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Temporary uterine artery occlusion for treatment of menorrhagia and uterine fibroids using an incisionless Doppler-guided transvaginal clamp: Case report

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We report the successful treatment of a 43-year-old woman with menorrhagia and multiple uterine fibroids by temporary uterine artery occlusion. Using a Doppler-guided transvaginal clamp, her uterine arteries were non-invasively identified and occluded by mechanical compression against the cervix for 6 h. Following removal of the clamp, blood flow in the uterine arteries returned immediately. Menorrhagia symptoms were tracked with the Ruta Menorrhagia Severity Scale. Uterine and fibroid volumes were measured by analysis of magnetic resonance images. The patient's self-reported menorrhagia symptoms were significantly reduced at 6 months (70% reduction in Ruta score) and both uterine volume and fibroid volume had decreased by more than 44% at 6 months. This case report illustrates the potential applicability of a simple-to-use, non-surgical device for the treatment of menorrhagia and uterine fibroids by temporary uterine artery occlusion.

Key words: fibroid/leiomyoma/menorrhagia/uterine artery occlusion

Uterine artery occlusion has been demonstrated to be an effective treatment for symptomatic uterine fibroids, whether by permanent laparoscopic occlusion or by uterine artery embolization (UAE) (Pron *et al*., 2003; Hald *et al*., 2004; Spies *et al*., 2004). The purpose of this study was to examine the safety and effectiveness of a transvaginal system when used for a temporary 6-h occlusion of the uterine arteries in the treatment of symptomatic uterine fibroids. This system, the Flostat™ system (Vascular Control Systems, San Juan Capistrano, CA, USA), is currently cleared by the United States Food and Drug Administration for identification and temporary occlusion of the uterine arteries in conjunction with conservative gynaecological surgery.

Case report

A 43-year-old nulliparous woman presented with menorrhagia. After a routine pelvic examination had identified uterine fibroids in conjunction with her menorrhagia complaint, the patient was offered enrolment in an ethics committee-approved pilot study of the Flostat system that identifies and temporarily occludes the uterine arteries.

Following informed consent and prior to the temporary occlusion treatment, the patient was examined by magnetic resonance imaging (MRI) of the pelvis. The patient demonstrated a moderately enlarged uterus of 310 cc populated by four fibroids ranging in diameter from 3 to 6 cm. To quantify the patient's menorrhagia symptoms, the Ruta Menorrhagia Severity Scale was administered before the procedure and during follow-up visits at 1, 3 and 6 months (Ruta *et al*., 1995).

The Flostat system consists of (a) a guiding cervical tenaculum, (b) a transvaginal vascular clamp with integrated Doppler ultrasound crystals, (c) a coupler that advances the clamp over the tenaculum and (d) a battery-powered ultrasound transceiver that generates an audible Doppler signal (Figures 1 and 2).

At the time of treatment, the patient was placed in the lithotomy position in a surgical suite. Following routine hysteroscopic examination of the uterus and a diagnostic dilatation and curettage, the guiding tenaculum was placed with the securing hook in the 6 o'clock cervical position. The transvaginal clamp was articulated to the guiding tenaculum and advanced along the guide with the coupler to place the tips of the clamp in the lateral vaginal fornices at the 9:00 o'clock and the 3:00 o'clock positions.

When the ultrasound crystals at the tips of the clamp contacted the lateral vaginal mucosa, they returned audible Doppler signals from the right and left uterine arteries. As the clamp was further advanced along the guiding tenaculum, the clamp folded vaginal tissue around the uterine arteries and displaced the uterine arteries superior to their insertion points into the uterus. When closed, the clamp occluded the uterine

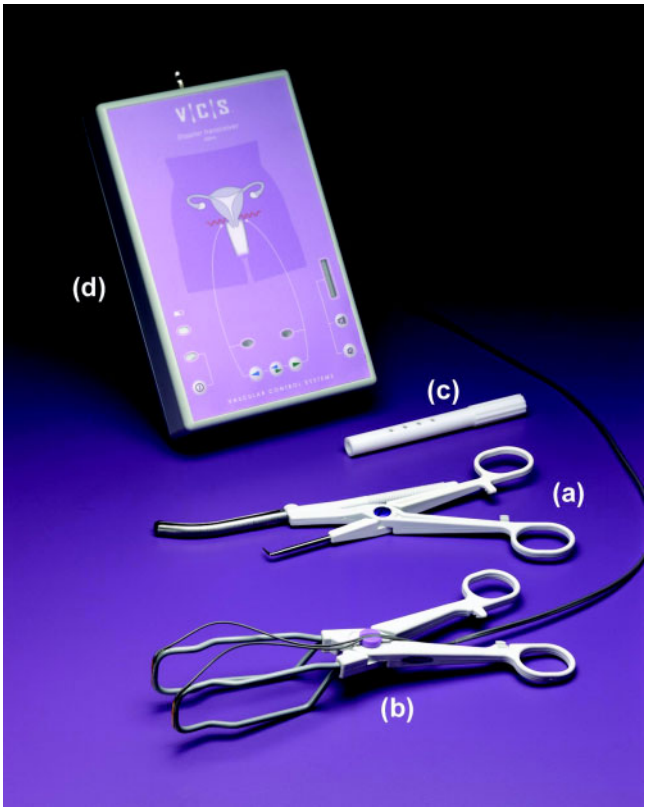

Figure 1. The current Flostat system consists of (a) a guiding cervical tenaculum, (b) a transvaginal vascular clamp with integrated Doppler ultrasound crystals, (c) a coupler that advances the clamp over the tenaculum, and (d) a battery powered ultrasound transceiver that generates an audible Doppler signal. 404 × 411 mm (72 × 72 d.p.i.).

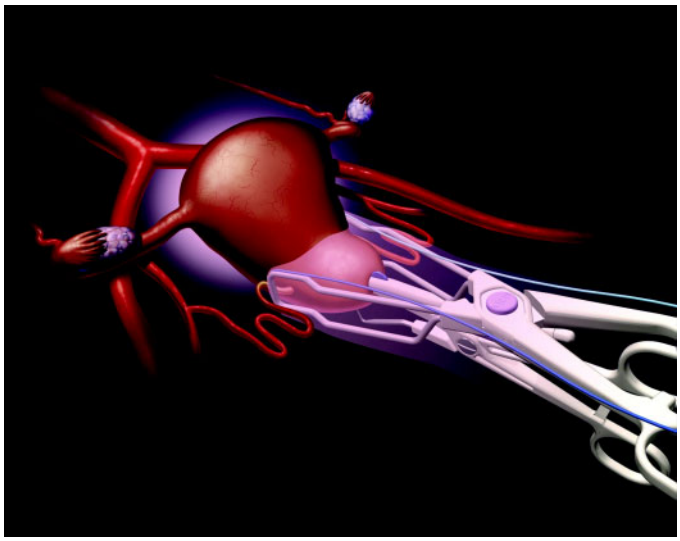

Figure 2. Schematic diagram of the Flostat system. 127 × 100 mm (150 × 150 d.p.i.).

arteries bilaterally by squeezing the vaginal mucosa and the uterine arteries against the lateral borders of the lower uterus. Uterine artery occlusion was confirmed by cessation of the audible Doppler signal.

After a short period in the postsurgical recovery area, the patient was transported to the gynaecology ward, where she remained for the remainder of the 6-h occlusion period. The device was removed at the patient's bedside. At the moment of clamp release, a Doppler signal was immediately returned from each uterine artery. No injury to the vaginal mucosa was observed at the time of removal of the guiding tenaculum and clamp or at subsequent follow-up examinations.

For the procedure, the patient was prepared with epidural anaesthesia (bupivacaine 0.25%, 48 ml over the treatment period) and morphine (50 mg over the treatment period) i.v. for pain control. Ondansetron (4 mg) and dimenhydrinate (50 mg) were also administered for nausea control. No additional pain medications were given while the patient was in the hospital, and the patient did not require pain medications upon discharge the morning after the procedure. The 24 h post-uterine artery occlusion renal ultrasound was reported as normal. This indicated that the ureters were not adversely affected by the clamp.

The Ruta Menorrhagia Severity Scale is a self-administered quality of life instrument comprising 13 questions to assess the patient's menstrual experience from the prior 3 months. A higher score indicates a lower quality of life. This test for menorrhagia has been validated previously for internal reliability and test–retest reliability, as well as being validated against the Short Form-36 (Ruta *et al*., 1995). Prior to treatment, the patient reported a Ruta score of 20. At her 6-month follow-up examination she reported a score of 6, a 70% reduction in menorrhagia severity.

MRI showing uterine and fibroid volumes before treatment and 8 months after treatment is presented in Figure 3. Volumes (in cc) were calculated using the formula for the volume of a prolate ellipse [length × width × anterior–posterior diameter × (π/6), each measured in cm]. The uterus diminished 44% in volume by 8 months, the four measured fibroids decreasing by 71, 84 and 99%. One of the fibroids, as demonstrated in Figure 3, can no longer be identified. The fourth fibroid that was followed and measured cannot been seen in this view as it is lateral of midline.

Discussion

These data on uterine and fibroid volume reduction and menorrhagia symptom relief compare favourably with published data for permanent laparoscopic uterine artery occlusion and UAE. In a comparative study of permanent laparoscopic occlusion versus embolization, Hald *et al*. (2004) reported uterine shrinkage of 36.7% for permanent occlusion and 40.1% for embolization at 6 months of follow-up. Likewise, dominant fibroid shrinkage was reported as 36.2% for occlusion and 45.1% for embolization at the same interval. The authors determined that these reductions were not statistically different between these two populations. However, they did observe significant differences in patient pain after the procedure between the two populations, as measured with a visual analogue scale and by the consumption of pain medication. The laparoscopic treatment group required significantly less pain medication following treatment than the embolization group.

In a second study group, Pron *et al*. (2004), reporting on behalf of the Ontario Uterine Fibroid Embolization (UFE) Trial,

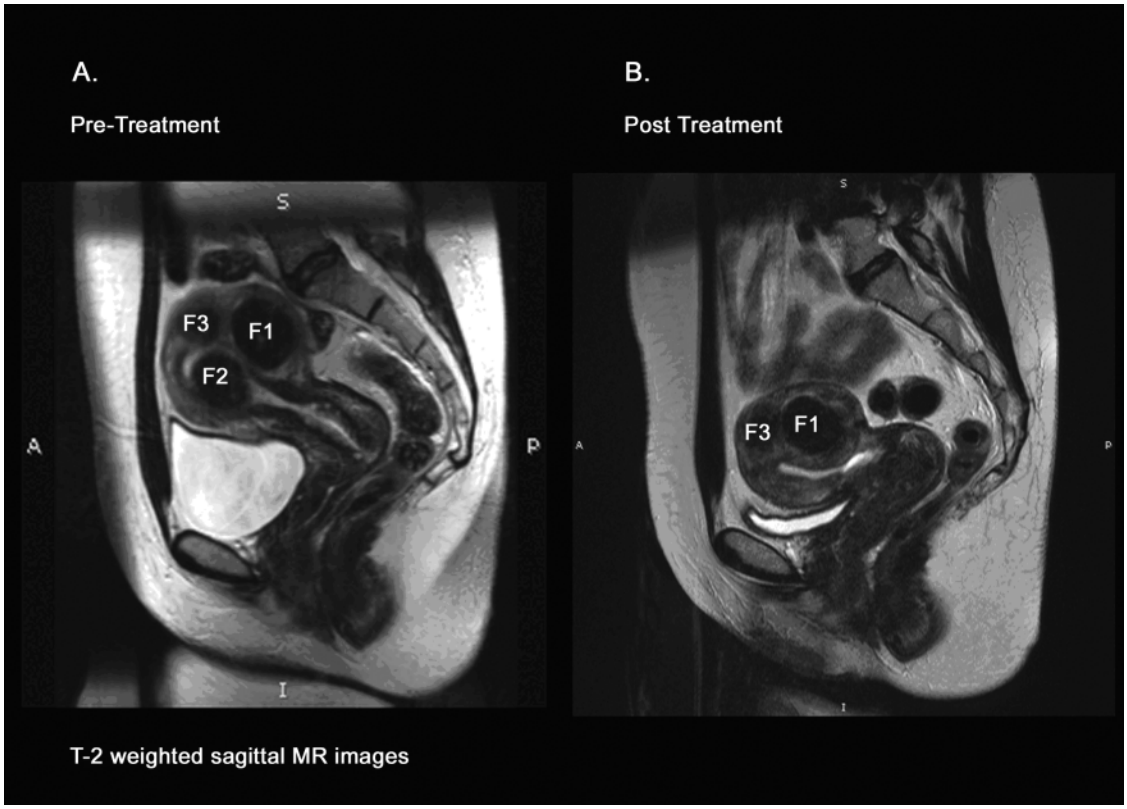

Figure 3. (A) Pretreatment T2-weighted midline, sagittal magnetic resonance image showing the uterus and one 4 cm (F1) and two 3 cm (F2, F3) fibroids. (B) Eight months after temporary uterine artery occlusion, demonstrating uterine volume reduction (44%) and reductions in the fibroids: F1 (71%), F2 (100%; no longer identified), F3 (84%). 740 × 529 mm (72 × 72 d.p.i.).

observed that 6% of those treated by embolization needed to make an emergency room visit for management of continued post-procedural pain. We believe temporary uterine artery occlusion may lead to even lower levels of postoperative pain as circulation to the uterus is restored immediately upon device removal.

In another recent embolization series of 102 patients, Spies *et al*. (2004) reported mean uterine and fibroid volume reduction of 33.1 and 54% respectively at 6 months. This series also yielded a reduction in menorrhagia scores of 58.1% at 6 months. However, this series also reported amenorrhoea in seven patients (6.8%) and an overall morbidity rate of 15%.

Other embolization studies have reported similar complications. Pron *et al*. (2004), reporting on behalf of the Ontario UFE Trial, reports an amenorrhoea rate of 8%. Because temporary uterine artery occlusion does not rely on particulate embolization for fibroid treatment, the effects of non-target embolization of the ovaries and resulting ovarian dysfunction may be avoided.

Six hours of occlusion of the uterine arteries with a Doppler-guided transvaginal clamp was an effective therapy for the treatment of menorrhagia and fibroids in this patient. The 6-h duration was derived from a previous study of laparoscopic bilateral uterine artery permanent occlusion that indicated that the myometrium was reperfused within 6 h in approximately 80% of women (Lichtinger *et al*., 2004).

This simple-to-use, non-surgical device can be placed by any gynaecologist and may provide treatment results in these patients which are comparable to those of more invasive global fibroid treatment methods. Further studies are presently on-going with a larger number of patients.

References

Hald K, Langebrekke A, Klow NE, Noreng HJ, Berge AB and Istre O (2004) Laparoscopic occlusion of uterine vessels for the treatment of symptomatic fibroids: Initial experience and comparison to uterine artery embolization. Am J Obstet Gynecol 190,37–43.

Lichtinger M, Burbank F, Hallson L, Herbert S, Uyeno J and Jones M (2004) The time course of myometrial ischemia and reperfusion after laparoscopic uterine artery occlusion. Theoretical implications. J Am Assoc Gynecol Laparosc 10,553–556.

Pron G, Mocarski E, Bennett J, Vilos G, Common A, Zaidi M et al. (2003) Tolerance, hospital stay, and recovery after uterine artery embolization for fibroids: the Ontario Uterine Fibroid Embolization Trial. J Vasc Interv Radiol 14,1243–1250.

Pron G, Bennett J, Common A, Wall J, Asch M and Sniderman K (2003) The Ontario Uterine Fibroid Embolization Trial. Part 2. Uterine fibroid reduction and symptom relief after uterine artery embolization for fibroids. Fertil Steril 79,120–127.

Ruta DA, Garratt AM, Chadha YC, Flett GM, Hall MH and Russell IT (1995) Assessment of patients with menorrhagia: how valid is a structured clinical history as a measure of health status? Qual Life Res 4,33–40.

Spies JB, Cooper JM, Worthington-Kirsch R, Lipman JC, Mills BB and Bennetati JF (2004) Outcome of uterine embolization and hysterectomy for leiomyomas: results of a multicenter study. Obstet Gynecol Surv 59,819–820.

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