META-ANALYSIS

A systematic review and meta-analysis of the safety and efficacy of uterine artery embolization vs. surgery for symptomatic uterine fibroids

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ABSTRACT

Purpose: The aim of this study was to systematically review the safety and efficacy of uterine artery embolization (UAE) versus surgery for symptomatic uterine fibroids.

Materials and Methods: An electronic search of the Cochrane Library, PubMed, Embase and Web of Science databases was conducted from their inception to May 2017 for randomized controlled trials (RCTs) that assessed UAE versus surgery for the treatment of symptomatic uterine fibroids. The references of the included studies were also retrieved. Two reviewers independently screened the studies based on the inclusion and exclusion criteria, extracted the data, and assessed the methodological quality. The meta-analysis was conducted using RevMan 5.3 software.

Results: A total of seven RCTs involving 859 patients were included. The results of the meta-analysis showed a shorter hospital stay and recovery time for UAE as compared to surgery. Surgery was not reported to be better for improving health-related quality of life in any of the included studies. There were no significant differences in patient satisfaction (1-2 and 5 years), and intra-procedural complications or major complications (1 year). However, the rates of minor complications (1 year) and further interventions (2 and 5 years) were significantly higher in patients who underwent UAE rather than surgery. The rates of pregnancy and live births were significantly lower among patients who underwent UAE than surgery.

Conclusion: UAE is safe and effective, and has the advantages of shorter hospital stay and recovery time as compared to surgery. However, UAE has the risk of re-intervention, and lower pregnancy and live birth rates.

Keywords: uterine artery embolization; surgery; meta-analysis

INTRODUCTION

Uterine fibroids are the most common benign gynecological tumors. Studies have shown that 35% of premenopausal women have a previous diagnosis of fibroid tumors and 51% of undiagnosed premenopausal women have ultrasound evidence of fibroid tumors (1). The location of the tumor, volume, adjacent organs and other factors can lead to varied clinical symptoms. The symptoms cause varying degrees of discomfort to the patients, mostly requiring clinical therapy. Surgery is the traditional therapy, and surgical options mainly include hysterectomy (HY) and myomectomy (MY). HY can completely cure the uterine fibroids, but is considered to be too radical by many patients, regardless of fertility concerns. The advancement of laparoscopic techniques, combined with the strong desire of young women to maintain menses and fertility, has led to a significant increase in cases of MY, including trans-abdominal MY, laparoscopic MY and hysteroscopic MY, in recent years. MY can cure some patients and save the uterus, but has serious complications, such as increased intraoperative bleeding, postoperative infection, pelvic adhesions and omission of tumors, which restrict its application.

In 1991, French clinician Ravina employed uterine artery embolization (UAE) for the first time and reported its use for the treatment of uterine fibroids in 1995 (2). More in-depth studies using UAE to treat uterine fibroids showed...
excellent results. In most guidelines, UAE has been accepted as an alternative treatment to surgery for symptomatic fibroids in women who do not want to become pregnant. However, further interventions, fibroid recurrence rate, infertility, etc., remain controversial. To the best of our knowledge, a comprehensive meta-analysis has not been conducted. Herein, a detailed meta-analysis was conducted to further assess the safety and efficacy of UAE versus surgery for symptomatic uterine fibroids.

MATERIALS AND METHODS

Eligibility Criteria

Only true randomized controlled trials (RCTs) were included, regardless of blinding or publication status. The target population was patients who suffered from symptomatic uterine fibroids. Symptoms could be either subjective or objective. The main symptoms were menorrhagia or uterine bleeding, including pain and symptoms caused by massive tumor. The intervention in the experimental group was bilateral UAE with permanent embolic agents. The intervention in the control group was surgery (HY or MY). Every method of intervention was the initial and only intervention. Publications such as meeting abstracts, regular reviews, systematic reviews, meta-analyses and editorials were excluded. Various results from the same study program and several papers published in various periodicals at different times were integrated into the comprehensive analysis.

Literature Retrieval

The PubMed, Embase, Web of Science and Cochrane Library (No. 5, 2017) databases were searched from inception to May 2017. In addition, we searched ProQuest Diploma Paper Full Text Database and the MDlinx Database for gray literature. The last search was conducted on May 30, 2017. The search was simultaneously and independently conducted by two authors (Shiwei Tang and Xinjian Zhao). Discrepancies were resolved through discussion. Search key terms were: leiomyoma, uterine fibroids, surgery, hysterectomy, uterine myomectomy, uterine artery embolization, randomized controlled trial. Using PubMed as an example of the specific search procedures: (leiomyoma[MeSH] OR "uterine fibroids") AND (surgery)[MeSH] OR hysterectomy[MeSH] OR "uterine myomectomy"[MeSH]) AND "uterine artery embolization"[MeSH] AND randomized controlled trial).

Study Selection and Data Collection Process

Two authors (Shiwei Tang and Xinjian Zhao) screened the literature, and extracted and cross-checked the data. Differences were resolved through discussion with inputs from a third author (Zhongmin Wang). Data extraction primarily included general information, research features and outcome indicators.

Risk of Bias and Quality Assessment

Two authors (Shiwei Tang and Xinjian Zhao) used the Bias Risk Assessment method, which is recommended by the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (3), to assess the methodological quality of the included studies. Differences were resolved through discussion with inputs from a third author (Zhongmin Wang). Based on the results of systematic reviews, we assessed the evidence quality using the GRADE method (4) and sorted the evidence quality using GRADEpro 3.6 software.

Outcomes and Definitions

This paper provides a detailed analysis from the following eight perspectives: HR-QOL, patient satisfaction (1-2 years and 5 years), complications, hospital stay, recovery time, fibroid recurrence rate (UAE vs. MY), further interventions (2 and 5 years), pregnancy and live birth rates (UAE vs. MY).

Data Synthesis and Analysis

RevMan 5.2 software was used for the meta-analysis. Dichotomous data were evaluated using the odds ratio (OR) and 95% CI. Continuous variables were characterized by mean difference (MD) and 95% CI. The inspection level was α=0.05. Heterogeneity was analyzed using the chi-squared test. The fixed-effect model was used in the meta-analysis of homogeneous studies (p>0.10, I² <50%). If heterogeneity existed (p≦0.10, I²≧50%), we checked the source data first and then used the Meta XL function in Excel to repeatedly analyze the same index. One study was deleted every time to show its implications on the combined effects; thus, that study could be excluded, and a sensitivity analysis could be performed. Simultaneously, the subgroup heterogeneity test was conducted during the subgroup analysis, especially when heterogeneity existed in the subgroup. If the included data were unsuitable for meta-analysis, we analyzed them through descriptive characteristics only.

RESULTS

Figure 1. PRISMA diagram.
Study Selection and Study Characteristics

A total of 291 articles were preliminarily retrieved from the four databases and then managed by EndNote X7 software. A total of 106 articles were excluded as duplicates, 136 articles were excluded after reading the titles and abstracts, and 42 articles were excluded after reading the full texts. Finally, 12 articles were suitable for analysis. Of these, eight were reports from three separate study programs (four articles from one study and two articles from each of the remaining two studies). Therefore, seven unique studies were included, namely, Pinto 2003, Mara 2006-2008, Ruuskanen 2010, EMMY 2005-2013, REST 2007-2013, Manyonda 2012 and Jun 2012. Of the 859 patients, 464 were in the experimental group, and 395 in the control group (Fig. 1). The characteristics of the included studies are shown in Table 1.

Risk of Bias and Quality Assessment

Due to the differences between UAE and surgery, none of the included studies implemented a blinded study approach. Pinto 2003 reported incomplete data because they originally planned to follow-up patients for two years but only reported the outcome of 6-month follow-up. Ruuskanen 2010 planned to design an RCT, but the random sequence generation and allocation concealment was not reported in the study. We contacted the authors by e-mail but did not receive a reply. The outcomes are shown in Table 2.

The GRADE system categorizes the confidence in estimates (quality of evidence) as high, moderate, low or very low (17). We performed a graded assessment of the quality of evidence, including patient satisfaction (1-2 years), minor post-procedural complications (1 year), major post-procedural complications (1 year), hospital stay, recovery time and further interventions (2 years). The outcomes are shown in Table 3.

Table 1 Characteristics of the included studies.

| Study                  | Country | Study type | Experimental (T) | Control (c) | PVA (μm) | Cases (T/C) | Age (Mean±SD (Min-Max) years) |
|------------------------|---------|------------|------------------|-------------|----------|-------------|-------------------------------|
| Pinto 2003(5)          | Spain   | RCT        | UAE              | HY          | 400-600  | 40/17       | 46.4±4.4 (35-55)              |
| Mara 2006-2008(6, 7)   | Australia | RCT      | UAE              | MY          | 500-900  | 58/63       | 32.4± (--)                   |
| Ruuskanen 2010(8)      | Finland | RCT        | UAE              | HY          | 550-700  | 27/30       | 48.5±3.6 (41-57)              |
| EMMY 2005-2013(9-12)   | Netherlands | RCT    | UAE              | HY          | 355-500  | 88/89       | 44.6±4.8 (--)                |
| REST 2007-2013 (13, 14)| England  | RCT        | UAE              | HY/MY       | 500-710  | 106/51      | 43.6±5.5 (--)                |
| Manyonda 2012 (15)     | England  | RCT        | UAE              | MY          | 355-500  | 82/81       | 44 ± 5.7 (31-50)              |
| Jun 2012 (16)          | China    | RCT        | UAE              | HY/MY       | 500-700  | 63/64       | 43.5 ± 5.1 (32-55)           |

Table 2 Bias risk assessment.

| Study                  | Random sequence generation | Allocation concealment | Blinding | Incomplete outcome data | Selective reporting | Other bias |
|------------------------|----------------------------|------------------------|----------|-------------------------|---------------------|------------|
| Pinto 2003             | ●                         |                        | △        | △                       | ●                   | ●          |
| Mara 2006-2008         | ●                         | ●                      | △        | ●                       | ●                   | ●          |
| Ruuskanen 2010         | △                         | △                      | △        | ●                       | ●                   | ●          |
| EMMY 2005-2013         | ●                         | ●                      | △        | ●                       | ●                   | ●          |
| REST 2007-2013         | ●                         | ●                      | △        | ●                       | ●                   | ●          |
| Manyonda 2012          | ●                         | ●                      | △        | ●                       | ●                   | ●          |
| Jun 2012               | ●                         | ●                      | △        | ●                       | ●                   | ●          |

Low: ● high: △

Meta-analysis Results

The EMMY 2005-2013 study used the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) and EuroQol-5D to assess HR-QOL methods and
found significant differences between UAE and surgery after 1, 2 and 5 years of follow-up. The REST 2007-2013 study used SF-36 and EuroQol-5D to assess HR-QOL at the 1 and 5-year follow-up and found no significant difference between the UAE and surgery groups. Manyonda 2012 used UFS-QOL to assess HR-QOL at the 1-year follow-up. The assessment measures included symptom severity, concerns, activities, mood, control, self-control, sexual function and HRQL. Relative to baseline, there were no significant differences between the UAE and surgery groups (all p >0.05). Jun 2012 used SF-36 to assess HR-QOL at the 6-month follow-up. The UAE group had significantly greater improvement in scores than the surgery group for five components (all p <0.05).

### Table 3 Quality of the evidence (GRADE).

| Outcomes                        | Illustrative comparative risks* (95% CI) | Relative (95% CI) | Effect | No of participants (studies) | Quality of the evidence (GRADE) |
|---------------------------------|----------------------------------------|-------------------|--------|-----------------------------|---------------------------------|
| Patient satisfaction (1-2 years) | 861 per 1000 (785 to 901)              | OR 0.94 (0.59 to 1.48) | 640    | moderate                   |
| Minor post-procedural complications (1 year) | 259 per 1000 (785 to 901)          | OR 2.17 (785 to 901) | OR 2.17 (0.32 to 0.99) | (6 studies) | moderate |
| Major post-procedural complications (1 year) | 85 per 1000 (785 to 901)            | OR 0.56 (785 to 901) | OR 0.56 (0.32 to 0.99) | (7 studies) | moderate |
| Hospital stay                   | 2.83 lower (3.65 to 2.02 lower)       |                    | 800    | No blinding                |
| Recovery time                    | 19.19 lower (25.24 to 13.14 lower)    |                    | 588    | No blinding                |
| Further interventions            | 72 per 1000 (785 to 901)              | OR 3.5 (785 to 901) | 694    | No blinding                |

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval. 1 No blinding.

GRADE Working Group grades of evidence

- **High quality**: We are very confident that the true effect is close to that of the estimate of the effect.
- **Moderate quality**: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low quality**: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
- **Very low quality**: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.

Six studies (N=549) reported patient satisfaction after 1-2 years of follow-up. A heterogeneity test showed no heterogeneity (p=0.39, I²=5%) among these studies. The fixed-effect model was used to conduct the meta-analysis, and there were no significant differences between the UAE and surgery groups (OR=1.15, 95% CI (0.57, 2.29), p=0.70) (Fig. 2C).

Two studies (N=258) reported patient satisfaction after 5 years of follow-up. A heterogeneity test showed no heterogeneity (p = 0.36, I² =0%). The fixed-effect model was used to conduct the meta-analysis, and there was no significant difference between the UAE and surgery groups after 5 years of follow-up [OR=0.93, 95% CI (0.46, 1.88), p=0.85] (Fig. 2B).

Four studies (N=390) reported intra-operative complications. A heterogeneity test showed minimal heterogeneity among these studies (p=0.27, I²=24%). The fixed-effect model was used to conduct the meta-analysis, and there were no significant differences between the UAE and surgery groups [OR=0.56, 95% CI (0.32, 0.99), p=0.05] (Fig. 3B).
Figure 2. A: Patient satisfaction at the 1-2 year follow-up. B: Patient satisfaction at the 5-year follow-up. C: Intra-operative complications.
Figure 3. A: Minor post-procedural complications within 1 year. B: Major post-procedural complications within 1 year. C: Hospital stay (excluding the heterogeneous studies).
Seven studies (N=800) reported hospital stay. A heterogeneity test showed significant heterogeneity (p<0.00001, I²=87%) between the UAE and surgery groups, likely related to different management styles of the patients. The
random-effect model was used to conduct the meta-analysis, and the results showed a significantly shorter hospital stay in the UAE group than in the surgery group [MD=-2.83, 95% CI (-3.65, -2.02), p<0.00001] (Fig. 3C).

Six studies (N=588) reported the recovery time as an important index. A heterogeneity test showed significant heterogeneity among the studies (p<0.00001, I² =89%), likely due to the different standards of recovery. The random-effect model was used to conduct the meta-analysis, and the UAE group had a significantly shorter recovery time than the surgery group [MD=-19.19, 95% CI (-25.24, -13.14), p<0.00001] (Fig. 4A).

Six studies (N=694) reported the need for further interventions within two years of follow-up. A heterogeneity test showed minimal heterogeneity among the studies (p=0.17, I² =36%). The fixed-effect model was used to conduct the analysis, and there was a significant difference between the two groups. Further interventions occurred more frequently in the UAE group than the surgery group [OR=3.50, 95% CI (2.10, 5.83), p<0.00001] (Fig. 4B).

Two studies (N=289) reported further interventions within five years of follow-up. A heterogeneity test showed significant heterogeneity among these studies (p=0.09, I² =65%), likely due to the different surgical options. The random-effect model was used to conduct the meta-analysis, and there was a significant difference between the two groups, wherein further interventions occurred more frequently in the UAE group than the surgery group [OR=2.10, 95% CI (1.11, 4.02), p<0.0001] (Fig. 4C).

Mata 2006-2008 (N=66) was the only study that reported the pregnancy and live birth rates. The results showed that 13 out of 26 patients in the UAE group became pregnant as compared to 31 out of 40 patients in the surgery group. There was a significant difference between the two groups (p=0.02). The pregnancy rate in the UAE group was lower than in the surgery group. In addition, five out of 26 patients in the UAE group had safe deliveries, while 19 out of 40 patients in the surgery group had safe deliveries. There was a significant difference between the two groups (p=0.02). The live birth rate of the UAE group was much lower than that of the surgery group.

**DISCUSSION**

During UAE, the fibroid artery is embolized, which kills the fibroid due to poor blood circulation. However, the influence on normal tissues is minimal, permitting the retention of uterine function while controlling symptoms related to the fibroid. With the development of minimally invasive techniques, UAE gradually became an important method for treating uterine fibroids. This meta-analysis used the available evidence to examine the safety and efficacy of UAE versus surgery in order to provide a reference for clinical use.

The results of the meta-analysis showed that recovery time and length of stay were reduced during UAE as compared to surgery. Surgery was not reported to be better for improving health-related quality of life in any of the included studies. There were no significant differences in patient satisfaction (1-2 and 5 years) and intraprocedural complications or major complications (1 year). However, the rate of minor complications (1 year) and the need for further interventions (2 and 5 years) were significantly higher for patients undergoing UAE. In addition, the rates of pregnancy and live births were significantly lower in patients undergoing UAE as compared to surgery.

Many studies have shown that MY can control symptoms and improve fertility, but blood loss, peritoneal adhesions and recurrence are more prevalent as compared to UAE (18, 19). However, Joao M. Pisco (20) found that out of 74 patients who planned to become pregnant after UAE, 44 were successful, resulting in 33 live births, demonstrating a pregnancy rate as high as 75% and a live birth rate of 59.5%. Their conclusion was that UAE is safe for patients planning to become pregnant. In contrast, Woodruff J. Walker (21) found that only 27 out of 108 women planning to become pregnant were successful and resulted in 24 live births after UAE, demonstrating pregnancy and live birth rates of 33.5% and 72.7%, respectively. Hence, pregnancy and live birth are possible for patients after UAE. However, the extent to which UAE affects fertility remains unknown and needs further study.

The studies included in this analysis did not limit the number of uterine fibroids or distinguish between open vs. laparoscopic surgery. Radosa MP (22) found that multiple uterine fibroids are a risk factor for recurrence after laparoscopic surgery, and that the recurrence rate is 38.71%. Therefore, HY is often the main treatment for multiple uterine fibroids. However, Malartic C (23) found UAE to be a safe and effective alternative to radical HY. There is no evidence on the effect of UAE vs. open or laparoscopic HY.

All seven studies included in this analysis used PVA as the embolization agent, but the sizes ranged from 355-900 μm. The rates of minor complications and the need for further intervention (2 and 5 years) were higher in patients undergoing UAE as compared to surgery, which may be related to PVA sizes. Bilhim T (24) found that the initial use of PVA particle sizes 350-500 μm was associated with a higher mean pain score during and after UAE, although the outcome at six months was similar as compared to the initial use of particle sizes 500-700 μm. Kroencke TJ (25) found that the use of 500-700 μm spheres and a limited embolization resulted in an unacceptably high rate of failed tumor infarction, but superior imaging results and fewer repeat interventions can be achieved with 700-900 μm spheres, with stasis as the angiographic endpoint. In addition to PVA, many new embolization agents are used, including TAGM (26). By standardizing the usage of PVA, and developing and using new embolization agents, UAE is expected to reduce the damage to normal tissue, complica-
tions, regrowth and further interventions, and improve fertility.

Some high quality non-randomized controlled trials may have been excluded since only RCTs were included in this analysis, which can lead to bias. Since seven studies were included, this analysis included varied operation methods in the comparison group, resulting in heterogeneity and bias. Due to the lack of more suitable HR-QOL data, this analysis could not be performed. Hence, descriptive analyses were conducted instead. Only one study reported pregnancy and live birth rates in this analysis, which made it difficult to accurately assess the effects of UAE on fertility. Therefore, more RCTs are needed.

UAE is safe and effective, and has the advantages of shorter hospital stay and recovery time as compared to surgery. However, UAE has the risk of re-intervention, and lower pregnancy and live birth rates.

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