Uterine Artery Embolization (UAE) for Fibroid Treatment – Results of the 7th Radiological Gynecological Expert Meeting

Uterusarterienembolisation (UAE) zur Myombehandlung – Ergebnisse des 7. radiologisch-gynäkologischen Expertentreffens

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ABSTRACT

Uterine artery embolization (UAE) is a safe and effective organ sparing treatment for fibroid-related symptoms based on a broad range of published evidence including randomized-controlled trials. Indication for treatment by means of UAE are symptomatic uterine fibroids. UAE is an alternative to surgical and medical treatment for uterine fibroids as well as treatment by MRgFUS. This consensus paper covers the structural prerequisites, the criteria for technical and clinical success, contraindications, side effects and complications as well as the role of UAE treatment in women wishing to conceive and gives guidance on radiation safety measures and clinical follow-up.

ZUSAMMENFASSUNG

Die Uterusarterienembolisation (UAE) ist ein organerhaltendes Verfahren zur Behandlung myombedingter Beschwerden, dessen Sicherheit und Effektivität durch eine breite Evidenz einschließlich randomisiert-kontrollierter Studien abgesichert ist. Die Indikation für eine UAE zur Myombehandlung (Myomembolisation) ist ein symptomatischer Uterus myomatosus. Die UAE stellt eine Alternative zur operativen und medikamentösen sowie zur Myomtherapie mittels fokussiertem Ultraschall dar. Das Konsensuspapier stellt die strukturellen Voraussetzungen, die Erfolgskriterien, die Kontraindikationen, mögliche Nebenwirkungen sowie die Rolle der UAE bei Kinderwunsch dar und gibt Empfehlungen zum Strahlenschutz und zu Nachuntersuchungen.

* For the participants of the consensus meeting 2019 listed in alphabetical order at the end of the article.

Key Points

- The therapeutic aim of UAE for fibroids is the improvement (alleviation) or disappearance of fibroid-related symptoms.
- The indication for UAE treatment is based on a gynecological examination incl. ultrasound performed by a specialist.
- UAE is an alternative to surgical or medical therapy of fibroids as well as fibroid treatment by means of MRgFUS, independently of the size and number of fibroids (leiomyoma) or previous surgery.
- The decision to offer UAE should be based on the wish of the patient and having regard to treatment alternatives, their success rates, limitations and side effects.
- For women with uterine fibroids who wish to conceive the role of UAE as a treatment options is still not clarified based on the current state of knowledge.

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Introduction

Uterine artery embolization (UAE) is an organ-preserving, established, safe, and effective method in the spectrum of procedures for treating fibroid-related symptoms.

The aim of UAE is the reduction or elimination of fibroid-related symptoms, not the removal of the fibroid. At the same time the size of the fibroid is reduced.

There is consensus between the disciplines of gynecology and interventional radiology that the determination of the required treatment for uterine fibroids should be based on an examination and counseling by a gynecologist. Comprehensive counseling regarding treatment options for symptomatic uterine fibroids encompasses not only medication-based and surgical options but also UAE. The decision for or against an alternative therapy should be made under consideration of the patient's wishes and with knowledge of other treatment options, their chances of success, limitations, typical side effects and possible complications (informed decision).

In Germany, Austria and Switzerland, UAE treatment represents a treatment option for patients with fibroid-related symptoms and allows further treatment individualization for uterine fibroids.

Aim of the Consensus Meeting

The intention of the consensus meeting was to evaluate UAE. After taking into account the current literature, internationally published recommendations** and their own experience, and after extensive discussion, the participants in the meeting of ra-

diological-gynecological experts came to a consensus between the two disciplines.

The panel of experts was aware that this was an assessment of the possibilities and limitations of a radiological treatment method held in conjunction with gynecology specialists who do not perform the procedure themselves but have experience with the diagnosis and treatment of disorders of female reproductive organs.

The group of experts composed of 12 radiologists and 9 gynecologists which met on January 12, 2019 in Berlin for the 7th radiological-gynecological consensus meeting included radiologists and gynecologists from Switzerland and Austria. After an extensive – and at times controversial – discussion, the group came to a consensus regarding the following recommendations.

The consensus paper is supported by the gynecologists and radiologists listed at the end of the article.

The paper reflects the current state of knowledge.

Structural Prerequisites and Quality Assurance for Performing UAE

UAE should be performed only at clinics possessing the requisite gynecological and radiological knowledge regarding all fibroid treatment methods and possessing the necessary radiological expertise for performing UAE and regarding adequate and structured pain management after the intervention, the management of side effects, and the non-surgical and surgical treatment of fibroids.

Particularly due to the necessity for postinterventional pain management, UAE should be performed on an inpatient basis at a suitable clinic.

Prior to introducing UAE, theoretical and practical training at a center with extensive UAE experience is recommended. In addition to the legally required documentation, the calculated key radiation exposure figures (dose area product, fluoroscopy time) for UAE should be critically reviewed and optimized for quality assurance.

Participation in suitable quality assurance as defined by the professional associations is recommended.

Examinations Required Prior to UAE

A gynecological examination incl. ultrasound performed by a specialist must be performed prior to treatment decisions. If ultrasound does not allow definitive diagnosis, MRI examination is indicated.

Prior to fibroid embolization, the indication for hysteroscopy and fractionated curettage must be examined. Unremarkable cytological smear findings of the uterine cervix must have been obtained within the previous 12 months.

Pregnancy test results as well as the following laboratory results must be available: creatinine, coagulation status, thyroid values (in the case of a history of thyroid disease), blood count, and CRP. Acute inflammation must be ruled out in the case history and clinically.

According to the current state of knowledge, it is not necessary to remove an implanted IUD prior to UAE.

** The appendix contains references to selected relevant publications.

Within the context of the informed consent discussion prior to UAE, the patient should be informed of the lack of preinterventional histological confirmation of the presumed uterine fibroids, as is the case with all other organ-preserving fibroid therapies.

The total risk of an undetected uterine malignancy (including uterine sarcoma) in patients undergoing surgery for a presumed fibroid is specified between 0.09 and 0.18% in the current literature. Symptoms and imaging do not allow exclusion of a uterine sarcoma in particular.

The decision for an organ-preserving medication-based, surgical, or interventional-radiological treatment option should therefore include explanation of the risks of delayed diagnosis of a sarcoma. The spreading of tumor cells after UAE has not been observed. In the case of a lack of response to treatment or a lack of a reduction in the size of the leiomyoma(s), an insufficient embolization result and the presence of a uterine sarcoma must be considered in the differential diagnosis.

Indications for UAE

A symptomatic uterine fibroid is an indication for uterine artery embolization. UAE represents an alternative to surgical and medication-based procedures and to fibroid treatment with focused ultrasound regardless of the size and number of fibroids or previous surgeries. Treatment should be selected based on the objective of the treatment as well as the wishes of the patient.

Success Criteria for UAE

UAE treatment success is primarily defined as improvement or complete elimination of the (fibroid-related) symptoms specified by the patient and to a lesser extent as a reduction in the volume of the dominant fibroid or the entire uterus after treatment.

Medication-based Treatment***

According to the current state of knowledge, the administration of ulipristal acetate does not play a role in the indication for UAE or the performing of the procedure and does not affect the results.

Contraindications for UAE

Anatomical

Relative

- Isolated, submucosal fibroids type 0 and I of the FIGO classification (Fédération Internationale de Gynécologie et d'Obstétrique) that are accessible for hysteroscopic ablation
- Isolated pedunculated subserosal fibroids
- Supply of the fibroid(s) via an ovarian artery; the benefits and risks of additive embolization of the relevant ovarian artery should be considered.

*** The use of GnRH analogs in fibroid treatment is no longer clinically relevant and the available data regarding the interaction with UAE is unclear.

Clinical

Absolute

- Primarily Malignancy
- Pregnancy
- Acute genital infection
- Clinically manifest hyperthyroidism/acute thyroiditis in hyperthyroidism and planned or ongoing radioiodine therapy if iodine-containing contrast agents are used

Relative

- Documented allergic reaction to contrast agents containing iodine
- Postmenopausal patient
- Allergy to local anesthesia
- Latent hyperthyroidism
- Renal insufficiency
- Desire to become pregnant

UAE in Patients Wishing to Become Pregnant

UAE is to be considered at most a last resort in patients wishing to become pregnant.

UAE in Patients with a Latent Desire for Children

For patients with a symptomatic uterine fibroid and a latent desire for children, the role of UAE as a treatment option is still not sufficiently defined in the current literature.

Pregnancy after UAE is possible. In addition to miscarriage, placental problems and periparturient hemorrhage may be more common after fibroid embolization (insufficient reliable data).

Prior to UAE, the preservation of fertility and a latent desire for children should be discussed with every patient on an interdisciplinary basis in connection with age, previous interventions, prior pregnancies, and imaging findings.

Before a hysterectomy is performed in a patient with extensive uterine fibroid disease who wishes to become pregnant, the possibility of performing UAE should be investigated.

Pregnancy after UAE

A minimum wait time of approximately 6 months between fibroid treatment with UAE and conception is recommended.

Special Case: Preoperative Uterine Artery Embolization (PUAE)

PUAE, embolization as preparation immediately before surgical myoma enucleation, can be considered and offered in individual cases for patients who absolutely want to preserve their uterus but in whom a significantly increased bleeding risk can already be assumed preoperatively and/or in whom the risk of the ultimate

need for a hysterectomy is estimated to be very high “for technical reasons” (e.g. very large fibroid and/or multiple fibroids, large fibroid that is difficult to remove, fibroid with unfavorable location).

Radiation Protection

Radiation protection is particularly important in UAE. Pulsed fluoroscopy should be used. Serial angiography and oblique projections should be kept to a minimum. A scan frequency of 1 frame/second is typically sufficient. Under normal conditions, the average dose area product should be less than $50 \text{ Gy} \times \text{cm}^2$ (corresponding to $5000 \text{ cGy} \times \text{cm}^2$ or $5000 \mu\text{Gy} \times \text{m}^2$) for pulsed systems. The radiation exposure in this case would correspond approximately to 2 to 3 abdominal CT scans.

Side Effects

The following are described as relevant side effects and complications of UAE: post-embolization syndrome, amenorrhea as a consequence of disruption or failure of ovarian function, pain, discharge, angiography-related complications (e.g. groin hematoma), vaginal discharge of fibroid material, hot flashes, endometritis/myometritis, deep vein thrombosis/pulmonary embolus.

Uterine discharge can be normal in the first weeks after UAE. In the case of abnormal vaginal discharge, the patient should be diagnosed and treated for infection. Menorrhagia, cramping of the lower abdomen, discharge of tissue components can occur in the case of submucosal fibroids in particular. Depending on the clinical symptoms and the findings of diagnostic imaging, hysteroscopic myomectomy or vaginal myomectomy as in a fibroid in statu nascendi (fibroid expulsion) may be indicated. Hysterectomy is not indicated a priori. In cases of doubt, the center in which the UAE procedure was performed should be contacted.

Post-treatment Examination After UAE

Post-treatment examination by a specialist is recommended approx. 6 months after UAE.

Imaging procedures are useful (e.g., sonography in conjunction with Doppler sonography, MRI). Further diagnostic workup is required if the therapy is unsuccessful (no improvement of symptoms and/or size progression of the fibroid) or there are abnormalities on the imaging (increase in the size of the fibroid(s) or uterus) and/or there is a lack of devascularization of the fibroid(s).

Outlook

These recommendations regarding uterine artery embolization in the case of fibroid-related symptoms are to be revised again in 2021 based on the available data and experience.

The participants of the consensus meeting recommend the preparation of an interdisciplinary guideline on all aspects of the diagnosis and treatment of uterine fibroids.

Appendix

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Participating professional societies and professional organizations

BVF, Berufsverband der Frauenärzte
[Professional Association of Gynecologists]
DeGIR, Deutsche Gesellschaft für Interventionelle Radiologie
und minimal-invasive Therapie [German Society for Interventional
Radiology and Minimally Invasive Therapy]
DGGG, Deutsche Gesellschaft für Gynäkologie und Geburtshilfe
[German Society of Gynecology and Obstetrics]
DRG, Deutsche Röntgengesellschaft
[German Radiological Society]
NOGGO, Nordostdeutsche Gesellschaft für Gynäkologische
Onkologie [Northeastern German Society of Gynecological
Oncology]

ÖGIR, Österreichische Gesellschaft für interventionelle Radiologie und minimal-invasive Therapie [Austrian Society of Interventional Radiology and Minimally Invasive Therapy]
SSVIR, Swiss Society of Vascular and Interventional Radiology

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Conflict of Interest

The authors declare that they have no conflict of interest.

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