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Embolisation of Uterine Fibroids as an Alternative to Hysterectomy: A Breakthrough Approach and its Implementation in Bulgaria

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ABSTRACT

The embolisation of the uterine artery is a novel option for the treatment of uterine fibroids. It is a minimally invasive, organ sparing procedure that has established itself as a safe and efficient method in the contemporary treatment guidelines. The article presents an overview of the method, its indications, and contraindications, as well as the results of major clinical studies comparing embolisation with surgical interventions, such as myomectomy and/or hysterectomy. It discusses the implementation of UFE in Bulgaria and presents the clinical case of a low-risk patient in reproductive age referred for hysterectomy and treated by UFE instead.

Keywords: Uterine Fibroids; Embolisation of the Uterine Artery; Myomectomy; Hysterectomy; Microparticles; Computerised Tomography (CT); Magnetic Resonance Imaging (MRI)

Abbreviations: MRI: Magnetic Resonance Imaging; CT: Computerised Tomography

Introduction

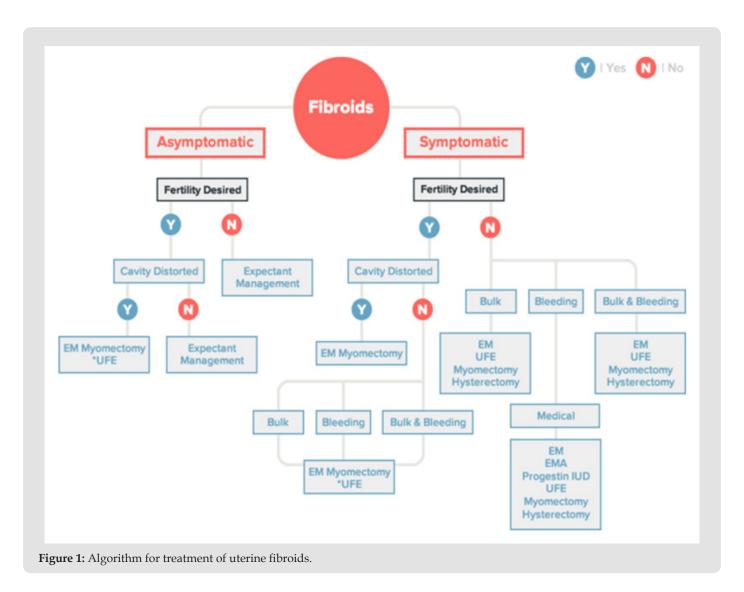
Fibroids are the most common uterine tumour and also the most common benign pathology in gynaecology. 20% to 80% of women develop uterine fibroids prior to the age of 50years [1]. According to some surveys, uterine fibroids can be found in up to 40% of women over 35years of age. The symptoms include severe metrorrhagias in 84.5% of women, pelvic pain in 62% of patients and bulk syndrome in 83.9% of women [2]. The condition could be associated with problematic pregnancy, early abortions, and reproductive disorders. Subject to treatment are patients experiencing pain, bleeding, and significant increase in the size of the fibroids. Treatment depends on the woman's age, the fibroids' localisation and size, and on the

symptoms. Conservative treatment is administered via hormonal preparations, whereas surgical treatment includes myomectomy or hysterectomy. A novel option for the treatment of uterine fibroids is the embolisation of the uterine artery. It is a minimally invasive procedure that has been in use for nearly 20years and has already established itself as a means of treatment in the contemporary treatment guidelines based on a multitude of clinical trials with extended follow-up. The embolisation of the uterine artery is an organ sparing procedure; it is a safe and efficient method within the array of procedures for treatment of uterine fibroids. The aim is to reduce or take away the symptoms related to the condition,

as well as to decrease the size of the fibroids. There is a consensus between the fields of obstetrics and interventional radiology that determines the required treatment.

The decision in favour of or against alternative therapy ought to be made in regard to the patient's wishes, and to the knowledge of other treatment options (Figure 1). In 1974, French radiologist Jean-Jacques Merland performed successfully in Paris the first embolisation of the uterine artery for the treatment of severe metrorrhagia in a woman with uterine fibroids. Several years later, together with gynaecologist Jacques Ravina, he performed embolisation prior to myomectomy to reduce intraoperative blood loss and the need of blood transfusion [3]. In 1993, Dr. Ravina and Dr. Merland launched the first multi-centric study on the efficacy and

safety of the procedure as an alternative to surgical treatment. Over the past decade, the procedure has become more widely spread as a method of treatment. In the USA alone, nearly 13,000-14,000 embolisations are performed on an annual basis. Embolisations of the uterine artery for heavy post-partum haemorrhages have been performed routinely for over 35years now. Prior to the decision for embolisation, a gynaecologist should perform a gynaecological exam, including an ultrasound examination. If the ultrasound does not allow for making a final diagnosis, MRI is the diagnostic imagery exam with the greatest precision. A gynaecological exam to rule out all possible causes for uterine bleeding, such as cervical cancer, uterine cancer, or endometrial hyperplasia, is a compulsory part of the preparation prior to the procedure.



Other prerequisites include a negative pregnancy test; laboratory tests (full blood count as a screening for anaemic syndrome); coagulation status; creatinine; a hormonal profile is recommended. In the context of the discussion for informed consent prior to embolisation, the patient should be notified of the lack of histological verification of the supposed diagnosis. The total risk of undetected malignant tumour of the uterus (including uterine sarcoma) in patients subjected to surgical treatment varies between 0.09% and 0.18% in contemporary literature. As any procedure, embolisation has indications and contraindications. Indicated are patients with symptomatic leiomyomatosis (severe uterine bleeding, dysmenorrhea, and pain) since asymptomatic fibroids are common and do not require treatment. Another indication is the patient's wish for a minimally invasive procedure prior to the surgical intervention or unsuccessful prior interventions. The patient's refusal to undergo hysterectomy may include various reasons, such as reproductive age or religious beliefs. Absolute contraindications include the presence of a urinary or genital infection; doubts regarding the diagnosis; an asymptomatic patient; pregnancy; previous radiation therapy because of the risk of tissue necrosis after the embolisation; angiography contraindications (severe coagulopathies and severe allergy to iodine contrast matter).

The relative contraindications are associated with the

localisation: pedunculated or intraligamental uterine fibroids, due to the risk of peritoneal adhesions following the embolisation, as well as fibroids engaging the endometrial canal; adenomyosis; the patient's wish to preserve her reproductive ability; renal failure; large fibroids (in the presence of a bulk syndrome due to the lesser reduction of their volume after the procedure). The procedure is carried out under short-term intravenous sedation or analgesia via an epidural catheter. Using brachial or femoral arterial access and under angiographic control, the uterine arteries are catheterised selectively. Most often embolisation particles between 700 and 900 microns in size are injected. There is a variety of microparticles with little evidence of advantages of some over others. When comparing Polyvinyl alcohol (PVA) with Tris-acryl Gelatin Microspheres- Embospheres, the latter have shown better results. [4] The aim of embolisation is to achieve occlusion of the uterine artery, and, in consequence, stasis and thrombosis of the vessels in the myometrium, ischaemia, and fibrosis of the fibroids. Figure 2. Medication prior to, during and after the procedure includes: analgesics (usually a combination of non-steroid antiinflammatory drugs and opioid analgesics), antibiotic prophylaxis with a broad-spectrum antibiotic, which has no clear indications, and antiemetics. Randomized trials: Pinto et al published the first randomized trial comparing the results between surgical treatment and embolisation [5,6].

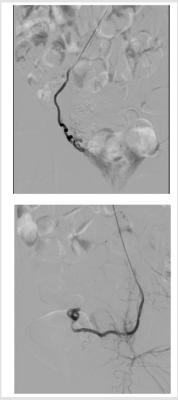


Figure 2: Right and left uterine artery angiography after embolisation.

Results showcased fewer complications and shorter hospital stay with good management of the pain symptom in 86% [7]. REST trial (The Randomized Trial of Embolization versus Surgical Treatment for Fibroids) is a multi-centric study comparing surgical treatment (hysterectomy in 51 patients or myomectomy in 8 patients) with embolisation. Early results revealed more rapid recovery and greater reduction of the pain syndrome in patients with UFE. The results at year one were even. The two-year trials displayed a greater percentage of reintervention in patients who have undergone embolisation. EMMY trial is the first large multicentric study comparing embolisation and hysterectomy. The results showed 18% of unsuccessful embolisation procedures, in all likelihood due to inexperience. In both groups, the results regarding the management of symptoms were similar. The quality of life improved in 92% of women with UFE compared to 90% in hysterectomy cases. The two-year results demonstrated 24% of recurrence of the symptoms in women with UFE, which had led to hysterectomy [8-10]. Recently, the latest consensus on the therapeutic and diagnostic approach when making a decision about embolisation of uterine fibroids [11] has been published, as well as the results of long-term follow-up of 950 patients. After an average follow-up of seven years, the study has found that women subjected to myomectomy have a greater percentage of postinterventional complications, including 2.9% of blood transfusions, which is considerably higher than the 1.1% in women treated with embolisation. The patients in both therapeutic groups have demonstrated a significant increase in their haemoglobin levels one year after the primary procedure due to reduced bleeding [12].

widely spread practice and has not become a routine procedure yet. One of the reasons for that is the lack of a team approach to patients. In order to perform such a procedure, the team has to include a gynaecologist whose task is to refer patients and to decide whether they are eligible for this treatment or should undergo hysterectomy instead. Our team is the first one to gather such a team of specialists and to work purposefully to impose this world practice in the country, as well as to make it into a routine procedure, as is the case in many countries. Our personal experience includes 70 women, whose average age is 38 years, and who have undergone embolisation of the uterine artery. The women have been recruited over a period of 3 years and 6 months, and have reported for followup visits on months 1, 3, 6, and 12. We have patients in childbearing age who wish to get pregnant, as well as one woman with cervical cancer. All patients have proven multiple or single intramural myomatous fibroids, have symptoms, and suffer from uncontrolled metrorrhagia against the backdrop of optimal drug treatment. During their hospitalisation, patients are subjected to magnetic resonance imaging (MRI) to objectify the size, number, and localisation of the fibroids. In all patients, brachial access has been used with a single-stage embolisation of the two uterine arteries with microparticles between 700 and 900 microns in size. The results prove a reduction in the size of the fibroids whose average diameter at the outset was 68.4 mm, to an average diameter of 49 mm on month 12, considerable reduction of the bleeding and the symptoms in all patients, as well as improvement in their quality of life. None of the patients has had complications in the early and the late follow-up period up to month 12 (Figures 3 & 4).

The Bulgarian Experience

In Bulgaria, the embolisation of the uterine artery is still not a

Reduction of t millimetres)	he uteri	ne	fibroids' d	iameter (in
	Mean	N	Std. Deviation	Std. Error Mean
Prior	68.4	23	16.85446	5.08181
1-year follow-up	49.0	23	23.41367	7.05949

Figure 3: Statistically significant reduction of the uterine fibroids' diameter.

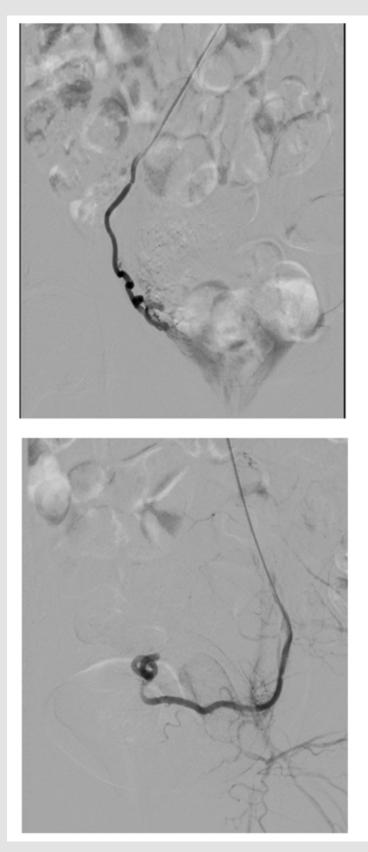


Figure 4: Right and left uterine artery angiography after embolisation.

Clinical Case. Embolisation or Hysterectomy for a Low-Risk Patient in Reproductive Age

- a) 40-year-old female patient, referred for surgery (hysterectomia)
 - b) No concomitant diseases

- c) Complaints: pelvic pain with irradiation to hips, heavy metrorrhagia
 - d) Ultrasound shows 7 intramural nodules
- e) MRI shows several fibroids of varying size, the two largest 43 and 30 mm in diameter (Figures 5 & 6).

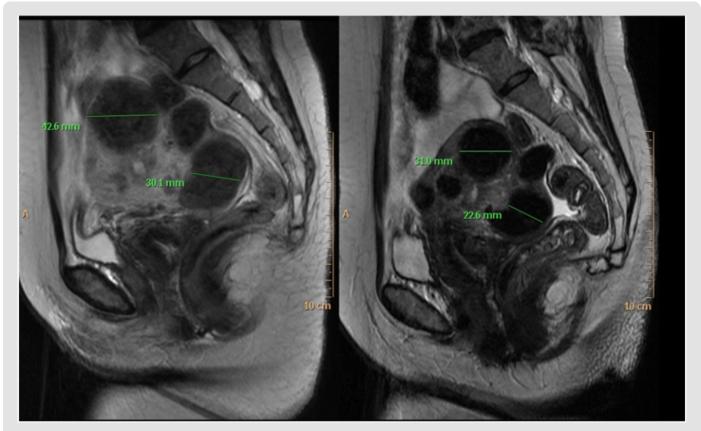
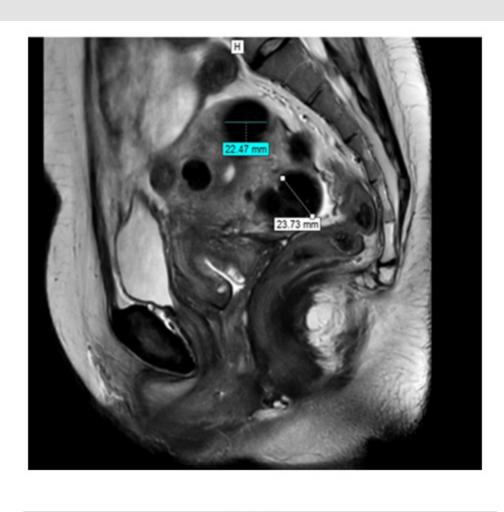


Figure 5: Initial MRI scan and follow-up on 3rd month.



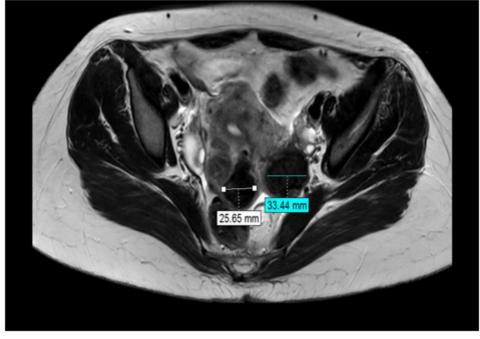


Figure 6: Follow-up MRI scan on 6th month.

Procedure

- 1 Local anesthesia with ropivacaine via epidural catheter was used.
- 2.. Via brachial access, a single-stage embolisation of both uterine arteries was performed.
- Microparticles between 700 and 900 microns in size were 3. used.
- No postprocedural complications. 4.
- The patient was discharged on the third day without any early complications and complaints.
- Follow-up MRI on the third month showed significant reduction in the number and size of the larger nodules (30 and 22 mm, respectively), as well as in the contrast intensity.
- Follow-up MRI on the 6th month showed reduced diameter of the largest nodules to 22.47 and 23.73 mm.
- Follow-up showed reduction of pain and bleeding, and improved quality of life.
- Embolisation is a gentle method, related to fewer risks to the patient, faster recovery and a shorter hospital stay.
- 10. Clinical trials comparing the effect of embolisation and surgery (hysterectomy or myomectomy) show similar results, regarding the clinical signs, quality of life, and the prognosis of lower perioperative risk.

Conclusion

The treatment of uterine fibroids may vary from observation of the fibroids or administration of drugs to relieve the symptoms to more invasive approaches, such as myomectomy and hysterectomy. Embolisation is a minimally invasive procedure, and an alternative to the surgical intervention. The multidisciplinary approach and the individual selection of the eligible patients have proved that embolisation is a safe and efficient method of treatment.

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