

Evaluation of the Efficacy and Complications of Uterine Artery Embolization in Comparison with Laparotomy-Myomectomy in the Treatment of Uterine Myomas: A Randomized Clinical Trial

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Abstract

Background: Due to the high prevalence of uterine fibroids or leiomyomas in women of reproductive age and the many treatment options for myomas, finding the best treatment is a challenge for surgeons. Therefore, this study aimed at evaluating the efficacy and safety of 2 treatment options surgical interventions and uterine artery embolization (UAE) in patients with uterine myoma.

Methods: The present study was a single-blind randomized clinical trial. The study population included all women with uterine myoma. Hence, 80 patients were divided into 2 groups of 40. The first group underwent laparotomy-myomectomy and the second underwent UAE. These patients were evaluated for clinical symptoms, menstrual disorders, estimated blood loss per menstrual cycle, and pain and complication on the 10th day, and at 2, 6, and 12 months after the intervention. The data were analyzed with SPSS software (Version 25) using an independent samples t test, a repeated measure analysis, and a chi-square test.

Results: Ten days, 2, 6, and 12 months after the intervention, there was no significant difference between the 2 approaches in terms of their decreasing effects on per menstrual cycle blood loss ($p > 0.05$), respectively. After 10 days and 2 months, the pain intensity in the embolization group was higher than laparotomy group ($p = 0.045, 0.060$), respectively. The pain intensity was also not significantly different between the 2 groups after 6 months and 1 year ($p > 0.05$), respectively. Also, the frequency of fever was higher in the embolization group ($p = 0.745$). However, the documented post-procedural complications indicated that hemoglobin level declined post-operation ($p > 0.050$).

Conclusion: The results showed no significant difference between the 2 groups in terms of post-procedural mensuration blood loss or pain intensity and the incidence of menstrual disorders within 1 year. It seems that there is no significant difference between the 2 groups and it may be possible to use the UAE depending on the patient's condition.

Keywords: Uterine Artery Embolization, Laparotomy, Myomectomy, Uterine Leiomyoma, Individualized Medicine

Conflicts of Interest: None declared

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Introduction

Uterine fibroids or leiomyomas are considered one of the most prevalent benign tumors in women of reproduc-

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↑What is “already known” in this topic:

The high prevalence of myoma and its associated symptoms in the reproductive age is one of the challenges for women and health care providers in this area. In this regard, the use of treatment procedures such as UAE or myomectomy with preservation of the uterus depending on the patient's condition and individually in the management of this disease has long been considered by experts. In developing countries, because of limited resources, further studies seem to be necessary.

→What this article adds:

The UAE method can be used instead of laparotomy depending on the patient's condition, as it is a minimally invasive approach capable of reducing leiomyoma blood supply by creating a clot in the uterine arteries, and because pain intensity, per menstrual cycle blood loss and the occurrence of possible complications were not significantly different between the two methods in long-term follow-up.

tive age (1). The prevalence of leiomyomas has been estimated to be 25% to 77% in reproductive age (2), which makes the clinician admit it as one of the most common causes of menstrual irregularities (3, 4). Although one-half of leiomyomas are asymptomatic and found accidentally, the mentioned signs or the unbearable symptoms such as abnormal uterine bleeding, abdominal pain pressure symptoms such as constipation recurrent urination, and hydro-nephrosis are supposed to be one of the main reasons for surgical planning, myomectomy, or even hysterectomy, as a major gynecological procedure with numerous short- and long-term complications (2, 5-8).

Uterine artery embolization (UAE) is a minimally invasive approach with the capability of reducing the leiomyoma blood supply by creating a clot in the uterine arteries as an alternative surgery in candidate patients. Already, there is a controversial recommendation about the reasonability of UAE in women who strongly desire fertility savings (9-11).

The rationality of UAE with nonpreventable side effects such as hypoxic pain in the pelvis, the need for hospitalizations, the minimal shrinkage and decrease in fibroids size that may result in the need for additive surgical management, the radiation exposure, and theoretically fertility suppression has been questioned in recent years with the introduction of minimally invasive surgical techniques (12, 13). In contrast, Goldman et al had indicated UAE only to decrease the bleeding tendency and exactly before laparoscopic myomectomy (14). Moreover, Goldberg et al emphasized both modality efficacy in case of precise patient selection; their study also explained that although the chance of post-UAE pregnancy is acceptable, myomectomy is suggested as the treatment of choice in case of fertility desire (15).

The current study was designed to evaluate the efficacy and safety of two of these treatment options, surgical interventions, and UAE, in a low-resource setting with limited equipment and experience in this field, based on the remaining challenge of the post-preference method for eliminating the chief complaint of women with leiomyoma.

Methods

The present study was a single-blind randomized clinical trial. The study population included all women with intramural and subserosal uterine myoma in size of less than 8 cm that were referred to Al-Zahra and Beheshti hospitals in Isfahan during 2019 and 2020.

The sample size in each group was estimated to be 40, based on the ratio of abnormal bleeding rates in the UAE and myomectomy groups, respectively, equal to 100% and 80%, and taking into account the results of previous studies (5) based on the ratio of abnormal bleeding rates in the UAE and myomectomy groups, respectively, equal to 100% and 80%. Women aged 30 to 45 years old who had clinical symptoms related to intramural and subserosal uterine leiomyoma in size less than 8 cm that had been detected for the first time, had no history of empirical treatment for leiomyoma, and had no fertility decision and/or fertility desire but agreed to participate in the study

were included. All patients were evaluated for other causes of abnormal uterine bleeding, including thyroid disease hypertension, and hyperprolactinemia. All patients were euthyroid and had normal prolactin and controlled blood pressure and blood sugar. Also, the renal function of all patients was in the normal range.

If patients have any history of myomectomy or embolization, adenomyosis (based on transvaginal sonography before surgery), any suspicious of malignancy in their imaging, any history of positive biopsy for malignancy, pregnancy, any sign of acute pelvic inflammatory disease, and/or sensitivity to the contrast agent were not included in the study. Also, those who did not complete their follow-ups were excluded and replaced by alternatives.

An ethics code was obtained from the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1398.357 and approval no: 398514) the clinical trial code (IRCT20200825048515N19), written informed consent was obtained from eligible patients. Then, the characteristics information, including age, gravidity, prior obstetric and medical history, the most worrying complaint, and the leiomyoma size/diameter were recorded and patients were divided into 2 groups of 40 cases by random allocation software.

The first group had a laparotomy-myomectomy, which required hospitalization the night before the procedure and, if necessary, bowel preparation. Fasting for 8 hours was also required of the patients. UAE was the planning modality in the second group and 8 hours of fasting was required. After confirming the patient record, the target area for catheter insertion, which is usually the groin, was disinfected and anesthetized. The catheter has then entered the artery under the guidance of an X-ray and the polyvinyl alcohol was then released alternately into the uterine arteries. Finally, after removal of the catheter from the artery, the perforated area was pressed to prevent bleeding and the patient was monitored for 8 hours and blood hemoglobin was measured again. The patient was discharged from the hospital if they were stable, did not lose hemoglobin, and had no hematoma in their groin.

It should be noted that to adjust the role of surgeon skill as a cofounder, operations were done by a single expert surgeon. Moreover, the data collector and statistical analyst were blind to the intervention in each avoiding the bias against the condition of the patient's follow-up.

The studied patients in both groups were followed in case there were any complained symptoms, pain and fever, or menstrual disorders on the day 10 as well as 2, 6, and 12 months later. Patients' pain intensity was evaluated based on the visual analog scale (VAS), with scores ranging from 0 to 10. Furthermore, the estimated menstrual blood loss was equalized in these categories: less than 4 (cm) (light or score 1), less than 6 cm (moderate or score 2), and saturated maxi pad within 1 hour (heavy or score 3), respectively, based on the mean size of colored stain on a maximize-pad within 1 hour in the first 2 days of each cycle.

If there was a drop in each group or a lack of follow-ups, the patient was replaced by someone else to keep the sample size (Fig. 1).

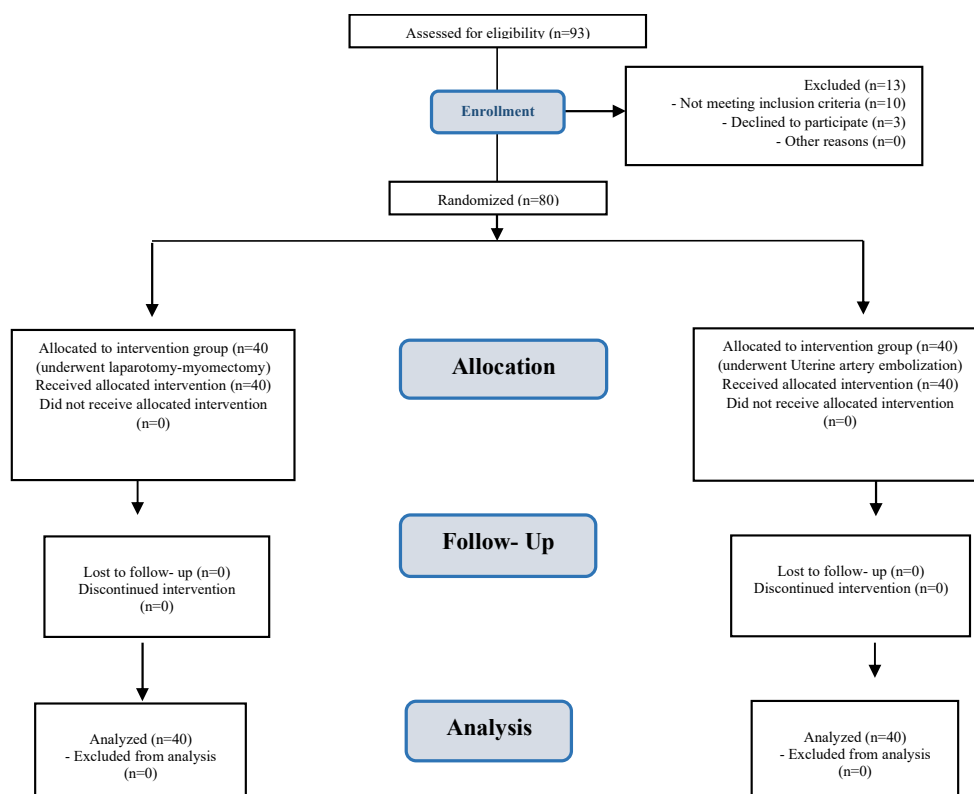


Fig. 1. Consort flowchart of patients

Statistical Analysis

Finally, the collected data were entered into SPSS software (Version 25) and were expressed as frequency (%) or means \pm standard deviation. According to the results of the Kolmogorov-Smirnov test indicating the normal distribution of data, an independent samples t test was used to compare the means of quantitative data between the 2 groups. Moreover, the repeated measures analysis was used to compare the mean scores of pain intensity and amount of blood loss per menstrual cycle between the 2 groups by adjusting the age, myoma size/diameter, and the additional dose of analgesic. Also, this analysis was used to compare the mean of quantitative data over time in 1 year in each group. Furthermore, a chi-square test was

also used to compare the qualitative data. The significance level was considered less than 0.05 in all analyses.

Results

In the present study, 40 patients undergoing laparotomy-myomectomy had a mean age of 37.33 ± 6.14 years, and 40 patients undergoing UAE had a mean age of 36.53 ± 6.01 years ($p = 0.558$). Moreover, there was no significant difference between the 2 groups in terms of the number of pregnancies ($p = 0.059$), history of prior childbirth ($p = 0.410$), past medical history ($p = 0.682$), and myoma size/diameter ($p = 0.107$) (Table 1).

There was no significant difference in the estimated blood loss per menstrual cycle before and even 10 days, 2,

Table 1. Determination and comparison of the basic and clinical characteristics of patients in the two groups

Characteristics	Laparotomy-myomectomy	Embolization	P-value
Age (year)	37.33 \pm 6.14	36.53 \pm 6.01	0.558
Number of pregnancies			
1	23 (57.5%)	16 (40.0%)	0.059
2	13 (32.5%)	14 (35.0%)	
3	2 (5.0%)	7 (17.5%)	
≥ 4	2 (5.0%)	3 (7.5%)	
history of prior child birth			0.410
Cesarean section	15 (37.5%)	17 (42.5%)	0.682
Natural vaginal delivery	25 (62.5%)	23 (57.5%)	
Past Medical History			
Hypothyroidism	5 (12.5%)	2 (5%)	0.107
Hypertension	1 (2.5%)	0 (0%)	
Diabetes	2 (5%)	3 (7.5%)	
Size of myoma (cm)	6.78 \pm 1.27	5.93 \pm 2.48	0.107
Hospitalization length	3.45 \pm 1.04 (hour)	11.00 \pm 1.75 (day)	<0.001
Candidate of Blood transfusion	16 (40.0%)	-	-

Table 2. Determination and comparison of the amount of blood loss per period before and after the intervention between the two groups

Amount of blood loss per menstrual cycle	Laparotomy-myomectomy	Uterine artery embolization	P ₁
Before intervention	3 (1-3) 2.50±0.68	3 (2-3) 2.73±0.45	0.154
10 days after the intervention	1 (1-2) 1.48±0.51	2 (1-3) 1.60±0.59	0.251
2 months after the intervention	1 (1-2) 1.33±0.47	1 (0-3) 1.30±0.61	0.992
6 months after the intervention	1 (1-2) 1.30±0.46	1 (0-3) 1.20±0.85	0.558
One year after the intervention	1 (1-3) 1.20±0.52	1 (0-3) 0.95±0.90	0.083
P ₂	0.003	0.019	
Reduce bleeding	1.30±0.79	1.77±0.97	0.109

Significance level obtained from repeated measure analysis by adjusting age and myoma size:
1- Comparison between two groups; 2- Intergroup comparison (variable changes by over time)

6, and 12 months after the intervention ($p > 0.05$). However, both groups had experienced a significant reduction in the amount of blood loss per menstrual cycle within 1 year based on the results of the repeated measures analysis ($p = 0.003$; 0.019), respectively (Table 2).

Moreover, the frequency distribution of blood loss per period revealed that no cases of amenorrhea were found in the laparotomy group. Furthermore, the heavy bleeding and irregular uterine bleeding were lower in the laparotomy group as compared with the UAE group, and a large percentage of patients reached the light bleeding volume (Fig. 2). About 20% of myomas larger than 5 cm in size who underwent embolization had heavy uterine bleeding. about 5% (2 patients) of women who underwent embolization underwent hysterectomy because of severe post embolization pain and heavy bleeding, while the myomectomy surgery group did not require additional intervention but also in the laparotomy group about 5% of people continued to severe bleeding.

The pain and fever in the embolization group with a mean of 5.55 ± 2.30 was higher than that of the laparotomy group with a mean of 2.50 ± 2.25 after 10 days ($p = 0.045$). The pain was so severe within 10 days that about 20% of people who underwent UAE required 1-day hospitalization and even opium injection.

After 2 months following the intervention, respectively, this difference was not statistically significant ($p = 0.060$). In addition, the pain intensity was not significantly different between the 2 groups 6 months and 1 year after the intervention ($p > 0.05$), respectively. Moreover, the reduction of pain during 1 year was not significantly different between the laparotomy group, with a mean of 6.07 ± 1.97 , and the embolization group, with a mean of 5.25 ± 3.02 ($p = 0.176$) (Table 3).

Figure 2 addresses the patients' pain reduction trend that is compared in the follow-ups performed after the intervention. The findings revealed that there was no significant difference between the 2 groups in terms of the percentage of patients' pain reduction 10 days after the intervention as compared with before the intervention ($p = 0.051$). The percentage of pain reduction 2 months after the intervention as compared with before the intervention was 55.4% and 21.2% in the laparotomy-myomectomy and UAE groups, respectively ($p = 0.029$).

However, the pain reduction in the laparotomy group

with the percentages of 83.3% and 100% was not significantly different from that of the UAE group with the percentages of 67.9% and 90% six months and 1 year after the intervention as compared before the intervention, respectively ($p > 0.05$) (Fig. 3).

Finally, postintervention complications indicated that the incidence of decreased hemoglobin in the laparotomy group with 42.5% was significantly higher than that of the embolization group with 5% ($p < 0.001$). Furthermore, 1 (2.5%) of patients with menstrual abnormalities (amenorrhea) and 2 (5%) of patients with recurrent symptoms (severe uterine hemorrhage and pain) needed reoperation and hysterectomy, respectively ($p > 0.05$) (Table 4).

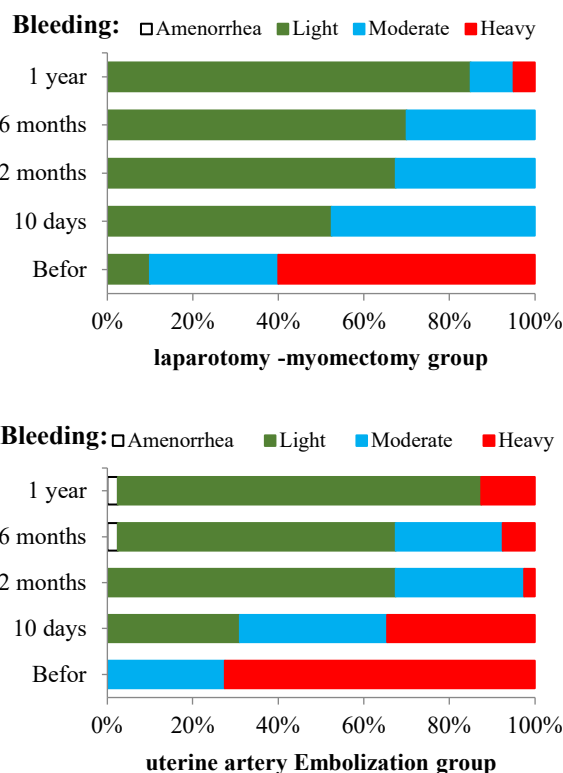


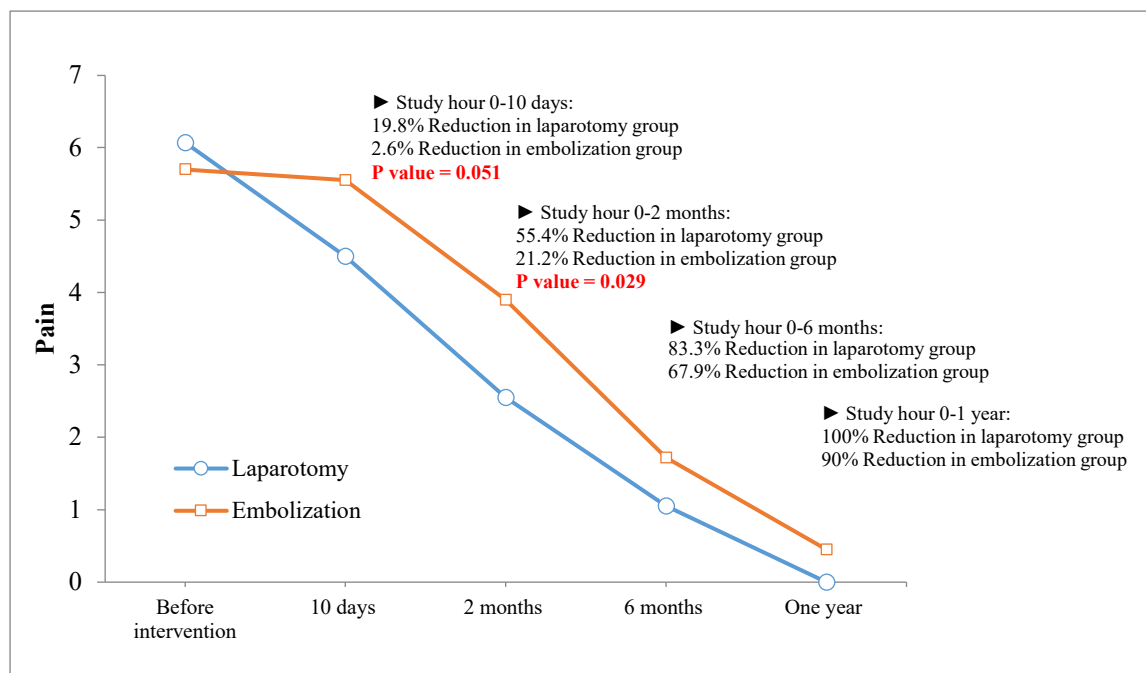
Fig. 2. Frequency distribution of blood loss per period before and after the intervention in the two groups

Table 3. Determination and comparison of the pain intensity level before and after the intervention between the two groups

Pain intensity	Laparotomy-myomectomy	Uterine artery embolization	P ₁
Before intervention	6.07±1.97	5.70±2.52	0.411
10 days after the intervention	2.50±2.25	5.55±2.30	0.045
2 months after the intervention	2.55±2.21	3.90±2.47	0.060
6 months after the intervention	1.05±2.21	1.72±2.71	0.991
One year after the intervention	0	0.45±1.74	0.146
P ₂	0.230	0.166	
Reduce pain	6.07±1.97	5.25±3.02	0.176

Significance level obtained from repeated measure analysis by adjusting age, myoma size and additional dose of analgesic:

1- Comparison between two groups; 2- Intergroup comparison (variable changes by over time)

**Fig. 3.** Percentage of pain reduction for the two groups in the follow-up after the intervention as compared to before the intervention**Table 4.** Determination and comparison of the post-procedural complication between the two groups

Complication	Laparotomy-myomectomy	Uterine artery embolization	P
Fever	5 (12.5%)	10 (25%)	0.745
Decreased level of hemoglobin	17 (42.5%)	2 (5%)	<0.001
Recurrence symptom	0 (0%)	2 (5%)	0.152
Menstrual disorders (amenorrhea)	0 (0%)	1 (2.5%)	0.364
Need for emergent Hysterectomy	0 (0%)	2 (5%)	0.152
Need for additional dose of analgesic/ non-tolerable pain within first 10 days.	8 (20%)	17 (42.5%)	0.030

Discussion

This well-designed clinical trial was proposed to compare the short- and long-term effects of the 2 methods of UAE and laparotomy myomectomy in the treatment of uterine fibroids. This study revealed that both procedures were successful in decreasing the estimated amount of blood loss per menstrual cycle within 1 year but none of the procedures was superior in this regard.

UAE, a minimally invasive procedure that causes temporary occlusion of the uterine artery and thus ischemic infarction of the leiomyoma by biocompatible particles, was superior in terms of shorter hospital stays, anesthetic drug administration, and earlier return to normal activities, but this group of participants required more additional intervention than that suggested in previous reports (16-18).

It is also worth mentioning that in the method of UAE, as mentioned before, nearly 2.5% of cases in the UAE group had experienced amenorrhea after 1 year while heavy bleeding continued in approximately 20% of them. These findings are consistent with the rate of efficacy in reducing menstrual bleeding in previous trials in acceptable instances and over time, which ranged from 24% to 76%, compared with 48.8% to 66.2% in the UAE (19-22).

In this regard, Manyonda et al found the higher quality of life in the myomectomy group, similar blood loss per menstrual cycle in both, and more likelihood of needing additional procedures in the UAE group in their multicenter, randomized trial, which is similar to our result except for assessing the quality of life, which was not determined in the current study and might be considered as an important limitation that persuades further studies (23).

Bautista Jia et al found UAE to be more effective in symptomatic menorrhagia (24) than surgical myomectomy, but only in younger patients aged 30 to 39 years, not in older patients or long-term follow-up. This needs to be re-evaluated by a larger randomized trial shortly to precisely determine the exact candidate of UAE versus surgical myomectomy. In addition, the results of the present study indicate that menstrual irregularities, and amenorrhea are rare, similar to mentioned reports. Thus, it must be emphasized on the different designs of these studies that make it hard to assure the most reliable result for individualized planning. In confirmation of this assumption, by creating a long-term follow-up study, Poulsen et al and Scheurig-Muenkler et al discovered a decreasing probability of recurrences with time, although having a higher rate of symptomatic-leiomyoma recurrences that typically resulted in hysterectomy (25, 26). Also, Daniels et al showed in their recent study that although myomectomy has played a greater role in improving the quality of life than UAE, in the long-term follow-up, no significant difference can be made between the 2 methods. To emphasize the better generalizability of the results, they have emphasized further studies in this field (27).

Spies et al revealed a significant discovery from a long-term follow-up, which should be considered as a point in future investigations; they detected a decrease in patient satisfaction following UAE over time, which should be contrasted with surgical efficacy in future studies. Although over 93% remained symptom-free in the first 3 months of the follow-up, these figures drop to 87%, 85%, 83%, and 79%, respectively, in the first, second, third, and fourth years following UAE (13).

In light of the current study's findings, it appears that UAE efficacy and complications are slightly higher than surgical myomectomy, but it is important to remember that the study design was limited to symptomatic patients with leiomyoma sizes ranging from 4 to 8 cm. Although the adjusted size of leiomyoma in both groups is a strong point in the analysis of the findings, the results cannot be applied to every case of leiomyoma, emphasizing the importance of tailored management in a future study.

Conclusion

According to the results of the present study, there was no significant difference between the 2 groups of UAE and laparotomy-myomectomy in terms of postprocedural mensuration blood loss or postoperative pain. However, the incidence of menstrual disorder was higher in the embolization group for 1 year. This finding could point to a restriction in the embolization therapy options for uterine myoma. Before increasing UAE usage to young women of reproductive age, more research is needed.

Acknowledgment

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Ethical Considerations

The present study is derived from the residency dissertation approved by Isfahan University of Medical Sciences

(IUMS), with the ethical code of IR.MUI.MED.REC.1398.357. Also, ethical issues (including plagiarism, data fabrication, and double publication) have been completely observed by the authors.

Conflict of Interests

The authors declare that they have no competing interests.

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