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CLINICAL STUDY

Intraprocedural complications of uterine fibroid embolisation and their impact on long-term clinical outcome

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ABSTRACT
OBJECTIVES: Authors evaluate the impact of intraprocedural complications on successful technical realisation and long-term clinical outcome of the uterine fibroid embolisation.
BACKGROUND: The uterine artery embolisation (UAE) has become an accepted treatment method for uterine fibroids. In general, the unilateral embolisation is considered to be insufficient due to poor clinical effect.
METHODS: Overall, 165 uterine artery embolisations were analysed (retrospectively-prospectively) in 163 female patients. Intraprocedural complications and their impact on the possibility to perform bilateral embolisationwere evaluated. In patients with unscheduled unilateral embolisation, short-term as well as long-term clinical effects were observed with mean follow-up period of 41 months.
RESULTS: The bilateral uterine artery embolisation was possible in 95.7 % (95 %, CI 91.3–99.4 %) procedures. The unilateral embolisation was reported in 7 procedures (4.3 %, CI 1.2–8.3 %) and reasons were following: resistant arterial spasm in 4 patients (2.5 %, CI 0.7 %–5.3 %) and impossible catheterisation due to unfavourable anatomic situation in 3 patients (1.8 %, CI 0.3–4.1 %). Other complications, such as dissection and perforation, did not affect the successful technical realisation. The long-term clinical effect of unscheduled unilateral embolisation was reported in 5 patients.
CONCLUSION: The results of our series of unscheduled unilateral uterine fibroid embolisation had high long-term clinical success rate. In way of unscheduled unilateral embolisation, we recommend MRI follow-up and reintervention only in way of persistence or recurrence of symptoms with concurrent MRI finding of residual fibroids*(Tab. 5, Fig. 3, Ref. 12)*. Text in PDF *www.elis.sk.*
KEY WORDS: uterine fibroid embolisation, unilateral embolisation.

Introduction

The uterine artery embolisation (UAE) has become an accepted treatment method for uterine fibroids. Similar to other treatment procedures, also UAE has its intraprocedural, early and late complications. The authors determine the frequency and severity of intraprocedural complications. Their impact on successful technical completion of the procedure and short-term as well as long-term clinical outcomes of the treatment were evaluated.

Materials and methods

165 uterine artery embolisations (UAEs) were performed in 163 female patients with symptomatic uterine fibroids at our workplace from July 2007 to August 2017. Two interventional radiologists with years of professional experience in radiological interventions performed all embolisations.

Prior to intervention, the number, location and dimensions of fibroids were verified via the transabdominal and transvaginal ultrasound (USG) examination (USG instruments HDI-5000 ATL, Sonoscape 5000, Aloka 2500) and MRI examination (Siemens MAGNETOM Symphony 1.5T). Female patients with USG-suspected pendulating fibroid, adenomyosis, non-specific fibroid, or multiple fibroids underwent MRI examination. The inclusion criteria included symptomatic intramural fibroid or fibroids which did not invade subserosally or submucosally by more than one half of their volume. The size of dominant fibroid in its largest dimension was at least 3 cm; neither the upper limit of fibroid´s size nor uterine size was limited. Also patients with known adenomyosis and endometriosis were included in the study set. Besides contraindications (current pregnancy, indeterminate uterine tumour other than fibroid, malignant tumour in the pelvis, inflammation of the urogenital tract, or other acute or active inflammatory disease in the pelvic region), exclusioncriteria included pendulating fibroid or fibroids which invaded subserosally by more than one half of their volume, menopause, and endometrial hyperplasia.

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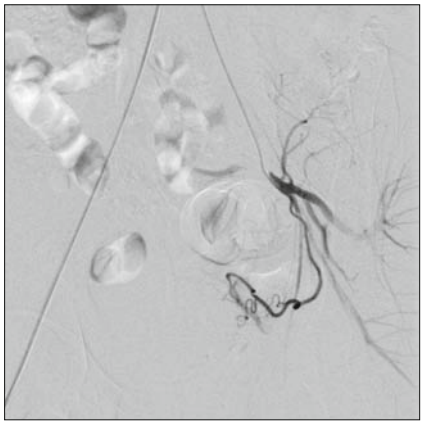

Fig. 1. RUC catheter inserted into the branch of the left internal iliac artery (Archive of the Clinic of Radiology, LFUK, SZU and UNB).

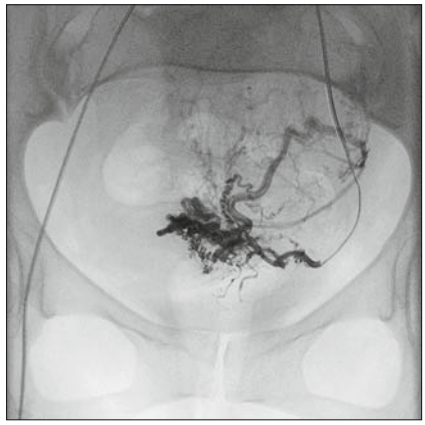

Fig. 2. Microcatheter inserted deep into the left uterine artery (Archive of the Clinic of Radiology, LFUK, SZU and UNB).

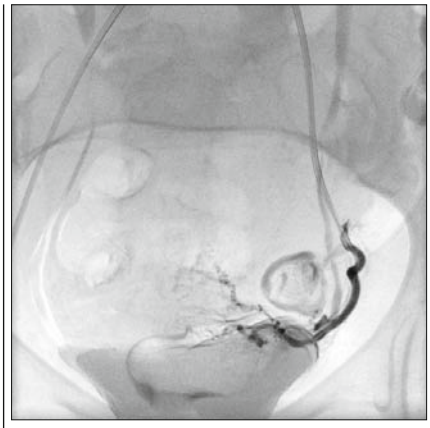

Fig. 3. Status after the left-sided embolisation (Archive of the Clinic of Radiology, LFUK, SZU and UNB).

After the procedure, patients came for scheduled follow-ups at intervals of 1, 3, 6, 12, and 24 months to detect early and late complications, evaluate regression of dominant fibroid and evaluate resolution of clinical difficulties. USG examination and laboratory testing (blood count, inflammatory markers) were performed during these follow-ups. Patients with pre-procedural MRI underwent a follow-up MRI examination 6 months after the procedure.

The same endovascular technique under general anaesthesia with the access site in the right common femoral artery through 5F sheath was used in all procedures. Using 5F catheter Cobra (Terumo Europe N.V. Leuven, Belgium) and 0.035 inch Guide Wire M, angled (Terumo Europe N.V. Leuven, Belgium), we catheterised the contralateral common iliac artery (CIA). For catheterisation of the internal iliac artery (IIA) (Fig. 1) and branches of the uterine artery (UA), we used a reshaped catheter RUC (Roberts Uterine Curve) (COOK, Wiliam Cook Europe, Bjaeverskov, DK). We catheterised the distal course of UA (Fig. 2) with micro-instruments using coaxial technique (0.025“ System Micro Catheter, Progreat, Terumo Europe, N.V., Leuven, Belgium or EmboCath Plus 0.028 inch and micro-guide wire Sequitor 0,018“ BioSphere medical, S.A., Paris Nord 2, France). We always placed a microcatheter beyond the branches of cervicovaginal arteries. Microparticles PVA500, size 500–710 μm, and microparticles PVA700, size 710–1000 μm (COOK, William Cook Europe, Bjaeverskov, DK), or trisacrylgelatin microspheres Embosphere, size 500 μm and 700 μm (Biosphere Medical, Rockland, USA), were used as an embolisation material. If the utero-ovarian anastomosis was found, we firstly placed a micro-coil Trufill (Cordis Endovascular Systems, Inc., Miami, FL, USA) into it to prevent non-targeted embolisation of ovarian vascularisation. After the completion of the left UA embolisation (Fig. 3), we catheterized the right UA in the same way. The access site was endovascularly closed to reduce the risk of haemorrhagic complications and improve the patient´s comfort after the procedure. FemoSeal (Terumo Medical Corporation, Cottontail Lane, Somerset, USA).

We considered the bilateral embolisation as successful if the flow in the uterine artery slowed down or stagnated with no saturation of pathological vascularisation of the fibroid and with preservation of perfusion in cervicovaginal small branches and, where appropriate, also a part of typical myometrial small branches. If only unilateral embolisation was possible, we considered such procedure as technically unsuccessful.

During the procedure, we observed intraprocedural complications, such as resistant spasm, dissection, perforation, unfavourable anatomic course or absence of the uterine artery, and acute allergic reaction to contrast agent. We evaluated their association with the technical success of embolisation retrospectively and observed their impact on clinical success of the therapy prospectively.

Spasms which did not respond to vasodilators (Isoket, UBC Pharma, Germany), did not resolve after 30 minutes since their onset, and resulted in inability to perform catheterisation and embolisation of affected UA were evaluated as resistant arterial spasms.

5 patients underwent scheduled unilateral embolisation due to clearly unilateral supply of the fibroid based on angiographic finding.

In the practical part of the study, tools of descriptive statistics were used. We used characteristics of the position, such as mean, modus, median, and characteristics of variability, such as variance and standard deviation. For statistical analysis, we used frequency tables, including confidence intervals for portions, contingency tables and Fisher´s exact test, Pearson´s correlation coefficient, and linear regression. Data was analysed using IBM SPSS Statistics 20 software.

Results

Overall, 165 embolisations of uterine arteries were performed in 163 patients with symptomatic uterine fibroid; two patients underwent repeated embolisation. The mean age of patients in the study set was 37.9 years, ranging from 22 to 51 years (Tab. 1).

The most common indications for the procedure included menorrhagia reported by 104 patients (78.79 %), pelvic pain, symptoms due to the pressure of the fibroid and enlarged uterus onto the surrounding tissue (bulky symptom), primary or secondary sterility, progression in fibroid growth, and recurrence after previous myomectomy (Tab. 2). 57 patients (43.18 %) experienced more than one of these symptoms. The unilateral embolisation, evaluated as technically unsuccessful, was performed in 7 procedures (4.3 %, CI 1.2 %–8.3 %). There was no situation where one of the uterine arteries could not be embolised. None of occurred peri-operative complications was life-threatening; no surgical intervention was required. There was no statistically significant difference in the age-related incidence of technically unsuccessful embolisation (p =1.000).

Tab. 1. Characteristics of the study set and follow-up period.

163 patients treated with UAE due to symptomatic uterine fibroid
Age between 22 years and 51 years (mean age 37.9 years)
31 patients only with short-term follow-up period ≤6 months
Patients living in other regions of Slovakia, who did not respond to the contact via telephone or email.
132 patients observed for ≥12 months
Mean follow-up period 54.36 months
Median 48.5
Standard deviation 31.49
Age between 25 years and 49 years
(mean age 38 years, median 38 years, standard deviation 5.21)
109 patients observed for ≥24 months
Mean follow-up period 62 months
Median 62,93
Standard deviation 27,83
Age between 25 years and 48 years (mean age 37.2 years, median 37 years, standard deviation 5.05)

Tab. 2. Indications for embolisation therapy.

Indications	Number of patients	Proportion in the study set
Sterility (primary, secondary)	16	12.12 %
Bleeding	104	78.79 %
Pelvic pain	40	30.30 %
Symptoms of bulky uterus	13	9.85 %
Progression in fibroid growth	34	25.76 %
Recurrence after myomectomy	14	10.61 %

One of the causes of technical failure was the uncrossable spasm that we observed in 4 procedures (2.5 %, 95 % CI 0.7 %–5.3 %). Another cause of UAE technical failure was anatomically unfavourable branching of the uterine artery that we observed in 2 patients. In one patient, there was an occlusion of UA as a consequence of a gunshot wound, however 3 collaterals supplying the fibroid and branching from ipsilateral internal iliac artery could be embolised. The anatomically unfavourable branching and missing uterine artery was the cause of technical failure in 3 patients (1.8 %, 95 % CI 0.3 %–4.1 %). Other complications included 4 perforations of uterine arteries (2.5 %, 95 % CI 0.7 %–5.3 %). Perforations were non-severe in all patients, they closed spontaneously during the embolisation and did not avoid the successful completion of the procedure. A haemodynamically non-significant dissection of internal iliac artery occurred in one patient (0.61 %, 95 % CI 0.0 %–2.0%). In 7 of 12 patients, mentioned complications resulted in a technical failure (Tab. 3). Complications associated with catheterisation, such as retroperitoneal haematoma, post-catheterisation pseudoaneurysm or arteriovenous fistula and allergic reaction to contrast agent, did not occur in our study set. Overall, 156 procedures were successfully technically completed during the first session (95.7 %, 95 % CI 91.3 %–99.4 %).

In 4 procedures of unscheduled unilateral embolisations, the fibroid was dominantly supplied from the side that can be treated. Only small arterial conjunctions to the fibroid were present on the untreated side. Since the unilateral treatment resulted in the clinical success with resolution of symptoms, we did not indicate the reintervention.

Due to persistent clinical symptomatology, in two patients with technical failure the reinterventionwas performed. The fibroid was dominantly supplied from untreated uterine artery in both patients. In the first patient, it was caused by the uncrossable spasm and the embolisation was successful in the second session with good clinical response and resolution of symptomatology. Although only unilateral embolisationwas performed, MRI after 6 months showed 90 % devitalisation of the dominant fibroid with 58 % volume reduction and resolution of clinical symptoms (Tab. 4). The disease had recurred after 5 years and it was treated with myomectomy. Also the patient with missing uterine artery after the gunshot wound was included in the evaluation of clinical success rate of unilateral embolisation (Tab. 4).

Tab. 3. Overview of intraprocedural complications.

Type of complication or problematic condition		Number	Impact on successful technical completion of the procedure	Impact on clinical outcome of the embolisation
Dissection of the internal iliac artery		1	No	No
Perforation of the uterine artery		4	No	No
Spasms with no response to treatment		4	Yes	Yes (1x)
				No (1x) (Short follow-up period)
				No (2x)
Inability to probe the uterine artery due to anatomy	Absence of the uterine artery after the gunshot wound	1	Yes	Short-term success
	Unfavourably arched branch of the uterine artery	2	Yes	No
Total number		12	Yes (7x)	Yes (1x)

Tab. 4. Technical failure of UAE.

Patient	Age (years)	Supply of the fibroid	Embolisation (side)	Cause of failure	Volume regression	Clinical success	Disease recurrence	Duration of the follow-up period (months)
1	42	Dominant from the left side	From the left side	Spasm	Yes 34.6 %	Yes	No	6
2	35	Bilateral	From the right side	Missing uterine artery on the left	No	Short-term	After 2 years	27
3	48	Dominant from the left side	From the left side	Spasm	Yes 84,6 %	Yes	No	108
4	45	Dominant from the left side	From the left side	Spasm	Yes 30 %	Yes		36
5	40	Dominant from the left side	From the left side	Arched branch	Yes 81,4 %	Yes	No	12
6	31	Bilateral	1st session, only right one 2nd session, unsuccessful	Arched branch	Yes 58 %	Yes	After 5 years	72
7	39	Dominant from the left side	1 session, only right one 2nd session, left one	Spasm	No Yes	No Yes	No	26

Tab. 5. Scheduled unilateral embolisation.

Patient	Age (years)	Unilateral supply of the fibroid	Unilateral embolisation from any side	Volume regression	Clinical success	Disease recurrence	Duration of the follow-up period (months)	Other notes
1	25	From the right side	From the right side	Yes 92,6 %	Yes	No	36	Parturition 3 years after UAE
2	28	From the right side	From the right side	Yes 62,3 %	Yes	Myomectomy after 7 years	120	Parturition 7 years after UAE
3	28	From the right side	From the right side	Yes 57,4 %	Yes	Myomectomy after 10 years	120	–
4	48	From the right side	From the right side	Yes 98,7 %	Yes		84	–
5	33	From the left side	From the left side	Yes 45,6 %	Short-term improvement	Hypermenorrhoea during hormone therapy after a year	24	Unsuccessful IVF after UAE

In five procedures of scheduled unilateral embolisation, the angiography showed the unilateral supply of the fibroid. Only vascularisation of the myometrium was displayed from the contralateral uterine artery. Due to young age of majority of patients who have been planning a family, we decided to minimize the radiation load and risk of non-targeted embolisation in the utero-ovarian conjunction and perform the embolisation only from the supply side of the fibroid. We achieved a long-term clinical success in 4 patients; 2 patients became pregnant and gave a birth within 3 and 7 years. In one patient, hypermenorrhoea recurred after 12 months. In the long-term follow-up period, we reported 2 recurrences, 7 and 10 years after the embolisation, in this set of patients (Tab. 5).

Discussion

At workplaces performing UAEs worldwide, there are various minor modifications to the generally accepted technical process of this procedure. The highest percentage of the technical failure (17 %) was published in EMMY study (Volkers et al, 2006) probably due to the fact that it was a multicentric study in which many surgeons completed only a small number of procedures. In large studies: FIBROID (Worthinton-Kirsch et al, 2005; Goodwin et al, 2008), REST (Edwards et al, 2007; Moos et al, 2011), FUME (Manyonda et al. 2001), the technical failure ranging from 3.0 % to 5.8 % was reported. We observed 4.3 % technical failure in our study set.

In our study, we only focused on arterial catheterisation-associated complications during the procedure. We evaluated not only technical success of the procedure but also the the clinical effect of the treatment in condition of technical failure. In our study set, 95.7 % of procedures were successfully completed and it corresponds with published data and recommendations (Toor et al, 2012; Dariushnia et al, 2014).

Generally, the unilateral embolisation is considered to be insufficient since fibroids are usually supplied bilaterally. A risk of opening of contralateral collaterals, leading to a continuous perfusion of the tumour tissue, has been described after the unilateral embolisation. It results in insufficient fibroid necrosis associated with poor volume reduction and persistence of clinical

symptomatology. Conclusions from several large studies strongly recommend bilateral embolisation which has better clinical outcomes and less percentage of treatment failure versus unscheduled unilateral embolisation. (Gabriel-Cox et al, 2007, Spies et al, 2005).

In the study with scheduled unilateral embolisation and its good clinical effect, the fibroid was dominantly supplied by one uterine artery and the second artery supplied a healthy myometrium (Bratby et al. 2008).

In the study (Stall et al, 2011) evaluating 1431 uterine artery embolisations, 28 scheduled unilateral fibroid embolisations with fibroids supplied only by ipsilateral uterine artery were identified. Compared to the same set of bilateral embolisations, there was no significant difference in a complete fibroid necrosis (92 % vs 88 %); and less intensive post-embolisation pain with lower doses of anaesthetic agents and shorter total skiascopy time were reported in the set of unilateral embolisations.

In our study set, the clinical success was observed in 6 of 7 unscheduled unilateral embolisations. In one patient with missing left uterine artery, the clinical success was short-term and the patient experienced the recurrence of symptoms after 2 years.

Conclusion

Our results show that also the unscheduled unilateral embolisation has high long-term clinical success rate, especially provided that the treated uterine artery was the main supply source for the fibroid. The scheduled unilateral embolisation is clinically effective and reduces the duration of the procedure as well as the radiation dose, reduces the risk of non-targeted embolisation of ovarian circulation only to one ovary and half of healthy uterine tissue. Based on our results from individual patients long-term follow-up as well as published papers, we prefer the unilateral embolisation if the fibroid is only supplied by one uterine artery. In young patients who plan a family, it is also possible to consider the unilateral embolisation also in fibroids which are dominantly supplied from one side with good conjunctions from the second uterine artery. In patients with unscheduled unilateral embolisation, we recommend MRI follow-up and reintervention only in insufficient clinical outcome and concurrent MRI finding of residual fibroids.

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