

# Complications and Reinterventions in Uterine Artery Embolization for Symptomatic Uterine Fibroids: A Literature Review and Meta Analysis

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## Abstract

**Purpose** To perform a literature review of the spectrum of complications associated with UAE relative to surgery and compare the risk of reintervention as well as minor, major, and overall complications.

**Materials and Methods** Literature review was conducted in PubMed, MEDLINE, Cochrane, and CINAHL databases, and meta-analysis was performed.

**Results** In randomized clinical trials, common complications were discharge and fever (4.00 %), bilateral uterine artery embolization (UAE) failure (4.00 %), and postembolization syndrome (2.86 %). Two trials showed a significantly decreased risk in major complications with UAE, with odds ratios (ORs) of 0.07143 (0.009426–0.5413) and 0.5196 (0.279–0.9678). None of the trials showed a significant difference in OR for minor complications of UAE. None of the trials showed a significant difference in risk for overall complications of UAE. Three trials showed a significantly increased risk for reintervention with UAE with ORs of 10.45 (2.654–41.14), 2.679 (1.289–5.564), and 9.096 (1.269–65.18). In 76 nonrandomized studies, common complications were amenorrhea (4.26 %), pain (3.59 %),

and discharge and fever (3.37 %). In 41 case studies, common complications were discharge and fever ( $n = 22$  cases), repeat UAE ( $n = 6$  cases), and fibroid expulsion ( $n = 5$  cases).

**Conclusion** Overall, UAE has a significantly lower rate of major complications relative to surgery, but it comes at the cost of increased risk of reintervention in the future. Educating patients about the rate and types of complications of UAE versus surgery, as well as the potential for reintervention, should help the patient and clinician come to a reasoned decision.

**Keywords** Embolization · Embolotherapy · SUB-specialty technique · Uterine artery embolization (UAE) · Uterine fibroid embolization (UFE)

## Introduction

Uterine leiomyomas (fibroids) are the most common solid benign pelvic tumor in women, causing significant morbidity [1]. Uterine artery embolization (UAE) is a safe and effective procedure known to provide improvements in quality-of-life assessments, shorter hospital stays, and shorter recovery times [2]. UAE was first described as a treatment for symptomatic uterine fibroids in 1995 [3], but as it has gained utility as a treatment, complication rates have not been broadly documented in the literature. Case studies provide an avenue for rare complications to be documented, whereas clinical trials involve a very select group of patients and may not represent the true complication rate in the general population receiving the treatment. The aim of this article is to understand the spectrum of complications of UAE and systematically review the major and minor complication rates as well as the rate of reintervention of UAE.

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## Methods

We conducted a meta-analysis of studies reporting the use, efficacy, and complications of UAE for the treatment of symptomatic uterine fibroids. Articles were identified in the PubMed, MEDLINE, Cochrane and CINAHL databases in addition to a search of relevant citations in the articles reviewed. The search keywords were “uterine fibroid embolization” and “uterine artery embolization.” Papers were manually selected from the results to ensure they pertained to UAE as a treatment for uterine fibroids.

Major and minor complication rates, reintervention rates, and specific complications were coded by two reviewers and compared for intraobserver agreement. Once coded, the complications were compiled, and the rate of complications was calculated. Results were stratified into randomized clinical trials (RCTs), nonrandomized studies (excluding case studies), and case studies. Clinical trials were chosen based on the following criteria: (1) RCT, (2) comparison of UAE with surgery, and (3) participants with symptomatic uterine fibroids. Complications from all three groups were catalogued, and the clinical trial data were analyzed using open-source statistical software.

## Results

### RCTs

A total of eight RCTs [4–11] were assessed and 350 UAE cases identified. In this group of trials, patients with an average age of 41.90 years underwent UAE with an average follow-up time of 1,022.63 days (1332.68 weighted follow-up days [days/patient]).

The most common complications were bilateral UAE failure (4.000 %), discharge and fever (4.000 %), and postembolization syndrome (PES; 2.857 %). Rare complications included deep vein thrombosis (DVT) (0.286 %), severe vasovagal event (0.286 %), and hematometra (0.286 %) (Table 1). No deaths were noted. For the 346 surgery cases in the RCTs, the most common complications were urinary stress incontinence (3.757 %), pressure symptoms (2.890 %), and menorrhagia (2.601 %). Rare complications included vesical fissure (0.289 %), DVT (0.289 %), and intra-abdominal abscess (0.289 %) (Table 2).

Three trials had major complication rate data available [5, 7, 8]. The risk ratios and associated 95 % confidence intervals for major complication rates were 0.427 (0.195–0.936), 3.556 (0.349–36.196), and 0.0476 (0.00534–0.424) (Fig. 1), showing a significantly decreased risk in major complications with UAE in two of the three trials [7, 8]. The test for heterogeneity was significant ( $p = 0.0291$ ), so the random

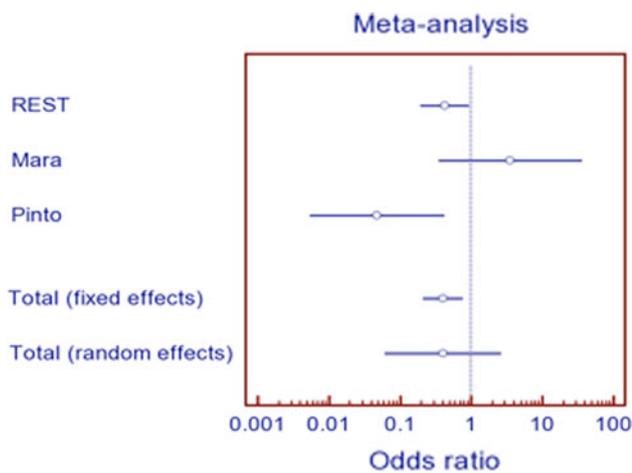
effect model was more suited for this variable. The total odds ratio was 0.406 (0.0617–2.675), showing no significant difference.

**Table 1** Complication rates of UAE in eight clinical trials ( $n = 350$ )

Complications	No. of cases	Rate (%)
Bilateral-failure UAE	14	4.000
Discharge, fever	14	4.000
PES	10	2.857
Pain	10	2.857
Groin complications	10	2.857
Repeat UAE	8	2.286
Fibroid expulsion	6	1.714
Uterine infection	4	1.143
Uterine artery dissection	2	0.571
Amenorrhea	2	0.571
Vesicovaginal fistula	1	0.286
Stress incontinence	1	0.286
Dyspareunia	1	0.286
DVT	1	0.286
Severe vasovagal event	1	0.286
Haematometria	1	0.286
Pelvic abscess	1	0.286
Death	0	0.000
Unilateral-failure UAE	0	0.000
Total	87	24.86

**Table 2** Complication rates of surgery in six clinical trials ( $n = 346$ )

Complications	Rate (%)
Urinary stress incontinence	3.757225434
Pressure symptoms	2.89017341
Menorrhagia	2.601156069
Transfusion	1.734104046
Urinary frequency	1.734104046
Febrile morbidity	1.445086705
Infection	1.445086705
Wound hematoma	1.156069364
Wound infection	0.867052023
Lower abdominal pain	0.867052023
Wound abscess	0.867052023
Operative hemorrhage	0.578034682
Anesthetic complication	0.578034682
Urinary retention	0.578034682
Dysmenorrhea	0.578034682
Anal sphincter damage	0.289017341
Bladder lesion	0.289017341
Vesical fissure	0.289017341
DVT	0.289017341
Intra-abdominal abscess	0.289017341
Total	23.12138728



**Fig. 1** Forest plot showing OR of major complications with UAE versus surgery

Three trials had minor complication rate data available [5, 7, 8]. The risk ratios and associated 95 % CIs for minor complications were 1.012 (0.530–1.932), 0.941 (0.3350–2.531), and 1.000 (0.289–3.454), respectively. The trials showed no significantly increased or decreased risk in minor complications with UAE. The test for heterogeneity was not significant ( $p = 0.9928$ ), so the fixed effect model was more suitable for this variable. The total OR was 0.992 (0.604–1.628), which showed no significant difference.

Four trials had overall complication rate data available [5, 7, 8, 11]. The risk ratios and associated 95 % CIs for overall complication rates were 0.596 (0.310–1.147), 1.250 (0.459–3.403), 0.462 (0.0393–5.423), and 3.222 (1.050–9.891), respectively. None of these trials showed a significantly increased or decreased risk in overall complications with UAE. The test for heterogeneity was not significant ( $p = 0.0682$ ), so the random effect model was more suitable for this variable. The total OR was 1.108 (0.473–2.596), which showed no significant difference.

Four trials had reintervention data available [5, 6, 8, 11]. The risk ratios and associated 95 % CIs for reintervention were 10.853 (1.438–81.913), 3.959 (1.660–9.440), 26.773 (5.345–134.107), and 1.742 (0.371–8.178), respectively. Three of these trials showed a significantly increased risk for reintervention with UAE relative to surgery [5, 6, 8]. The test for heterogeneity was not significant ( $p = 0.0748$ ), so the random effects model was more suitable for this variable. The total odds ratio was 6.042 (2.016–18.113), which showed increased odds for reintervention with UAE.

#### Non-Randomized Studies

A total of 76 non-randomized studies were found, and 11195 cases were identified. In this group, patients with an

average age of 41.31 years had UAE with an average follow-up time of 734.33 days, 909.13 weighted follow-up days (days/patient). The most common complications were amenorrhea (4.261 %), pain (3.591 %), discharge & fever (3.377 %). Rare complications included Asherman syndrome (.018 %), septicemia (0.009 %), and cardiopulmonary arrest or resuscitation (0.045 %). No deaths were noted. Total rate of complication for UAE was 24.86 %.

#### Case Studies

A total of 41 case studies were found, and 83 cases were identified. In this case study group, patients with an average age of 43.53 years underwent UAE with an average follow-up time of 282.97 days (255.51 weighted follow-up days [days/patient]).

The most common complications were discharge and fever (0.1965 %), fibroid expulsion (0.0446 %), and fibroid amenorrhea (0.0268 %). Rare complications included pulmonary embolism (PE; 0.0089 %), myocardial infarction (MI; 0.0089 %), and watershed infarcts in the brain (0.0089 %). Three deaths were noted. The total rate of complications for UAE was 0.550 %.

#### Discussion

##### Complication Rates

Our analysis showed that although overall and minor complication rates were not significantly different between UAE and surgery, there was a significantly decreased risk of major complications with UAE. Two of the three trials with available data showed a significant risk reduction of 95 and 57 % with UAE, which is a substantial improvement compared with surgery. These data, however, must be interpreted with caution. First, the decreases in major complications come at the cost of increased reintervention, which will be discussed later in the article. Second, the patient sample size across all three trials is fairly limited, spanning 227 patients in the UAE groups and 104 in the surgery group. This small sample size means that the true risk reduction with UAE may not be closely approximated. A finding suggesting an opposite trend was found in one of the trials, with an increase of major complications in UAE by a factor of 3.556, albeit this was statistically insignificant. Last, success rates and complication rates with UAE are related to operator experience, so in a large trial, with many operators being involved, the efficacy and complication rate of UAE may be worse than in studies where a single (or a few) operator(s) performed the surgery. A larger clinical trial with a limited, experienced number of

operators is required to show the true risk reduction of major complications with UAE. Minor and overall complication rates showed no significant differences between UAE and surgery, suggesting that there was no advantage for UAE in preventing these complications. Of course, the aforementioned biases and limitations must be taken into account when considering these data (Tables 1, 2, 3, 4, 5, 6, 7, 8; Figs. 2, 3, 4).

**Table 3** Odds of major complications with UAE versus surgery

Study	UAE	Surgery	OR	95 % CI
REST	20/157	13/51	0.427	0.195–0.936
Mara	3/30	1/33	3.556	0.349–36.196
Pinto	1/40	7/20	0.0476	0.00534–0.424
Total (fixed effects)	24/227	21/104	0.398	0.209–0.761
Total (random effects)	24/227	21/104	0.406	0.0617–2.675
Q	7.0707			
df	2			
Significance level	$p = 0.0291$			

df degrees of freedom

**Table 4** Risk of minor complications with UAE versus surgery

Study	UAE	Surgery	OR	95 % CI
REST	62/157	20/51	1.012	0.530–1.932
Mara	15/30	17/33	0.941	0.350–2.531
Pinto	10/40	5/20	1.000	0.289–3.454
Total (fixed effects)	87/227	42/104	0.992	0.604–1.628
Total (random effects)	87/227	42/104	0.992	0.604–1.628
Q	0.01453			
df	2			
Significance level	$p = 0.9928$			

df degrees of freedom

**Table 5** Risk of overall complications with UAE versus surgery

Study	Intervention	Controls	OR	95 % CI
REST	82/157	33/51	0.596	0.310–1.147
Mara	18/30	18/33	1.250	0.459–3.403
Ruuskanen	1/27	2/26	0.462	0.0393–5.423
Pinto	29/40	9/20	3.222	1.050–9.891
Total (fixed effects)	130/254	62/130	0.955	0.598–1.525
Total (random effects)	130/254	62/130	1.108	0.473–2.596
Q	7.1196			
df	3			
Significance level	$p = 0.0682$			

df degrees of freedom

**Table 6** Risk of reintervention with UAE versus surgery

Study	Intervention	Controls	Odds	95 % CI
REST	28/157	1/51	10.853	1.438–81.913
Kooij	26/81	8/75	3.959	1.660–9.440
Mara	19/30	2/33	26.773	5.345–134.107
Ruuskanen	5/27	3/26	1.742	0.371–8.178
Total (fixed effects)	78/295	14/185	5.842	3.120–10.938
Total (random effects)	78/295	14/185	6.042	2.016–18.113
Q	6.9120			
df	3			
Significance level	$p = 0.0748$			

df degrees of freedom

The Society of Interventional Radiology (SIR) clinical practice guidelines provide a classification scheme for complications [12], but much of the literature does not follow this classification. In addition, many of the complications may fit into multiple categories depending on the severity of the complication and the clinical picture. Few papers included how they classified specific complications but instead described the rates of complications within major or minor categories. Because the guidelines offer broad categories of complications, there may be significant interobserver differences for determining where a particular complication fits, especially with complications that have much variability in severity, such as pain. Therefore, we were unable to organize complications according to SIR guidelines. Further trials and studies investigating the efficacy of UAE versus surgery could categorize their complications according to these guidelines so that complication rates can be compared between studies.

Although simply creating a catalogue of complications from UAE does not allow for statistical inferences, it allows the clinician to understand the broad spectrum of complications that may occur from UAE but may not necessarily be captured in a clinical trial or even a meta-analysis. Many complications have been listed in the literature, but there has been little attempt to compile them. The surgical complications were generated from a sample size of 346 patients, whereas the UAE group had 350, thus allowing for easier comparison between the two groups. After comparing the spectrum of complications to the surgical arm, an interesting trend begins to appear.

Although the minor and overall complication rates were similar in the clinical trials, the complications with surgery were generally more serious, with many requiring further surgery or causing severe morbidity. Urinary and defecation dysfunction, febrile morbidity, and systemic and localized infections were documented for the surgical patients. The UAE patients had complications such as

**Table 7** Rates of complications in 76 nonrandomized studies ( $n = 11,195$ )

Complications	No. of cases	Rate (%)
Amenorrhea	477	4.261
Pain	402	3.591
Discharge, fever	378	3.377
Fibroid expulsion	172	1.536
Hot flashes	160	1.429
Uterine infection/infection	155	1.385
Sloughing	123	1.099
Repeat UAE	61	0.545
Intrauterine necrosis	52	0.464
Unilateral-failure UAE	41	0.366
Groin complications	39	0.348
Minor complications	31	0.277
Dysmenorrhea	30	0.268
Bilateral-failure UAE	29	0.259
Abdominal swelling	26	0.232
PES	24	0.214
Yellowish lesions	19	0.170
Headache	18	0.161
Adhesions	15	0.134
Urinary bladder symptoms/urinary retention	9	0.080
Nausea	6	0.054
Blood transfusion required	5	0.045
Cardiopulmonary arrest or resuscitation	5	0.045
Oligomenorrhea	3	0.027
Pelvic infection	4	0.036
Allergic reaction to contrast	4	0.036
Asherman syndrome	2	0.018
Pollakiuria	2	0.018
Cystitis	1	0.009
Drug reaction	1	0.009
Tumor regrowth	1	0.009
Vaginal dryness	1	0.009
Ischemia of labia	1	0.009
Postprocedural hypotension	1	0.009
Sexual dysfunction	1	0.009
Early menopause	3	0.027
Vulvovaginitis	1	0.009
Sensitivity to pain medication	1	0.009
Rash	1	0.009
Septacemia	1	0.009
Decreased orgasm	1	0.009
Tubo-ovarian abscess	1	0.009
Death	0	0.000
Total	2308	20.616

fever, PES, and local groin complications, which are much more manageable in a clinical setting and generally require less treatment.

UAE is a safe and effective alternative to surgery for symptomatic fibroids, but it also comes with complications. Acute complications (e.g., groin hematoma) can be detected easily because they are related to vascular access, thrombotic events, or pain. Chronic complications (e.g., infection) pose a problem for clinicians, especially because some of the complications may not be detected on routine follow-up or may not be attributed to the procedure.

Postprocedurally, complications are generally related to vascular access, thrombotic events, and pain. Although several complications were noted in this study, many of them are attributable to vascular access and not UAE specifically. These complications include groin hematoma, contrast allergy, artery dissection, and infection. Although these complications were fairly uncommon (2.86, 0.57, and 1.96 %, respectively), it is important that the operator be aware of these immediate problems and be prepared to handle them effectively.

A good avenue for improvement in detection of short- and long-term complications is education regarding the complications of UAE as well as how to detect them. By educating the referring clinician, family physician and patient, fewer postprocedural complications will be missed, thus ensuring an improved overall outcome.

#### Common Reported Complications of UAE

##### *Post-Embolization Syndrome (PES)*

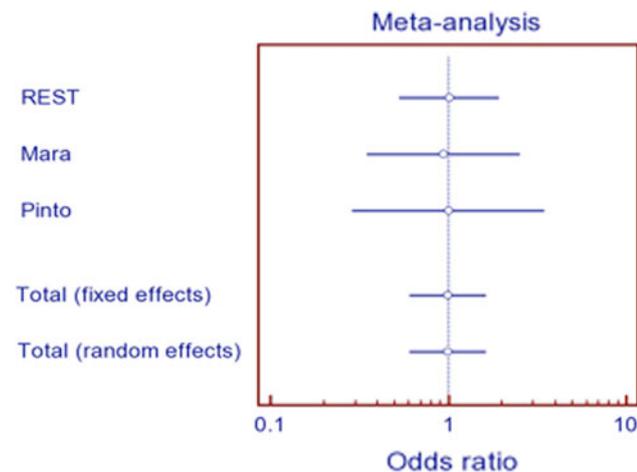
PES was a common postprocedural complication seen in our study (2.86 %). The syndrome is characterized by fever, abdominal pain, and leukocytosis after embolization. It is likely caused by an inflammatory response to necrotic tissue [13]. Fever was classified as oral temperature  $\geq 37.7$  °C (99.9 °F). This syndrome usually occurs within  $24 \pm 48$  h of the procedure, lasts for  $\leq 7$  days, and is more severe when a large volume of tissue has been embolized [14]. In a recent study, PES acted as a surrogate of other poor prognostic features, thus dictating a slightly worse outcome [13]. Some studies show that a tapering 2-week dose of prednisone may relieve symptoms and decrease the occurrence of PES [15].

##### *Fibroid Passage*

Fibroid passage is a complication that presents as severe menstrual cramping with the possibility of discharge, tissue

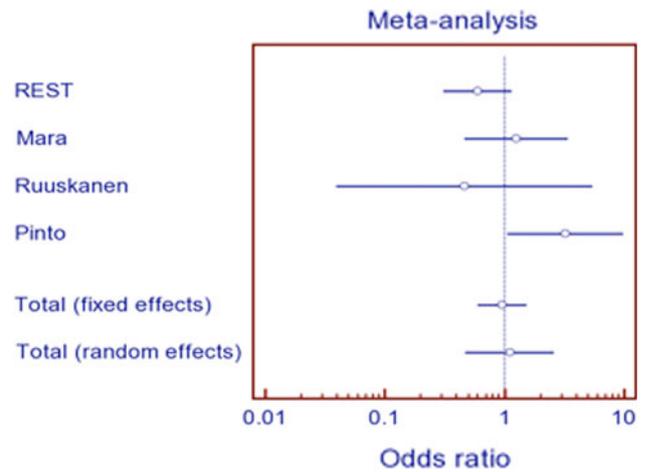
**Table 8** Complication rates in 41 case studies ( $n = 11,195$ )

Complications	Rate (%)
Discharge, fever	0.1965
Fibroid expulsion	0.0446
Amenorrhea	0.0268
Uterine infection	0.0268
Death	0.0357
Uterine tissue necrosis	0.0268
Vesicouterine fistula	0.0179
Necrotized fibroid	0.0179
Cervical and vaginal necrosis	0.0179
Ovarian–uterine anastomosis	0.0089
Nontarget internal pudendal artery embolization	0.0089
Edema	0.0089
Reperfusion of fibroid	0.0089
PE	0.0089
MI	0.0089
Watershed infarcts in brain	0.0089
Uteroenteric fistula	0.0089
Endometrial atrophy	0.0089
Seizures	0.0089
Hot flashes	0.0089
Vaginal dryness	0.0089
Ovarian failure	0.0089
Right uterine artery communication with obturator artery	0.0089
Defect in bladder with extravasation of contrast into uterus and vagina	0.0089
Total	0.5449

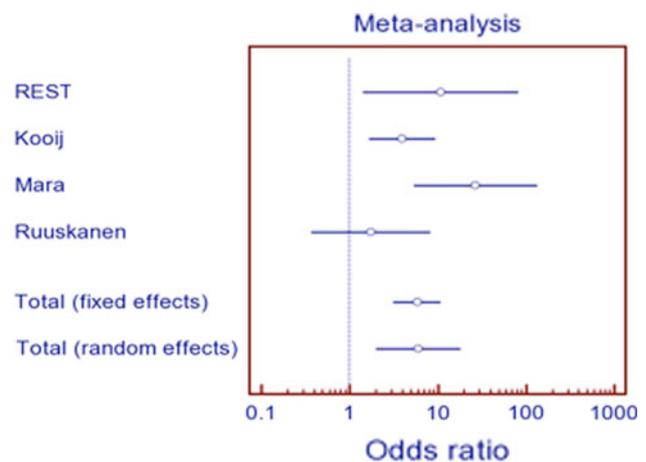


**Fig. 2** Forest plot showing OR of minor complications with UAE versus surgery

passage, and heavy bleeding [16]. Among all studies, of 400 patients, 2.5 % were found to pass fibroid fragments [16], and our study records a rate of 1.71 % among the



**Fig. 3** Forest plot showing OR of overall complications with UAE versus surgery



**Fig. 4** Forest plot showing OR of reintervention with UAE versus surgery

RCTs examined. Clinically, expulsion of fibroids may be followed by abdominal pain and fever, especially when secondary infection occurs [17].

*Age-Related Complications*

Some of the complications documented, including amenorrhea and hot flashes, may be influenced by the age of the patient. Because patient-specific age was not included in the literature, it is not possible to determine which of these complications are physiological and which are pathological.

*Major (Serious) Reported Complications*

**Pulmonary Embolism (PE)** DVT complicating UAE has been documented previously with an incidence of 2/400 (0.5 %) and 5/1,200 (0.4 %), respectively [16, 20]. Two

case reports have noted PE resulting in death [18, 19]. Although the rate of PE is extremely low (>30,000 cases have been performed worldwide [20]), it is important for clinicians to recognize the symptoms in patients who have undergone UAE and to educate patients so they can recognize the symptoms themselves. Most patients had onset of symptoms after hospital discharge [20], which makes patient education crucial.

**Infection** The incidence of infection after UAE was 1.95 % in a series of 414 patients and required antibiotics or surgery [21]. Because PES may mask some of the symptoms of infection, prophylactic antibiotics may be warranted in patients with PES. Delayed infection has been reported in case reports [21, 22] and may lead to fatal complications, such as septicemia and sepsis [23, 24]. Ideally, acute versus delayed infection rates would be available, but this was not documented in the literature.

The effectiveness of prophylactic antibiotics can certainly be debated. Although some units have decided to administer periprocedural antibiotics, this may not necessarily result in lower infection rates. It has been suggested that antibiotics destroy gram-positive organisms, thus allowing fewer opportunities for gram-negative bacteria to proliferate [25]. Studies have also shown that infective complications can occur weeks or months after the procedure [10, 16]. Patient education is critical with this complication because infection can occur well after the procedure and may not be present on routine follow-up. Patients should be informed of the symptoms and advised to seek medical attention if the symptoms develop  $\leq 6$  months after the procedure [26].

**Death** At least four deaths associated with UAE have been documented in the literature. One death occurred secondary to a large pulmonary embolus [18], and two deaths, respectively, resulted from uterine necrosis and sepsis with multiorgan system failure [23, 24]. One death was caused by nontarget embolization resulting in pulmonary, myocardial, and systemic infarction [19].

#### Repeat UAE and Reintervention

When comparing UAE with surgery for the treatment of uterine fibroids, reintervention rates must be taken into account. Although UAE has great success in the short-term while preserving uterine function, it also has a substantial reintervention rate in some of the trials. Many studies have attempted to characterize the reintervention rate; however, only a few have been able to do so effectively due to inappropriate follow-up time.

The REST and EMMY trials are the two largest RCTs comparing UAE versus surgery for women with

symptomatic uterine fibroids. Main outcome measures were quality of life, and secondary measures were adverse events, complications, and need for further intervention. The follow-up period was 5 years, which allowed the researchers to capture a more precise need for reintervention with UAE versus surgery. The REST trial documents a reintervention rate for UAE of 13 % at 1 year to 32 % at 5 years compared with 2 % for surgery at both 1 and 5 years [8]. The EMMY trial showed a 23.5 % reintervention rate for UAE at 2 years and 28.4 % at 5 years. After 5 years, 10.7 % of women in the surgery group required reintervention [6].

These results include all invasive treatments whether for complications or for persistent or recurrent symptoms. Our study indicates a repeat UAE rate of 2.29 % in the RCT group, much lower than that of the aforementioned trial. However, reintervention rates in the trials included hysterectomies and other additional interventions, which added up to a much larger value than that of repeat UAE alone. In the RCT group of our study, hysterectomy rate was 13.71 %, yielding a total reintervention rate of 16.00 %. In addition, much of the literature failed to publish the rates of reintervention, so the percentage of repeat UAE is heavily diluted. Underreported reinterventions, coupled with a short follow-up period, may account for much of the discrepancy between the reintervention rates found in the REST and EMMY trials and our study. The minimally invasive benefits of UAE must be weighed against increased reintervention rates for patients undergoing UAE.

#### Conclusion

UAE is a safe and effective alternative to surgery for symptomatic fibroids. However, it does come with its own risks. Postprocedural as well as delayed complications can present a challenge to both the patient and the clinician if not caught early. Acutely, complications related to vascular access, PE, PES, and groin complications were of concern. In the long term, infection and fibroid passage, often occurring weeks after the procedure, presented problems.

Routine imaging follow-up does not offer much benefit for the detection of complications. By educating the referring clinician, the family physician, and the patient, fewer postprocedural complications will be missed, and delayed complications can be discerned by the patient and managed appropriately.

Overall, UAE has a significantly lower rate of major complications relative to surgery, but it comes at the cost of increased risk of reintervention in the future. Educating patients about the rate and types of complications of UAE

versus surgery, as well as the potential for reintervention, should help the patient and the clinician come to a reasoned decision.

**Conflict of interest** Jason Martin, Kunal Bhanot, and Sriharsha Athreya have declared no conflict of interest.

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