



## Research Article

# Pregnancy Outcome Following Selective Uterine Fibroid Embolization in Infertile Women

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### Abstract

**Objective:** To evaluate the efficacy of uterine fibroid embolization in achieving pregnancy in infertile women with uterine fibroids.

**Study design:** A single centre based study on 30 patients who were keen to conceive and had uterine fibroids. Uterine Fibroid Embolization (UFE) was performed using polyvinyl alcohol particles.

**Result:** Out of 30 women both volume and size of fibroids had reduced and 14 (47%) of them had conceived 6-24months after the procedure.

**Conclusion:** UFE appears to be a safe method in patients with uterine fibroid who want to preserve their fertility and the pregnancy outcome also seems to be quite promising.

**Keywords:** Fertility; Fibroid; Pregnancy; Uterine fibroid embolization

### Introduction

Uterine fibroids have been observed to create an unsuitable environment for conception as well as continuation of pregnancy. The very presence of it may cause hindrance in pregnancy by distortion of the normal uterine anatomy or by implantation failure. Non-surgical techniques, such as Uterine Artery Embolization (UAE) was first reported by Ravina et al., to treat symptomatic leiomyoma, who were otherwise planned for myomectomy [1]. UAE is a general term which

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is used not only for uterine fibroid embolization but also for management of Postpartum Haemorrhage (PPH) or anticipated PPH. Hence UFE is a more specific term for UAE directed towards the fibroid.

There are major (4%) and minor (23%) complications like pelvic infections, tissue ischaemia, diminished ovarian reserve or premature ovarian failure, radiation injury, postembolization syndrome, pulmonary embolism, contrast allergy, nephropathy etc., according to Society of Interventional Radiology. The procedure has been documented to be relatively safe by many authors [2]. It has also been stated, on identifying utero-ovarian anastomosis respective ovarian bed either needs to be protected by super selective coils (Hilal, Cook, Bloomington, USA) using microcatheters, or, by upsizing the particles.

The aim of this study was to demonstrate the effect of UFE on uterine fibroids in infertile women and outcome of pregnancy following the procedure.

### Material and Method

UFE was performed on 30 women seeking treatment at our unit from January 2014- October 2019. These patients were not a part of a big cohort. Patients had complaints of menorrhagia and dysmenorrhea; few had increased frequency of micturition due to pressure by the fibroid and had undergone treatment with Ulipristal Acetate (UPA) or Gonadotrophin (GnRH) analogue, before the procedure. Patients were explained about the procedure and complications regarding conception and pregnancy post-procedure and 30 of them had agreed to undergo the procedure.

### Consent and ethical committee clearance

Written informed consent was obtained from every patient concerned and Institutional Ethical Committee clearance was also obtained regarding analysis of retrospective data.

### Selection of patients

#### Inclusion criteria

In couples who tried for pregnancy for at least 1 year with or without ovulation induction (primary infertility)

- Any woman with uterine fibroid distorting the cavity
- Largest fibroid size <10cm ; intramural or submucosal type
- Multiple small to medium fibroids (<5cm), scattered in the uterine wall

Tubal patency was checked and was found to be present in all except 2 who had tubal block due to position of the fibroid. There was no detectable ovarian pathology in these patients. An initial transabdominal or transvaginal ultrasound was followed with a dedicated pelvic MRI without contrast to characterize the fibroids and to exclude endometriosis in all cases and were reported by a qualified radiologist. AMH, complete blood count and coagulation parameters were assessed in all patients.

Solitary intramural fibroid (<10cm) - 6  
Multiple small, medium fibroids - 5  
Submucosal fibroids encroaching cavity - 2  
Intramural fibroid and submucosal fibroid - 3

#### Exclusion criteria

- Patients with low AMH, premature ovarian failure
- Subserous fibroid (for the purpose of the study)
- Secondary infertility
- Stage 3 and Stage 4 endometriosis

#### Counseling of patients

Couples were explained about different treatment procedures of uterine fibroid including myomectomy, hormone treatments and High Intensity Focused Ultrasound (HIFU). These procedures and medical treatments were discussed in detail along with drawbacks and were consented for prior to the procedure.

#### Procedure

Pregnancy test, urine microscopy and a urinary catheterisation was performed prior to the procedure. UFE was performed using bilateral femoral artery catheterisation under local anaesthesia and conscious sedation using previously described techniques in an interventional catheterisation laboratory. The common femoral arteries are accessed under ultrasound guidance and 5F sheaths were placed. 5F reverse inferior mesenteric catheters (RIM, Cook Medical, Bloomington, USA) were used to access the contralateral internal iliac arteries. Uterine arteries were selectively cannulated under road map guidance. In 6 cases, a microcatheter (Progreat 2.7F, Term Corp, Japan) was used to cannulate or enter deeply into the uterine artery branches for ovarian artery protective coiling (see below). Formal digital subtraction angiography was not routinely performed to reduce radiation exposure. After satisfactory positioning beyond the cervico-vaginal branch, embolic material (TAGM, Merit Medical Systems and USA) was injected into the uterine artery on each side to occlude the vessels of the fibroid. Similar procedure was repeated on the contralateral uterine artery as blood supply to a fibroid is usually bilateral. Embolisation was commenced 500-700um TAGM microspheres and then increasing to 700um-900um microspheres for the latter part of the procedure. When an utero-ovarian anastomosis was identified the respective ovarian bed was either protected by super selective coils (Hilal, Cook, Bloomington, USA) using microcatheters, or, by upsizing the particles. Stasis in the uterine artery was taken as the end point of embolisation. Gelfoam slurry was used in the end to embolise the distal trunk of the uterine artery. Haemostasis was secured by manual compression.

A standard anaesthesia cocktail comprising of titred quantities of per rectal Diclofenac sodium, morphine, midazolam, fentanyl and paracetamol was used during and after the procedure. A single dose of a broad spectrum cephalosporin was administered. Patients were admitted for one day and had intravenous paracetamol and a fentanyl patch if required. 28/30 patients were discharged on the first post operative day. Review in the interventional clinic with a pelvic ultrasound was performed after 1 month and a repeat MRI was performed at 6-12 month following the procedure to assess uterine integrity, volume reduction of uterus and dominant fibroid.

#### Statistical methods

Categorical variables are expressed as Number of patients and percentage of patients. Continuous variables are expressed as Mean, Median and Standard Deviation. The statistical software SPSS version 20 has been used for the analysis. The statistical significance of UFE has been calculated by Pearson's Chi-Square test.

#### Results

Bilateral UFE was technically successful in all the cases. Mean procedure time was 52 minutes and the mean screening time was 8 minutes. Ovarian anastomosis protection was used in 9 patients. A mean of 2.8 bottles of TAGM was used (range 2 to 6). Mean hospital stay was 1.1 day (range 1 to 3 days). There was no 30 day mortality and no Society of Interventional Radiology grade IV or V complications [1]. Minor Grade I to III complications were reported in 5 patients (minor haematoma in 3 patient and additional hospital stay due to nausea and pain in 2 patients). Fibroid expulsion was reported by two patients in the first 3 months. 27/30 patients reported significant improvement in their menorrhagia, dysmenorrhoea and bulk symptoms on subsequent clinical follow up. MRI with contrast performed at 6 to 12 months following UFE showed >90% necrosis of the dominant fibroid in 28/30 patients.

Out of 30 women who had undergone UFE, 14(47%) had achieved pregnancy within 6-24months of treatment. 12 of them had spontaneous conception or by Ovulation Induction (OI), Intrauterine Insemination (IUI) and 2 patients had conceived by Assisted Reproductive Technique (ART) (*In-vitro* Fertilisation-IVF) (Table 1).

	Uterine size Mean(cc)	Largest fibroid size Mean(cm <sup>2</sup> )
Before UFE	528	42
After UFE	277	16
% Reduction	52%	38%

Table 1: Uterine volume and fibroid size reduction following UFE.

11 of 30 patients had complaints of menorrhagia and dysmenorrhoea; 3 of them were having increased frequency of micturition due to the fibroid in-situ and 2 of them had undergone treatment with UPA (2 cycles) and injection GnRH before the procedure. 3 patients had diagnosed distorted uterine cavity due to fibroid; 3 of the patients had cornual fibroid resulting in tubal block.

All patients were explained and counselled regarding the mode of delivery and all of them had undergone lower- segment caesarean section by choice. Our patients were of 26-36years of age (Mean age - 31.75 years; SD - 3.04); 14 (47%) of them had conceived after UFE and 3 (10%) of them had spontaneous miscarriage at about 6-9 weeks of gestation. All of the pregnancies were in between 6-24 months (Mean time - 14.63 months; SD - 6.21) after completion of treatment. Most of them had a term pregnancy with two preterm births (Mean - 32.75 weeks; SD - 10.03).

We have compared our data of infertile patients with uterine fibroids who were treated with either Ulipristal Acetate (2 cycles) or myomectomy (both laparoscopy and open) with those patients treated with UFE, over the same time period as mentioned earlier

(Tables 2 and 3). Though there was no established statistical difference among the pregnancy rates (p value - 0.218) and live birth rate (p value - 0.345) of the existing modalities of treatment and UFE, yet the procedure has been accepted very well by patients of younger age group and can be considered as a way out to treat fibroid in infertility in cases where medical management fails (Table 4). The efficacy of UFE is quite evident from the pregnancy rate of 47% in comparison to 34.5% when other modes of treatment have been used, though the current data is not statistically significant.

## Discussion

Uterine leiomyoma are one of the most common benign tumours in women of reproductive age, prevalence being 30%. Women are asymptomatic usually, but few experience symptoms like pelvic pain, pelvic pressure, urinary frequency and abnormal uterine bleeding [3]. Myomectomy has been the standard approach in patients desiring a future pregnancy, especially with submucosal and intramural fibroids [4,5].

Patient No.	Age (years)	Previous obstetric history	Pregnancy -Months after UFE	Weeks of pregnancy	Live birth	Neonatal outcome
1	29	OI-miscarriage	24;OI	36	Yes	
2	31	Spontaneous-miscarriage	14;OI	37	Yes	
3	33	OI-miscarriage	12;OI	35	Yes	Neonatal support- hypoglycemia
4	26	OI-miscarriage	18;OI	37	Yes	
5	37	IUI failure	11;spontaneous	37	Yes	
6	34	IVF/ART failure	6; IVF/ART	36	Yes	Neonatal support; hyperbilirubinemia
7	30	OI- miscarriage	10 spontaneous	8	-(miscarriage)	
8	32	IUI-miscarriage	22;IUI	36	Yes	
9	31	Spontaneous - miscarriage	No		NA	
10	29	Spontaneous - miscarriage	No		NA	
11	35	Primary infertility	No		NA	
12	33	Primary infertility	No		NA	
13	30	Primary infertility	No		NA	
14	34	Primary infertility	No		NA	
15	36	IVF/ART failure	No		NA	
16	28	Primary infertility	No		NA	
17	33	OI-miscarriage	14;OI	35	Yes	
18	29	OI-miscarriage	18;OI	36	Yes	
19	37	IUI failure	13;spontaneous	37	Yes	
20	35	IVF/ART failure	8; IVF/ART	36	Yes	
21	31	OI-miscarriage	10 spontaneous	6	(miscarriage)	
22	28	IUI-miscarriage	22;IUI	9	(miscarriage)	
23	31	OI-miscarriage	No		NA	
24		Spontaneous - miscarriage	No		NA	
25		Spontaneous - miscarriage	No		NA	
26		Primary infertility	No		NA	
27		Primary infertility	No		NA	
28		Primary infertility	No		NA	
29		Primary infertility	No		NA	
30		IVF/ART failure	No		NA	

**Table 2:** Data of patients who had pregnancy and live-birth after UFE.

Previous obstetric history	Mode of treatment	Number of patients	Pregnancy	Live birth	Neonatal outcome
Primary infertility	Tranexamic acid	46	16	11	
Spontaneous-miscarriage	Tranexamic acid	52	18	13	
IUI failure	UPA	5	1	1	
IVF/ART failure	Myomectomy	9	2	1	Neonatal hyperbilirubinemia
IUI-miscarriage	UPA	6	4	2	
Primary infertility	UPA	36	12	7	
Primary infertility	Myomectomy	11	4	3	

**Table 3:** Data of patients with fibroid treated with other modalities (without UFE) and outcome.

Result analysis supports Level 2 Evidence (OCEBM 2011).

		Not UFE	UFE	p Value	Significance
Pregnancy	Yes	57(34.55)	14(46.67)	0.218	Not Significant
	No	108(65.45)	16(53.33)		
	Total	165(100)	30(100)		
Live Birth	Yes	38(66.67)	11(78.57)	0.345	Not Significant
	No	19(33.33)	3(21.43)		
	Total	57(100)	14(100)		

**Table 4:** Comparison of pregnancy rate, live birth rate in patients who have or have not undergone UFE.

According to a randomized controlled trial, following myomectomy the pregnancy rate was 78%, the delivery rate 48%, and the abortion rate 23% which appeared to be quite promising [6]. Recent evidence still appears to be insufficient to establish a valid treatment option for women with symptomatic fibroids, who want to preserve their fertility. Various medical treatments like Ulipristal Acetate (UPA), leuprolide acetate, selective progesterone receptor modulators, have been tried for these women who were unwilling to undergo any surgical procedure. These are not without any side effects. In 47 patients who had spontaneous conception post-UPA treatment, 31 (66%) women had live birth and 13 of them had miscarriage at early weeks [7]. In our study about 36.1% women had conception after treatment with UPA. No recurrence of fibroids has also been documented by few [8].

UFE is a unique accepted quasi-surgical treatment for symptomatic uterine fibroids but its safety in women desiring future childbearing is still pondered over. Initially UFE was even contraindicated in nulliparous women probably because of chance of impaired ovarian function and endometrial damage [3,9]. However, the incidence of amenorrhea has been reported in less than 5% of these patients and has been clearly exacerbated by advanced age or their perimenopausal status [10]. But many authors have stated that women had shown promising increase in pregnancy rate and live-birth rate following this procedure [11]. Previous literature shows that almost 32% patients had conceived after laparoscopic myomectomy and about 78% had viable pregnancies [12]. Pregnancy rate following UFE was 50%, the delivery rate 19%, and the abortion rate 64% which was less compared to myomectomy [5]. But this is not necessarily true for women with >6 fibroids. Given that increasing the number of fibroids removed is associated with increased intraoperative blood loss, the risk of surgical complications from myomectomy may outweigh the fertility benefit for these women [13]. Myomectomy like every other surgical procedure leads to development of intrapelvic adhesions which subsequently results in iatrogenic infertility. UFE has the advantage of embolizing all fibroids in a single procedure. Our study shows that pregnancy after UFE appears to be safe, with low morbidity. Therefore, the desire to conceive is not a contraindication for fibroid embolization.

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