VASCULAR-INTERVENTIONAL



# Fertility after uterine artery embolization for symptomatic multiple fibroids with no other infertility factors

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#### Abstract

*Objectives* To evaluate the fertility of women eligible for surgical multiple myomectomy, but who carefully elected a fertility-sparing uterine artery embolization (UAE).

*Methods* Non-comparative open-label trial, on women  $\leq$ 40 years, presenting with multiple symptomatic fibroids (at least 3,  $\geq$ 3 cm), immediate pregnancy wish, and no associated infertility factor.

Women had a bilateral limited UAE using tris-acryl gelatin microspheres  $\geq$ 500  $\mu$ m.

Fertility, ovarian reserve, uterus and fibroid sizes, and quality of life questionnaires (UFS-QoL) were prospectively followed.

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*Results* Fifteen patients, aged 34.8 years (95%CI 32.2–37.5, median 36.0, q1-q3 29.4–39.5) were included from November 2008 to May 2012.

During the year following UAE, 9 women actively attempting to conceive experienced 5 live-births (intention-to-treat fertility rate 33.3%, 95%CI 11.8%–61.6%). Markers of ovarian reserve remained stable. The symptoms score was reduced by 66% (95%CI 48%–85%) and the quality of life score was improved by 112% (95%CI 21%–204%). Uterine volume was reduced by 38% (95%CI 24%–52%).

Women were followed for 43.1 months (95%CI 32.4– 53.9), 10 live-births occurred in 8 patients, and 5 patients required secondary surgeries for fibroids.

*Conclusion* Women without associated infertility factors demonstrated an encouraging capacity to deliver after UAE. Further randomized controlled trials comparing UAE and myomectomy are warranted.

Key points

- Women without infertility factors showed an encouraging delivery rate after UAE.
- For women choosing UAE over abdominal myomectomy, childbearing may not be impaired.
- Data are insufficient to definitively recommend UAE as comparable to myomectomy.
- Further randomized trials comparing fertility after UAE or myomectomy are warranted.

**Keywords** Leiomyoma · Uterine artery embolization · Symptoms · Fertility · Clinical trial

#### Abbreviations

AMH	anti-Mullerian	hormone

- FSH follicle stimulation hormone
- IUI intra-uterine insemination

MRI	magnetic resonance imaging
ODP	oocytes donation programme
UAE	uterine artery embolization
UFS-	symptom and quality of life questionnaire vali-
QoL	dated for fibroids
95%CIs	95% confidence intervals

# Introduction

Since the first uterine artery embolization (UAE) of symptomatic fibroids in 1995 [1], the use of this technique in women seeking future fertility remains a matter of debate. About four hundred births have been reported after UAE [2]. However, UAE complications, such as hysterectomy for necrosis (0.2 to 2% [3–5]), persistent amenorrhea (2 to 5% [4–7]) related to ovarian insufficiency [3, 4, 8] or endometrium atrophy [9] could compromise future fertility. A randomized controlled trial reported better outcomes after surgical myomectomy compared to UAE, although this study wasn't designed for fertility comparison and numerous biases raise questions about the validity of the conclusions [10]. To favour subsequent fertility, a fertility-sparing method of UAE, aiming to a limited embolization of the perifibroid plexus, leaving patent the main uterine artery [11], was developed in an animal model [12, 13]. However, limiting the embolization might also result in the need for more secondary surgery to address symptom recurrence, postponing their long-term fertility [14].

As a result of these uncertainties surrounding fertility after UAE, learned societies recommend a restrictive use of UAE in young women [15], as a second-line treatment [16], or in difficult cases whereby surgical myomectomy is contraindicated [17]. The baseline fertility potential of this selected population might be impaired. It's unknown whether the poor fertility outcome observed after UAE [2] is due to treatment and/or associated infertility factors, such as extent of disease or prior interventions [18].

To answer this question, we evaluate fertility of childbearing-age women, with the desire for immediate pregnancy and no known infertility factors, eligible for myomectomy, but who decided to have fertility-sparing UAE.

#### Material and methods

This study was approved by our ethics committee, and registered in the Clinical Trial registry (P071006). Informed consent was obtained from all included women.

We conducted a prospective non-comparative open-label

trial in two academic centres for uterine fibroids

# Patients

treatment. The study was planned at first to last 30 months; a secondary extension of 12 extra months was accepted by the ethics committee, due to an unexpected low rate of recruitment. Patients were recruited from November 2008 to May 2012.

Each woman of childbearing age referred to our centres underwent pelvic magnetic resonance imaging (MRI), and was evaluated by a fertility surgeon and an interventional radiologist, both experienced in fibroids management.

Women >18 years and  $\leq$ 40 years, with a desire for immediate pregnancy, presenting with multiple symptomatic uterine fibroids ( $\geq$ 3, at least 1 of them  $\geq$ 3 cm), suitable for multiple myomectomy, were eligible for the study. Relevant symptoms were menorrhagia, metrorrhagia, abdominal or pelvic pain, and/or bulk-related symptoms such as rectum or bladder compression.

Women fulfilling the inclusion criteria received appropriate information on multiple myomectomy as a classical therapeutic option and fertility-sparing UAE as a research alternative. Women interested in UAE were asked to complete an ovarian and pelvic work-up in order to be considered for the study. The work-up included an assessment of ovarian reserve [day 3 follicle stimulation hormone (FSH) and/or anti-Mullerian hormone (AMH)], and an office hysteroscopy. Infertile women (absence of spontaneous conception with 2 years of attempts) were also asked to complete an infertility work-up, including a tubal assessment (hysterosalpingography, and pelvic ultrasound), and a sperm assessment for their partner. Women with a history of pelvic surgery (including fibroids removal) were included if they got pregnant after this surgery.

Infertile women with an identified cause including tubal infertility (i.e. occlusion of both tubes [19]), hydrosalpinx, ovulation disturbance (amenorrhea, spaniomenorrhea, FSH > 20 IU/L), deep endometriosis, or male infertility, were excluded [2].

Other exclusion criteria were diffuse adenomyosis, (i.e. judged responsible for the symptoms), suspicion of uterine malignant disease, fibroids accessible for laparoscopic removal (i.e. pedunculated subserosal fibroid with narrow basis of implantation) or hysteroscopic removal (i.e. pedunculated submucosal fibroid, with the largest diameter inside the uterine cavity), ongoing pregnancy, emergency treatment, severe renal failure, immune deficiency or contraindication to treatment (anaesthesia rejection due to contraindication to surgery, allergy to contrast agents). Women inaccessible for multiple myomectomy (i.e. surgical cleavage plans presumably difficult to find via MRI, suspicion of severe adhesions, or previous repetitive fibroid surgeries, with no subsequent fertility) were excluded, and proposed for another study [2]. No exclusion criterion was applied for maximum number of fibroids or uterus volume.

## Procedures

A bilateral superselective UAE, using a 2.7 French microcatheter (Terumo Progreat, Leuven, Belgium), and trisacryl gelatin microspheres (Embosphere; Merit Medical, Roissy, France) ≥500 µm in diameter was performed, as previously described [2, 12, 20]. The unique operator has hundreds of procedures performed and more than 10 years of experience. Briefly, the catheter was placed in each uterine artery, distally to cervico-vaginal branches, through a right transfemoral approach. Embolization was performed in free flow, with neither spasm nor reflux, avoiding non-target embolization of uterine-to-ovarian anastomosis by upsizing microspheres. The embolization end-point was a pruned-tree appearance corresponding to limited UAE targeting the perifibroid arterial plexus and sparing normal adjacent myometrial arteries. Patient-controlled nalgesia was used for 3 days, as post-procedure care.

Women were asked to avoid attempting conception post procedure until the 3 month follow-up, with uterine and pelvic assessments completed.

# Outcomes

The primary outcome was the spontaneous fertility rate within 1 year of first conception attempt, ranging from 3 [21] to 15 months after UAE.

Secondary outcomes were the longer-term fertility, uterine and fibroid volume changes, symptom and quality of life progress, uterine and pelvic anatomical modifications and ovarian reserve evolution after UAE.

#### **Follow-up**

Women were prospectively followed 3, 6, 12 and 15 months after UAE, and annually thereafter. We intended to contact women lost to follow-up by phone and by mail.

During the first 15 months, scheduled appointments were planned. A pelvic MRI, and a laparoscopy with a dye test and hysteroscopy were scheduled 3 months after UAE. Fertility obstacles (adhesions, tubal occlusions, fibroids developed in the uterine cavity,etc.) were diagnosed and cured. Women were then allowed to try to conceive spontaneously; those who actually intended spontaneous conception were tracked and their associated fertilities were recorded, as intra-uterine, ongoing, and viable pregnancy [2]. Symptom and quality of life questionnaire, validated for myomas (UFS-QoL [22]), and ovarian reserve assessment were completed at each appointment.

The subsequent annual follow-up was performed via telephonic interview, in which we recorded fertility attempts, need for assisted reproduction techniques, pregnancy occurrences and outcomes, symptom recurrence and the need for additional surgery.

#### Sample size

We adopted an optimal Simon's two-stage design for phase II clinical trial [23]. Based on fertility reports after UAE [2], considering fertility rate as low if below 10% and as acceptable if above 30%, with type I and II errors  $\alpha = 1\%$  and  $\beta = 5\%$  respectively, n = 24 women should optimally be included.

## Statistical analysis

Data were analyzed using Stata version 10.0 (Stata Corp., College Station, TX, USA). Means and 95% confidence intervals (95%CIs) were computed for quantitative variables. Categorical variables were expressed as percentages and 95%CIs, computed with a binomial method. Comparable changes between before and after embolization were assessed utilizing a paired Student's *t* test. A Kruskal–Wallis test was used for follow-up evaluation of ovarian markers. P < 0.05was considered significant. The probability of conception after UAE was expressed in the whole population and in the population actively seeking conception, and computed using the monthly fecundability rate. The evaluation was based on the number of spontaneous conceptions per person and per month of follow-up [24].

## Results

Fifteen women were included from March 2009 to January 2011 during the first period of inclusion; no woman was included during the extension of the inclusion period. The sample size was not achieved due to difficulties in recruitment and restrictive entrance criteria. Characteristics of included women are summarized in Table 1. All had a bilateral UAE with  $8.4 \pm 4.5$  ml of 500–700-µm tris-acryl gelatin microspheres (95% CI 6.5–10.3). Six additional millilitres of 700–900-µmparticles were required for one patient. Two patients had fibroids partially vascularised via an utero-ovarian anastomosis, but the ovarian arteries weren't embolized. Fluoroscopy lasted  $18.4 \pm 4.6$  minutes (95% 15.8–21.1, min 12.1 max 29.9), with an associated radiation dose of  $147.6 \pm 68.2$  Gy/cm<sup>2</sup> (95% 108.3–187.0, min 52.2 max 290.0). No procedure-related complications occurred.

## Post-operative work-up

Three months after UAE, MRI demonstrated a significant reduction of uterine and dominant fibroid volumes in all women, 38.1% (95%CI 24.2%–52.1%, final volume  $305.6 \pm 245.6 \text{ cm}^3$ ) and 49.2% (95%CI 20.2%–76.0%, final volume

Table 1	Characteristics of the				
studied p	opulation at				
embolization					

	Studied population $(n = 15)$	95%CI	Range
Age (years $\pm$ sd)	$34.8 \pm 4.8$	32.2–37.5	27–40
Ethnicity			
Afro caribbean, N (%)	10/15 (66.7)		
Caucasian, N (%)	3/15 (20.0)		
Other, N (%)	2/15 (13.3)		
<b>Body mass index</b> $(kg/m^2 \pm sd)$	$24.8 \pm 3,0$	22.4-27.2	18.4–32.9
Marital status			
Married N (%)	10/15 (66.7)		
In couple N (%)	5/15 (33.3)		
Pelvis surgical history			
No N(%)	8/15 (53.3)		
Hysteroscopic myomectomy N (%)	2/15 (13.3)		
Abdominal myomectomy N (%)	2/15* (13.3)		
Unrelated to myomas N (%)	4/15* (26.6)		
Fertility status	±		
Conceived previously, N (%)	9/12 <sup>†</sup> (75.0%)		
Number of conceptions per included patient (± SD)	$2.5 \pm 2.6$	0.8–4.2	0–9
Delivered previously, N (%)	4/12 <sup>†</sup> (33.3%)		
Number of deliveries per included patient (± SD)	$0.4 \pm 0.7$	0.0–0.8	0–2
Infertile, N (%)	5/15 (33.3%)		
Infertility delay (months $\pm$ SD)	$31.0 \pm 28.8$	-4.8-66.8	5-78
Fertility work-up			
Hysterosalpingography			
Not done, N	2		
One patent tube, N (%)	5/13 (38.5%)		
Two patent tubes, N (%)	8/13 (61.5%)		
Chlamydia serology			
Not done	1		
Negative	12/14 (85.7%)		
Positive	2 (14.3%)		
Ovarian reserve			
Day 3 FSH (UI/ $l \pm sd$ )	$6.5 \pm 1.8$	5.5-7.5	2.9-9.5
$AFC (\pm sd)$	$11.2 \pm 9.0$	5.5-17.0	0-33
Women with AFC $< 6 \text{ N} (\%)$	4/12 <sup>†</sup> (33.3%)		
AMH $(ng/ml \pm sd)$	$2.3 \pm 1.7$	1.4-3.3	0.2-6.3
Women with $AMH < 1.2 \text{ ng/ml}(\%)$	4/15 (26.7)		
Spermogram			
Not done	7		
Normal, N (%)	8/8 (100%)		
Abnormal, N (%)	0/8 (0%)		
Magnetic resonance imaging			
Mean uterine volume, $(cm3 \pm sd)$	$438.2 \pm 277.4$	262.0-613.5	92.0-1050.8
Mean dominant fibroid volume,	$115.9 \pm 142.2$	25.5-206.6	20.0-556.0
$(cm3 \pm sd)$			
Number of fibroids, $N \pm sd$	$4.7 \pm 0.7$	4.3-5.1	3–5
Dominant fibroid location			
Submucosal N (%)	4/32 (12.5)		
Intramural N (%)	19/32 (59.4)		
Subserosal N (%)	8/32 (25.0)		
Transmural N (%)	1/32 (3.1)		
	· /		

\*A woman had an abdominal myomectomy and a caesarean section.  $^\dagger 3$  women didn't specify their fertility history and didn't perform AFC

 $78.7 \pm 90.2 \text{ cm}^3$ ), respectively. One patient was diagnosed with a deep endometriosis nodule of the left utero-sacral ligament, with upstream hydronephrosis, which was surgically removed, with an urethral fistula as a complication. This patient was kept in the study group, in an intention to treat principle.

Post-UAE hysteroscopy was available for 11 patients. Light synechia of the uterine cavity was diagnosed and treated in 2/11 patients (18.2%). Four patients (1 with synechia) had type 0, 1 or 2 fibroids disease, necessitating hysteroscopic resection (4/11 36.4%). Among these 5 patients treated with operative hysteroscopy (5/11 45.5%), 2 had endometrial thinning visualized (2/11 18.2%), but histological assessment was normal. Three patients had fibroid debris in the uterine cavity (3/11 27.3%). Five women had a normal uterine cavity (5/11 45.5%).

Post-UAE laparoscopy was performed in 13 patients. Tubal permeability was reported during laparoscopic dye testing for all women, 3 of them (23.1%) having only one tube patent (previously diagnosed at hysterosalpingography in 2). Four women (30.8%) had pelvic adhesions including tubes and ovaries (2 of them having a positive serology for chlamydia at inclusion). All these patients had destruction of adhesions. One woman required an additional tubal fimbrioplasty. One dye test was complicated by a localized uterine rupture with fibroid expulsion into the abdominal cavity. Laparoscopic myomectomy with a uterine suture was performed in this patient and in another one with an uncomplicated pediculated fibroid.

## Short-term follow-up

Among the 15 patients included for fertility assessment, loss to follow-up included one woman who completed 10.5 months of the planned 15 months follow-up and couldn't be contacted thereafter (Figs. 1 and 2).

## Fertility

Eight of the patients (53.3%) actively sought to conceive, of which five pregnancies occurred. Others didn't attempt fertility for personal reasons. All pregnancies were followed by favourable full-term delivery (Table 2). One of the deliveries was complicated by a moderately low birth weight (i.e. slightly below the 10th percentile). We considered the 15 included women for intention to treat analysis, and the 8 women having actively sought to conceive for per protocol analysis. The monthly fecundability rate and the 1-year fertility rate were 3.3% (95%CI 1.1%-7.6%) and 33.3% (95%CI 11.8%-61.6%), respectively, if we considered the entire population, in an intention to treat principal. They were 7.0% (95%CI 2.3%-15.7%), and 62.5% (95%CI 24.5%-91.5%),

respectively, considering only women actively seeking to conceive, in a per protocol analysis.

## Ovarian reserve, symptoms, and quality of life follow-up

Markers of ovarian reserve were not significantly changed during the short-term follow-up period (P = 0.310 for day 3 FSH, and P = 0.418 for AMH, Fig. 3). Evolution of the UFS-QoL scores is presented in Fig. 4. Up to 6 months after UAE, the symptom score was significantly reduced by 66.5% (54.5/100 to 20.9/100, 95%CI 48.1%–84.8%). In parallel, the quality of life score was significantly improved by 112.3% (46/100 to 78.4/100, 95%CI 20.8%–203.8%).

#### Long-term follow-up

The 15 studied women were prospectively followed during 44.3 months (95%CI 34.0–54.6). Four women (26.6%) were lost to follow-up 10.5 to 26.8 months after UAE.

#### Fertility

Six women intended to conceive during the long-term followup period (three of them continuing in their initial wish to conceive and three deciding to try fertility long-term after UAE). Six additional pregnancies were reported. In all, 8 patients had 12 pregnancies (1 miscarriage, 10 live births with uneventful deliveries, and 1 ongoing pregnancy) after UAE (Fig. 2, Table 2). Three women resorted to assisted reproductive techniques. One of them, aged 40 years at UAE, had 2 unsuccessful intra-uterine inseminations (IUI), and entered an oocyte donation program (ODP) with 3 embryos being transferred without pregnancy. Another woman, aged 37 years at UAE, had altered ovarian markers at inclusion, and is entering an ODP. A third woman, aged 34 years at UAE, had 2 unsuccessful IUI and declined further infertility treatments. The woman being treated for deep endometriosis never tried to conceive.

#### Symptoms and needs for additional surgery

Among the 11 women followed after UAE, 5 reported fibroids symptoms reappearance but only 2 required surgical interventions: one with abdominal polymyomectomy 19 months after UAE, and the other (who previously had a hysteroscopic myomectomy 3 months after UAE) for whom 2 subsequent hysteroscopic myomectomies were performed 2 years after UAE.

## Discussion

In this prospective study, women without infertility factors suffering from symptomatic fibroids were durably treated by



a limited fertility-sparing UAE and experienced a substantial rate of subsequent fertility.

Fig. 1 Flow-chart

Many authors have suggested there is an adverse effect of UAE on fertility, arguing its detrimental consequences on the ovarian reserve [25], the endometrium [9], and the myometrium [2]. In the uncertainty surrounding postoperative fertility, UAE has been recommended in childbearing-age women as a second-line treatment [17]. The reported series thus included women beyond childbearing age [2], with severe or recurrent fibroids disease, whose fertility may be impaired regardless of the treatment utilized [2, 26]. Moreover, these women could have attempted pregnancy at an older age, and less often [27]. These recruitment biases contribute to the

poor reputation of UAE regarding post-treatment fertility, which is made worse by the recall bias associated with this type of retrospective study.

Few prospective studies with higher methodological quality also reported low fertility after UAE, further suggesting caution in recommending UAE in this population. For instance, Torre et al. prospectively followed the fertility of 66 young women not eligible for surgical myomectomy and treated with UAE [2]. Entrance criteria were fibroid recurrence despite a previous surgery or current risks for surgery, i.e. associated infertility factors. Thirty-one patients intended to get pregnant after UAE. Five patients resorted to in vitro fertilization with 22 embryos being transferred, and 3 women



Fig. 2 Evolution of the number of women with no pregnancy with time, following UAE

Patient	Age at UAE (years)	Previous infertility	Fibroid surgery before pregnancy	Pregnancy						
		mennity		Rank	Delay since UAE (months)	Type of delivery	Term of delivery (weeks + days of amenorrhea)	Birth weight (grams)	Neonatal state	Pregnancy disease
1	32	Yes		1	5.6	Vaginal	39WA + 5	2400	Intra-uterine growth restriction	None
				2	44.6	Vaginal	36WA + 4	3080	Pre-term	None
				3	56.8	Vaginal	41WA + 4	2800	Normal	None
2	29	No		1	6.9	Caesarean section	39WA + 0	3460	Normal	Breech
				2	48.5	Ongoing pregnancy				
3	39	No	Hysteroscopic myomectomy before UAE	1	10.9	Vaginal	41WA + 1	3140	Normal	None
4	27	No		1	11.9	Vaginal	39WA + 0	2930	Normal	None
5	29	Yes	Abdominal myomectomy before UAE	1	13.2	Caesarean section	38WA + 5	4030	Normal	
6	27	No	Intra uterine synechia after UAE	1	19.2	Caesarean section	34WA + 6	1980	Pre-term	HELLP syndrome
7	37	No		1	22.5	Vaginal	39WA + 5	2850	Normal	None
8	36	No	Intra uterine synechia and hysteroscopic	1	44.3	First trimester miscarriage				
			myomectomy before UAE	2	49.3	Caesarean section	34WA + 1	1900	Pre-term	Premature rupture of membrane

 Table 2
 Fertility outcomes after embolization. All pregnancies were obtained with spontaneous conception



**Fig 3** Evolution of markers of ovarian reserve after UAE



Fig. 4 Evolution of symptoms and quality of life after UAE, according to UFS-QoL scores

entered an ODP, with 8 embryos being transferred. No birth was reported. The data may suggest a deficiency in implantation capacity in these patients, which could be due either to UAE and/or associated infertility factors [18]. In a randomized controlled trial, Mara et al. compared the fertility of 121 women treated either with surgery or UAE [10]. The birth rate was significantly higher in the myomectomy group (48%), compared with UAE (19%). However, the trial wasn't specifically designed for fertility comparison, resulting in very few fertility attempts (65% and 45% of women over a 2-year period, after myomectomy or UAE, respectively). Additionally, several major biases favoured the surgery group: 65% of included women had a unique fibroid, making the myomectomy easier. Moreover, hysteroscopy—likely to improve fertility [28]was only performed in the surgery group. The interventional radiologist was less experienced in UAE and the fertilitysparing method wasn't used for each patient. Finally, 32.8% of women treated with UAE demonstrated residual images of fibroids on MRI, 6 months after treatment, and were scheduled for additional surgery, delaying their fertility onset. Our prospective study included only women with multiple fibroids and no other infertility factors, eligible for poly-myomectomy. UAE was performed by an experienced interventional radiologist, utilizing a fertility-sparing embolization method with tris-acryl gelatin microspheres, shown to better preserve fertility than polyvinyl alcohol or gelatin sponge particles in an ewe model [29, 30]. Our annual fertility rate after UAE (33.3% for the whole population, 62.5% for women intending to conceive) could compare favourably with the 40% to 61%fertility outcome after abdominal myomectomy, the alternative surgical treatment [31].

Pregnancy obtained after UAE in our study had reassuring outcomes, contrasting with the higher complication rate reported in 50 deliveries after UAE [32], in women of older age [33]. Miscarriages after UAE were low in our study (10%), whereas appearing very frequent in the reported retrospective series (29.8%) [2], as well as in Mara's prospective study (52.9%) [10]. Our cohort is too small to draw any conclusion. The relatively high rate of caesarean section (40%) observed in our study has also been noticed in a retrospective series (58 to 63%) [2, 32], and might be due to anatomical deformations of the uterus associated with fibroids [34].

The fertility-sparing method used in the present study, based on a limited UAE, was developed in an animal model [12]. Subsequently, there are concerns that the fertility-sparing UAE technique could compromise the long-term efficiency on fibroid symptoms and be responsible for more secondary fibroid surgery. In the present study, 54.5% of the women had an abnormal uterine cavity after UAE, in agreement with in an earlier study [35]. In women seeking to conceive, a secondlook hysteroscopy is thus justified after UAE, as it might be recommended after all fibroids surgery, whatever the route used [36, 37]. A secondary fibroid surgery was necessary, either in the short term in 36.4%, or long term in 18.2%, at frequencies which might seem high. However, this technique allowed the control of fibroid-related symptoms, and a subsequent substantial and long-lasting fertility, permitting women to complete their family.

The major limitation of our study is the small size of our sample. Selective inclusion and exclusion criteria made women recruitment difficult: women in this age, with partners, and no infertility factors were rarer than planned. Furthermore, since 2010, we progressively reported preliminarily disappointing fertility outcomes after UAE in women with fibroids and associated infertility factors [2]. Moreover, in 2011, the French College of Obstetricians and Gynaecologists edited recommendations unfavourable to UAE in women of childbearing age [16]. This progressively contributed to worsen the reputation of UAE regarding subsequent fertility, as the study advanced, discouraging us and our correspondents to enrol women. We were unable to include the scheduled number of patients despite the extension of the recruitment period, resulting in a smaller-than-planned sample size and much less accurate estimates of true fertility rates after UAE. Another limitation is the absence of a control group, which is conceivable for a pilot study, but does not allow direct comparison. Our dataset should thus be interpreted with caution and no definitive conclusion can be drawn.

# Conclusion

While the fertility outcomes from this study are encouraging and demonstrate the capacity for women of childbearing age to become pregnant and deliver after UAE, the data are not yet sufficient to definitively recommend UAE as comparable to myomectomy and further study is warranted [38]. Acknowledgements The authors thank Doctor Benedicte Paillusson, Doctor Penelope Labauge and all the staff of the gynecology and radiology departments of the Poissy Hospital for their skilled technical assistance. The authors thank Curt Cornell for his kind help in reviewing the English of the paper, and Sylvain Goupil, from the Clinical Research Department of Assistance Public Hôpitaux de Paris, for his help in constituting the database.

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All procedures performed in the women included in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The authors declare there is no potential conflict of interest, of a financial or any other nature.

Clinical trial P071006 (February 2009, https://clinicaltrials.gov)

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