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Conservative two-step procedure including uterine artery embolization with embosphere and surgical myomectomy for the treatment of multiple fibroids: Preliminary experience

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ABSTRACT

Objective: To evaluate the feasibility and safety of combined uterine artery embolization (UAE) using embosphere and surgical myomectomy as an alternative to radical hysterectomy in premenopausal women with multiple fibroids.
Materials and methods: Mid-term clinical outcome (mean, 25 months) of 12 premenopausal women (mean age, 38 years) with multiple and large symptomatic fibroids who desired to retain their uterus and who were treated using combined UAE and surgical myomectomy were retrospectively analyzed. In all women, UAE alone was contraindicated because of large (>10 cm) or subserosal or submucosal fibroids and myomectomy alone was contraindicated because of too many (>10) fibroids.
Results: UAE and surgical myomectomy were successfully performed in all women. Myomectomy was performed using laparoscopy ($n=6$), open laparotomy ($n=3$), hysteroscopy ($n=2$), or laparoscopy and hysteroscopy ($n=1$). Mean serum hemoglobin level drop was 0.97 g/dL and no blood transfusion was needed. No immediate complications were observed and all women reported resumption of normal menses. During a mean follow-up period of 25 months (range, 14–37 months), complete resolution of initial symptoms along with decrease in uterine volume (mean, 48%) was observed in all women. No further hysterectomy was required in any woman.
Conclusion: In premenopausal women with multiple fibroids, the two-step procedure is safe and effective alternative to radical hysterectomy, which allows preserving the uterus. Further prospective studies, however, should be done to determine the actual benefit of this combined approach on the incidence of subsequent pregnancies.

1. Introduction

The treatment of uterine fibroids depends on several parameters, which include presenting symptoms, location and size of fibroids as well as number of fibroids present. In addition, because uterine fibroids are found in up to 45% of pre-menopausal women [1] a number of patients desire to retain their uterus to not preclude future pregnancies. In this regard, whereas radical hysterectomy is still the standard treatment for large or multiple fibroids in post-menopausal women, conservative surgical myomectomy in now commonly offered in women wishing to retain fertility [2]. However, conservative surgical myomectomy is not always feasible because too many fibroids are present so that radical hysterectomy is the single therapeutic option.

Since the initial description of uterine artery embolization (UAE) for the treatment of uterine fibroids [3], the procedure has gained wide acceptance as its results in lesser invasiveness and post procedural discomfort by comparison with surgical hysterectomy [4] and because clinical results with respect to bleeding, pelvic pain and bulk-related symptoms are excellent [5,6]. Although initially specifically restricted to women with fibroids without desire of future pregnancy because of concerns about radiation, potential ovarian dysfunction and further pregnancy outcome, UAE is now offered to women who are keen to have conservative treatment in order to maintain future reproductive capabilities [7]. However, the use of UAE is limited by the presence of specific contraindications, which include subserosal or submucosal fibroids and presence of large fibroids (i.e., larger than 10 cm) [8–10].

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In women with too many fibroids for whom conservative myomectomy cannot be done, it is not rare to have coexisting large or subserosal or submucosal fibroids of which presence precludes UAE. As a consequence, a conservative treatment using a single technique cannot be considered and radical hysterectomy is the single option that can be offered. To overcome the respective limitations and contraindications of UAE alone and surgical myomectomy alone, we assumed that a combined procedure including definitive UAE and selective surgical myomectomy might be an appropriate approach [11]. Accordingly, we report our experience involving 12 women with multiple and large fibroids for whom either UAE alone or surgical myomectomy alone could not be performed and who were treated with a two-step procedure because they wished to retain fertility with a hope to conceive.

The goal of this study was to evaluate the feasibility and safety of the combination of UAE using embosphere and surgical myomectomy as an alternative to radical hysterectomy in premenopausal women with multiple fibroids very keen to have conservative management.

2. Methods

This retrospective study was conducted according to the guidelines of our institutional review board. Written informed consent was obtained from the patients, who agreed to have their personal medical and imaging data used for research purpose.

2.1. Patients

From January 2007 to October 2007, 12 women with a mean age of 38 years (range, 31–42 years) had a two-step procedure for the treatment of multiple and large symptomatic fibroids. Fibroids-related symptoms were menometrorrhagia with clotting in seven women (7/12; 58%), pelvic pain with fullness and frequent urination in three women (3/12; 25%), and an association of both symptoms in two women (2/12; 17%). All women had more than 10 fibroids, with at least one of more than 10 cm in diameter. In addition, nine women had subserosal fibroids, two had submucosal fibroids and one woman had one of each.

During the dame period, 45 women had UAE alone and 67 women had surgery alone for the treatment of uterine fibroids.

2.2. Pretherapeutic evaluation

MR Imaging - All MR examinations were performed with the same protocol, using a 1.5-T clinical MR unit (Magnetom Avanto, Siemens Healthcare, Erlangen, Germany) with 18 receiver channels, using one anterior torso phased-array coil with 6 channels and two posterior spine clusters with 3 channels each, with the patient in supine position. The gradient strength of the magnet was 45 mT/m with a maximal gradient slope of 200 mT/m. All patients had T2-weighted fast spin-echo (T2WFSE) and T1-weighted three-dimensional gradient echo (3D VIBE) sequence. No specific bowel preparation was used before MR examination and no antispasmodic agents were given to the patients. The patients voided immediately before the start of MR study.

T2WFSE MR images were obtained in the axial and sagittal planes, with and without fat-suppression with the following parameters: repetition time (TR), 6140 msec; echo time (TE), 143 msec; matrix size, 384×384; section thickness, 6 mm; intersection gap, 1.2 mm; voxel size, $0.8 \times 0.8 \times 6.0\,mm^3$; field of view 300–340 mm; number of signal averages, one; parallel imaging (GRAPPA, with acceleration factor of 2); echo train length, 26; echo spacing, 11.9 msec; receiver bandwidth, 129 Hz/pixel; 20 axial sections acquired; acquisition time, 120 sec; acquisition time, 2 min 46 sec.

T1-weighted MR images were obtained in the axial and sagittal planes with fat-suppression, with the following parameters: repetition time, 5.9 msec; echo time, 2.4 msec; flip angle, 15°; matrix size, 174×192; section thickness, 1.8 mm; voxel size, $1.5 \times 1.5 \times 1.8\,mm^3$; field of view 280–300 mm; number of signal averages, one; parallel imaging (GRAPPA, with acceleration factor of 2); 88 axial partitions acquired; acquisition time, 26 sec.

2.3. Image analysis and therapeutic decision

After clinical examination, MR images were prospectively interpreted by two interventional radiologists and two gynecologists working in consensus. MR images were analyzed with respect to number, size and location of each fibroid using a PACS viewing station (Directview, 10.1 sp1 version, Kodak-Carestream Health Inc, Rochester, NY, USA).

Number of visible fibroids was tabulated. Uterine and fibroid volumes were determined with the following formula $A \times B \times C \times 0.52$ where A, B, and C represent the dimensions in the three orientations assuming that the uterus and the fibroids had an ellipsoid shape. Each visible fibroid was categorized as submucosal, intramural, or subserosal according to a well-established classification [12]. In addition, submucosal and subserosal fibroids were further classified as pedunculated or not pedunculated [12]. The presence of diffuse or focal widening of the junctional zone with a width of more than 12 mm was considered as indicating adenomyosis [13].

The indications for each therapeutic approach were determined in a standardized fashion. When five or less than five fibroids were present, surgical myomectomy was the preferred option. Hysteroscopic resection was considered for any pedunculated submucosal fibroid and for submucosal fibroids with a diameter less than 5 cm, when the thickness of the posterior myometrial wall was more than 4 mm [14]. Laparoscopic myomectomy was considered when three or less intramural or subserosal fibroids with a cumulated diameter of less than 9 cm were present [15,16]. Open laparotomy was considered when at least one intramural or subserol fibroid of more than 10 cm in diameter was present. When more than five fibroids were present, UAE was the preferred option [6]. The presence of at least one subserosal or submucosal fibroid of more than 10 cm in diameter was a contraindication for UAE alone because of the potential risk of bowel necrosis or further vaginal discharge [9,17]. Adenomyosis was considered as contraindication for UAE for women over 35 years, and surgery was preferred [18].

After therapeutic strategies were determined by the gynecologists and the interventional radiologists, the potential risks and advantages of surgical myomectomy alone, UAE alone and the combination of both approaches were then discussed with the patients.

2.4. Procedures

Embolization.- UAE was performed by two interventional radiologists with experiences in pelvic embolization of 8 and 17 years.

All procedures were performed with the same protocol via a right-sided unifemoral catheterization, using a 5-French cobra-shaped end-hole catheter (Cobra® Radifocus, Terumo Corporation, Tokyo, Japan) and a hydrophilic polymer-coated 0.032-inch angled soft guide wire (Radifocus, Terumo Corporation) after placement of a 5-F introducer (Introducer II Radifocus, Terumo Corporation, Tokyo, Japan). Angiographic studies were obtained with iodixanol (Visipaque® 270, GE Healthcare, Pistacaway, NJ). Because of concerns regarding patients radiation exposure, aortography was not performed [19]. Contrast material was injected by hand. Oblique projections were obtained in all procedures.

Bilateral internal iliac artery angiography was made to localize the origin of the uterine arteries in all women. Catheterization of the uterine arteries was obtained with the help of digital road map guidance, using a coaxial 2.7- French micro catheter (Progreat® Radifocus, Terumo Corporation) in association with a hydrophilic polymer-coated 0.014-inch soft guide wire (Whisper® Hi-torque, Abbott Laboratories, Abbott Park, Illinois, USA). The embolic material used for all women was 500–700 μm and 700–900 μm diameter gelatine-coated trisacryl microspheres (Embosphere; Biosphere Medical, Rockland, Ma, USA) that were introduced under fluoroscopic control. The 5-F introducer was removed immediately after UAE. All women were closely monitored during the 24 h following the procedure and had repeated clinical examinations by the obstetrician and the interventional radiologist. The endpoints of UAE were to achieve devascularization of the perifibroid plexus of all visible fibroids during angiography, and to obtain bilateral stasis of the flow in the distal portion of uterine arteries along with decrease of the flow in the proximal portion of the uterine arteries.

Myomectomy. – Surgical myomectomy was performed the same day, one day or two days after UAE by a panel of four different gynecologists who decided on the best surgical approach among hysteroscopic resection, laparoscopic resection or resection during open laparotomy on the basis of MR imaging findings. Only fibroids, for which potential complications following UAE were anticipated because of their subserosal or submucosal location, were removed. Hysteroscopic approach was the favored option for submucosal fibroids with a diameter less than 5 cm. Laparoscopic myomectomy was favored for subserosal fibroids with a diameter less than 10 cm. Open laparotomy was decided for any other situation.

Laparoscopic myomectomy was performed after incision using a monopolar electrode. After fibroids were enucleated, suturing of the myometrium was performed with an individual stitch of Vicryl 0 or 1. When needed, coagulation of bleeding sites was done using bipolar forceps. Hysteroscopic myomectomy was performed with rigid resectoscope after cervical dilation using Hegar dilators. The uterine cavity was distended with a nonconductive hypotonic solution instilled under manometric control. Resections were performed using monopolar-cutting loop, and fibroids were shaved gradually until complete resection.

2.5. Procedure and Follow-up Evaluation

Intraoperative blood loss was evaluated by comparing serum hemoglobin levels before and the day after the two-step procedure. Each complication was recorded as its occurred during the hospital stay. Existence of fever or any other complication was reported, as well as the duration of hospital stay.

After discharge, all women had oral and written instructions to call either the interventional radiologist or the gynecologist should any adverse events or complications be noticed. All women underwent gynecologic assessment at regular intervals. Each woman was prospectively followed-up clinically for a minimum of 14 months after the two-step procedure. Clinical data were collected at approximately 3 months, 6 months, 12 months for all women, two years for 8 women, and three years for 5 women. If any, postoperative complications and fibroids-related symptoms were noted, as well as return to normal menses. In addition, all women had MR imaging at intervals that mirrored those of clinical evaluation after the procedure to determine the degree of infarction of fibroids treated with UAE as well as uterine volume reduction. The same MR protocol as described above was used in all patients with an additional gadolinium chelate-enhanced T1-weighted MR sequence, using intravenous administration of 0.1 mmol of gadopentetate dimeglumine (Gd-DOTA, Dotarem®, Guerbet, Roissy, France) per kilogram of body weight followed by a 20 mL saline flush, at an injection rate of 2 mL/sec, using a power injector (Optistar®; Mallinckrodt, Cincinnati, OH, USA).

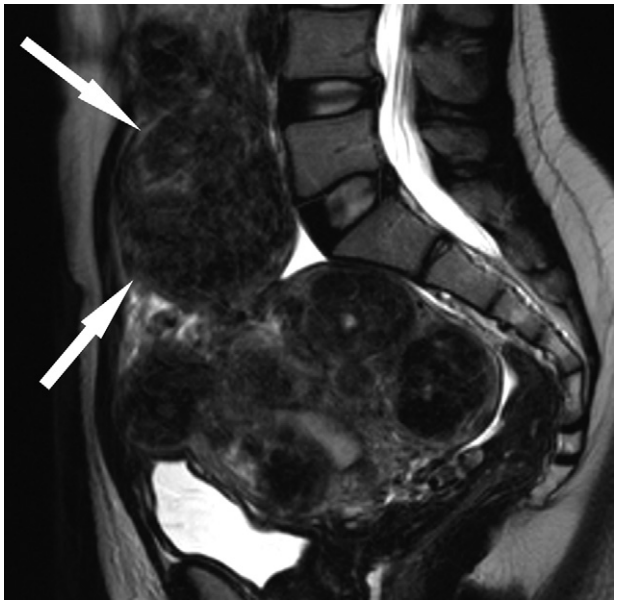

Figure 1. 36-year-old woman with multiple uterine fibroids, complaining from menometrorrhagia with clotting. T2-weighted fast spin-echo MR image in the sagittal plane shows multiple intrauterine fibroids in association with a large, protruding subserosal fibroid (arrows). The subserosal fibroid was resected using laparoscopic myomectomy while the intrauterine fibroids were left in place and treated with uterine artery embolization.

3. Results

3.1. Short-term outcome

On the basis of MR imaging findings, UAE alone was contraindicated in all women: Nine women had extrauterine, pedunculated subserosal fibroids (Fig. 1), two women had intracavitary, pedunculated submucosal fibroids (Fig. 2) and one woman had both subserosal and submucosal pedunculated fibroids. Similarly,

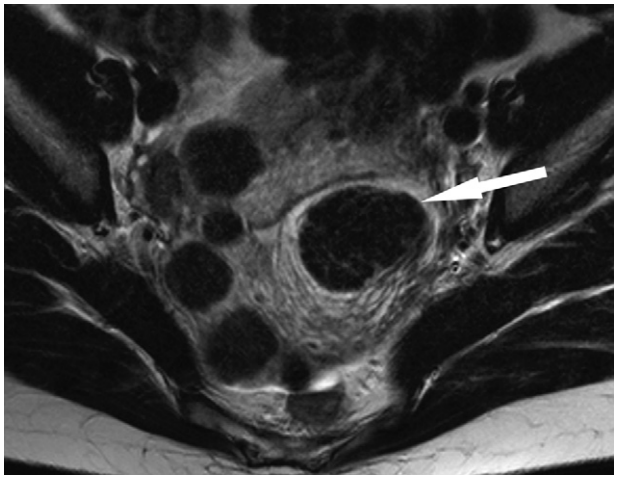

Figure 2. 38-year-old woman with multiple uterine fibroids, complaining from menometrorrhagia with clotting. T2-weighted fast spin-echo MR image in the axial plane shows multiple intrauterine fibroids in association with a submucosal fibroid (arrow). The submucosal fibroid was resected hysteroscopically while the intrauterine fibroids were left in place and treated with uterine artery embolization.

surgery alone was contraindicated in all women because of the presence of more than 10 fibroids. The mean initial uterine volume was 519 $cm^3 \pm 536\ cm^3$ (SD) (range, 95 –2196 cm^3).

Bilateral and definitive UAE was successfully performed in all women without any complications during the procedure. Mean UAE time was 62 min (range, 45 –95 min).

Myomectomy was performed the same day than UAE in six women, one day after in four and two days after in two. Laparoscopy alone was performed in six women, laparotomy alone in three, hysteroscopy alone in two, and the association of laparoscopy and hysteroscopy in one woman. Mean operating time was 86 min (range, 20–220 min). Mean number of removed fibroids was 2 (range, 1–4). Mean diameter of removed fibroids was 6.5 cm (range, 3 –11 cm). No major adverse outcomes related to surgery were observed for any of the 12 women. The mean drop in serum hemoglobin levels as calculated on day 1 postoperative was 0.97 g/dL (range, 0.4 g/dL–2.9 g/dL). No blood transfusions were required in any women.

No major complications occurred during the hospital stay and no women experienced postoperative fever. One woman reported minor allergic reaction possibly related to analgesic drug. Mean overall hospital stay duration was 5 days [3 –7 days]. No complications were observed after a three-month follow-up. Neither vaginal discharges nor fibroid passages were noted. All women recovered normal menses at 3 months and were free of any initial symptoms. Mean initial percentage of fibroid devascularization was 98% ± 3% (range, 90%–100%).

3.2. Mid-term outcome

During a mean follow-up period of 25 ± 9 months (SD) (range, 14–37 months), complete resolution of initial symptoms along with decrease in uterine volume was observed in all women. No further hysterectomy was required in any woman. Mean uterine volume during the last follow-up evaluation was 239 $cm^3 \pm 202\ cm^3$ (SD) (range, 80 cm^3–795 cm^3), resulting in a mean volume reduction of 48% ± 19% (SD) (range, 16%–81%). No women became pregnant at the time the results are reported.

4. Discussion

We have developed a two-step procedure that consists in the sequential application of UAE using embosphere and surgical myomectomy. This technique was offered as an alternative to radical hysterectomy to 12 premenopausal women with multiple fibroids who were very keen to conserve their uterus and for whom either UAE or surgical myomectomy was not feasible if used alone. We found that this combined approach is technically feasible and safe, without any major complications and is associated with a substantial uterine volume reduction. In addition, our results suggest this two-step procedure may help lessen intraoperative blood loss and requirements for blood transfusion. However, this procedure should be restricted to highly selected women. In our preliminary study, the two-step procedure including surgical myomectomy and UAE was the favored option only for women with symptomatic, multiple and large fibroids who were keen to preserve future fertility after failure of first line medical treatment. Inclusion criteria for two-step procedure included the presence of symptomatic fibroids (abnormal uterine bleeding, pelvic pain and bulk-related symptoms), premenopausal status, keenness to conservative treatment, presence of contraindication for UAE alone and presence of contraindications to surgical myomectomy alone.

Hysterectomy is often regarded as a standard treatment for women with large and multiple fibroids. Hysterectomy is preferred to multiple surgical myomectomies, which are believed to be more technically challenging. In addition, multiple myomectomies often result in severe intraoperative blood loss. In this regard, Ginsburg et al. found in a prospective randomized trial that blood loss during myomectomy was primarily correlated with preoperative uterine volume, total weight of fibroids removed and operating time [20]. Moreover, multiple myomectomies convey a potential risk for intraoperative complications such as digestive and urinary tract injuries and may result in an increased risk of uterine rupture during labor [6,9,21].

UAE is considered as an effective alternative to myomectomy for the treatment of uterine fibroids when a conservative strategy is considered in order to maintain future fertility. This is especially true when surgery is thought to be risky because of multiple or large fibroids or when extensive adhesions due to prior surgery are anticipated [4,6,22]. In addition myomectomy carries the risk of periprocedural and postprocedural complications such as severe blood loss, infection, ileus, bladder and ureteral injury and peritoneal adhesions [23,24,25]. One advantage of the two-step procedure is that the use of UAE allows to restrict resection to a limited number of fibroids. In this regard, after UAE, resection mainly involves subserosal, submucosal and pedunculated fibroids which are preferred indications for surgical myomectomy. Therefore, the two-step procedure results in less extensive resection and less reconstruction of the uterus, thus potentially limiting the above-mentioned myomectomy-related risks by comparison with a more extensive resection [11]. As a limitation, however, myomectomy should be performed shortly after UAE to limit development of inflammatory adhesions that occur after UAE and that may make surgery more difficult.

As a limitation to the use of UAE, several adverse effects have been reported. They include bowel inflammation and necrosis, peritonitis, sepsis, uterine necrosis and ovarian dysfunction, which for some of them may require surgery for cure [8,10]. However, as experience accumulates, the contraindications along with the potential risks of UAE become more evident. Bowel necrosis and pelvic inflammation predominantly occur when UAE is used for the treatment of subserosal fibroids, either pedunculated or not pedunculated [9,22]. Uterine necrosis and severe uterine sepsis predominantly occur when UAE is used for the treatment of submucosal fibroids [9]. As a consequence, UAE should be disregarded for these categories of fibroids [9,22,23]. Spies et al. found that fibroids passage can occur in 2% of cases [26]. Fibroids passage and vaginal discharge are more likely to occur after UAE for submucosal fibroids. In addition, there is an increased risk for adhesions after UAE for large fibroids [27].

In women with multiple fibroids, it is not rare to find fibroids that are large or pedunculated or have different types of location on MR imaging. As a consequence, some fibroids should be ideally treated with UAE and not with surgery while others would be perfect indications for surgical myomectomy and not for UAE. In general, three therapeutic scenarios are offered in women with multiple fibroids. One, which consists in radical hysterectomy, is not acceptable for premenopausal women who wish to conserve their uterus. The second option is UAE alone, but this technique is associated with an increased risk for well-known complications when large or pedunculated or subserosal or submucosal fibroids are present. The third option is extensive surgical myomectomy alone, which carries the risk for other complications. Although we agree that our results should be further confirmed by larger, prospective and controlled studies, they suggest, however, that the two-step procedure may be now considered as a fourth option, which is conservative in nature, with a potential for retaining future fertility.

Procedures that combine preoperative, temporary occlusion of uterine arteries using UAE with absorbable gelatin sponge and surgical myomectomy have been already described for the treatment

of women with large fibroids. In such cases, the use of preoperative UAE with absorbable gelatin sponge is advocated to minimize intraoperative blood loss [28]. Although in our study UAE was not primarily performed to reduce intraoperative blood loss but for the definitive treatment of fibroids that were left in place during surgery, it may be reasonable, however, to assume that UAE might have had a favorable impact on intraoperative blood loss.

Several limitations may be raised with respect to our study. The first relates to the retrospective nature, which might have introduced selection bias. A second limitation relates to the limited number of patients, so that it may be possible that some complications might have been observed after a larger number of procedures. A third limitation is due to the fact that no control groups were obtained, including a group of women treated by UAE alone and a group of women treated by surgery alone, so that the actual benefit of the two-step procedure by comparison with a simple procedure could not be determined. A fourth limitation is that the potential to retain fertility was not fully evaluated because of the relatively short follow-up period. However, our study has to be considered as preliminary and as a feasibility study.

In conclusion, our preliminary experience suggests that the two-step procedure is a technically feasible and safe procedure which can be reasonably offered to premenopausal women with multiple fibroids as an alternative to hysterectomy when UAE alone or conservative surgery alone cannot be done. The combination of the two techniques, which allows minimizing the inherent complications of each technique alone while maximizing the advantages of both techniques yields favorable short-term and mid-term outcomes. However, this combined approach needs a careful preoperative evaluation which should ideally be performed using MR imaging [29]. As a limitation, however, this technique should be restricted to highly selected premenopausal women with a strong desire of future pregnancy. Further prospective studies, evaluating long-term outcome, should be done to determine the actual benefit of this combined approach on the incidence of subsequent pregnancies.

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