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CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

Uterine Artery Embolisation for Symptomatic Adenomyosis with Polyzene F-Coated Hydrogel Microspheres: Three-Year Clinical Follow-Up Using UFS–QoL Questionnaire

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Abstract
Purpose This study was designed to assess midterm outcome of uterine artery embolisation (UAE) for women with therapy-resistant adenomyosis using polyzene F-coated hydrogel microspheres.
Methods Between September 2006 and January 2010, 29 consecutive women with adenomyosis (15 in combination with fibroids) were treated with UAE using polyzene F-coated hydrogel microspheres. Junction zone thickness was assessed with MRI at baseline and 3 months. Women filled out the uterine fibroid symptom and quality of life questionnaire at baseline, 3 months and after a mean clinical follow-up of 37 months (median 35, range 29–64 months).
Results At baseline, symptom severity score of 29 women was mean 67 (median 72, range 23–100). At 3 months, this score decreased to mean 22 (median 15, range 0–66) and mean 15 (median 17, range 0–34) at final follow-up. At final follow-up of mean 37 months (median 35, range 29–64 months), 22 of 29 (76 %) patients were asymptomatic. Of these 22 women, 3 underwent a second UAE at 6, 7, and 14 months. The remaining seven patients clinically improved but still had symptoms; one underwent a hysterectomy. There was no difference in outcome between women with pure adenomyosis and women with additional fibroids. The junction zone of 4 women with additional therapy was significantly thicker compared with the remaining 25 patients.
Conclusions In women with therapy resistant adenomyosis, UAE using polyzene F-coated hydrogel microspheres resulted in 3 years preservation of the uterus in 28 of 29 (97 %) with good clinical outcome in the vast majority of patients. Initial thickness of the junction zone is related to additional therapy.

Keywords Clinical practice · Arterial intervention · Embolisation · Urogenital

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Introduction

Adenomyosis of the uterus is defined as the presence of ectopic endometrial glands and stroma within the myometrium [1]. This benign disease occurs as a single entity or in combination with uterine fibroids. Clinical symptoms of adenomyosis are similar to those of fibroids and include menorrhagia, dysmenorrhea, and dyspareunia. Adenomyosis

is a common disease in premenopausal women with an estimated prevalence of 20 %. After menopause, the disease is self-limiting. Clinical diagnosis can be confirmed with transvaginal ultrasound (TVUS) or magnetic resonance imaging (MRI), showing enlargement of the uterus with a thickened junction zone with or without the presence of fibroids. Treatment options consist of hormonal therapy and endometrial ablation. However, when these therapies fail, hysterectomy may be considered as a definitive treatment [2].

Uterine artery embolisation (UAE) for adenomyosis was considered controversial by some authors since recurrence of symptoms has been observed in small case series [3, 4] using polyvinyl alcohol (PVA) particles with a diameter of 355–500 μm. However, years later, UAE has emerged as an effective alternative therapy for adenomyosis with preservation of the uterus [5–7].

Being a referring center for symptomatic fibroids, we improved our experience in UAE and extended the indication to fibroids accompanied with adenomyosis or in women with pure adenomyosis. In the past, we used various embolic agents (plugs, pledgets, (non-)spherical particles) for UAE. In the belief that good results were related to necessary deep infarction of adenomyosis and the advent of the color-coded narrow-size tightly calibrated 500 μm polyzene F-coated hydrogel microspheres (Embozene®), we hoped to further increase the procedural safety, optimize the embolisation procedure with improvement of deep penetration for optimal infarction of adenomatous tissue [8].

In this study, we present the mid-term outcome of 29 patients with adenomyosis with or without fibroids embolized with calibrated polyzene F-coated hydrogel Embozene microspheres.

Materials and methods

Patients

The Institutional Review board approved this observational study with a waiver for informed consent. We prospectively evaluated 234 symptomatic women between September 2006 and January 2010, referred by the gynecologists as candidates for UAE with heavy menstrual bleeding, pelvic pain, and bulk related symptoms, or a combination of these symptoms. All patients underwent baseline MRI and completed the standardized symptom severity and health-related quality of life questionnaire [uterine fibroid symptom and quality of life (UFS–QoL)] on the day of the diagnostic MRI [9, 10]. Of these 234 women, 29 (12 %) consecutive symptomatic women with pure adenomyosis or adenomyosis with fibroids were confirmed with MRI and included in the study.

The inclusion criteria were women with therapy-resistant adenomyosis with or without fibroids suffering from heavy menstrual bleeding, pain, or bulk related symptoms, or a combination. Exclusion criteria for UAE were pregnancy, suspicion or presence of a malignancy or infection, already infarcted fibroids, postmenopausal status, asymptomatology, and women who wished to conceive.

All 29 women (mean age 42.1 years; median 45, range 29–64) underwent UAE. Race distribution was Caucasian in 24, African in 2, and Asian in 3. Of 29 women, 14 had pure adenomyosis and 15 had adenomyosis in combination with fibroids. Diagnosis was established clinically and confirmed with MRI. Main presenting symptoms of the 29 women with adenomyosis were dysmenorrhea in 25 (86 %), menorrhagia in 22 (76 %), and bulk related symptoms in 8 (28 %). In all women, therapy with progestogens, haemostatic agents, or gonadotrophin-releasing hormone agonists had insufficient clinical response. In women who sought to preserve the uterus, embolisation was offered as treatment to relief clinical symptoms.

MRI at baseline and 3 months follow-up

MRI consisted of T2- and T1-weighted contrast-enhanced images and was performed before embolisation and at 3-month follow-up. The following standardized criteria were used for diagnosis of adenomyosis: low myometrial signal intensity on T2-weighted images, diffuse or focal thickening of the junction zone exceeding 12 mm with or without high signal-intensity foci corresponding to myometrial cysts [11–14]. At 3 months follow-up, the decrease in junction zone was measured on the posttreatment MRI. MRI was used to assess the uterine volume at baseline and 3 months follow-up using the formula of an ellipsoid. In addition, infarction percentage of fibroids and uterus was estimated by eye-balling.

UAE embolisation

UAE was performed after selective catheterization of both uterine arteries via an unilateral or bilateral approach according to the standard of care [15–17]. Embolisation was performed through a microcatheter (EmboCath, Merit Medical Systems, South Jordan, UT) using 500 μm (±700/900) calibrated polyzene F-coated hydrogel microspheres (Embozene, Celonova Bio Sciences, San Antonio, TX, USA). The main reason to choose these microspheres is the availability of exact size calibration. In adenomyosis, the afferent arterioles are generally somewhat smaller than in the perifibroid plexus. Therefore, embolisation was started with Embozene 500 μm to first block these smaller vessels. Subsequently, embolisation was continued with Embozene 700 μm followed by Embozene 900 μm when judged

Table 1 Clinical and MR imaging results at baseline, 3 months and final follow-up (mean 37 months) after UAE in women with symptomatic adenomyosis with or without fibroids

Women with adenomyosis with or without fibroids ($n = 29$) 14 women: pure adenomyosis 15 women: adenomyosis mixed with fibroids			
	Baseline	3 months follow-up	Final follow-up
Symptom severity score			
Pure adenomyosis (average)	73	23	17
Adenomyosis mixed with fibroids (average)	60	21	13
Overall (average, median, range)	67 (72; 23–100)	22 (15; 0–66)	15 (17; 0–34)
HR–QoL score			
Pure adenomyosis (average)	42	82	80
Adenomyosis mixed with fibroids (average)	58	87	95
Overall (average, median, range)	51 (51; 20–88)	85 (91; 55–100)	88 (99; 29–100)
Junction zone thickness (mm) (average, median, range)	24 (20; 12–50)	15 (10; 7–42)	Not applicable
Uterus volume (cc)			
Pure adenomyosis	214	162	Not applicable
Adenomyosis mixed with fibroids	351	231	Not applicable
Fibroid infarction rate (%)	0	97 (70–100)	Not applicable

necessary. The end point of embolisation was until complete stasis of contrast in the distal ascending segment of the uterine artery on both sides. Blockage of the microcatheter by the microspheres and complications were recorded. During and after UAE, intravenous narcotics with the use of a patient controlled analgesia (PCA) pump, antiemetic, and nonsteroidal anti-inflammatory drugs were administered for adequate pain control and to reduce symptoms, such as mild fever, nausea, and vomiting [18]. One hour before UAE, all patients received 1 gram of a broad-spectrum antibiotic as a profylax (Cefazoline, Kefzol, Eurocept, Ankeveen, the Netherlands).

Clinical assessment at baseline and follow-up

Baseline clinical status was assessed using a standardized questionnaire (UFS–QoL) consisting of a symptom severity score and health-related quality of life score. The UFS–QoL consists of an 8-item symptom severity scale containing questions addressing topics, such as menstrual bleeding characteristics, pelvic pain, urinary discomfort, and fatigue, with 29 health-related quality of life items comprising 6 domains: concern, activities, energy/mood, control, self-consciousness, and sexual function [9, 10]. The same questionnaire was used at 3 months follow-up and final follow-up at mean 37 months, in February 2012. Women with a symptom severity score <20 in combination with an overall health-related QoL score >80 were considered asymptomatic. In patients with additional UAE or hysterectomy during follow-up, timing was recorded.

Statistical analysis

Summary descriptive statistics were used for demographic parameters. Complications of UAE were expressed as a proportion with 95 % confidence interval (CI).

In women with additional UAE or hysterectomy during follow-up, mean junctional zone thickness on MRI at 3 months was calculated as a proportion of baseline value and compared with women with UAE as a single therapy. Uterine volume reduction 3 months after UAE was compared in patients with pure adenomyosis and adenomyosis with fibroids. In addition, overall fibroid infarction was calculated as a proportion from baseline value.

χ^2 test was used for proportions and unpaired Student's t test was used for comparison of means; $P < 0.05$ was considered significant. Statistical analysis was performed with MedCalc statistical software (Med-Calc, Mariakerke, Belgium).

Results

Uterine artery embolisation

All embolisations were technically successful. Blockage of the microcatheter by the embolic agent did not occur. One patient developed a false aneurysm of the femoral artery postembolisation that was treated with thrombin injection. During a mean follow-up of 37 months (range 29–64), two women (both age 41 years) had transient amenorrhea and four women (aged 40, 43, 46, 48 years) developed

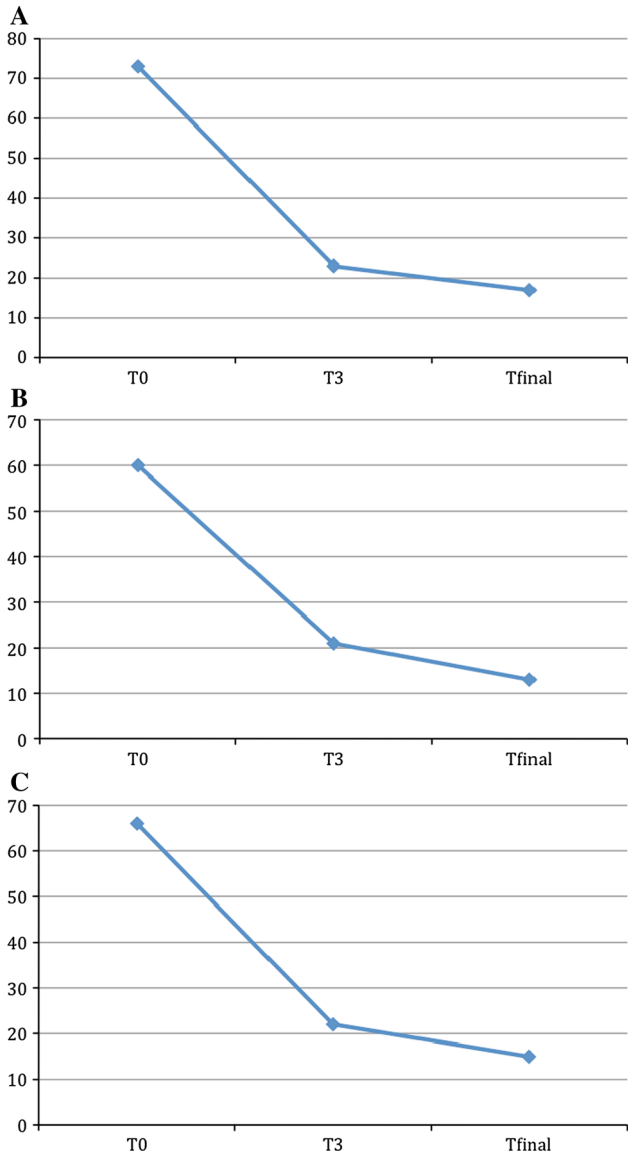

Fig. 1 Average symptom severity scores over time for women with pure adenomyosis, mixed with fibroids, and overall; at baseline (T0), 3 months follow-up (T3), and final follow-up 37 months (Tfinal). **A** Women ($n = 13$) with pure adenomyosis (including the patient who underwent a second embolisation and excluding the patient who underwent hysterectomy). **B** Women ($n = 15$) with adenomyosis in combination with fibroids (including the two patients who underwent a second embolisation). **C** Overall ($n = 28$) excluding the patient who underwent hysterectomy

permanent amenorrhea. Two women with pure adenomyosis experienced early uterine infections that were treated with antibiotics in both and curettage in one.

Clinical results

An overview of clinical results is provided in Table 1. At baseline, the symptom severity score of 29 women was mean 67 (median 72, range 23–100). At 3 months, this score decreased to mean 22 (median 15, range 0–66) and mean 15 (median 17, range 0–34) at final follow-up (Fig. 1). At final follow-up of mean 37 months (median 35, range 29–64 months), 22 of 29 (76 %) patients had symptom severity scores <20 in combination with overall health-related quality of life scores >80 indicating they were asymptomatic. Of these 22 women, 3 had a second UAE at 6, 7, and 14 months. The remaining 7 of 29 patients clinically improved but still had symptoms. One of these seven women underwent a hysterectomy at 17 months. The other six patients sought no additional treatment because of mild symptoms with symptom severity scores between 21 and 34 and health-related quality of life scores between 56 and 78. These symptoms did not interfere with daily activities. There was no difference in clinical outcome between women with pure adenomyosis and women with additional fibroids. There was a negative correlation with significant difference of the symptom severity and health-related quality of life score between the four patients who needed additional therapy (3 for repeat UAE and 1 hysterectomy) versus the six patients without additional therapy in the group of patients with insufficient response.

MRI results

Mean junction zone thickness at baseline was 24 mm (median 20, range 12–50 mm) and at 3 months 15 mm (median 10, range 7–42 mm; Table 1). Mean junction zone reduction was 9 mm (38 %). There was no difference in mean junction zone thickness reduction between patients with pure adenomyosis or combined with fibroids.

Mean junction zone thickness at baseline for the ten patients with insufficient clinical response (including 3 women who underwent repeat UAE, 1 woman a hysterectomy, and 6 women with improvement but remaining symptoms) was 28 ± 14 mm, and for 19 patients with favourable clinical response this was 22 ± 9 mm. This difference was not significant ($P = 0.17$).

However, the mean junction zone thickness of 4 patients that needed additional therapy at follow-up was 38 ± 16 mm and of the remaining 25 patients this was 21 ± 9 mm. This difference was significant ($P = 0.004$).

Mean overall fibroid infarction rate was 97 % (range 70–100 %), and mean volume reduction of the uterus was 34 % (from 351 to 231 cm^3). In the patients with pure adenomyosis, the uterine volume decreased with 25 % (from 214 to 162 cm^3; Table 1).

Discussion

In this study, we found that in the vast majority of women with therapy-resistant adenomyosis, UAE with the use of

polyzene F-coated hydrogel microspheres results in preservation of the uterus. All patients with preserved uterus were either cured or clinically improved according to health-related QoL. Initial thickness of the junction zone was a predictor of clinical response to UAE: substantial thicker junction zones on baseline MRI were apparent in patients with repeat UAE or hysterectomy. The presence or absence of fibroids additional to the adenomyosis had no relation to clinical outcome.

Polyzene F-coated hydrogel microspheres (Embozene®) have been used in patients with symptomatic fibroids with good clinical results [19]. This study demonstrated that Embozene microspheres can be used with similar good clinical response in patients with symptomatic adenomyosis.

Examples of embolic agents available for UAE may be categorized in three groups. Group A comprises the embolisation plug or pledget, such as Spongostan or Gelfoam. Group B with irregular-shaped PVA particles, e.g., Contour (Boston Scientific, Natick, MA, USA) and Ivalon (Cook Medical, Bloomington, IN, USA). Group C comprises the embolisation microspheres with examples, such as spherical-shaped PVA Contour SE (Boston Scientific), spherical acrylamido PVA BeadBlock (Biocompatibles Inc., Oxford, UK), tris-acryl gelatin microsphere EmboSphere (Merit Medical Systems Inc.), and the polyphosphazene-coated hydrogel Embozene microsphere (CeloNova Biosciences Inc.). The group A embolic agents are primarily used in case of postpartum bleedings treated with emergent proximal UAE for cessation of blood flow. Group B is used for UAE in treating uterine fibroids with or without adenomyosis with more distal UAE with permanent occlusion of feeding vessels and intentional infarction of the area. In relation to groups A and B, group C represents the more calibrated embolic agents, with smooth surfaces, slightly compressible and elastic to prevent (micro-)catheter clogging and the advantage of more selective, reliable, and consistent distal occlusion of uterine artery branches of the perifibroid plexus and the deep penetrating tiny branches of the adenomatous tissue in the uterine stroma aiming complete infarction [7, 20, 21]. In comparison to the other group C embolics, Embozene is the most tightly calibrated narrow-size spherical agent in group C, available in various specific sizes from 40 to 1,300 μm, with no (micro-)catheter clogging and the advantage of more selective and targeted embolisation [22]. Their uniform size and shape, their constant compressibility, and elasticity results in deeper penetration into the small arterioles. This spherical embolic agent is color-coded for each size, thus highly visible through the syringe for instant size confirmation during the embolisation procedure to improve procedural safety.

During the past 10 years, UAE has been investigated as a possible therapy for adenomyosis. The results of this study are in concordance with previous published results of UAE for adenomyosis. In a study by Kim et al. [23], who used particle PVA 250–355–(500–710) μm and gelatine sponge plugs, until complete stasis, the clinical success of UAE after 3.5 years was achieved in 50 of 54 women (93 %) and 31 women (57 %) were still asymptomatic. During the follow-up period, five women underwent hysterectomy for recurrence of symptoms. In a small case series of 18 patients by Pelage et al. [6], who used PVA or tris-acryl gelatin sponge microspheres in the range of 500–900 μm, until near stasis, most patients had improvement or cure of symptoms, and 5 (28 %) patients underwent hysterectomy at various time intervals during follow-up. In a study of 30 patients by Jha et al. [13], who used PVA 355–500 μm, good outcome was reported in all patients after 1-year follow-up. Froeling used sizes ≥500 μm spheres reported good clinical response in 29 of 40 women (72.5 %) after a mean follow-up of 40 months. Like in our study, Froeling et al. [24] found no difference in outcome between patients with pure adenomyosis and with concomitant fibroids. Most studies concerning the subject comprise mostly small case series with variable follow-up.

In the meta-analysis by Popovic et al. [25], the results of 15 studies comprising 511 patients with adenomyosis were summarized. Improvements were reported by 387 patients (75.7 %). The median follow-up was 26.9 months. Short-term outcomes regarding symptom relief after UAE for pure adenomyosis and adenomyosis with uterine leiomyomas ranged from 83.3 to 92.9 %. In the long-term, patients reported symptomatic improvement of 64.9 % in pure adenomyosis and 82.4 % in adenomyosis with leiomyomas.

The most widely used embolic agent is nonspherical PVA particles ranging 255–900 in size [25]. More recently, however, more and more interventional radiologists prefer the use of spherical embolics, such as polyzene F-coated hydrogel Embozene microspheres in this study. Spherically shaped particles were introduced into the armamentarium of embolisation to overcome disadvantages of irregularly shaped particles, such as promotion of catheter clogging, incomplete occlusion of the target vessels, and unpredictable behaviour. In contrast to this, spherically shaped particles should provide a more predictable and controlled targeted vessel occlusion because of better size calibration and more complete and permanent vessel occlusion [8]. The current available data do not seem to indicate a preferred embolic agent for use in women with symptomatic adenomyosis. Although in part on speculation, deep penetration with the embolic agent seems to be needed for optimal infarction of areas of adenomyosis [7, 20, 21].

In the meta-analysis, various types of embolic agents were used and the incidence of permanent amenorrhea was reported in 3 studies comprising 62 patients. Thirteen

patients (20.9 %), all older than age 45 years, developed permanent amenorrhea after UAE. The incidence in our study (13.8 %, 4/29) is in the same range. Transient or permanent amenorrhea after UAE in fibroids has been reported as a result of partial nontarget embolisation of the ovaries and subsequent reduction in ovarian reserve. Amenorrhea is seen in 2–5 % of women after embolisation of fibroids; permanent amenorrhea occurs in <2 % of women, nearly all of whom are of perimenopausal age [26]. The slightly higher percentage of permanent amenorrhea after UAE, due to nontargeted embolisation of the ovaries through a uterine–ovarian shunt, in women with adenomyosis might be explained by the embolisation technique in two ways. In general, slightly smaller embolic agents (e.g., 500 μm instead of ≥700 μm Embozene microspheres for women with fibroids only) are used to occlude the smaller arterioles for adequate infarction of adenomyosis and the angiographic embolisation endpoint is until full stasis (as opposed to near stasis in women with uterine fibroids). It must be emphasized that especially young women who suffer from adenomyosis and who desire pregnancy should be properly counseled about the incidence of premature menopause.

Recent studies tried to identify MRI predictors for clinical response of UAE in patients with symptomatic adenomyosis [5, 13, 14, 23]. Decrease of uterine volume and junction zone thickness and infarction pattern after UAE were inconsistently observed in women with and without favourable clinical response. Therefore, follow-up MR is of limited value in prediction of clinical outcome. However, MRI may be helpful to diagnosis adenomyosis and assess concomitant fibroids. In concordance with the findings by Smeets et al. [21], we observed that a thick junction zone at baseline is a risk factor for additional therapy, which is important when counseling patients before UAE. Patients with a thick junction zone may be informed about the lower chance of clinical success.

Evolution of symptoms is the most important parameter in the follow-up after UAE. MRI follow-up may not be necessary in patients with sufficient improvement of symptoms. However, in patients with insufficient clinical response, MRI can be helpful in guiding clinical decision making to compare thickness of the junction zone, uterine volume, and other parameters with baseline findings.

Our study has several limitations. First, there were a small number of patients despite more than 3 years of recruitment. Therefore, strong conclusions may not be drawn about what type of adenomyosis may respond best and the implications of devascularized areas after UAE. Secondly, although we subdivided women in subgroups, the study group is not homogenous with pure adenomyosis, adenomyosis dominance with fibroids in various sizes, numbers, and locations of fibroids or fibroid dominance with adenomyosis. A third limitation is the absence of long-term data with 5-year follow-up; as a result we cannot comment on the long-term durability of UAE like Smeets et al. [21] already reported. To further improve the level of evidence for UAE in women with symptomatic adenomyosis, a large, randomized, controlled trial would be ideal to provide physicians and patients more information for decision making.

Conclusions

Our mid-term follow-up results of patients with adenomyosis embolized with Embozene microspheres confirmed good clinical outcome of previous studies. We found no difference in clinical outcome between women treated with UAE for pure adenomyosis or in combination with fibroids. MR imaging is helpful in diagnosis of adenomyosis and assessing the thickness of the junction zone. A thick junction zone at baseline seems to be a predictor of additional therapy after UAE.

Conflict of interest Nijenhuis, Smeets, Morpurgo, Boekkooi, Reuwer, Smink, and van Rooij has no conflict of interest. Lohle Consultant for Celonova Bio Sciences, San Antonio, TX.

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