Uterine Artery Embolization for Pedunculated Subserosal Fibroids: A Systematic Review and Meta-Analysis

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ABSTRACT

Purpose: To provide a comprehensive overview of the literature assessing the safety and efficacy of uterine artery embolization (UAE) for patients with pedunculated subserosal fibroids.

Materials and Methods: MEDLINE and Embase databases were searched without language or publication type restrictions for observational studies to estimate safety (adverse events) and efficacy (devascularization, fibroid volume reduction, and uterine volume reduction) outcomes. Case reports were included to qualitatively report adverse events. Meta-analysis was performed for single proportions and mean changes with random-effects modeling.

Results: Of 98 eligible articles, 11 studies were included in the final analysis. Of the adverse events detailed in these cases, 5 events were mild, 2 were moderate (torsion of pedunculated fibroid requiring laparoscopic myomectomy and persistent bleeding after embolization requiring hysterectomy), and 1 was severe (fibroid necrosis causing bowel obstruction requiring bowel resection and hysterectomy). There were no deaths reported in the literature. The pooled risk of adverse events was 1.7% (95% confidence interval [CI], 0.29%–9.2%; 4 of 181; I^2 = 0%). The pooled devascularization rate was 75.9% (95% CI, 62.4%–85.6%; 140 of 189; I^2 = 75%) at 3.91 months of follow-up. The percent volume reduction of the dominant pedunculated fibroid was 38.6% (95% CI, 33.0%–44.2%; I^2 = 0%) at 4.3 months of follow-up. The percent uterine volume reduction was 36.7% (95% CI, 30.3%–43.0%; I^2 = 47%) at 3.5 months of follow-up.

Conclusions: UAE for pedunculated subserosal fibroids has a low risk of adverse events and effectively reduces fibroid and uterine size.

ABBREVIATIONS

CI = confidence interval, NICE = National Institute for Clinical Excellence, UAE = uterine artery embolization

Uterine artery embolization (UAE) is increasingly used to manage symptomatic fibroids, with randomized trials and observational studies supporting its use as a uterine-sparing procedure for women who may consider future fertility (1,2). Despite its success in treating symptomatic fibroids, there has been caution in performing UAE in patients with pedunculated subserosal fibroids because studies have highlighted the potential risk of torsion or separation of pedunculated fibroids after UAE (3). However, torsion of pedunculated subserosal fibroids has also been reported in patients without previous UAE, with incidence rates of <0.25% (4). Accordingly, there has been substantial variation in guidelines discussing UAE in patients with pedunculated fibroids. In fact, a systematic review (5) of the UAE guidelines indicated that there are differences in which fibroids are contraindicated for embolization. Some guidelines list subserosal pedunculated fibroids as a contraindication (6), whereas others cite evidence suggesting that the complication risk is no different than nonpedunculated fibroids (7).

There is considerable clinical equipoise regarding recommendations for UAE for pedunculated subserosal fibroids. The available evidence includes observational studies and scattered case reports detailing serious adverse events; however, no comprehensive synthesis of evidence has been conducted. Therefore, a systematic review and meta-analysis evaluating the safety and efficacy of UAE in patients with pedunculated subserosal fibroids was performed.

Figures E1–E4 and **Table E1** can be found by accessing the online version of this article on *www.jvir.org* and selecting the Supplemental Material tab.

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RESEARCH HIGHLIGHTS

- This systematic review and meta-analysis evaluated the safety and efficacy of uterine artery embolization for pedunculated subserosal fibroids.
- The pooled risk of adverse events was 1.7% (95% confidence interval [CI], 0.29%–9.2%).
- The mean dominant fibroid volume decreased by 38.6% (95% CI, 33.0%–44.2%), whereas the mean uterine volume decreased by 36.7% (95% CI, 30.3%–43.0%).
- Addition of case reports spanning over 20 years of literature added 3 cases of adverse events to this review, including pedunculated fibroid torsion or bleeding, requiring surgical management.

STUDY DETAILS

Study type: Systematic review and meta-analysis

Level of evidence: 3 (SIR-C)

MATERIALS AND METHODS

A systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (8) and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (9). MEDLINE and Embase databases were searched with no restrictions on article language or publication type from inception through July 3, 2021 (the search strategy is shown in **Table E1**, available online on the article's Supplemental Material page at *www.jvir.org*). Variations of key terms such as "fibroid," "leiomyoma," and "pedunculated" were used. Articles were screened for randomized controlled trials and observational studies evaluating the safety and efficacy of UAE in patients with pedunculated subserosal fibroids. The search was supplemented by searching the references of the included articles. The references of the narrative reviews identified during title and abstract screening were also reviewed. Relevant textbook chapters were reviewed by searching the electronic university library using *LibrarySearch* with the key word "uterine artery embolization." Institutional review board approval was not required because the studies were publically available without any patient identifiers.

Literature search results were screened by 2 reviewers (N.R.P., S.A.K.) independently and in duplicate, with disagreements resolved through discussion and consensus. A third reviewer (A.K.) screened the references of relevant studies. Where necessary, the corresponding authors of relevant articles were contacted for clarification. The risk of bias was determined using a version of the Newcastle-Ottawa scale (10), modified for single-arm observational studies, which has been previously performed (11). Five categories were used: (*a*) enrolment of a representative study sample, (*b*) attrition bias (high risk if >10% attrition), (*c*) outcome adjustment for the length of follow-up, (*d*) selective outcome reporting, and (*e*) additional biases. A study was rated as overall high risk of bias if there were any domains rated as high risk. Data extraction was performed independently and in duplicate by 2 authors (N.R.P., A.K.), with disagreements resolved through discussion and consensus.

Reported adverse events were described qualitatively, which were obtained from observational studies and case reports. All the reported adverse events were classified according to the New Adverse Event Classification by the Society of Interventional Radiology (SIR) Standards of Practice Committee (12).

Statistical Analysis

A meta-analysis of single-arm observational studies was performed for single proportions and mean change between before and after embolization. The following outcomes were analyzed as single proportions: (*a*) presence of symptom improvement, (*b*) satisfaction of UAE, (*c*) devascularization, and (*d*) adverse events. The following outcomes were analyzed as mean changes: (*a*) fibroid volume change and (*b*) uterine volume change. A random-effects model was used for all outcomes. Generalized linear mixed modeling was used for pooling proportions (13). The Clopper-Pearson method was used to construct confidence intervals (CIs) for meta-analysis of proportions (14). Heterogeneity was quantified using the I^2 statistic (15). Publication bias was assessed using the Egger weighted linear regression test and depicted with funnel plots. A P value of $<.05$ was considered statistically significant. Statistical analysis was performed with package meta using R statistical software version 3.6.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Of 96 unique records initially identified, 22 articles were reviewed as full text. A total of 11 studies were included in the systematic review, of which 8 observational studies (3,16–22) and 3 were case reports (23–25) detailing adverse events (**Fig 1**). Seven observational studies were included in the meta-analysis (3,16–21). There were no case reports included in the meta-analysis. The risk of bias is reported in **Table 1**. Of the 7 observational studies evaluating safety and efficacy, 2 were rated as low risk of bias, and 5 were rated as high risk of bias. Domain 3 (outcome adjustment for the length of follow-up) was most frequently rated as high risk of bias (3/7 studies) because some studies did not adjust for variable patient follow-up, which is particularly important for outcomes such as devascularization rate,

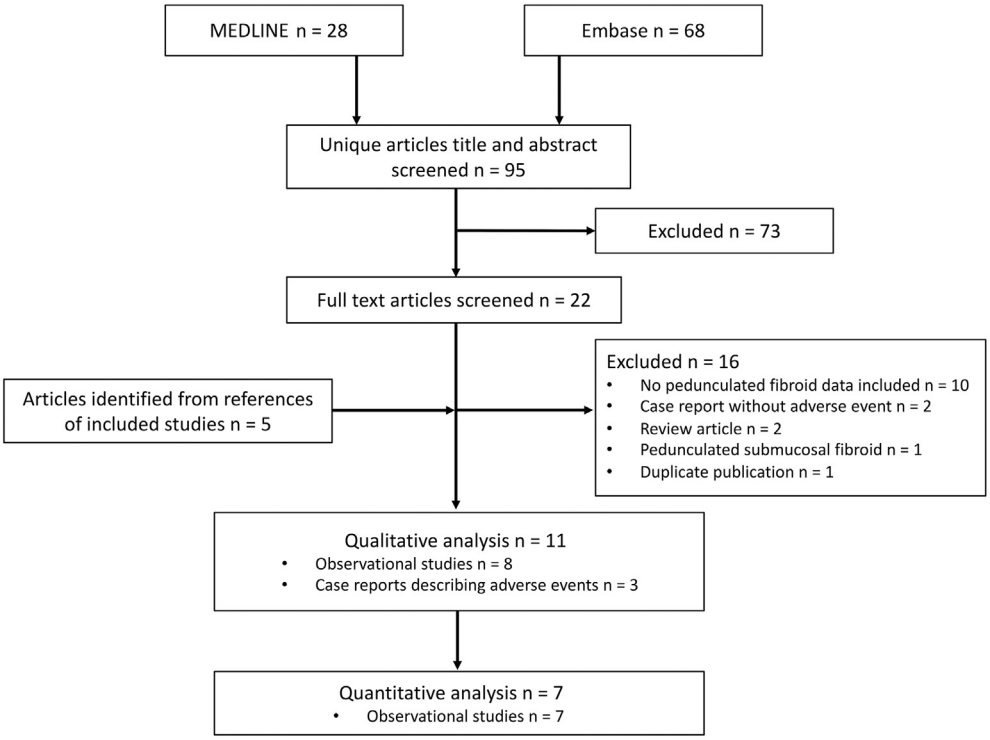

Figure 1. Flow of literature review study selection.

Table 1. Characteristics of Included Observational Studies Reporting Safety and Efficacy Outcomes

Study author, year	Country	Study period	No. of patients and fibroids	Dominant fibroid volume before embolization	Embolic agent	FU time points	Risk of bias
Margau, 2008 (16)	Canada	2004–2006	16, NR	Mean, 372 cm^3	335–500 PVA	Mean, 10 mo	Low
Katsumori, 2005 (3)	Japan	1997–2003	12, 15	Mean, 279 cm^3 (range, 26–1,424 cm^3; 95% CI, 87.7–469.3)	500–1,000 gelatin sponge	1 wk, 4 mo, 1 y	High
Kim, 2018 (17)	South Korea	2007–2016	55, 66	Mean, 111 cm^3 (SD ± 96.8 cm^3; range, 6.1–451.5 cm^3)	355–500 or 500–700 PVA	3 mo (median, 96 d; range, 36–348 d)	High
Smeets, 2009 (18)	Netherlands	1996–2008	29, 31	Mean, 168 cm^3 (range, 26–502 cm^3)	500–900 (various embolic agents not specified)	3 mo	Low
Lacayo, 2017 (19)	United States	2002–2004; 2009–2011	NR, 51	NR	NR	3 mo	High
Toor, 2008 (20)	Canada	2003–2007	18, 27	NR	350–500 PVA	3, 4, 6, and 12 mo	High
Verma, 2008 (21)	United States	2004–2006	NR, 8	NR	500–700 PVA or 500–700 tris-acryl gelatin microspheres	Mean, 125 d (range, 40–140 d) for imaging follow-up	High

Note–In 1 observational study, Tropeano et al (23) reported outcomes on all types of fibroids. It is included in Table 2 because it reported an adverse event only for a patient with a pedunculated subserosal fibroid.
CI = confidence interval; FU = follow-up; NR = not reported; PVA = polyvinyl alcohol.

which has been shown to reduce over time (26). One study (3) was notably rated as high risk of bias because patients with pedunculated fibroids with stalks <2 cm were excluded from the pool of eligible patients. Two studies (19,21) were also rated as high risk because they reported the number of pedunculated fibroids but not the number of patients. The mean fibroid volume before embolization was 227.4 cm^3 (95% CI, 118.7–336.0 cm^3). Follow-up ranged from 3 months to 1 year. A variety of embolic agents were used in studies, such as 350–500-μm polyvinyl alcohol particles (20) and 500–1,000-μm gelatin sponge particles (3).

The systematic review for adverse events for UAE of pedunculated subserosal fibroids included 8 cases from 6 articles (Table 2). Using the SIR classification (12), the adverse events in 5 cases were categorized as mild (grade 1),

Table 2. Summary of Published Adverse Events

Study author, year	Description of adverse event	Classification of adverse event
Margau, 2008 (16)	Postembolization pain requiring prolonged hospital stay of 36 h	Mild (grade 1)
Kim, 2018 (17)	Fibroid expulsion*	Mild (grade 1)
	Fibroid expulsion*	Mild (grade 1)
	Pelvic pain after hospital discharge that required emergency department visit without hospitalization	Mild (grade 1)
Tropeano, 2014 (22)	Readmission for torsion of pedunculated subserosal leiomyoma requiring laparoscopic myomectomy	Moderate (grade 2)
Ravina, 1995 (24)	Persistent heavy vaginal bleeding after embolization, requiring hysterectomy	Moderate (grade 2)
Ravina, 1998 (25)	Dissection of the uterine artery without clinical consequences	Mild (grade 1)
Braude 2000 (23); Ravina, 1998 (25)	Complete necrosis of a large pedunculated subserosal fibroid, causing bowel obstruction and requiring total hysterectomy with 50-cm bowel resection 8 d after embolization†	Severe (grade 3)

*Expulsed fibroids were likely submucosal fibroids that were also found in the patient who underwent uterine artery embolization for a pedunculated subserosal fibroid.

†The details of 1 case were described in 2 articles, one by Braude, 2000 (23) and 1 by Ravina, 1998 (25).

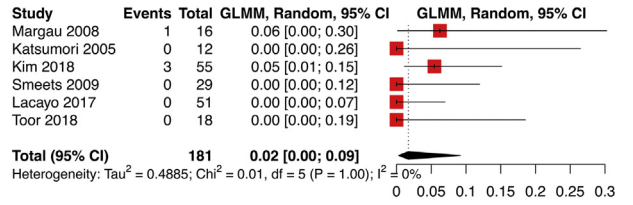

Figure 2. A forest plot of the random-effects meta-analysis of 6 studies for adverse events showed a pooled incidence of 2.0% (95% confidence interval [CI], 0.3%–9.0%; I^2 = 0%) represented by the lower black diamond. GLMM = generalized linear mixed model.

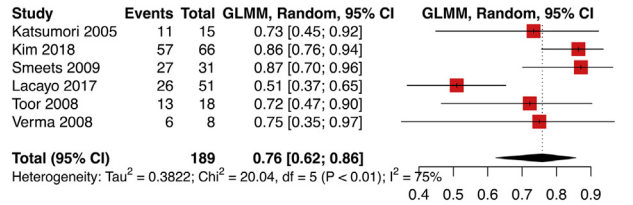

Figure 3. A forest plot of the random-effects meta-analysis of 6 studies for devascularization rate showed a pooled incidence of 76% (95% confidence interval [CI], 62%–86%; I^2 = 75%) represented by the lower black diamond. GLMM = generalized linear mixed model.

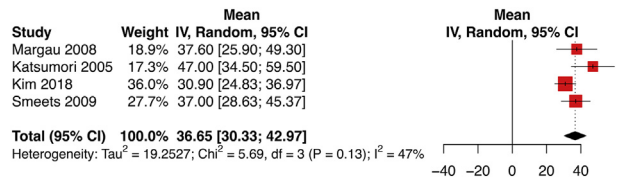

Figure 4. A forest plot of the random-effects meta-analysis of 5 studies for volume reduction of dominant pedunculated subserosal fibroids showed a pooled percent reduction of 39% (95% confidence interval [CI], 33%–44%; I^2 = 0%) represented by the lower black diamond. IV = inverse variance.

those in 2 cases were categorized as moderate (grade 2), and that in 1 case was categorized as severe (grade 3). Two cases of mild adverse events involved prolonged pelvic pain, one of which required prolonged initial hospital stay (16) and another required an emergency department visit after the initial hospital stay (17). There was 1 case of a mild adverse event that involved dissection of a uterine artery without clinical consequences (25). The remaining 2 cases of mild adverse events involved patients with a diagnosis of pedunculated subserosal fibroids who experienced vaginal expulsion of 2, presumably additional, submucosal fibroids; there were no adverse events related to the pedunculated subserosal fibroids for these 2 patients (17). For moderate adverse events, 1 patient required readmission for torsion of pedunculated subserosal leiomyoma, requiring laparoscopic myomectomy (22), whereas another had persistent heavy vaginal bleeding after embolization, requiring hysterectomy (24). There was 1 severe adverse event that involved complete necrosis of a large pedunculated subserosal fibroid causing bowel obstruction, which required total hysterectomy and 50-cm bowel resection 8 days after embolization (25). This final case was formally reported by Ravina et al (25). Braude et al (23) referenced this case in their narrative review and reported additional details, including the fact that the fibroid became septic and the length of bowel resection was 50 cm. A series by Katsumori et al (3) referenced these articles as 2 distinct cases; however, upon further evaluation, it is likely that the additional details provided by Braude et al (23) refer to a single case. Furthermore, a review of relevant textbook chapters on UAE described 2 unpublished cases, which involved exophytic pedunculated fibroids that detached from the uterus into the peritoneal cavity, requiring laparotomy for removal (27).

Meta-analysis for adverse events demonstrated a pooled proportion of 1.7% (95% CI, 0.29%–9.2%; 4/181; I^2 = 0%; 6 studies; Fig 2). These adverse events were classified as mild. The pooled devascularization rate was 75.9% (95% CI, 62.4%–85.6%; 140/189; I^2 = 75%; 6 studies; Fig 3) at a pooled imaging mean follow-up of 3.91 months. The percent volume reduction of the dominant pedunculated fibroid was 38.6% (95% CI, 33.0%–44.2%; I^2 = 0%; 5 studies; Fig 4) at a pooled imaging mean follow-up of 4.3 months. The percent volume reduction of the uterus was

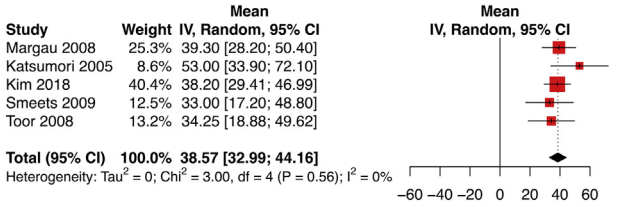

Figure 5. A forest plot of random-effects meta-analysis of 4 studies for volume reduction of uterus showed a pooled percent reduction of 37% (95% confidence interval [CI], 30%–43%; I^2 = 47%) represented by the lower black diamond. IV = inverse variance.

36.7% (95% CI, 30.3%–43.0%; I^2 = 47%; 4 studies; **Fig 5**) at a pooled follow-up of 3.5 months. Two studies reported the binary outcome of symptom reduction, which demonstrated a pooled rate of 97% (95% CI, 88.8%–99.3%; I^2 = 0%; 2 studies) at pooled follow-up of 3.6 months. Of these studies, 1 reported all 12 patients to endorse symptom improvement (15), whereas the other reported 55 of 57 patients endorsing symptom improvement (16). Satisfaction was reported in 2 small studies including 12 and 29 patients, which showed a pooled satisfaction rate of 90% (95% CI, 76.7%–96.3%; I^2 = 0%; 2 studies) at a mean follow-up of 18.4 months.

Meta-analysis for the amount of analgesia used was not possible because only 1 study reported the outcome. Katsumori et al (3) reported a mean total dose of 23.8 mg of morphine hydrochloride (range, 15.5–35 mg; 95% CI, 19.9–27.7 mg) in 11 of 12 patients after embolization. Only Smeets et al (18) reported the outcome of reintervention: 4 of 29 patients underwent hysterectomy at various intervals after UAE because of persistent complaints and imaging findings that demonstrated persistently enhancing fibroids. Of these 4 patients, 1 was found to have a leiomyosarcoma at pathologic examination. Only Katsumori et al (3) reported the recovery rates: the mean length of recovery from postprocedural pain was 13.6 days (95% CI, 3.8–23.4 days), and the mean length of full recovery was 28.3 days (95% CI, 13.1–43.6 days). The study by Katsumori et al (3) was also the only study to report the mean length of hospital stay, which was 4.3 days (95% CI, 3.2–4.3 days).

There was no publication bias detected using the Egger linear regression test for the outcomes of adverse events (P = .095), devascularization (P = .359), volume reduction of dominant pedunculated subserosal fibroid (P = .668), and uterine volume change (P = .088). Funnel plots for these outcomes are depicted in **Figures E1–E4** (available online at *www.jvir.org*). Publication bias was not evaluated for the remaining outcomes because too few studies were included.

DISCUSSION

UAE in patients with pedunculated subserosal fibroids is controversial. This systematic review evaluated the safety and efficacy of UAE in this patient population. The risk of adverse events of UAE for pedunculated subserosal fibroids was 1.7%, of which all were categorized as mild using the classification by the SIR guidelines (12). The rate of devascularization was 76%, which is comparable with the rates of 52%–78% reported by previous studies (19,28) for nonpedunculated fibroids. Other efficacy outcomes, such as fibroid volume reduction, uterine volume reduction, and patient satisfaction, were within the range for nonpedunculated fibroids. However, publication of 2 moderate and 1 severe adverse events as single case reports, which were not included in the meta-analysis, suggests the possibility of reporting bias.

The National Institute for Clinical Excellence (NICE) commissioned a systematic review (29) evaluating UAE, which included 1 randomized trial, 2 comparative cohort studies, and 32 case series. This work reported a mean uterine volume reduction of 26%–59% and a mean fibroid volume reduction of 40%–75% at 6 months of follow-up (29). There was no mention of patients with pedunculated subserosal fibroids in this review. The findings of the present systematic review indicated a uterine volume reduction of 37%, which is comparable with the range provided by the NICE systematic review (29). The findings of this review also demonstrated a pooled fibroid volume reduction of 39%, which was below the range of 40%–75% for nonpedunculated fibroids provided by the NICE systematic review (29). For the outcome of devascularization, studies evaluating patients with nonpedunculated fibroids reported rates of 52%–78% (19,28), which are similar to the present study's pooled devascularization rate of 76%. Lacayo et al (19) included pedunculated (n = 51) and nonpedunculated (n = 305) fibroids and found that compared with transmural fibroids, pedunculated subserosal fibroids were significantly less likely to completely devascularize (odds ratio, 0.24; P = .01); however, there was no reporting of whether additional covariates, such as fibroid volume, were adjusted for in the model. The fact that the rates of devascularization in this study of pedunculated fibroids are similar to those of nonpedunculated fibroids in the literature is promising for future patients with pedunculated fibroids considering UAE. In fact, evidence has demonstrated that the degree of postprocedural infarction rate is associated with long-term symptom control (26,28).

A concern that influences guidelines to label pedunculated subserosal fibroids as a contraindication for UAE is the potential risk of these fibroids infarcting their stalk and detaching into the peritoneum resulting in sepsis. This risk theoretically increases as the fibroid stalk narrows (27). However, torsion of pedunculated subserosal fibroids has also been reported without previous UAE, highlighting that UAE is not a prerequisite for fibroid torsion (4). One of the limitations in the literature is the absence of outcomes evaluation according to stalk size. Four (3,16–18) of the 7 observational studies included in the meta-analysis documented stalk size but did not compare outcomes to stalk size. Unfortunately, the studies included in this review had

too few adverse events (n = 3) to perform a meta-regression to identify the relationship of stalk diameter and risk change for adverse events. Therefore, despite there being no direct evidence indicating that patients with adverse events had pedunculated fibroids with particularly narrow stalks, clinical judgment may still be required when deciding whether to pursue UAE for these patients. Alternatives may include deferring UAE and pursuing myomectomy or performing myomectomy to remove the pedunculated fibroid followed by UAE to infarct the remaining fibroid disease that may be at higher surgical risk.

A systematic review (5) of guidelines for fibroid disease identified inconsistencies in recommendations for pedunculated fibroids. Specifically, there were differences in whether all pedunculated fibroids, all pedunculated and all submucosal, or all pedunculated subserosal only should be contraindications for UAE (5). The 2014 SIR guidelines reported that on the basis of the literature, pedunculated fibroids should not be a contraindication to UAE (7). Severe adverse events have also been reported in UAE for nonpedunculated fibroids, including sepsis and bladder necrosis (30) and fatality from septic shock (31). However, it is not possible to directly compare the risks of UAE in pedunculated versus other fibroids using case reports describing rare adverse events. Although mortality has been described in UAE of a nonpedunculated fibroid, no mortality is described in pedunculated fibroids; this may be because a vastly greater number of procedures are performed in the former population. Therefore, from an evidence-based standpoint, there is limited literature to recommend against using UAE in pedunculated subserosal fibroids.

This review is not without limitations. First, single-arm retrospective cohort studies were included, which are generally considered as high risk of bias. Selection bias and possible confounding may be present if the included cases were prognostically favorable. Furthermore, these single-arm studies do not make comparisons with other groups of patients or other interventions; therefore, it is not possible to directly compare outcomes in different patient populations (UAE in pedunculated subserosal fibroids vs UAE in nonpedunculated fibroids) or evaluate whether an alternative intervention, such as myomectomy, may have yielded improved outcomes altogether. Second, the included observational studies had small sample sizes, which reduced the overall statistical power of the present study even when pooling outcomes. This further adds caution to the confidence of effect estimates of the safety and efficacy of UAE. Third, it was not possible to perform subgroup analyses because of insufficiently granular reporting of data in the included studies; however, in an already small population that undergoes UAE, the statistical power of these analyses would have been low. Finally, the assessment of publication bias was limited given the small number of studies for each outcome. Despite there being no statistically significant results when testing for publication bias, publication bias cannot be ruled out (32). Several of the outcomes approached but did not reach statistical significance ($.05 < P < .1$); accordingly, the lack of statistical significance may be from the insufficient number of studies included. From a clinical perspective, publication bias may be suspected given that there is already caution in performing UAE in this patient population. In fact, this review's literature search identified a textbook chapter (27) that disclosed 2 known but unpublished cases where pedunculated fibroid detachment required laparotomy for fibroid retrieval. Therefore, despite the favorably low risk of mild adverse events of 1.7%, it is not possible to discount the influence of publication bias contributing to this low estimate.

In conclusion, UAE for pedunculated subserosal fibroids has a low risk of adverse events and effectively reduces fibroid and uterine size. Patients with pedunculated subserosal fibroids at a higher surgical risk may benefit from being counseled on these risks and benefits of UAE. These findings offer future guidelines a comprehensive overview of the safety and efficacy of UAE for pedunculated subserosal fibroids.

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None of the authors have identified a conflict of interest.

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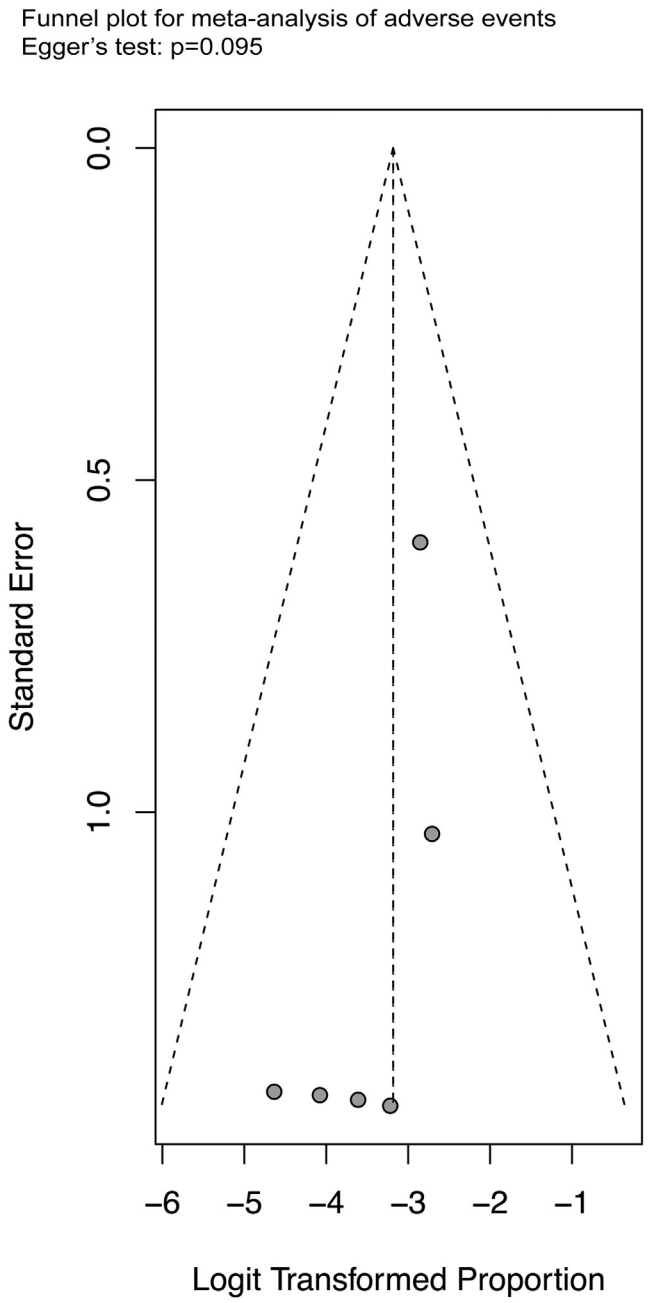

Figure E1. A funnel plot assessed the publication bias for meta-analysis of adverse events.

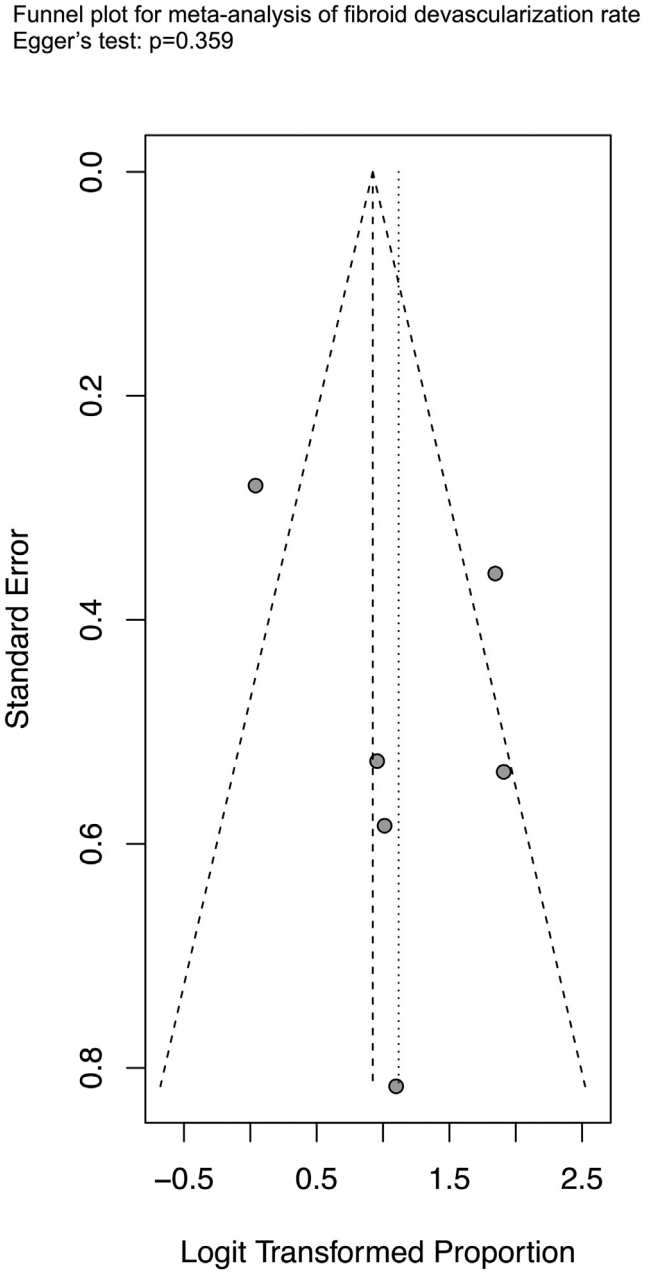

Figure E2. A funnel plot assessed the publication bias for meta-analysis of the fibroid devascularization rate.

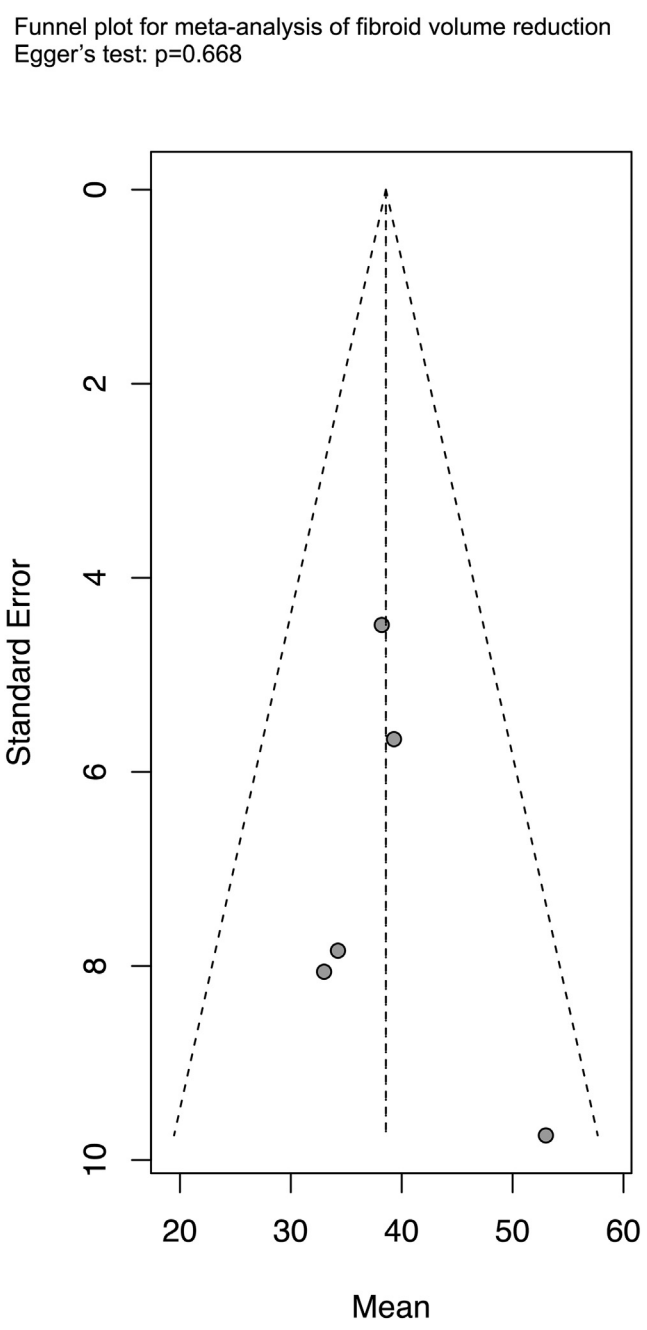

Figure E3. A funnel plot assessed the publication bias for meta-analysis of the volume reduction of dominant pedunculated subserosal fibroid.

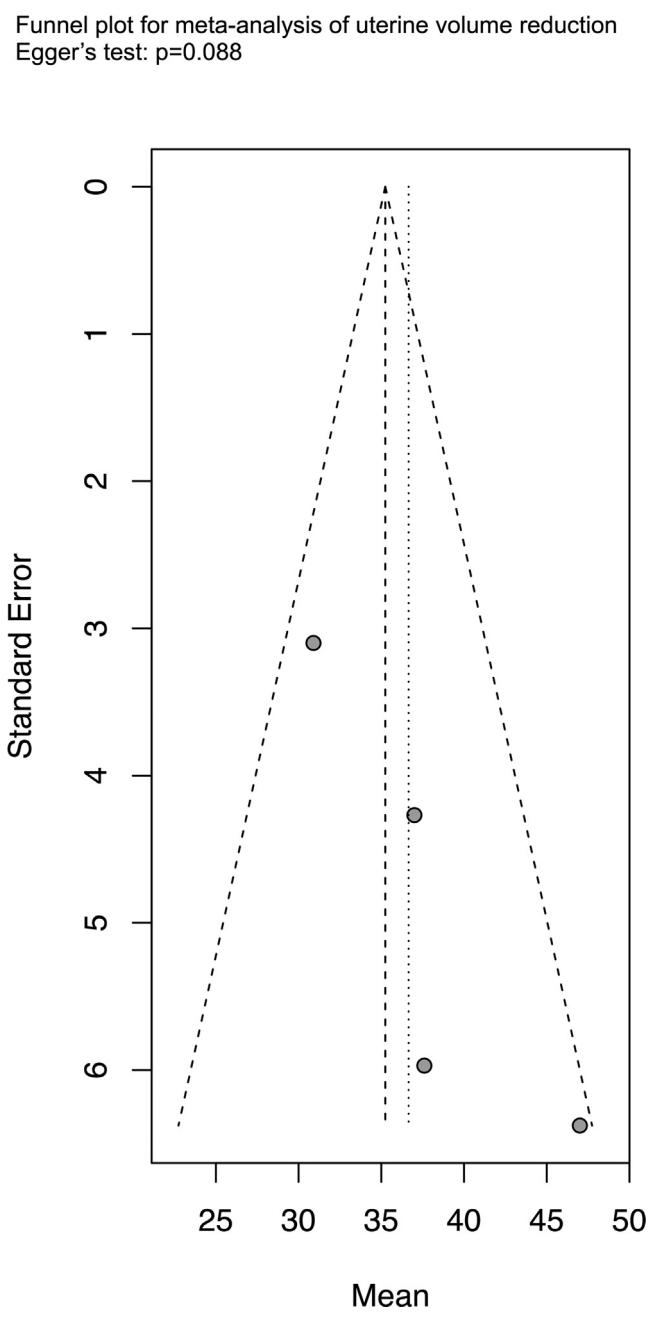

Figure E4. A funnel plot assessed the publication bias for meta-analysis of the uterine volume change.

Table E1. Embase Search Strategy

Search line	Search terms	Number of results
1	pedunculate*.mp.	5,827
2	exp leiomyoma/ or exp myoma/	39,504
3	(leiomyoma* or myoma*).tw.	25,101
4	fibro*.tw.	793,690
5	exp Embolization, Therapeutic/	55,901
6	(uter* arter* adj3 emboli?ation*).tw.	3,400
7	UAE.tw.	6,666
8	OR/2-4	825,557
9	OR/5-7	61,729
10	1 AND 8 AND 9	68