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ORIGINAL RESEARCH

Comparison of the Efficacy of Polyvinyl Alcohol Colorless Embolic Microspheres (8Spheres) and Gelatin Embolic Microspheres (Embosphere) in Uterine Artery Embolization for Symptomatic Uterine Fibroids in Women Without Fertility Requirements: A Multicenter Observational Study

Songkun Gao[1,*], Fengshuang Li[1,*], Fang Song[1], Xiaofeng Zhang[2], Yan Wang[1], Jiandong Wang[1]

[1]Department of Gynecologic Oncology, Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing Maternal and Child Health Care Hospital, Beijing, 100026, People's Republic of China; [2]Department of Radiology,Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing Maternal and Child Health Care Hospital, Beijing, 100026, People's Republic of China

*These authors contributed equally to this work

Correspondence: Yan Wang; Jiandong Wang, Department of Gynecologic Oncology, Beijing Obstetrics and Gynecology Hospital, Capital Medical University, Beijing Maternal and Child Health Care Hospital, Qihelou Street, Dongcheng District, Beijing, 100006, People's Republic of China, Email wwyy3196@ccmu.edu.cn; wangjiandongxy@ccmu.edu.cn

Objective: To evaluate the differences in efficacy between polyvinyl alcohol colorless embolic microspheres (8Spheres®) and gelatin embolic microspheres (Embosphere®) in uterine artery embolization for symptomatic uterine fibroids.

Methods: We included 259 patients from 12 hospitals who underwent uterine artery embolization for symptomatic uterine fibroids. We collected preoperative general conditions, menstrual status, and uterine and fibroid sizes as indicated by magnetic resonance imaging, as well as changes in ovarian hormone levels before and 6 months after the procedure. Differences in uterine fibroid scores and health-related quality of life scores between the two types of microspheres were compared using analysis of covariance (ANCOVA). Differences in the largest fibroid volume, uterine volume, total menstrual bleeding score, and ovarian hormone levels were compared using *T*-tests or Mann–Whitney *U*-tests.

Results: There was no significant difference in clinical efficacy between the two types of microspheres at 6 months post-operatively (P=0.4081). No significant differences were observed in uterine fibroid volume or symptom-related scores.There were no significant differences in ovarian hormone levels between the two groups or within each group before and after the procedure.

Conclusion: The use of 8Spheres® is effective for symptomatic uterine fibroids and is comparable to the currently clinically used Embosphere® microspheres in terms of efficacy for symptomatic uterine fibroids.

Keywords: symptomatic uterine fibroids, uterine artery embolization, polyvinyl alcohol colorless embolic microspheres, gelatin embolic microspheres

Introduction

Uterine fibroids are one of the most common uterine diseases among women of reproductive age, with an estimated lifetime prevalence of 40%–89% in postmenopausal women.[1] Uterine fibroids are heterogeneous in size, number, location, and clinical presentation.[2] Approximately half of women with uterine fibroids experience significant symptoms, including heavy menstrual bleeding and abdominal pain.[3] Medical therapy is usually the first-line treatment for

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symptomatic uterine fibroids, including non-hormonal medications (nonsteroidal anti-inflammatory drugs and tranexamic acid or aminocaproic acid) and hormonal medications (combined oral contraceptives, gonadotropin-releasing hormone agonists, etc).[4,5] However, for persistent abnormal uterine bleeding, surgical treatment remains the first choice and has the best therapeutic effect.[6] Traditionally, myomectomy or hysterectomy has been considered one of the treatments for symptomatic uterine fibroids. Uterine artery embolization (UAE) emerged in 1990 as a new surgical option. UAE is usually performed under local anesthesia, using bio-compatible particles to temporarily block the arteries supplying the uterus, thereby inducing ischemic infarction of the fibroids.[7] Because UAE may have an impact on ovarian and uterine function, it is not considered suitable for women planning pregnancy. However, for middle-aged women without fertility plans, UAE can help shorten hospital stays and allow for earlier resumption of activities, while also satisfying some patients' desire to preserve the uterus and achieve therapeutic effects for 1–2 years.[8,9]

A variety of materials have been considered for use in UAE.[10,11] 8Spheres conformal microspheres (Suzhou Hengrui Callisyn Biomedical Technology Co., Ltd, China) have been used to embolize benign tumors.[12,13] This study was conducted as an observational study in 12 hospitals in China to evaluate the efficacy differences between polyvinyl alcohol colorless embolic microspheres (8Spheres) and gelatin embolic microspheres (Embosphere) in UAE for symptomatic uterine fibroids in women without fertility requirements.

Methods

Patients

We included women without fertility requirements who chose uterine artery embolization (UAE) for symptomatic uterine fibroids at 12 medical institutions from January 2018 to July 2021.The enrollment process is illustrated in Figure 1.

Inclusion Criteria:[1] Age 18–55 years;[2] Menorrhagia and/or compressive symptoms caused by uterine fibroids;[3] The largest fibroid diameter <10 cm;[4] Women who wished to preserve the uterus but had no fertility requirements;[5] Women who voluntarily consented to undergo UAE and signed the informed consent form.

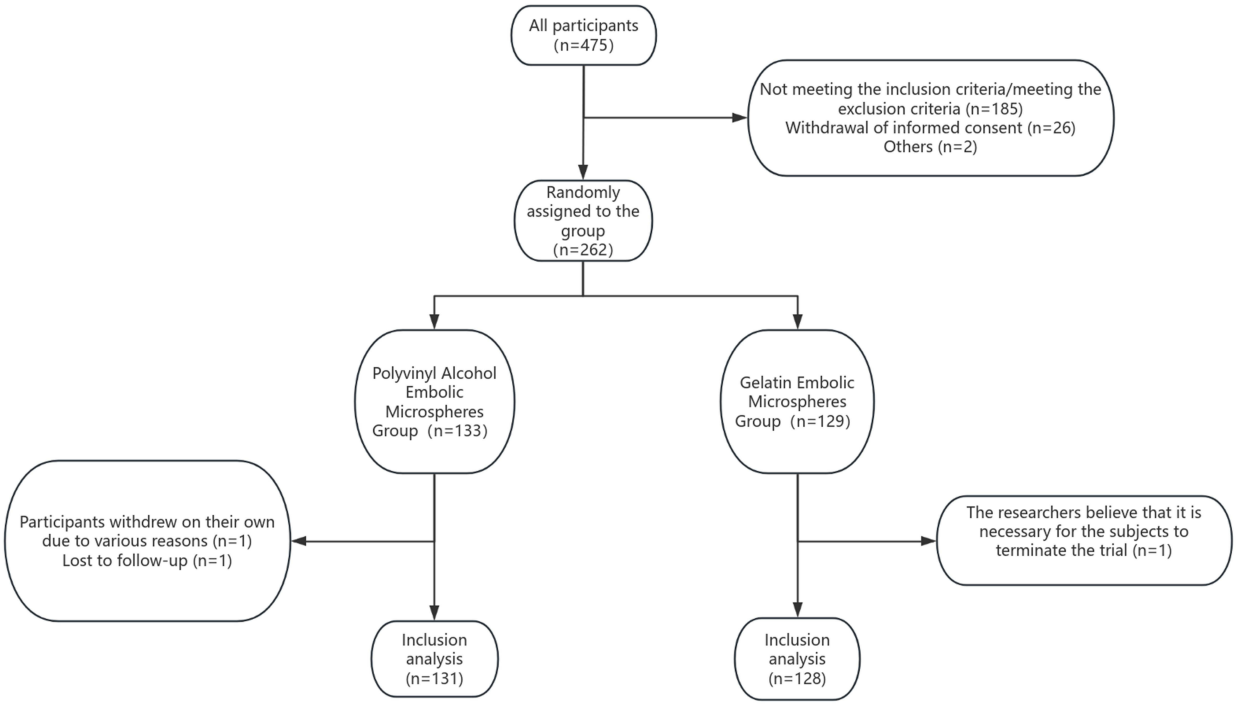

Figure 1 Patient Enrollment Flowchart.

Exclusion Criteria:[1] Pregnancy;[2] Postmenopausal status;[3] Suspicion of uterine leiomyosarcoma;[4] Inability to differentiate from adnexal masses;[5] Significant blood supply to the fibroid from ovarian arteries or other sources;[6] Subserosal fibroids with a narrow pedicle or broad ligament fibroids;[7] Uterine arteriovenous fistula;[8] Treatment with medication for fibroids within the past 3 months;[9] Previous history of UAE;[10] Allergy to multiple contrast agents;[11] Abnormal coagulation mechanism;[12] Acute pelvic inflammatory disease;[13] Severe dysfunction of any organ;[14] Atherosclerosis.

Data

We collected data on patient age, pregnancy history, childbirth history, menorrhagia, irregular menstrual duration, irregular menstrual cycles, dysmenorrhea, clotted menstrual blood, urinary frequency, and constipation. The severity of uterine fibroid symptoms was assessed based on the patients' self-evaluation of their symptoms over the preceding three months.The impact of symptoms was categorized as "none", "mild", "moderate", "severe", and "very severe".

All patients underwent magnetic resonance imaging (MRI) at Beijing Obstetrics and Gynecology Hospital or the hospital where they were recruited, both before treatment and at the 6-month follow-up, to assess uterine volume and the volume of the dominant fibroid through unified film reading. Experienced radiologists evaluated the MRI images to determine whether the ovarian arteries were enlarged and whether they contributed to the blood supply of the fibroids. If this could not be determined from the MRI, digital subtraction angiography was used for clarification. Using the MRI, we measured the uterine volume and the volume of the largest uterine fibroid. The volume was calculated using the formula 6ABCπ=(ABC×0.5236) cm3 (where A, B, and C are the three-dimensional diameters of the uterus or fibroid). For patients with multiple fibroids, we calculated the volume of the largest fibroid and counted the number of fibroids with a diameter greater than 2 cm.

Patients did not receive any additional treatments (such as oral progestogens, GnRH-a, etc) after the procedure. A reduction in menstrual bleeding of ≥50% from baseline and a decrease in fibroid volume of ≥20% at 6 months post-treatment were considered as effective treatment.[15,16] Patients were required to complete a symptom-related questionnaire at 6 months postoperatively. The questionnaire included information on menstrual improvement and quality of life assessment. The menstrual improvement rate was defined as the proportion of the preoperative score reduced by the postoperative menstrual diary card score. Quality of life was assessed using the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire.

Patients were asked to record the brand and type of sanitary pads used, as well as the number of days of use, in their menstrual diary cards. They were also required to document the area of blood saturation on the sanitary pads each day (if there were blood clots or continuous gushing, this would be reported separately).For detailed tables, see Supplementary File 1 (SP1). Prolactin, testosterone, progesterone, estradiol, luteinizing hormone, and follicle-stimulating hormone levels were measured before surgery and at 6 months postoperatively to evaluate the impact of the procedure on ovarian hormone secretion.

Surgical Procedure

The surgical procedure was standardized across the 12 participating medical institutions, with all operators being experienced senior physicians in interventional radiology. During the procedure, a suitable microcatheter was selected and inserted into the main branch of the uterine artery via a femoral artery approach, with superselection into the ascending branch of the uterine artery whenever possible. Polyvinyl alcohol colorless embolic microspheres (8Spheres, Suzhou Hengrui Jialisheng Biomedical Technology Co., LTD, China) or tris-acryl microspheres (Embosphere, Biosphere Medical SA, USA) were delivered to the target site through the catheter to complete the embolization. The selection of the two materials was performed randomly and in a single-blind manner.After waiting for 5–7 cardiac cycles to confirm no reperfusion of the target vessel, the puncture site was compressed and dressed.

Statistical Methods

For the analysis of demographic data, group t-tests were used to compare age, uterine volume, largest fibroid volume, menstrual bleeding score, uterine fibroid symptom score, and health-related quality of life score between groups based on the distribution characteristics of the variables. Chi-square tests or Fisher's exact tests were used to analyze the frequency of different impact levels of pregnancy history, childbirth history, menorrhagia, irregular menstrual duration, irregular menstrual cycles, dysmenorrhea, clotted menstrual blood, urinary frequency, and constipation.

For the analysis of clinical efficacy at 6 months, the Clopper-Pearson method was used to calculate the two-sided 95% confidence interval. The Cochran-Mantel-Haenszel (CMH) method, considering the center effect, was used to calculate the rate difference and its two-sided 95% confidence interval between the trial group and the control group. The CMH chi-square test or Fisher's exact test, considering the center effect, was used to assess the statistical significance of differences between groups.

Analysis of covariance (ANCOVA) was used to compare the changes in uterine fibroid symptom score and quality of life score from baseline to 6 months post-treatment. The model used the change in uterine fibroid symptom score/quality of life score at 6 months post-UAE as the dependent variable, with baseline uterine fibroid symptom score/quality of life score as covariates and group and center as fixed effects. The model estimated the least squares means and their two-sided 95% confidence intervals for the change in uterine fibroid symptom score from baseline to 6 months post-UAE in the trial and control groups, as well as the least squares estimate and its two-sided 95% confidence interval for the difference between the trial group and the control group.

The size of the largest uterine fibroid, uterine size, total menstrual bleeding score, and ovarian hormone levels were analyzed using either group t-tests or Mann–Whitney *U*-tests, depending on whether the data followed a normal distribution. The menstrual improvement rate was analyzed using chi-square tests.

All statistical analyses were performed using SAS software version 9.4 or higher and Sigma stat 3.5.

Results

A total of 259 patients were included in this study. The baseline characteristics of the patients are shown in Table 1. There were no significant differences between the polyvinyl alcohol embolic microspheres group and the gelatin embolic microspheres group in terms of age, obstetric history, and menstrual status.

Table 1 Baseline Characteristics of Patients in the Polyvinyl Alcohol Embolic Microspheres Group and the Gelatin Embolic Microspheres Group

	Polyvinyl Alcohol Embolic Microspheres Group (n=131)	**Gelatin Embolic Microspheres Group (n=128)**	**P**
Age	43.1±5.3	43.0±4.6	0.8630
Pregnancy History			
Yes	131	126	0.2433
No	0	2	
Birth History			0.3699
Yes	126	120	
No	5	8	
Number of Pregnancies	2.9±1.5	2.8±1.3	0.5937
Number of Childbirths	1.4±0.7	1.2±0.5	0.0105
Menorrhagia			0.1928
None(%)	20 (15.27)	17 (13.28)	
Mild(%)	25 (19.08)	16 (12.50)	
Moderate(%)	34 (25.95)	36 (28.13)	
Severe(%)	38 (29.01)	42 (32.81)	
Very severe(%)	14 (10.69)	17 (13.28)	
Irregular menstrual duration			0.9979
None(%)	49 (37.40)	53 (41.41)	
Mild(%)	46 (35.11)	36 (28.13)	
Moderate(%)	20 (15.27)	17 (13.28)	
Severe(%)	12 (9.16)	16 (12.50)	
Very severe(%)	4 (3.05)	6 (4.69)	

(*Continued*)

Table 1 (Continued).

	Polyvinyl Alcohol Embolic Microspheres Group (n=131)	Gelatin Embolic Microspheres Group (n=128)	P
Irregular menstrual cycles			0.8197
None(%)	48 (36.64)	51 (39.84)	
Mild(%)	44 (33.59)	36 (28.13)	
Moderate(%)	26 (19.85)	18 (14.06)	
Severe(%)	10 (7.63)	15 (11.72)	
Very severe(%)	3 (2.29)	8 (6.25)	
Dysmenorrhea			0.3019
None(%)	68 (51.91)	60 (46.88)	
Mild(%)	38 (29.01)	40 (31.25)	
Moderate(%)	15 (11.45)	8 (6.25)	
Severe(%)	7 (5.34)	12 (9.38)	
Very severe(%)	3 (2.29)	8 (6.25)	
Clotted menstrual blood			0.6592
None(%)	13 (9.92)	10 (7.81)	
Mild(%)	41 (31.30)	44 (34.38)	
Moderate(%)	47 (35.88)	38 (29.69)	
Severe(%)	23 (17.56)	29 (22.66)	
Very severe(%)	7 (5.34)	7 (5.47)	
Urinary frequency			0.2517
None(%)	60 (45.80)	49 (38.28)	
Mild(%)	40 (30.53)	44 (34.38)	
Moderate(%)	22 (16.79)	25 (19.53)	
Severe(%)	8 (6.11)	8 (6.25)	
Very severe(%)	1 (0.76)	2 (1.56)	
Constipation			0.6845
None(%)	102 (77.86)	101 (78.91)	
Mild(%)	15 (11.45)	18 (14.06)	
Moderate(%)	6 (4.58)	8 (6.25)	
Severe(%)	6 (4.58)	1 (0.78)	
Very severe(%)	2 (1.53)	0 (0.00)	

In the study, 80 patients (65.57%) in the polyvinyl alcohol embolic microspheres group and 71 patients (63.96%) in the gelatin embolic microspheres group were considered effective. There was no significant difference between the two groups (P = 0.4081). We evaluated the uterine fibroid symptom scores and health-related quality of life scores for patients before and 6 months after the procedure. The differences in these scores between pre- and post-treatment were analyzed for both groups. The results showed no significant differences in the score changes for either outcome between the two groups (P = 0.4827 and P = 0.5502, Table 2).

We documented the preoperative uterine fibroid status of the patients, as shown in Table 3. There were no significant differences between the two groups in terms of fibroid location or the presence of multiple fibroids. We also separately counted the number of fibroids larger than 2 cm, and no significant difference was observed between the groups (P = 0.089). Additionally, there were no significant differences in preoperative uterine volume or the volume of the largest fibroid.

At the 6-month follow-up, MRI was performed to assess the status of uterine fibroids in the patients. The results indicated that there were no significant differences between the polyvinyl alcohol embolic microspheres group and the gelatin embolic microspheres group in terms of uterine volume and its change (P = 0.362/0.799), or the volume of the largest fibroid and its change (P = 0.821/0.710).

Table 2 Uterine Fibroid Symptom Scores and Health-Related Quality of Life Scores in the Polyvinyl Alcohol Embolic Microspheres Group and the Gelatin Embolic Microspheres Group

	Polyvinyl Alcohol Embolic Microspheres Group (n=131)	Gelatin Embolic Microspheres Group (n=128)	P
Uterine Fibroid Symptom Score			0.4827
Preoperative	32.467±20.336	34.570±17.436	
6 months postoperative	14.623±14.400	16.309±12.239	
Difference in scores	17.844±18.367	18.262±17.100	
Health-Related Quality of Life Score			0.5502
Baseline	64.550±24.841	58.742±26.536	
6 months postoperative	81.258±19.386	80.408±19.203	
Difference in scores	16.708±23.798	21.666±22.404	

Table 3 Preoperative and 6-Month Postoperative Uterine and Fibroid Status in the Polyvinyl Alcohol Embolic Microspheres Group and the Gelatin Embolic Microspheres Group

	Polyvinyl Alcohol Embolic Microspheres Group (n=131)	Gelatin Embolic Microspheres Group (n=128)	P
Preoperative			
Location of uterine fibroids			0.938
Intramural	99	97	
Subserosal	22	20	
Submucosal	10	11	
Multiple fibroids			0.456
Yes	111	104	
No	20	24	
Number of uterine fibroids with a diameter > 2 cm	2 (1,3)	2 (1,4)	0.089
Uterine volume (cm^3)	281.8 (201.425, 404.125)	286.35 (197.9,410.8)	0.698
Volume of the largest fibroid (cm^3)	77.9 (42.75,118.45)	62.45 (27.95,135.3)	0.246
6 Months Postoperative			
Uterine volume (cm^3)	176.85 (126.4,261.3)	188.4 (128.3,268.45)	0.362
Volume of the largest fibroid (cm3)	34.25 (10.2,64)	29.05 (13.6,67.3)	0.821
Change in uterine volume (cm3)	84.35 (44.4,160.2)	94.15 (38.6,165.6)	0.799
Change in the volume of the largest fibroid (cm3)	30.15 (14.7,64)	30.4 (12.5,71.2)	0.710

We collected relevant data on menstrual bleeding score, and menstrual improvement rate. The results showed that there were no significant differences between the two groups in these parameters either before or after the procedure (Table 4).

We documented the ovarian hormone levels of patients before and after surgery to assess the impact of the procedure on ovarian hormone secretion, as shown in Table 5. In the polyvinyl alcohol embolic microspheres group, preoperative levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) were significantly higher than those in the gelatin embolic microspheres group ($P = 0.005$ and $P = 0.030$, respectively). No significant differences were observed between the two groups in preoperative levels of prolactin, testosterone, progesterone, and estradiol. At the 6-month follow-up, there were no significant differences between the two groups in the levels of the six hormones or in the changes in hormone levels over the 6-month period ($P > 0.05$).

Table 4 Changes in Menstrual Status in the Polyvinyl Alcohol Embolic Microspheres Group and the Gelatin Embolic Microspheres Group

	Polyvinyl Alcohol Embolic Microspheres Group	Gelatin Embolic Microspheres Group	P
Menstrual Bleeding Score			
Baseline	417.64±279.65	396.54±293.95	0.5543
6 months postoperative	134.99±155.66	128.29±159.99	0.7326
Difference	282.65±288.63	268.25±295.37	0.6919
Menstrual Improvement Rate			0.2572
Effective	86	93	
Ineffective	45	35	

Discussion

In this study, we adopted a multicenter, randomized, single-blind, parallel-controlled design to compare the efficacy of polyvinyl alcohol embolic microspheres (8Spheres) with that of the clinically widely used gelatin embolic microspheres in the treatment of uterine fibroids in women without fertility requirements. The results indicated that polyvinyl alcohol embolic microspheres achieved good therapeutic effects in terms of reducing uterine fibroid volume and alleviating menorrhagia symptoms, which were similar to the effects of the marketed materials. Additionally, the impact of the procedure on patients' ovarian hormone levels was also comparable between the two groups.

Uterine artery embolization (UAE) has increasingly been recognized as an important treatment modality for uterine fibroids. Various materials have been developed for UAE, including absorbable and non-absorbable agents.[14] Non-degradable microspheres are currently more widely used in clinical practice. In this study, we selected the 8Spheres embolic microspheres produced in China. Theoretically, an ideal embolic agent should temporarily occlude uterine blood supply, allowing the fibroid to infarct, followed by absorption of the embolic agent and restoration of uterine blood flow. However, recent studies have shown no significant differences in treatment efficacy and postoperative pain scores between absorbable and permanent embolic agents. For example, Han et al[17] compared absorbable microspheres with permanent tris-acryl gelatin microspheres (TAGMs) and found no differences in treatment outcomes. Similarly, in an animal study, the rate of uterine necrosis following embolization with soluble gelatin sponge particles was comparable to that with permanent microspheres.[18] Other studies have demonstrated that biodegradable starch microspheres used in UAE in sheep models can lead to reperfusion of the uterine artery, although further research is needed to compare their efficacy with that of permanent microspheres.[19,20]

Any new embolic agent must demonstrate similar efficacy to existing agents in terms of complete infarction of uterine fibroids.[21] In our study, no significant differences were observed between the two groups in terms of fibroid symptom relief rates and health-related quality of life scores. Additionally, there were no significant differences in menstrual status, uterine volume, and the volume of the largest fibroid at 6 months postoperatively. These findings suggest that polyvinyl alcohol embolic microspheres and gelatin embolic microspheres have similar therapeutic effects on patients with uterine fibroids, consistent with the study by Zhang et al.[13] This further provides supportive evidence for the application of 8Spheres microspheres in uterine artery embolization for uterine fibroids.

Ovarian hormone levels are one of the key focuses of research following UAE surgery. In both groups, a certain degree of decline in ovarian hormone levels was observed at 6 months postoperatively, with only prolactin showing a significant decrease ($P < 0.001$), while the other five hormones did not reach statistical significance. In a large-scale data study from South Korea, patients who underwent UAE had a significantly higher incidence of primary ovarian insufficiency (POF) and menstrual irregularities.[22] However, compared with traditional surgical treatments, UAE did not demonstrate an accelerated decline in ovarian function at 1 year postoperatively.[23] For women without fertility plans, hysterectomy is often used as a surgical treatment for uterine fibroids. In a meta-analysis, patients in the UAE group had significantly higher E2 levels at 6 months postoperatively compared with those who underwent hysterectomy, although no significant difference was observed at 12 months postoperatively. FSH and LH levels were significantly lower in the UAE group compared with the hysterectomy

Table 5 Ovarian Hormone Levels and Changes Before and After UAE

	Preoperative			6 Months Postoperative			Change		
	Polyvinyl Alcohol Embolic Microspheres Group	Gelatin Embolic Microspheres Group	P	Polyvinyl Alcohol Embolic Microspheres Group	Gelatin Embolic Microspheres Group	P	Polyvinyl Alcohol Embolic Microspheres Group	Gelatin Embolic Microspheres Group	P
Oxytocin (ng/mL)	15.5 (10.563,23.375)	15.06 (9.475,23.735)	0.598	11.77 (9.2,17.33)	13.735 (8.295,18.215)	0.579	−1.865 (−8.99,1.19)	−0.86 (−6.125,1.695)	0.230
Testosterone(ng/dl)	0.291 (0.17,0.81)	0.28 (0.181,0.68)	0.793	0.301 (0.2,0.72)	0.3 (0.196,0.671)	0.984	−0.02 (−0.1,0.091)	0.0125 (−0.06,0.108)	0.135
Progesterone (ng/mL)	0.6 (0.27,5.543)	0.56 (0.276,6.665)	0.637	1.02 (0.3,5.578)	1.08 (0.333,7.825)	0.563	0.0525 (−0.98,4.15)	0.04 (−2.557,3.769)	0.912
Estradiol (pg/mL)	114.3 (71.025,198.225)	123.9 (80,188.26)	0.786	113.6 (68.245,188.4)	134.02 (80.41,180.3)	0.306	−0.41 (−84.463,81.7)	10.975 (−51.15,67.2)	0.663
Luteinizing Hormone (IU/L)	8.12 (4.845,14.955)	5.82 (3.545,9.005)	0.005	6.515 (3.44,16.16)	5.905 (3.065,12.205)	0.313	−0.925 (−6.35,4.01)	0.37 (−2.455,4.635)	0.061
Follicle-Stimulating Hormone (IU/L)	6.76 (4.958,10.268)	5.94 (3.95,8.3)	0.030	6.67 (4.9,11.29)	6.2 (3.95,9.31)	0.071	−0.24 (−3.56,3.55)	0.18 (−2.525,3.015)	0.560

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group, and this difference persisted at 12 months postoperatively, suggesting that UAE may have less impact on ovarian function compared with hysterectomy.[24] Since the patients in this study had no fertility plans, AMH and ultrasound examinations were not performed, and the impact of the materials on fertility could not be assessed based on the patients' fertility status. However, a meta-analysis suggested that UAE does not appear to affect ovarian reserve function, as measured by serum AMH and FSH concentrations, in patients with uterine fibroids.[25] In comparing the two embolic materials, we focused on the changes in hormone levels from preoperative to 6 months postoperative. The results indicated that there was no significant difference in the impact on ovarian function between the two types of embolic materials.For patients with significant menopausal symptoms, hormone replacement therapy can effectively alleviate their symptoms. Avoiding more invasive procedures was a greater concern for these patients.

Limitations

This study was conducted to demonstrate the efficacy of the new polyvinyl alcohol embolic material in UAE for uterine fibroid patients without fertility plans. However, the follow-up duration was relatively short, limited to 6 months postoperatively. Therefore, data on fibroid recurrence rates and recurrence times were not available. Future long-term observational studies are still needed.Since the patients in this study had no fertility plans, we did not perform AMH tests or ultrasound examinations before and 6 months after surgery. As a result, we could not assess the impact of the material on fertility based on the patients' fertility status. Whether the new material has a significant impact on the fertility of women with fertility intentions remains to be studied.Although there were no significant differences in the changes in hormone levels from preoperative to 6 months postoperative between the two materials, the potential long-term effects on ovarian function, such as premature ovarian failure or early menopause, still need to be investigated in future longitudinal studies.

Ethical Approval

The study was carried out in accordance with the ethical standards laid down in the Declaration of Helsinki, and was approved by the ethics committees of Beijing Obstetrics and Gynecology Hospital, Capital Medical University (2017-JW -014). All participants were thoroughly informed about the details of the study by the staff of the hospital where they were treated. They were given ample time to consider their participation before voluntarily consenting and signing the informed consent form.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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