

Thermal balloon ablation versus transcervical endometrial resection: evaluation of postoperative pelvic pain in women treated for dysfunctional uterine bleeding

A. Vitagliano, M. Bertin, L. Conte, S. Borgato, C. Leggieri, S. Fagherazzi

Department of Women's and Children's Health, Obstetrics and Gynaecology Clinic, University of Padua, Padua (Italy)

Summary

Purpose of the study: To evaluate postoperative pain after mini-invasive surgical treatment for dysfunctional uterine bleeding (DUB) with transcervical endometrial resection or thermal ablation balloon. **Materials and Methods:** A longitudinal observational study, analyzing 47 women affected by DUB who underwent endometrial ablation was conducted. The authors collected evaluation of pelvic pain at one and four hours after intervention and the individual necessity of analgesics. After 30 days, all patients underwent a gynecological visit to evaluate postoperative outcome. **Results:** Pelvic pain was higher one and four hours after procedure in thermal balloon ablation group, and patients in the same group required more analgesic rescue dose. There were no complications such as uterine perforation, heavy blood loss or thermal injuries with both the procedures. **Conclusion:** Thermal balloon ablation appears a more painful procedure than endometrial resection, both in the immediate postsurgical time and 30 days after surgery. Ad hoc anaesthesiologic and analgesic protocol should be adopted to ensure quick recovery and good acceptance of the procedure.

Key words: Transcervical endometrial resection; Thermal balloon ablation; Pelvic pain; Complications; Dysfunctional uterine bleeding.

Introduction

Dysfunctional uterine bleeding (DUB) refers to uncategorized bleeding from the uterus that occurs in the absence of recognizable pelvic pathology, general medical disease, or pregnancy. It reflects a deregulation of the hormonal cyclic stimulation with a chronic unopposed estrogen to the endometrial lining. Most of time bleeding appears suddenly and it is unpredictable. It could be excessively heavy or light and it may be prolonged, frequent, or random. DUB is one of the most common presenting complaints encountered in a Gynecologist's office and accounts for almost 30% consultations in any busy out-patient clinic. It affects about 20% of women subjected to hysteroscopy and represents a major clinical problem for health economies [1]. The evaluation of women with DUB includes a thorough medical history and physical examination, appropriate laboratory and imaging tests, and consideration of age-related factors [2]. The diagnosis is made only after having excluded organic lesions as polyp, myoma, and endometrial cancer [3-6]. DUB can be managed with medical or surgical treatment because it can result in anemia, impaired quality of life, and psychological distress. Surgery should be considered in these cases in which medical treatment has failed, or when it cannot be tolerated or it is contraindicated. Surgical options could be both radical and conservative. The limit of surgical solution is that it often leads to perform a hysterectomy most

of time when it is not needed [7-9]. DUB are estimated to be responsible of over one-third of the hysterectomies annually performed in Europe and North America. Hysterectomy is associated with 100% success in treating heavy menstrual bleeding and a high patient satisfaction up to 95% [10, 11], but it can have complications and rarely operative mortality. For this reason, hysterectomy should be only considered when other treatment options have failed. Conservative treatments consist in eliminating the full thickness of endometrium without removing uterus, which signifies lower procedure-costs and less invasiveness. Nowadays two of the most conservative techniques used are Transcervical endometrial resection (TCER) and thermal balloon ablation (TBA); they both have demonstrated to be cost effective and well-accepted surgical alternatives to hysterectomy in women with DUB [12,13]. TCER was introduced by Neuwirth in 1976 as a conservative surgical technique and it is still effective in the treatment of recurrent menorrhagia, with a success rate of 75-80% at five years. Only 10-12% of women who experienced this treatment required a hysterectomy [14, 15]. The limit of this technique is that it is surgeon-dependent, namely it is a valid technique in a skilled surgeon's hand; therefore a long training curve is necessary to avoid the incidence of severe complications, such haemorrhage or metabolic effects. Nevertheless, this procedure could be currently used to treat atypical endometrial hyperplasia in young women with high success rate [16]. TBA belongs to the second generation techniques of endometrial ablation, introduced in the late nineties, with the aim of reduc-

ing both difficulties and complications of the first generation procedures. TBA was first described in 1993 and it is reported an overall success rate of 92%–98%, with an amenorrhea state of 22%–68% and a patient's satisfaction ranging from 57% up to 94% [17–19].

Materials and Methods

The authors conducted a longitudinal observational study and they analyzed the clinical history of 47 women affected by DUB who underwent endometrial ablation between 2010 and 2012 in the Unit of Minimally Invasive Pelvic Surgery and Operative Obstetrics, Department of Women and Children Health, University of Padua (Italy). The inclusion criteria were: recurrent menorrhagia, uterus length less than 12 cm, absence of any organic lesions and/or uterine malformations, and no previous hormonal therapy during the last six months. Women who desired future pregnancy were excluded. The preoperative check-up consisted in Pap smear, transvaginal ultrasound, and hysteroscopy with endometrial biopsy to exclude endometrial malignancies. All patients were free from any clinical or laboratory evidence of hepatic, renal, pulmonary, neurologic, metabolic or cardiovascular diseases. Blood tests such as hemoglobin concentration, serum urea and creatinine, fasting blood sugar, and electrocardiogram were within normal limits. Age, parity, and body mass index (BMI) were recorded. Surgical procedures were performed in the endometrial proliferative phase (7°–10° day of cycle), under mild unconscious sedation with spontaneous breathing. They were all administered fentanyl 0.1 mcg iv and propofol in appropriate doses respectively for induction and maintenance of sedation. The authors collected evaluation of pelvic pain in each patient one and four hours after intervention, using Visual Analogue Scale (VAS), and eventually analgesic therapy requested was recorded. Pelvic pain was considered mild if VAS was between 0 and 3; moderate from 4 to 7, and severe from 8 to 10. Analgesics after the procedure were administered only if requested by the patient. The first-line therapy was paracetamol one gr iv and in patients in whom paracetamol had not been resolute, the second-line therapy was tramadol 100 mg iv. After 30 days, all patients underwent a gynecological visit during which they were investigated for health, temperature, vaginal discharges, pelvic pain, and urinary symptoms.

Transcervical endometrial resection

This was performed, after cervical dilatation up to Hegar number 10, through operative resectoscope ten-mm diameter, using monopolar 90 degrees loop and hypotonic distension medium (1% glycine, 1% mannitol in 1,000 ml of water). To resect endometrium at the level of fundus and cornual region, the authors used rollerball.

Thermal balloon ablation

This was conducted according to standard procedure: the cervix was dilated to Hegar 6 and the catheter inserted into cavity, then the balloon was inflated using a syringe containing 30 ml of normal saline, until a stable pressure of 230–240 mmHg was obtained. The pressure allows an optimal contact with endometrial tissue. The heating destroys the endometrium and underlying myometrium to a depth of six to eight mm with an operating mean temperature range of 70–80°C. The time of procedure was standard and was between 12–14 minutes in which ten minutes are the standard time of ablation and remaining time is requested to dilate the cervix.

Table 1. — *Visual Analogue Score 1–4 hours after procedure.*

	Endometrial resection	Thermal balloon ablation	<i>p</i> value
VAS 1 H <4	14 (56%)	4 (18.2%)	0.010
VAS 1 H 4–6	10 (40%)	12 (54.5%)	
VAS 1 H >6	1 (4%)	6 (27.3%)	
VAS 4 H <4	18 (72%)	7 (31.8%)	0.014
VAS 4 H 4–6	7 (28%)	13 (59.1%)	
VAS 4 H >6	0	2 (9.1%)	

Table 2. — *Analgesic request after surgery.*

	Endometrial resection	Thermal balloon ablation	<i>p</i> value
Paracetamol (1 g iv)	6 (24%)	11 (50%)	0,064
Tramadol (100 mg iv)	0	5 (22.7%)	0,012

Statistical analysis

This was performed using SPSS for Windows, version 19.0. Data are expressed as frequency (percentage) for categorical variables as mean \pm standard deviation with continuous ones, Chi square test or Fisher's exact test when necessary was used. The level of significance was set at $p < 0.05$.

Results

Among the 47 patients enrolled, 39 (83%) were multiparous and eight (17%) nulliparous. The mean age was 46.5 ± 4.7 years and the mean BMI was 21.5 ± 2.2 . The procedure was completed in all 47 patients: 25 (53.2%) were submitted to TCER and 22 (46.8%) to the TBA. Surgical time, as measured from the initial introduction of the resectoscope to its final removal in case of TCER, was 19 ± 3.03 minutes, whereas surgical time with TBA ten minutes according to standard procedure. There were no complications such as uterine perforation, heavy blood loss or thermal injuries in both the procedures. In the group of patient submitted to TCER, VAS score one hour after treatment (VAS-1H) was mild in 14/25 (56%), moderate in 10/25 (40%) and severe in 1/25 (4%). In patient submitted to TBA, the VAS-1H was mild in 4/22 (18.2%), moderate in 12/22 (54.5%) and severe in 6/22 (27.3%). The VAS-1H was statistically different ($p < 0.05$) between the two groups (Table 1).

In the group of patient submitted to TCER, VAS score four hours after treatment (VAS-4H) was mild in 18/25 (72%), moderate in 7/25 (28%), and severe in 0/25. In patient submitted to TAB, the VAS-4H was mild in 7/22 (31.8%), moderate in 13/22 (59.1%) and severe in 2/22 (9.1%). The VAS-4H was statistically different ($p < 0.05$) between the two groups (Table 1).

Six patients (24%) of the group submitted to TCER and 11 (50%) of the group submitted to TAB requested paracetamol after procedure, with no statistically significant difference. No patients of the group submitted to TCER and

five (22.7%) of the group submitted to TAB requested tramadol in addition to paracetamol after procedure, and this difference was statistically significant ($p < 0.05$) (Table 2).

All patients submitted to TCER and 20 (90.1%) submitted to TAB were discharged within six hours after surgery, while two patients submitted to TAB were dismissed after 24 hours of observation because of abdominal pain.

At gynaecologic control 30 days after procedure, five (20%) patients of TCER group still reported mild pelvic pain associated with heavy menstrual bleeding, while in the TBA group, ten (45.4%) patients reported mild pelvic pain. In TBA group five (22.7%) patients complained for vaginal discharges and six (27.3%) referred symptoms of cystitis, not confirmed at urine culture test. No patient reported fever.

Discussion

The main option proposed to women with recurrent menorrhagia in the 1970s and 1980s, was total hysterectomy [7, 8]. In the last three decades the development of new endoscopic technology have led to the introduction of first and second generation endometrial ablation techniques.

Among first generation techniques, the endometrial resection is the gold standard technique [18]. The aim of this procedure is the excision or destruction of endometrium and basal layer in order to prevent tissutal proliferation and menstrual bleeding. Particularly the menses bleeding during the first six months after the treatment develops a progressive reduction, showing that it is an efficacious treatment. Some authors demonstrated the long-term efficacy of endometrial resection until eight years of follow up, particularly the efficacy become progressively higher with increasing age [20, 21]. The endometrial transcervical resection requires a specific skill, it requires a long learning curve and it shows a moderate rate of intraoperative complications such fluid overload syndrome with hyponatraemia, water intoxication, cerebral edema and cardiac overload, bowel or bladder thermal damage, and uterine perforation [22]. There are several new devices designed to perform global endometrial ablation without the use of resectoscope. These devices have been developed to reduce operative time, decrease risk of fluid overload syndrome, and to provide a means of performing endometrial ablation without the technical skill required for the use of a resectoscope [23, 24]. The new techniques developed are: the Hydro ThermAblator, a hysteroscopic system of circulating intrauterine heated normal saline [25-29]; NovaSure, which uses radiofrequency electrosurgical energy and thermal balloon ablation (TBA) which uses a heated intrauterine balloon. These new ablation techniques need simple instrumentation, their application is easier and the procedures are rapid; all of these aspects allowed the rapid diffusion of these techniques [30]. Moreover these procedures, thanks to the possibility of using spinal anesthesia, find indication in case of recurrent menorrhagia in women with

high anaesthetic risk as cardiovascular and/or autoimmune disease [31]. The thermal balloon endometrial ablation is performed by heating a fluid – filled balloon inside the uterine cavity and using both heat and pressure to disrupt the endometrium [32]. The balloon is filled with normal saline heated at 78-80° C for ten minutes with an internal pressure of 230 mmHg and it produces an endometrial necrosis coagulation thanks to indirect heat transfer from balloon to endometrium.

Many studies *in vitro* analysed hyperthermic effect on uterine myomas and close myometrium: the myometrial cell necrosis arise until 88% when they are exposed to the temperature of 80°C for ten minutes. Furthermore the intrauterine pressure is transmitted to myoma's vessels with subsequent hypoxia and necrosis [33]. Clearly the high temperature achieved with thermal balloon ablation causes an important pelvic discomfort in patients, therefore clinicians should assure a good analgesic cover both during and after the intervention. Most women treated with TCER, reported a low-moderate pelvic pain often solved within the first hours after surgery while TBA is associated with pelvic pain, vaginal discharge, and urinary symptoms up to one month after the procedure. From the analysis of our data, TBA resulted a more painful technique with a higher VAS score both after one and four hours from the procedure, and patients required more often analgesic rescue dose. Even if TBA could result an easier technique to be performed in contrast with TCER, TBA probably needs a specific anaesthesiologic protocol and more analgesic rescue doses in order to assure good control of postsurgical pain. An advantage of endometrial resection is the possibility, using a resectoscope, of removing some intracavity lesions as polyp or submucous myoma [5], which is impossible with TBA that should be used only when uterine cavity is normal, or when uterine lesions such as polyps or submucosal myomas have already been removed. On the other hand also TCER can be associated with some complications as: hemorrhage, pelvic inflammatory disease, endometritis, first-degree skin burns, hematometra, vaginitis, and cystitis [23]. Otherwise women with abnormal uterine bleeding and high-risk factors for endometrial carcinoma who did not respond to medical treatment may safely undergo endometrial ablation but they must have a preablation biopsy indicating normal endometrium, because persistent hyperplasia unresponsive to hormonal therapy should influence the selection of a hysterectomy [34, 35].

Conclusion

Surgical mini-invasive treatment for DUB are proved to be safe and effective. While TBA results easier to perform, it appears a more painful procedure than TCER, both in the immediate postsurgical time and 30 days after surgery. Ad hoc anaesthesiologic and analgesic protocol should be adopted to ensure rapid recovery and good acceptance of the procedure.

References

- [1] Cooper J.M.: "Contemporary management of abnormal uterine bleeding. Preface". *Obstet. Gynecol. Clin. North Am.*, 2000, 27, 11.
- [2] American College of Obstetricians and Gynecologists: "Diagnosis of abnormal uterine bleeding in reproductive aged women. Practice Bulletin No. 128". *Obstet. Gynecol.*, 2012, 120, 197.
- [3] Litta P., Merlin F., Saccardi C., Pozzan C., Sacco G., Fracas M., et al.: "Role of hysteroscopy with endometrial biopsy to rule out endometrial cancer in postmenopausal women with abnormal uterine bleeding". *Maturitas*, 2005, 50, 117.
- [4] Munro M.G., Critchley H.O., Broder M.S., Fraser I.S., FIGO Working Group on Menstrual Disorders: "FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age". *Int. J. Gynaecol. Obstet.*, 2011, 113, 3.
- [5] Saccardi C., Conte L., Fabris A., De Marchi F., Borghero A., Gizzo S., Litta P.: "Hysteroscopic Enucleation in Toto of Submucous Type 2 Myomas: Long-Term Follow-Up in Women Affected by Menorrhagia". *J. Minim. Invasive Gynecol.*, 2013. pii: S1553-4650(13)01374-5. doi: 10.1016/j.jmig.2013.11.007. [Epub ahead of print].
- [6] Litta P., Cosmi E., Saccardi C., Esposito C., Rui R., Ambrosini G.: "Outpatient operative polypectomy using a 5 mm-hysteroscope without anaesthesia and/or analgesia: advantages and limits". *Eur. J. Obstet. Gynecol. Reprod. Biol.*, 2008, 139, 210.
- [7] League D.D.: "Endometrial ablation as an alternative to hysterectomy". *AORN J.*, 2003, 77, 322.
- [8] Litta P., Saccardi C., Conte L., Florio P.: "Reverse hysterectomy: another technique for performing a laparoscopic hysterectomy". *J. Minim. Invasive Gynecol.*, 2013, 20, 631.
- [9] Tsai M.C., Goldstein S.R.: "Office diagnosis and management of abnormal uterine bleeding". *Clin. Obstet. Gynecol.*, 2012, 55, 635.
- [10] Farquhar C.M., Steiner C.A.: "Hysterectomy rates in the United States 1990-1997". *Obstet. Gynecol.*, 2002, 99, 229.
- [11] Marjoribanks J., Lethaby A., Farquhar C.: "Surgery versus medical therapy for heavy menstrual bleeding". *Cochrane Database Syst. Rev.*, 2006, 2, CD003855.
- [12] Clarke A., Black N., Rowe P., Mott S., Howle K.: "Indications for and outcome of total abdominal hysterectomy for benign disease: a prospective cohort study". *Br. J. Obstet. Gynaecol.*, 1995, 102, 611.
- [13] Lethaby A., Shepperd S., Cooke I., Farquhar C.: "Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding". *Cochrane Database Syst. Rev.*, 2000, CD000329.
- [14] Magos A.L., Baumann R.: "Transcervical resection of endometrium in women with menorrhagia". *BMJ*, 1989, 298, 1428.
- [15] Litta P., Merlin F., Pozzan C., Nardelli G.B., Capobianco G., Dessole S., Ambrosini A.: "Transcervical endometrial resection in women with menorrhagia; long term follow up". *Eur. J. Obstet. Gynecol. Reprod. Biol.*, 2006, 125, 99. Epub 2005 Sep 1.
- [16] Litta P., Bartolucci C., Saccardi C., Codrón A., Fabris A., Borgato S., Conte L.: "Atypical endometrial lesions: hysteroscopic resection as an alternative to hysterectomy". *Eur. J. Gynaecol. Oncol.*, 2013, 34, 51.
- [17] Friberg B., Ahlgren M.: "Thermal balloon endometrial destruction: the outcome of treatment of 117 women followed up for a maximum period of 4 years". *Gynaecol. Endosc.*, 2000, 9, 389.
- [18] Lethaby A., Penninx J., Hickey M., Garry R., Marjoribanks J.: "Endometrial resection and ablation techniques for heavy menstrual bleeding". *Cochrane Database Syst. Rev.*, 2013, 8, CD001501. doi: 10.1002/14651858.CD001501.pub4.
- [19] Iavazzo C., Salakos N., Bakalianou K., Vitoratos N., Vorgias G., Liapis A.: "Thermal balloon endometrial ablation: a systematic review". *Arch. Gynecol. Obstet.*, 2008, 277, 99.
- [20] Comino R., Torrejon R., Sanchez Ortega I.: "Long term results of endometrial ablation-resection". *J. Am. Assoc. Gynecol. Laparosc.*, 2002, 9, 268.
- [21] Boujida V.H., Philipsen T., Pelle J., Joergensen J.C.: "Five-year follow-up of endometrial ablation: endometrial coagulation versus endometrial resection". *Obstet. Gynecol.*, 2002, 99, 969.
- [22] Erian J.: "Endometrial ablation in the treatment of menorrhagia". *Br. J. Obstet. Gynecol.*, 1994, 101, 19.
- [23] Gurtcheff S.E., Sharp H.T.: "Complications associated with global endometrial ablation: the utility of the MAUDE database". *Obstet. Gynecol.*, 2003, 102, 1278.
- [24] DeCherney A.H., Diamond M.P., Lavy G., Polan M.L.: "Endometrial ablation for intractable uterine bleeding: hysteroscopic resection". *Obstet. Gynecol.*, 1987, 70, 668.
- [25] Bustos Lopez H., Baggish M., Valle R.F., Vadillo-Ortega F., Ibarra V., Nava G.: "Assessment of the safety of intrauterine instillation of heated saline for endometrial ablation". *Fertil. Steril.*, 1998, 69, 155.
- [26] Perlitz Y., Rahav D., Moshe B.A.: "Endometrial ablation using hysteroscopic instillation of hot saline solution into the uterus". *Eur. J. Obstet. Gynecol. Reprod. Biol.*, 2001, 99, 90.
- [27] Glasser M., Zimmermann J.: "The Hydrothermal ablator system for management of menorrhagia in women with submucous myomas: 12 to 20-month follow-up". *J. Am. Assoc. Gynecol. Laparosc.*, 2003, 10, 521.
- [28] Goldrath M.: "Evaluation of Hydrotherm ablator and Rollerball Endometrial Ablation for menorrhagia 3 years after treatment". *J. Am. Assoc. Gynecol. Laparosc.*, 2003, 10, 505.
- [29] Corson S.L.: "A multicenter evaluation of endometrial ablation by HydroThermAblator and rollerball for treatment of menorrhagia". *J. Am. Gynecol. Laparosc.*, 2001, 8, 359.
- [30] Leung L., Tam W.H., Yuen P.M.: "Hysteroscopic appearance of the endometrial cavity following thermal balloon endometrial ablation". *Fertil. Steril.*, 2003, 79, 1226.
- [31] Florio P., Puzzutiello R., Filippeschi M., D'Onofrio P., Mereu L., Morelli R., et al.: "Low-dose spinal anesthesia with hyperbaric bupivacaine with intrathecal fentanyl for operative hysteroscopy: a case series study". *J. Minim. Invasive Gynecol.*, 2012, 19, 107.
- [32] Brun J.L., Raynal J., Burlet G., Galand B., Quéreux C., Bernard P.: "Cavaterm thermal balloon endometrial ablation versus hysteroscopic endometrial resection to treat menorrhagia: The French, multicenter, randomized study". *J. Minim. Invasive Gynecol.*, 2006, 13, 424.
- [33] Romer T., Muller J., Foth D.: "Hydrothermal ablation. A new simple method for coagulating endometrium in patients with therapy resistant recurring hypermenorrhea". *Contrib. Gynecol. Obstet.*, 2000, 20, 154.
- [34] Tinelli R., Litta P., Meir Y., Surico D., Leo L., Fusco A., et al.: "Advantages of Laparoscopy Versus Laparotomy in Extremely Obese Women (BMI>35) with Early-stage Endometrial Cancer: A Multi-center Study". *Anticancer Res.*, 2014, 34, 2497.
- [35] Pluchino N., Litta P., Freschi L., Russo M., Simi G., Santoro A.N., et al.: "Comparison of the initial surgical experience with robotic and laparoscopic myomectomy". *Int. J. Med. Robot.*, 2013, Oct 3. doi: 10.1002/rcs.1542. [Epub ahead of print].

Address reprint requests to:
A. VITAGLIANO, M.D.
Department of Women's and Children's Health,
Obstetrics and Gynecology Clinic,
University of Padua
Via Giustiniani, 3 - 35128 Padua (Italy)
e-mail: a.vitagliano@email.it