbo Li contributed to data analysis, interpretation and the modification of the manuscript, Dr. Zhouzhou Liao and Dr. NiJi Li contributed to data analysis and data interpretation, Dr. Shuqin Chen was involved in all aspects of conducting this study, and is responsible for our study.

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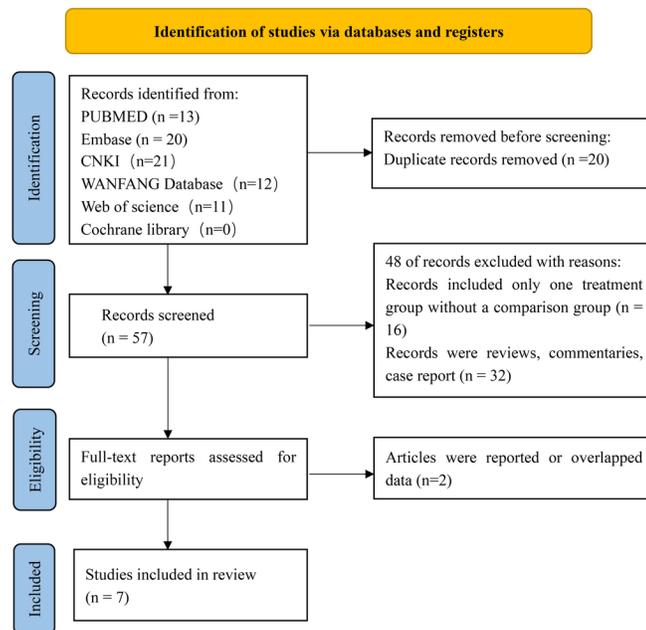
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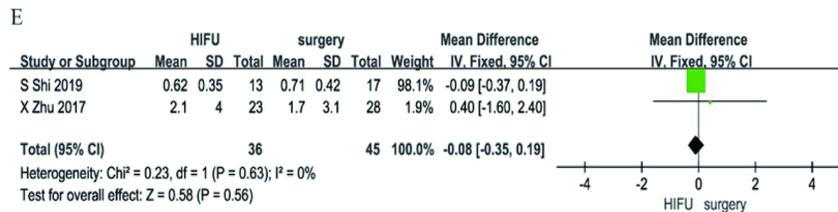
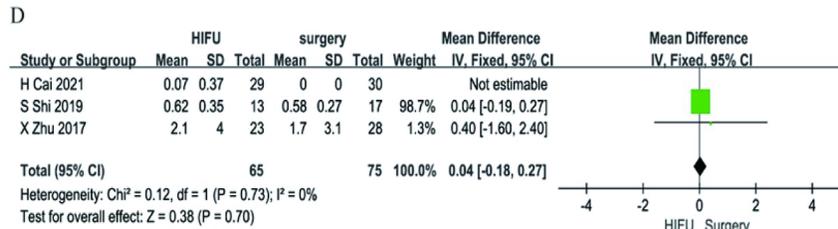
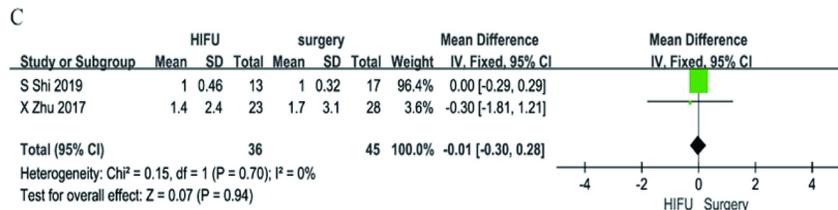
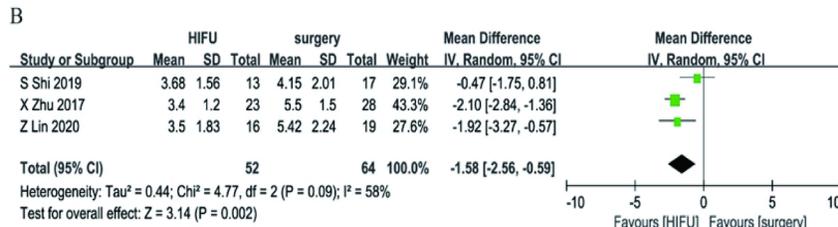
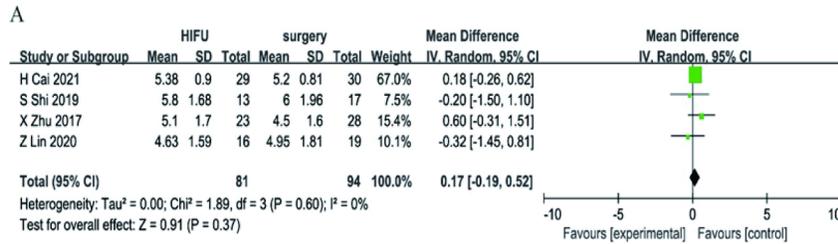
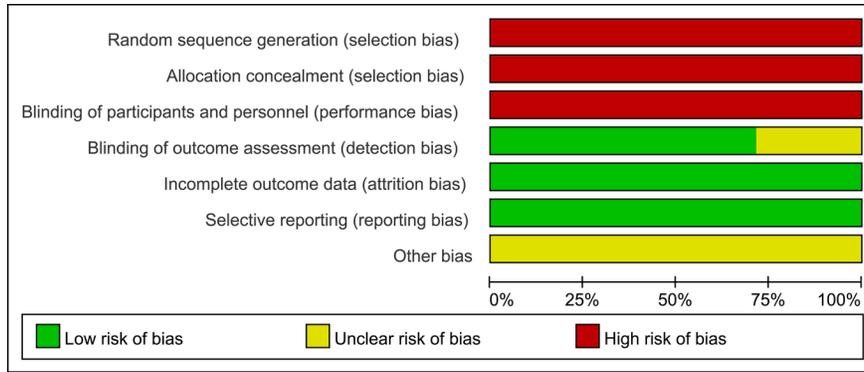
Conflicts of interest: We declare that there are no potential conflicts of interest.

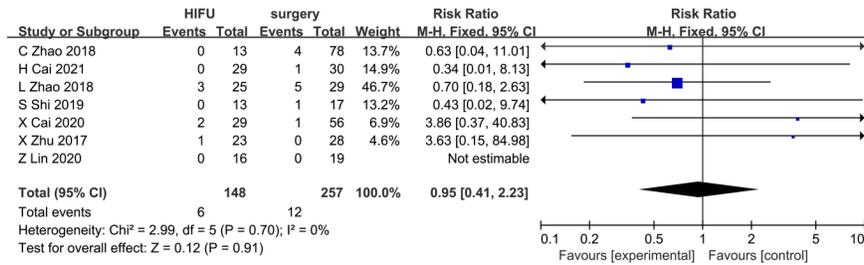
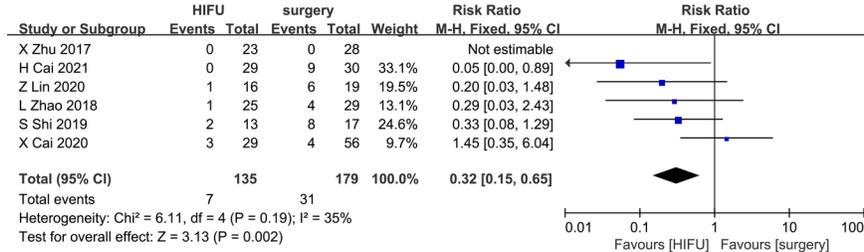
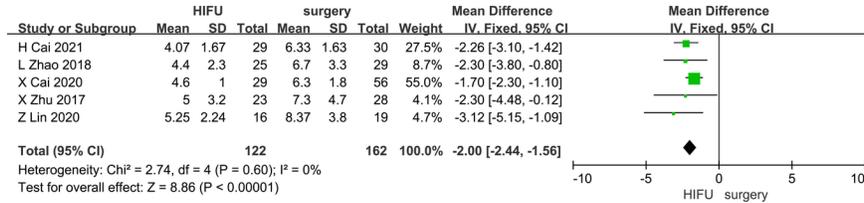
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Table 2.docx available at <https://authorea.com/users/651721/articles/659552-high-intensity-focused-ultrasound-ablation-versus-surgical-resection-for-treating-abdominal-wall-endometriosis-a-systematic-review-and-meta-analysis>

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Table 3.docx available at <https://authorea.com/users/651721/articles/659552-high-intensity-focused-ultrasound-ablation-versus-surgical-resection-for-treating-abdominal-wall-endometriosis-a-systematic-review-and-meta-analysis>