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The effectiveness of uterine fibroid embolization in 1000 women with symptomatic leyomyomas

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Summary

Background: Background: The effectiveness of uterine fibroid embolization in 1000 women with symptomatic leiomyomas. Uterine fibroid embolization (UFE) was introduced into practice in 1995. The aim of the study was to evaluate endovascular procedure efficacy in 1000 women with symptomatic leiomyomas.

Material/Methods: 1000 women with symptomatic leiomyomas underwent UFE. In all patients, fibroids were confirmed with MRI and the symptoms included abnormal bleeding and compression of other organs. MR follow-up was performed in 964 women 3 months later, and in 853 women 12 months after UFE.

Results: Technical success was achieved in 983/1000 cases. In 67 patients, the fibroid was supplied by the ovarian artery. In 3 women, massive spasm of the uterine artery was the reason for technical failure. 3 months after UFE, 877/ 964 (91%) were satisfied with endovascular treatment, 12 months later 699/ 853 (82%). 154 women were dissatisfied. 75 patients underwent at least one additional gynecological procedures 1–60 months after UFE. Dominant leiomyoma size reduction >30% was observed in all 964 patients 3 months after UFE. After 12 months, size reduction was >50% in 808/853 women. In 84/853 patients (11%), we found contrast enhancement within the fibroid but only 35 of them (4%) were symptomatic.

Conclusions: Uterine fibroid embolization is an effective and safe method of symptomatic leiomyoma treatment.

Key words: embolization • uterine leiomyoma

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Background

Uterine fibroid embolization (UFE) is an endovascular method of treatment used since 1995 [1]. Analysis of experience accumulated during over a decade resulted in the development of commonly accepted standards of the procedure [2–4]. In Poland, UFE has been used in clinical practice since 2001 [5]. Uterine fibroid embolization has become at the beginning of the 21st century the most dynamically developing method more and more commonly used to treat uterine leiomyomas. Wide interest in this method is due to its low-invasive character. The procedure requires 36-h hospitalization and in contrast to surgical treatment causes no disruption of tissue integrity. Promising results after short observation period, low complication rate, and, on the other hand, the fear of open surgery make embolization an attractive alternative chosen by more and more patients. Long-term maintenance of results is another advantage [6].

Decrease symptoms of myomas is, according to many authors, obtained in over 90% of women treated with embolization [7–10]. Reduction of dominant leiomyoma volume 3 months after embolization is estimated at 45–58%, and after 12 months 77% [9,11,12].

The aim of the study was to assess endovascular procedure efficacy in the treatment of symptomatic leiomyomas.

Material and Methods

Between November 2001 and January 2007, 1000 women aged 26–54 (43 years on the average) with symptomatic leiomyomas underwent embolization. Qualification for the procedure included radiological and gynecological evaluation. Patients with fibroids confirmed by magnetic resonance (MR) imaging and symptoms such as abnormal bleeding and compression of other organs were qualified for embolization. The exclusion criteria included pedunculated fibroids, pregnancy, no unequivocal visualization of leiomyomas in MR images. Before UFE, as well as 3 and 12 months after the procedure, MR 1.5 T of the pelvis minor was performed. T1- and T2-weighted images in sagittal, frontal and axial projections before and after intravenous paramagnetic contrast administration were obtained. The volume, location and number of leiomyomas was assessed. The volume was calculated on the basis of MR images according to the formula LxWxDx0.5233 where W, L, D stand for the largest dimensions of the fibroid in three projections. The mean volume of the dominant leiomyoma was 198 cm^3. All the patients underwent assessment of vaginal bacterial flora, levels of βHCG, C-reactive protein, Hb and blood leukocyte count, as well as functional tests of the coagulation system before the procedure. Hystological assesment of endometrium was performed in each patient over 40 years of age.

Embolization of uterine arteries was a typical, fluoroscopy-guided procedure performed under local anesthesia [5]. In 316 patients, a 2.7 F coaxial catheter was used because of narrow, or very tortuous, uterine arteries. A 4 F catheter was used in the remaining patients. Polyvinyl alcohol or trigliceride particles of 350–900 μm diameter were used as the embolization agents.

Subjective assessment of clinical symptoms by the patients was studied by means of a questionnaire with contained the questions concerning:

A. the intensity of: 1) menstrual bleeding 3 months after UFE in comparison with bleeding before the procedure, 2) pollakiuria, 3) constipations, 4) pains in the lumbosacral region, 5) hypogastric pain, 6) feeling of discomfort in the pelvis;

B. satisfaction with the procedure: 1) I am very/moderately satisfied, dissatisfied. 2) I would choose embolization again – yes/no.

Reduction of the dominant leiomyoma size was assessed by MR.

The questionnaire was completed by 964 patients 3 months after UFE, and by 853 patients 12 months after UFE.

Control MR was performed in 964 women 3 months after the procedure and in 853 after 12 months.

A satisfactory result was evidenced by reduced intensity of at least one of the clinical symptoms in combination with the patient's satisfaction with the procedure and reduction of the dominant leiomyoma volume by at least 30% 3 months after embolization.

Results

Satisfactory technical results of embolization – occlusion of the arteries supplying the leiomyomas with blood – was obtained in 983/1000 patients.

In 983 women the embolization procedure enabled occlusion of both uterine arteries. The procedure lasted 23–60 minutes (42min on the average) when standard 4 F catheters were used. In 316 patients, the use of 2.7 F coaxial catheters necessitated by narrow, or very tortuous, uterine arteries, prolonged the procedure time to 60–180 min. Seven patients had only one uterine artery. In one woman it was so tortuous, and in another one so narrow that catheterization was impossible, even with a 2,7F microcatheter. In 67 patients, at least one leiomyoma or over 30% of the dominant one was supplied by the ovarian artheries. In 12 of them, embolization of both uterine arteries failed to reduce pathologic bleeding. Control angiography performed a month later demonstrated that the main source of blood supply to the leiomyoma was the ovarian artery. After its selective embolization (4 patients), normalization of menstrual bleeding was obtained.

In 4 patients the myoma was supplied by the ovarian artery only. No ipsilateral uterine artery was visualized. In such cases, embolization was abandoned and the patients underwent surgical treatment. In 3 patients, the procedure had to be discontinued because of a massive uterine artery spasm, which occurred during catheter insertion. It was performed successfully on the following day after administration of vasodilators.

Satisfactory technical results involving occlusion of the arteries supplying the myoma with blood during the first procedure were obtained in 98% of cases (983/1000).

The questionnaires were completed by 964 women 3 months after treatment, and by 853 pts. 12 months after embolization of the arteries supplying the leiomyomas. The analysis of responses carried out after 3 months demonstrated significant improvement or complete regression of one or more clinical symptoms in 896 out of 964 treated patients (93%), and after 12 months in 716 out of 853 (84%).

After 3 months, 877 out of 964 respondents (91%) were satisfied with the procedure, and after 12 months – 699 out of 853 (82%). Embolization would have been chosen again in 906 out 964 women (94%) after 3 months and 674 out of 853 (79%) after a year.

No confirmation of satisfactory reduction of clinical symptoms after one year was obtained from 154 patients, including:
- 3 with incorrect diagnoses (endometriosis and ovarian tumor),
- 79 (51%) despite reduction of leiomyoma volume (30–50%),
- 19 (12%) with hypertrophic endometrium ingrowth in the reduced leiomyoma, causing spotting of several weeks' duration,
- 17 (11%) patients with reduced dominant leiomyoma volume by >60% after 3 months, in whom the residual part

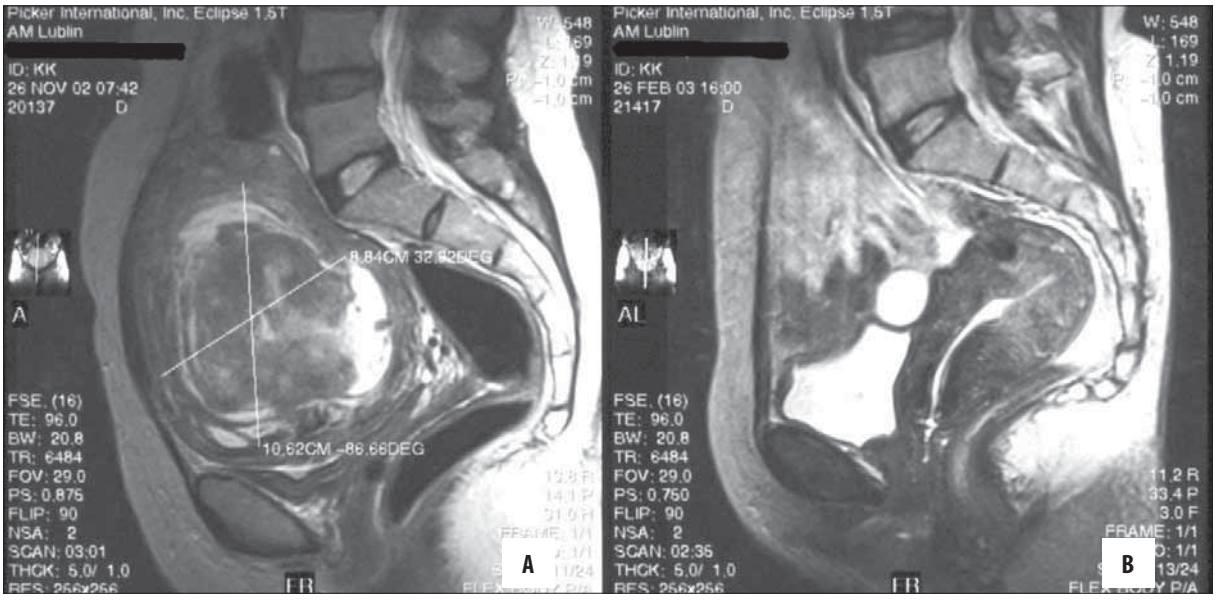

Figure 1. MRI T2-weighted sagittal images before UFE (**A**) and 3 months later (**B**). (**A**) large submucosal fibroid causes urinary bladder compression, abnormal bleeding and anemia (**B**) uterus after transvaginal expulsion.

of the lesion protruded into the uterine cavity and caused endometrial irritation,
- 1 patient with a new leiomyoma 7cm in diameter 3 years after embolization,
- 31 (20%) patients with signs of revascularization of the dominant leiomyoma (incomplete embolization and growth of the tumor portion receiving the residual blood supply),
- 4 patients with coincident malignant tumors developed at least 6 months after the procedure (3 × adenocarcinoma and 1 sarcoma).

This caused spotting from the reproductive organs lasting many days.

No correlations between therapeutic failures and leiomyoma size, location or MR presentation were found. At least 75 patients underwent additional gynecological procedures within 60 months after embolization:
- 19 – hysteroscopic evacuation of necrotic leiomyoma fragments protruding into the uterine cavity, which caused spotting,
- 34 – evacuation of a leiomyoma displaced into the vagina,
- 14 – hysteroscopic resection of hypertrophic endometrium ingrowth in the reduced leiomyoma,
- 4 – hysteroscopic resection of residual leiomyoma fragments before *in vitro* impregnation procedures,
- 4 – pan-hysterectomy.

Despite these additional procedures, 62 out of 75 patients declared satisfaction with the procedure and would have chosen embolization again as a method of leiomyomas treatment.

No hysterectomies were performed within 3 months after UFE.

Reduction of the dominant leiomyoma volume by >30% was seen in MR images in all 964 women 3 months after the procedure.

In 808 out of 853 women, MRI performed 12 months after UFE demonstrated further (>50%) reductions of the dominant leiomyoma volume (Figure 1).

The mean reduction of the largest leiomyoma volume after 3 months approximated 59%, and after 12 months – 81%. The uterine volume was reduced after 3 months by 36% and after 12 months by 42%.

In 84 out of 853 patients (11%), intravenous administration of paramagnetic contrast medium resulted in considerable contrast enhancement within the embolized leiomyomas and clinical symptoms such as increased menstrual bleeding were reported by 35 patients (4%).

Discussion

Satisfactory results of embolization were obtained 3 months after the procedure in 877 out of 964 patients (91%), and 12 months after the procedure in 699 out of 853 treated women (82%). Embolization would have been chosen again by 906 out of 964 women (94%) after 3 months and by 674 out of 853 (79%) after one year.

High technical efficacy of the procedure – 98% (983/1000) and its short duration (most of the procedures lasted ca. 40min) should be emphasized. Consistently with the reports by other authors, most technical problems arising during the procedures were associated with anatomical variations of the arteries providing blood supply to the leiomyomas (7,11,13,14). The possibility of blood supply from the ovarian artery also caused considerable problems. Most frequently the leiomyoma vascularized by the branches of the ovarian artery contained arterio-arterial shunts allowing complete embolization via the catheterized uterine artery. The complex and still not elucidated issue of the effect of ambilization material on the ovarian function extends beyond the scope of a paper concerning the efficacy of UFE.

In 3 cases, no improvement of clinical symptoms resulted from incorrect diagnosis. Despite the use of MRI, 2 patients with endometriosis and one with an ovarian tumors were qualified for embolizationcji [14]. All these women were diagnosed during the first year of embolization practice, and the error rate does not differ from that reported by other authors [10,11,15]. The reasons for no improvement or its transient character in 11 patients were difficult to determine. No correlations between treatment failures and leiomyoma size, location or MR presentation were found. Revascularization of the lesions may result from incomplete embolization due to aggregation of non-spheric particles of the embolization material, which failed to reach one of the small myomas. Since December 2003, our center has been using spheric PVA and triacrylic embospheres which undergo no aggregation during administration. The authors hope that the new technology of embolization material production will allow to avoid similar failures and to increase the efficacy of UFE procedures.

No correlations were found between embolization and development of tumor lesions in 4 patients within 5 years after the procedure. Embolization is not a prophylactic procedure preventing tumors of the reproductive organs. The incidence of intrauterine sarcoma only – 0.13–0.3% was higher than its occurrence in the study group [16,17]. Similarly, numerous cases of additional gynecological procedures performed in as many as 9% of patients (75) were independent of the procedure and unexpected. Many patients explained their dissatisfaction with embolization by pain experienced within 24 h after the procedure (post-embolic syndrome). The course of post-embolic syndrome in those patients was exceptionally severe. One dissatisfied patients associated the vascular approach in the groin with aggravation of her symptoms associated with coincident hip joint pathology.

An abscess, necessitating surgical hysterectomy, is the most serious complication associated with UFE. Its incidence has been estimated to range from 1/100 to 1/700 [9,11]. No hysterectomies due to complications or errors of embolization procedures have been performed in the Lublin center. It was most probably possible to avoid abscesses owing to: a) investigations of vaginal bacterial flora before the procedure, b) written education materials and oral instructions concerning the lifestyle to be maintained for 1 month following the procedure c) availability of phone contact with the surgical team for 12 months after embolization d) high health consciousness level of the treated population (93% of patients had completed academic level education).

The study demonstrated also a considerable discrepancy between satisfactory results of the procedure as assessed by MRI, the clinical symptoms and subjective assessment by the patient.

The problem of revascularization of the embolized myomas seems to be reduced by technological progress – improved embolization materials and microcatheters allowing to avoid vasospasms [18]. Additionally, it should be remembered that the mean age in the treated group was 43 years and moderate revascularization of the lesions, whose size had usually been reduced, led to no aggravation of clinical symptoms in most cases.

The effect of embolization on reproductive function extends beyond the scope of this paper. However, it is worth mentioning that despite the lack of unequivocal data concerning this problem, 30 of our patients gave birth to 32 healthy children. Embolization as an alternative to surgery may prove to be very helpful in case of young women with multiple leiomyomas who cannot be qualified for surgical treatment.

Undoubtedly, the lack of complete data is a disadvantage of the discussed results. The center in Lublin treats with UFE patients from all regions of Poland, and such scatter of that population is unfavorable for MR monitoring. Despite the aforementioned limitations, low invasiveness of the procedure, very high technical efficacy, reaching even 98% and the possibility to qualify over 95% of patients withy uterine leiomyomas confirmed by MR should be emphasized. It allow to expect that the role of embolization of uterine arteries in the treatment of leiomyomas will be increasing [19].

Conclusions

Uterine fibroid embolization is an effective and safe method of treatment of symptomatic leiomyomas.

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