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Treatment of Uterine Myomas with Transvaginal Uterine Artery Occlusion: Possibilities and Limitations

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ABSTRACT The objective of this pilot study was to evaluate the feasibility of a transvaginal clamp prototype used for temporary uterine artery occlusion as a treatment for myomas. In particular, we aimed to evaluate technical aspects of successful occlusion with angiography and magnetic resonance imaging (MRI) and to evaluate possible ureter occlusion with pyelography. Ten premenopausal women aged 34 to 37 years with menorrhagia and myomas were treated with a temporary uterine artery occlusion for 6 hours. Five patients did not complete the clamping procedure because of unsuccessful clamping. While the clamp was in position, angiographic examination of the uterine arteries and pyelography were performed in 8 of the patients. The clamps occluded both uterine arteries in 4 patients and 1 side in another 2. Two procedures occluded the ureter unilaterally. MRI with contrast was done before, the day after, and 3 months after the procedure. Three of 5 patients who completed the clamp treatment had reduced or no contrast enhancement at MRI afterward. Clinical effects were obtained in 3 patients. Difficulties with application of the vaginal clamp were related to initial learning and size of the myomas. Our initial experience shows that the treatment is feasible in some patients with symptomatic myomas. However, improvement of the technique and equipment is needed. Care with regard to the ureters is required during further studies aimed at evaluating this approach. Journal of Minimally Invasive Gynecology (2008) 15, 631–635 © 2008 AAGL All rights reserved.

Operative treatment for symptomatic myomas by hysterectomy or myomectomy involves considerable morbidity [1,2]. Surgical treatment with minimally invasive techniques (hysterectomy, myomectomy, myolysis) is beneficial for the patients, but the 5-year recurrence rate after laparoscopic myomectomy is reported to be about 50% [3,4]. However, many women prefer conservative nonsurgical treatment.

Alternatives to surgical treatment include medical therapy and treatments interfering with blood supply to the uterus and the myomas. Since the first publication by Ravina in 1995 [5], probably more than 100 000 women have been treated with uterine artery embolization. We have compared previously embolization with laparoscopic uterine artery occlusion [6]. Possible alternative treatment is a temporary uterine artery occlusion applied transvaginally. Preliminary studies have demonstrated its feasibility, safety, and short-term efficacy [7-10]. We have described previously our initial and positive experience with a temporary, noninvasive, Doppler-directed, transvaginal uterine artery clamp as a case report [7]. A multicenter study is now underway to evaluate a modified and renewed version of the clamp.

The aim of this study was to evaluate the feasibility of the transvaginal clamp treatment in a series of patients with symptomatic myomas. In particular, we aimed to evaluate technical aspects of successful occlusion with angiography and magnetic resonance imaging (MRI) and evaluate possible ureter occlusion with pyelography.

Materials and Methods

Ten patients with symptomatic uterine myomas were included. The median age was 43 years, range 34 to 47. The study was performed at the Department of Obstetrics and Gynecology and at the Department of Radiology, Ullevål University Hospital, Oslo, from January through June 2003. The Regional Committee for Medical Research Ethics, Eastern Norway, approved the study protocol. The investigator explained the purpose of the study, the procedures, and alternative options if the treatment did not meet the expectations. Written informed consent was obtained from the patient once it had been established that the patient met all eligibility criteria.

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The preoperative examinations included a gynecologic examination, ultrasonography, cervical smear, and endometrial biopsy. MRI with perfusion scanning was performed before the procedure. Inclusion criteria were age above 18 years, symptomatic uterine myomas, that the location and position of both uterine arteries could be confirmed with Doppler ultrasound examination, and willingness to consent and complete follow-up requirements of the study. Exclusion criteria were pregnancy confirmed by pregnancy test or a desire for future pregnancy as stated by the patient, active pelvic inflammatory disease, and use of an intrauterine device, intravaginal pessaries, or other devices. Patients on hormones, specifically estrogens, progesterone, gonadotropin-releasing hormones, or birth control pills within the previous 2 months were also excluded. Additional exclusion criteria were any disease conditions that were contraindications to undergoing the procedure, such as concurrent infection, premalignancy or malignancy, and major organ disease.

The Transvaginal Clamp Procedure

A prototype of the Doppler-directed, transvaginal uterine artery clamp system, Flowstat (Vascular Control Systems Inc., San Juan Capistrano, CA), was used. The clamp system has more recently been transferred and further developed by Johnson & Johnson (Somerville, NJ), who presently perform prospective studies in both Europe and the United States to evaluate the feasibility and the safety of the system. The system consists of a guiding cervical tenaculum, a transvaginal vascular clamp with integrated Doppler ultrasound crystals, and a small, battery-powered transceiver that generates audible Doppler sound. The clamp slides along the guiding tenaculum to the level of the lateral vaginal fornices at the 9 and the 3 cervical positions. When the crystals on the arms of the clamp contact the vaginal mucosa, they return audible signals from the right and the left uterine arteries. When the clamp is further advanced along the guiding tenaculum, the clamp displaces the uterine arteries superior to the point of insertion into the uterus. When closed, the clamp occludes the uterine arteries bilaterally by squeezing them against the lateral borders of the uterus, and the clamp remains in place for 6 hours. Nine patients underwent paracervical blockage with the addition of intravenous sedation, whereas 1 patient underwent general anesthesia with additional paracervical blockage when the clamp was applied.

Angiographic examination was performed with the clamps in position. A 5F pigtail catheter was placed into the abdominal aorta at the level of the renal arteries through right femoral artery puncture. Patency of the uterine arteries, as well as collateral vessels through the ovarian arteries, was evaluated. After the initial aortography, we waited until the renal pelvis and the ureters were filled with contrast to evaluate for any obstruction of the ureters. When the uterine arteries were not occluded, the clamp was repositioned, and aortography was repeated. Beforehand, the patients were offered immediate embolization should the clamps not occlude the uterine arteries.

MRI with gadolinium-enhanced scanning was performed the day after the procedure and again after 3 months. The MRI studies were performed with a 1.5T Magnet (Gyroscan NT; Intera Philips, Best, The Netherlands). With turbospin echo, T_1-weighted pulse sequence images were obtained in the transverse plane. With the use of T_2-weighted turbospin echo sequences, imaging was performed in the transverse and the sagital plane. Finally, transverse fast-field echo images were acquired after rapid intravenous administration of gadopentetate dimeglumine 0.1 mmol/kg/body wt (Magnevist; Schering, Stabekk, Norway). Images were obtained every 5 seconds between 30 and 180 seconds after contrast injection. The total uterine volume and the volume of the largest myoma were calculated from the sagittal and the transverse T_2 images.

A validated bleeding chart pictorial bleeding assessment chart [11] was filled in by the participants during the last menstrual period before treatment and before the follow-up appointment and the score was calculated. We also evaluated the subjective symptoms of bleeding and pressure, as well as relief of symptoms at follow-up. The patients stayed in the hospital for a period of 24 to 48 hours after the application of the clamp. Adverse effects of the treatment and complications were recorded while the patients were in the hospital, and the patients have been followed up for an average of 24 months after the treatment.

Results

Eight of 10 patients underwent angiography (Table 1). The remaining 2 patients did not undergo angiographic examination; one because of capacity problems at that particular time, and the other refused the angiographic procedure. In the initial 3 patients, the occlusion was not successful (Table 1). During the next 5 procedures, we succeeded to occlude both uterine arteries in 4 patients. However, in 1 of these the collateral filling from the ovarian arteries was so pronounced that we discontinued the clamp procedure. Two patients underwent clamping of the ureters. In one of these (patient 1), the right ureter was partially occluded and both renal pelvis were dilated. The other patient (no. 8) had complete obstruction of the 1 ureter, with no excretion of contrast on that side (Fig. 2). After removal of the clamp, the hydroureter and hydronephrosis resolved itself within a week, as evaluated by ultrasound examination. No biochemical alterations in the blood or the urine were recorded.

Five patients did not complete the planned clamping procedure because of unsuccessful clamping. Four were embolized, and 1 was treated laparoscopically with arterial occlusions. The size of the uterus and fibromas of the unsuccessful procedures tended to be larger with a median volume of 740 (418–869) mL compared with the successful procedures with a median volume of 366 (211–503) mL. The cervix or isthmus of the uterus was involved with the myoma in 7 of the 10 study subjects evaluated by MRI. There was a trend that a short distance between the fibroma and the