Comparison between Uterine Artery Embolization and Myomectomy in Treatment of Uterine Myoma Regarding Recurrence of Symptoms: A Randomized Clinical Trial

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Abstract

Background: Uterine fibroids or leiomyomas are considered one of the most prevalent benign tumours in women of reproductive age. The aim of the present study is to evaluate myomectomy, as compared with UAE, in women who had symptomatic uterine fibroids and did not want to undergo hysterectomy regarding recurrence of symptoms (pain and bleeding) and recurrence of tumours.

Methods: We performed a prospective randomized clinical trial on 100 symptomatic uterine fibroids. Patients were eligible if they have at least one symptom caused by uterine fibroids, such as menorrhagia, pain, or bulk-related symptoms that can be treated with myomectomy or uterine-artery embolization. Patients were randomly divided equally in two groups Group A(n=50): underwent Uterine Artery Embolization(UAE), Group B(n=50): underwent myomectomy

Results: Patients' satisfaction was significantly higher in group A compared to group B (86% vs. 64%, P=0.020), improvement of symptoms was significantly better in group A compared to group B (82% vs. 52%, P=0.003) and reduction in fibroids after 1 year was higher in group A than group B with no statistically significant difference between both groups. Regarding the recurrence of symptoms, group A showed significant improvement in postoperative bleeding and VAS at 1, 3 and 6 months compared to group B (P<0.05) whereas postoperative bleeding and VAS were comparable at 1-year between both groups.

Conclusion: UAE may be more effective in controlling patients' bleeding, pain, has lower rates of post-procedural blood transfusions, postoperative complications and higher rates of patients' satisfaction and symptoms improvement.

Keywords: Uterine Artery Embolization, Myomectomy, Uterine Myoma ,bleeding

Introduction

Uterine fibroids or leiomyomas are considered one of the most prevalent benign tumours in women of reproductive age [1]. The prevalence of leiomyomas has been estimated to be 25% to 77% in re productive age, which makes the clinician admit it as one of the most common causes of menstrual irregularities [2].
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 hydronephrosis are supposed to be one of the main reasons for surgical planning, myomectomy, or even hysterectomy, as a major gynaecological procedure with numerous short- and long-term complications [3, 4].

Leiomyomas are prevalent condition affecting women primarily between the ages of 30 and 55, and it is the leading cause of surgical intervention in both developed and emerging nations. Age remains a critical factor, with myomas escalating between 40 and 50 [5].

Nonsurgical treatment options include GnRH analogues, oral contraceptives, hormone-based preparations, levonorgestrel-releasing intrauterine devices, uterine artery embolization, focused ultrasound surgery, endometrial ablation, and radiofrequency fibroid ablation. For surgical treatment, conventional methods and laparoscopic and robot-assisted procedures can be considered [6].

Surgery, either myomectomy or hysterectomy, has traditionally been the primary approach for the management of symptomatic fibroids; uterine artery embolization emerged as an alternative during the 1990s [7].

Myomectomy involves the surgical removal of the fibroid and preservation of the uterus. Although myomectomy substantially reduces heavy bleeding, it is associated with myometrial trauma, and whether it results in improved reproductive outcomes is not known. Uterine-artery embolization, which is usually performed while the patient is under local anesthesia, involves temporary occlusion of the arteries supplying the uterus, with the use of biocompatible particles, to cause ischemic infarction of the fibroids [8].

As compared with myomectomy, uterine-artery embolization is associated with a shorter hospital stay and an earlier return to normal activities but also a higher likelihood of the need for additional intervention [9].

Concern regarding a possible effect on ovarian and uterine function has resulted in recommendations against the use of uterine-artery embolization in women who plan to become pregnant; however, the results of a previous study suggested no appreciable effect on ovarian reserve [10].

Previous study showed sustained improvements in quality of life, as measured with the use of the validated Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire, at 3-5 years after myomectomy or uterine-artery embolization, but long-term outcome data to directly compare these procedures are limited [11].

In two randomized trials comparing uterine-artery embolization with myomectomy in which data from a total of 243 women were analyzed, myomectomy was associated with a greater improvement in quality of life and better reproductive outcomes than uterine-artery embolization; however, there was substantial attrition in one trial (the FUME [Fibroids of the Uterus: Myomectomy versus Embolization] trial), and in both trials, complete follow-up occurred only through 1 year after randomization [12, 13].

Two other randomized trials compared uterine-artery embolization with hysterectomy or myomectomy [14, 15]. A meta-analysis that assessed rates of patient satisfaction after 2 years yielded inconclusive results, which underscores the need for more comparative evidence [16].

The aim of the present study is to evaluate myomectomy, as compared with UAE, in women who had symptomatic uterine fibroids and did not want to undergo hysterectomy regarding recurrence of symptoms (pain and bleeding) and recurrence of tumors.

PATIENTS AND METHODS

This prospective randomized clinical trial was carried out on 100 symptomatic uterine fibroids. Patients were eligible if they have at least one symptom caused by uterine fibroids, such as menorrhagia, pain, or bulk-related symptoms that was be difficult to manage by medication alone; that can be treated with myomectomy or uterine-artery embolization admitted to Department of Gynaecology Benha University Hospitals after approval of the institutional ethical committee (Approval number: 3-7-2023). The informed written consent was obtained from the patients.

Inclusion criteria were patient's age from >18 years old, patients with abnormal uterine bleeding not responding to medical treatment, seeking for minimally invasive therapy, refusing hysterectomy for fertility preservation and patients with symptomatic uterine fibroids, Premenopausal was not pregnant, postmenopausal and had symptomatic fibroids that was treated with myomectomy or uterine-artery embolization.

Exclusion criteria were patient refusal, pregnancy, recent or ongoing pelvic inflammatory disease, pelvic malignancy, contraindication to magnetic resonance imaging (MRI); or severe allergy to iodinated contrast

media, had a suspected or diagnosed cancer, , or undergone a previous open abdominal myomectomy or uterine-artery embolization.

The tumours were diagnosed as uterine fibroids by transvaginal ultrasound scope or enhanced pelvic MRI by experienced gynaecologists. Pap smear was confirmed to be negative in all patients before the procedure. Upper limits on the volume of the uterine fibroids and uterus was not set.

Randomization:

Patients were randomly divided in two groups (according to a computer-generated random sequence with a 1: 1 ratio). Group A (n=50): underwent UAE and group B (n=50): underwent myomectomy.

Owing to the nature of the procedures, blinding was not considered to be feasible. Computerized randomization was performed centrally through a secure Internet facility with the use of minimization to balance the treatment-group assignments.

All patients were subjected to the following: Demographic data (age, BMI, menstrual history, type, duration and amount of bleeding, any medications,). History of comorbidities (HTN, diabetes, smoking, dyslipidaemia. Clinical examination including HR, BP. Laboratory assessment including CBC, Hgb level, prothrombin time and concentration, INR, and kidney function. Pre-procedure transvaginal ultrasound examination and/ or pelvic MRI with contrast enhancement, to facilitate planning of the procedure.

Procedure evaluation:

Transcatheter uterine artery embolization using PHILIPS advanced ALLURA XPER FD20 X-RAY SYSTEM. The machine can perform serial radiography, digital subtraction, and road map images. Non-ionic contrast media (OMNIPAQUE 300 (Iohexol)) was used in all patients. Puncture Access needle, 6 Fr vascular femoral sheath, 0.035 hydrophilic guidewire (Radiofocus Inc), 5 Fr Cobra catheter (Angiodynamic / Cordis Inc) and 2.4–3 Fr Renegade® Hi Flo™ Microcatheter (Boston Scientific, Natick, MA) was be used. Different embolizing materials was be used in our study including mainly permanent embolizing particles like PVA and TAGM (Embosphere) as well as temporary embolizing materials as gelatine sponge (Gel foam).

Bilateral selective catheterization and embolization of the uterine arteries were performed under fluoroscopic guidance. The specific embolic agent used was at the discretion of the interventional radiologist, and the end point of the embolization procedure was complete or near complete stasis of blood flow in the uterine artery.

The endpoint of embolization depends on the uterine pathology to be treated; in uterine fibroid, embolization is continued until there is complete occlusion of the branch arteries penetrating the leiomyoma up to the distal main uterine artery. While in dysfunctional uterine bleeding and diffuse adenomyosis embolization was terminated once complete occlusion of the distal uterine artery spiral branches was be achieved.

Myomectomy was performed by the route preferred by the operating gynaecologist (open abdominal, hysteroscopic, laparoscopic, or a combination of these). A gonadotropin-releasing hormone analogue or ulipristal acetate was be administered before the procedure if it was be deemed by the gynaecologist to be essential. Concurrent procedures such as adhesiolysis was not restricted.

Post-procedure follow-up:

Using transvaginal ultrasound and pelvic MRI examination. The studied patients in both groups were followed in case there was any complained symptoms, pain and fever, or menstrual disorders at 1 month 3 ,6,12 months. Changes in fibroid-related symptoms was be classified as follows: markedly improved, moderately improved, slightly improved, unchanged, and worsened compared with preprocedural symptoms [17]. Furthermore, the estimated menstrual blood loss was be 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 coloured stain on a maximize-pad within 1 hour in the first 2 days of each cycle [18]. Patients' pain intensity was be evaluated based on the visual analogy scale (VAS), with scores ranging from 0 to 10 where 0 represented "no pain" and 10 represented "worst pain [19]. Patient satisfaction was be assessed by Likert scale [20].

Complications was be defined when patients underwent any additional interventions or treatments due to fibroid-related symptoms, including failure of symptom control and development of complication-related symptoms. Follow-up visits starting 3 months after the procedure,6m and lasting up to 12 months.
The primary outcome was the recurrence of bleeding, secondary outcomes were complications and pain and patient satisfaction.

Sample size calculation

The sample size calculation was performed using G. power 3.1.9.2 (Universität Kiel, Germany). The sample size was calculated according to amount of blood loss one year after the intervention (myomectomy 1.20±0.52 vs. UAE 0.95±0.90) according to a previous study [21]. Based on the following considerations: 0.05 α error and 80% power of the study, allocation ration 1:1. six cases were added to overcome dropout. Therefore, 100 patients will be allocated.

Statistical analysis

Statistical analysis was done by SPSS v28 (IBM©, Chicago, IL, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD) and were analyzed by unpaired student t-test. Quantitative non-parametric data were presented as the median and interquartile range (IQR) and were analyzed by Mann Whitney-test. Qualitative variables were presented as frequency and percentage (%) and analyzed using the Chi-square test or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered statistically significant.

RESULTS

In this study, 137 patients were assessed for eligibility, 23 patients did not meet the criteria and 14 patients refused to participate in the study. The remaining 100 patients were randomly allocated into 2 groups (50 patients in each). All allocated patients were followed-up and analyzed statistically. **Figure 1**

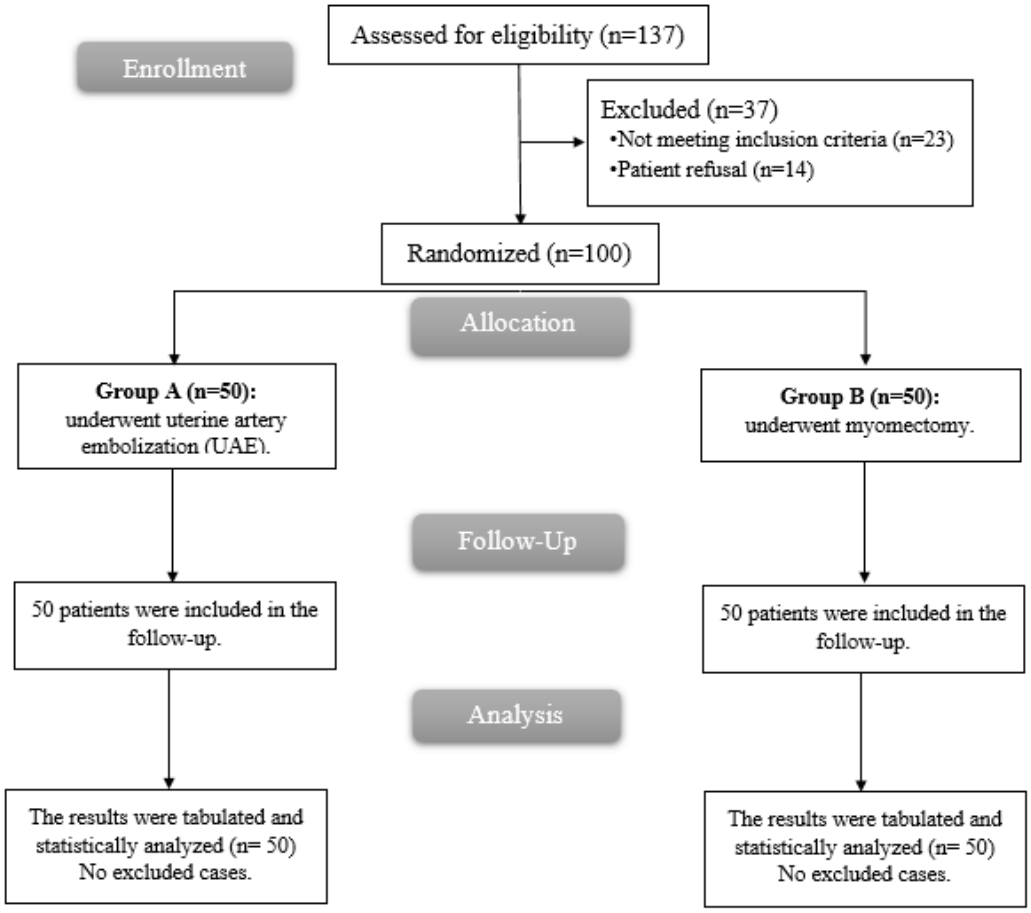

Figure 1: CONSORT flowchart of the enrolled patients

Baseline charactistics (age, weight, height, and BMI), associated comorbidities (HTN, DM, smoking and hyperlipidemia), menstrual status (all the studied patients were premenopausal) and parity were insignificantly different between both groups. **Table 1**

Table 1: Baseline charactistics between the studied groups

		Group A (n=50)	Group B (n=50)	P value
Age (years)		38.6 ± 7.07	36.5 ± 7.09	0.141
Weight (Kg)		77.8 ± 8.8	80.68 ± 8.71	0.103
Height (m)		1.64 ± 0.06	1.65 ± 0.07	0.736
BMI (Kg/m^2)		28.82 ± 3.41	29.74 ± 4.51	0.252
Comorbidities	**HTN**	14 (28%)	10 (20%)	0.482
	DM	11 (22%)	8 (16%)	0.610
	Smoking	12 (24%)	8 (16%)	0.453
	Hyperlipidemia	3 (6%)	4 (8%)	1.0
Menstrual status	**Premenopausal**	50 (100%)	50 (100%)	--
	Postmenopausal	0 (0%)	0 (0%)	
Parity	**Primiparous**	31 (62%)	36 (72%)	0.395
	Multiparous	19 (38%)	14 (28%)	

Data presented as mean ± SD or frequency, BMI: body mass index, HTN: hypertension, DM: diabetes mellitus

Preprocedural symptoms, pattern of bleeding, VAS, methods of fibroid assessment, existence of multiple fibroids, size of myoma and hospital stay were insignificantly different between both groups. **Table 2; Figure 2**

Table 2: Clinical data between the studied groups

		Group A (n=50)	Group B (n=50)	P value
Preprocedural symptoms	**Menorrhagia**	13 (26%)	11 (22%)	0.732
	Bulk symptoms	17 (34%)	12 (24%)	
	Pain	12 (24%)	11 (22%)	
	Both	8 (16%)	11 (22%)	
Bleeding	**Light**	15 (30%)	7 (14%)	0.149
	Moderate	19 (38%)	22 (44%)	
	Heavy	16 (32%)	21 (42%)	
Pain (VAS)		5.36 ± 1.45	5.54 ± 1.4	0.553
		5 (4-7)	6 (5-7)	
Fibroid assessment	**Magnetic resonance imaging**	20 (40%)	27 (54%)	0.229
	Ultrasonography	30 (60%)	23 (46%)	
Multiple fibroids		39 (78%)	40 (80%)	0.806
Size of myoma (cm)		6.53 ± 0.73	6.64 ± 0.68	0.473
Hospital stay`		1.96 ± 0.88	1.94 ± 0.77	0.904

Data presented as mean ± SD, median (IQR) or frequency. VAS: visual analogue scale

Laboratory investigations (Hb, platelets and INR) were insignificantly different between both groups. **Table 3**

Table 3: Laboratory investigations between the studied groups

	Group A (n=50)	Group B (n=50)	P value
Hb (g/dL)	11.7 ± 0.8	11.88 ± 0.86	0.302
Platelets (*10^9/L)	272.74 ± 53.86	270.28 ± 57.34	0.825
INR	1.053 ± 0.03	1.051 ± 0.03	0.715

Data presented as mean ± SD, Hb: hemoglobin, INR: international normalized ratio

Regarding the postoperative follow-up and complications, blood transfusion and incidence of fever were significantly lower in group A compared to group B (P=0.014, <0.001). Incidence of pelvic infection and rehospitalization were insignificantly different between both groups. **Table 4**

Table 4: Postoperative follow-up and complications between the studied groups

	Group A (n=50)	Group B (n=50)	P value
Blood transfusion	5 (10%)	16 (32%)	**0.014***
Pelvic infection	5 (10%)	2 (4%)	0.436
Fever	3 (6%)	7 (14%)	**<0.001***
Rehospitalization	2 (4%)	6 (12%)	0.269

Data presented as frequency. *: statistically significant as P value <0.05

Patients' satisfaction was significantly higher in group A compared to group B (86% vs. 64%, P=0.020), improvement of symptoms was significantly better in group A compared to group B (82% vs. 52%, P=0.003) and reduction in fibroids after 1 year was higher in group A than group B with no statistically significant difference between both groups. **Table 5**

Table 5: Patients' satisfaction and improvement of symptoms between the studied groups

	Group A (n=50)	Group B (n=50)	P value
Patients' satisfaction	43 (86%)	32 (64%)	**0.020***
Improvement of symptoms	41 (82%)	26 (52%)	**0.003**
Reduction in fibroids after 1 year	36 (72%)	26 (52%)	0.064

Data presented as frequency. *: statistically significant as P value <0.05

Regarding the recurrence of symptoms, group A showed significant improvement in postoperative bleeding and VAS at 1, 3 and 6 months compared to group B (P<0.05) whereas postoperative bleeding and VAS were comparable at 1-year between both groups. **Table 6; Figure 2**

Table 6: Recurrence of symptoms between the studied groups

		Group A (n=50)	Group B (n=50)	P value
Bleeding				
1-month	**Light**	15 (30%)	10 (20%)	**0.031***
	Moderate	26 (52%)	19 (38%)	
	Heavy	9 (18%)	21 (42%)	
	No	0 (0%)	0 (0%)	
3-month	**Light**	24 (48%)	15 (30%)	**0.036***
	Moderate	20 (40%)	19 (38%)	
	Heavy	6 (12%)	16 (32%)	
	No	0 (0%)	0 (0%)	
6-month	**Light**	21 (42%)	25 (50%)	**0.004***
	Moderate	11 (22%)	11 (22%)	
	Heavy	1 (2%)	9 (18%)	
	No	17 (34%)	5 (10%)	
1-year	**Light**	20 (40%)	21 (42%)	0.523
	Moderate	4 (8%)	8 (16%)	
	Heavy	4 (8%)	2 (4%)	
	No	22 (44%)	19 (38%)	
Pain (VAS)	**1-month**	3.92 ± 0.85	4.5 ± 1.11	**0.011***
		4 (3-5)	4 (4-5)	
	3-month	2.98 ± 0.71	4.54 ± 0.58	**<0.001***
		3 (2-3)	5 (4-5)	
	6-month	2.22 ± 0.74	3.16 ± 1.31	**0.001***
		2 (2-3)	3 (2-4)	
	1-year	1.12 ± 0.82	0.92 ± 0.8	0.245
		1 (0-2)	1 (0-2)	

Data presented as mean ± SD, median (IQR) or frequency. VAS: visual analogue scale, *: statistically significant as P value <0.05

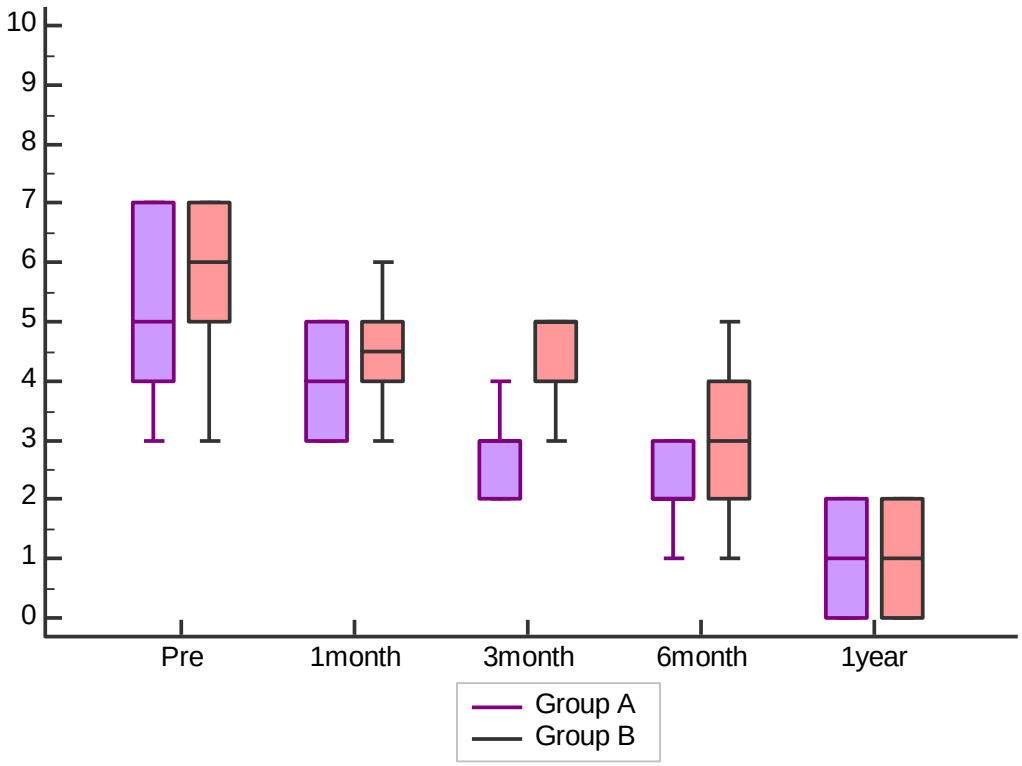

Figure 2: Visual analoue scale between the studied groups

DISCUSSION

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 [22, 23]

We found that UAE had less incidence of complications as need for blood transfusion and fever (P=0.014, <0.001).

This came in line with Narayan et al. [24] who found that UAE patients are more likely to report greater improvements in symptoms, fewer complications, pain and less additional interventions than myomectomy patients, while myomectomy patients are more likely to attempt to get pregnant. Furthermore, these improvements in symptoms persisted over long term follow up for patients in both treatment groups. Also, our results are consistent with prior studies comparing uterine artery embolization with myomectomy [25, 26].

Additionally, Jia et al. [27] performed a multicentre retrospective cohort study on Eight hundred and sixty-three patients are included in this analysis, 451 patients who underwent UAE and 412 patients who underwent myomectomy, and they demonstrated that UAE may be more effective in controlling patients' menorrhagia and has lower rates of post-procedural blood transfusions and complications.

However, Manyonda et al. [28] who performed a multicentre, randomized, open-label trial to evaluate myomectomy, as compared with uterine-artery embolization, in women who had symptomatic uterine fibroids and did not want to undergo hysterectomy. observed that improvement in participant-reported health-related quality-of-life scores was observed after both myomectomy and uterine-artery embolization at 2 years, the scores indicated a higher health-related quality of life among women assigned to undergo myomectomy. Menstrual bleeding scores appeared similar in the two groups. The overall incidence of complications associated with both procedures was low. Additional procedures were performed in 7% of the women in the myomectomy group, as compared with 16% in the uterine-artery embolization group; the median length of hospital stay was 4 days with myomectomy and 2 days with uterine-artery embolization.

They concluded that among women with symptomatic uterine fibroids, those who underwent myomectomy had a better fibroid-related quality of life at 2 years than those who underwent uterine-artery embolization. This may be due to different sample size and duration of follow up.

In the current study, group A showed significant improvement in postoperative bleeding at 1, 3 and 6 months compared to group B ($P<0.05$) whereas postoperative bleeding was comparable at 1-year between both groups. Our study found that rate of reduction in fibrosis and improvement was higher in group A than group B with no statistically significant difference between both groups. Patients' satisfaction was significantly higher in group A compared to group B (86% vs. 64%, P=0.020), improvement of symptoms was significantly better in group A compared to group B (82% vs. 52%, P=0.003).

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 [29-31].

Jia et al. [27] found UAE to be more effective in symptomatic menorrhagia 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 their 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. [32] and Scheurig- Muenkler et al. [33] discovered a decreasing probability of recurrences with time, although having a higher rate of symptomatic-leiomyoma recurrences that typically resulted in hysterectomy. Also, Daniels et al. [34] 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.

Spies et al. [35] 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.

Jia et al. [27] observed that the rates found for improvement in menorrhagia and bulk symptoms differed from previously reported rates. However, the literature overall varies widely. Rates of improvement in menorrhagia following UAE range between 51.2% and 92% [29, 30].[12,19-21]. Hamoda et al. [29] reported 51.2% rate of improvement in menorrhagia at 9–14 years following UAE in a study published in 2016 with a total of 197 patients. The Emmy trial reported a rate of 76% at 2 years [30]. These rates overall have a downward trend based on the length of the follow-up period. The median follow-up of patients in this study was 7 years and symptomatic improvement was gauged based on follow-up examinations during this time. This may help to explain why the rate of improvement in menorrhagia is at the lower end of this range [27].

In terms of rates of improvement in bulk symptoms following UAE, the reported rates range between 48.8% at 9–14 years by Hamoda et al. [29] and 66.2% at 2 years in the EMMY trial [30]. Again, a similar downward trend with time is noted and the results of this study are like the rates reported by Hamoda et al. [29] at 9–14 years.

Our study had some limitations including that our study is a single centre study with relatively small sample size , shorter duration of follow up . The results cannot be applied to every case of leiomyoma, emphasizing the importance of tailored management in a future study.

Conclusion: UAE may be more effective in controlling patients' bleeding, pain, has lower rates of post-procedural blood transfusions, postoperative complications and higher rates of patients' satisfaction and symptoms improvement.

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