Cavaterm™ plus treatment in high – risk surgical patients

Abstract

Background: The purpose of the study was to evaluate the effectiveness and safety of thermal balloon ablation in women with high anesthetic and surgical risk compared to invulnerable women according to the American Society of Anesthesia (ASA) physical status stratification.

Methods: This report was based on a retrospective cohort study of women with heavy menstrual bleeding (HMB) who were eligible for treatment with Cavaterm™ plus during 2012-2017. Women were classified as high-risk (HR) or low-risk (LR) cohorts based on ASA physical status stratification. The primary outcome includes amenorrhea in the twelfth months after the treatment. Risk adjustments were performed using regression models.

Results: This research study consisted of 63 women with mean age 44.42±5.48. Mean of body mass index (BMI) in the HR cohort was higher than the LR cohort (31.48±6.22 vs 26.83±3.51, P=0.005) and results were also similar considering the uterine length (mm) between HR and LR women (58.27±35.70 vs 30.92±35.30, P=0.01). The primary outcome of treatment after a one-year follow-up in the two groups (HR and LR) was 31 (93.9%) and 15 (78.9%), respectively. After adjusting for known confounders including age, uterine length, parity, dysmenorrheal, the adjusted odds ratio was 0.94 (95% CI, 0.14–2.5; P=0.60).

Conclusion: For women with high anesthetic and surgical risks derived from serious underlying co morbidities, endometrial ablation can provide a minimally invasive, safe, and effective therapy for heavy menstrual bleeding.

Keywords: Endometrial ablation, Menorrhagia, Amenorrhea, Recovery, Anesthesia, Obese women

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Based on our knowledge, few studies have been published to evaluate the efficiency, safety, and patient satisfaction of this procedure (13). The aim of this study was to examine the outcome of treatment with Cavaterm™ plus in women who are at high risk for surgery and anesthesia. The primary outcome was an amenorrhea rate at 12 months posttreatment with Cavaterm™ plus, whereas secondary outcomes were pain and patient satisfaction in the 3rd, 6th, and 12th months after treatment with Cavaterm™.

Methods

We performed a retrospective cohort study of women with HMB whose the pictorial blood assessment chart (PBAC) score was 100 or greater and were eligible for treatment with Cavaterm™ plus (16), from December 20, 2012, through December 22, 2017. This study was approved before sampling by the Research Ethics Committee of Babol University of Medical Sciences (ethics code: MUBABOL.HRI.1391.12).

Inclusion criteria consist of patients with prolonged uterine bleeding or heavy menstrual bleeding who were unresponsive to medical treatment, or all women with reported health problems who were considered as high-risk patients for hysterectomy. All women had undergone a sonography and it was used to rule out endometrial pathology and congenital anomaly. Women with uterine tumors (fibroids or polyps) were excluded. An endometrial biopsy was performed to assess endometrial cancer. Exclusion criteria included intra-cavitary pathology (fibroids or polyps), a uterine cavity of less than four cm, an active urinary tract infection, pelvic infection, the presence of coagulopathies, use of anti-coagulants desired to preserve fertility, history of surgery (myomectomy), endometrial ablation, and classical cesarean section.

Prior to preoperative care, patients were classified according to anesthetic risk. The American Society of Anesthesiologists’ (ASA) physical status classification stratified the study population into high-risk (HR) cohort and low-risk (LR) cohort, furthermore, the women were divided into low (ASA I and II) and high (ASA III and IV) anesthetic/surgical risk (17).

The Cavaterm endometrial thermal ablation was performed under general or regional anesthesia. The thermal balloon endometrial ablation depends on the transfer of heat from the heated liquid within a balloon that is inserted into the uterus (EEEE). The postoperative pain was assessed based on the visual analogue scale (VAS). The VAS is a straight line based on a scale of 0–10, where 0 stands for no pain and 10 for maximum pain. The pictorial blood assessment chart (PBAC) Scoring System was used to record the size of clots/flooding after the operation, the score of 100 and above indicated that the women had HMB and a score of zero defined “amenorrhea” (16).

The primary outcome was the amenorrhea rate after 12 months from the treatment with Cavaterm™ plus. Failure rate was defined if there were no signs of amenorrhea after 12 months from the treatment in each group (HR and LR), whereas secondary outcomes were pain and patient satisfaction in the 3rd, 6th and 12th months after the treatment. Women completed health status checklists, including questions about the amenorrhea, reduction of menstrual flow, and heavy bleeding in the 3rd, 6th, and 12 months after the treatment. The patient’s satisfaction was also assessed in the 3rd, 6th, and 12 months after the surgery. The answer options include: excellent, good, medium, and poor. The collected data were coded and entered into the 18th version of the SPSS program and was analyzed with t independent-test and chi-square tests. Risk adjustments were performed using regression models. Furthermore, p-values less than 0.05 were considered statistically significant.

Results

Fifty-two women with HMB underwent balloon ablation in this study. Their mean age was 43/38 ± 5/91 years. The LR cohort included 19 women (15 ASA I and 4 ASA II). The HR cohort consisted of 33 women (29 ASA III and 4 ASA IV). Patients in the HR cohort had higher BMIs than those in the LR cohort (P=0.005). Other characteristics were comparable between the groups shown in table 1. The HR cohort had more uterine length in women with heavy menstrual bleeding compared with those in the LR cohort (P= 0.01), but patients in the LR cohort had a higher score of bleeding than those in the HR cohort (P = 0.013) prior to the surgery (table 1). The mean duration of the anesthetic time was 13.35 min (S.D. = 1.84, range 12–16 min).

In all patients, after a one-year follow-up, the primary outcome of the treatment was 88.5% and six (11.5%) cases had a failure of treatment. All patients with a treatment failure were less than 45 years old and had not delivered. Also, their uterine length was less than 9 cm. The success rate of treatment after a one-year follow-up in the two groups (HR
and LR) was 31 (93.9%) and 15 (78.9%), respectively. Nonetheless, endometrial ablation had the same efficacy in both the HR and LR cohorts during one-year (failure rates of 6.16% and 21.1% (P=0.017), respectively).

The outcome of Cavaterm™ plus in high and low−risk surgical patients with heavy menstrual bleeding in the 3rd, 6th, and 12 months after surgery was shown in table 2. At 12 months, 17 out of 33 (51.5 %) patients had amenorrhea in the HR cohort compared with 6 out of 19 (31.6%) in the LR cohort, with an unadjusted odds ratio of 0.55 (95% CI, 0.17–1.74; P=0.93). After adjusting for known confounders including age >45 years, uterine length ≤9 cm, parity >5, and dysmenorrheal, the adjusted odds ratio was 0.94 (95% CI, 0.14–2.5; P=0.60). The satisfaction of surgery in the 3rd, 6th, and 12 months after surgery in the HR cohort and LR cohort were not statistically significant (table 2). There were no complications including fluid overload, laceration of cervix, uterine rupture, and hematometra in both groups.

### Table 1. Characteristics of the women in High and Low – Risk Surgical Patient with heavy menstrual bleeding undergoing endometrial ablation procedure (n=52)

| Characteristic                              | Patient group | HR     | LR     | P-value |
|---------------------------------------------|---------------|--------|--------|---------|
| Age, yr (Mean±SD)                           |               | 44.42±6.54 | 41.58±6.34 | 0.09    |
| Parity (Mean±SD)                            |               | 2.73±1.28  | 2.58±0.83  | 0.65    |
| BMI, kg/m² (Mean±SD)                        |               | 31.48±6.22  | 26.83±3.51  | 0.005   |
| Duration of menstruation, n (%)             |               | 11(33.3) | 2(10.5) | 0.09    |
| >8 days                                     |               | 22(66.7) | 17(59.5) |          |
| Score of bleeding (PBAC)                    |               | 342.76±201.18 | 507.84±256.62 | 0.013   |
| Preablation dysmenorrheal, n (%)            |               | 23(69.7) | 9(47.4) | 0.11    |
| Previous cesarean delivery n (%),           |               | 15(48.4) | 16(51.6) | 0.77    |
| Hemoglobin (g/dL), (Mean±SD)                |               | 11.15±1.29 | 11.10±1.66 | 0.89    |
| Uterine length (uterine sounding), cm (Mean±SD) |           | 58.27±35.70 | 30.92±35.30 | 0.01    |
| Anesthesia type, n (%)                      |               | 29(87.9) | 16(84.2) | 0.69    |
| Monitored anesthesia                        |               | 4(12.1) | 3(15.8) |          |
| Regional                                    |               |          |        |         |
| Operation time (minutes)                    |               | 13.27±1.66 | 13.47±2.17 | 0.70    |

### Table 2: Outcome of Cavaterm™ plus in High and Low – Risk Surgical Patient with heavy menstrual bleeding

| Outcome                                      | HR     | LR     | P value |
|----------------------------------------------|--------|--------|---------|
| pelvic pain/cramping at 1 hour (SD)          | 5.45±2.80 | 5.84±3.27  | 0.65    |
| pelvic pain/cramping at 1 week (SD)          | 1.03±1.96 | 0.47±1.42 | 0.28    |
| Amenorrhea rate at 3 months’, n (%)          | 30(90.9) | 12(63/2) | 0.02    |
| Amenorrhea rate at 6 months’, n (%)          | 27(81.8) | 11(57.9) | 0.1     |
| Amenorrhea rate at 12 months’, n (%)         | 17(51.5) | 6(31.6)  | 0.24    |
| Patient’ satisfaction rate at 3 months‘‘good’ to’excellent’, n (%) | 31(93.9) | 17(89.5) | 0.61    |
| Patient’ satisfaction rate at 6 months‘‘good’ to’excellent’, n (%) | 29(87.9) | 15(78.9) | 0.44    |
| Patient’ satisfaction rate at 12 months‘‘good’to’excellent’, n (%) | 31(93.9) | 15(78.9) | 0.17    |

### Discussion

Usually women with HMB who have had failed hormonal therapy apply for hysterectomy but hysterectomy is associated with the complications of major surgery (intraoperative or postoperative (18-21), especially in patients who were classified as HR cohort-based on the ASA physical status...
stratification. In this study, there was no significant difference in failure rate of treatment between the HR and the LR cohort (P= 0.17); it is similar to Mobolaji O et al. (2013). They reported after controlling for known confounders of treatment failure, failure rates remain unchanged(13). Other studies have compared endometrial ablation with hysterectomy for the treatment of AUB, finding that both have equally effective rates(15, 22) Endometrial ablation is a minimally invasive alternative to hysterectomy for abnormal uterine bleeding and its failure rate is low(23), considering that the incidence of obesity has increased dramatically over the last decade(24).

Anesthesiologists are increasingly being faced with treating obese patients(25). Obesity defined as the relationship between height and weight (weight [kg]/height2 [m2]), is measured by body mass index (BMI). The BMI is divided into five categories: <25 kg/m2 = normal, 25–30 kg/m2 = overweight, >30 kg/m2 = obese, >35 kg/m2 = morbid obesity, >55 kg/m2 = super morbid obesity(26). Obese women (BMI > 30) have a greater risk of complications than non-obese patients(27). Morbidity and mortality increases when the BMI is >30 kg/m2 and consequently, postoperative risks of hypoxemia and pulmonary complications are high in such women(28-30). Morbid obesity is associated with various pathophysiological changes, and it will affect the outcome of surgery and anesthesia. Planning for anesthesiology, various pathophysiological changes in morbid obesity should be considered(31). In this study, although patients in HR cohort had higher BMI compared with the LR cohort (P= 0.005), there were no complications with the anesthesia neither during the operation nor after the operation in both groups.

The shorter duration of endometrial ablation could explain the lower risk of surgery and anesthesia. The mean duration of the anesthesia was 13.35 min, in our study, also there was no difference in the duration of anesthesia between the two groups, but a hysterectomy involves a longer anesthesia overall. Prior reviews show that the mean duration of surgery was 56.4 minutes in an abdominal hysterectomy, whereas, it was 37.07 minutes in the vaginal(32). There was also blood loss during surgery, and the average hospital stay is longer with a hysterectomy(33). On the other hand, women with HMB also suffer from anemia, and preoperative anemia carries an increased risk of a longer hospital stay and increased postoperative morbidity and mortality regardless of the need for transfusion therapy (34-36). Age, obesity, duration of surgery, duration of hospital stay, and the mode of hysterectomy are known risk factors for postoperative patients (19, 20, 37-39). Consequently, patients may reject a hysterectomy as an initial treatment in HMB because it is invasive and requires time for recovery. In addition, women with menorrhagia are at a high risk because of bleeding disorders, morbid obesity, lung, and cardiac diseases, and other medical disorders, so, a thermal balloon endometrial ablation is safe and effective in treating abnormal uterine bleeding (AUB) in women who are stratified as HR according to the ASA physical status classification when other therapies are contraindicated or difficult to perform (40, 13).

Conclusion

In the present study, although patients in the HR group had a BMI above 30, nevertheless, endometrial ablation had comparable effectiveness both in the HR and LR cohorts. When women with HMB who had contraindications or that were difficult to perform a hysterectomy on, did not respond to medical therapy or other therapies, or reject a hysterectomy as an initial treatment, thermal balloon ablation is an effective and safe procedure.

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References

1. 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.
2. Bouzari Z, Yazdani S, RAD M, Bijani A. Is thermal balloon ablation in women with previous cesarean delivery successful? Turk J Med Sci 2018; 48: 266-70.
3. El-Nashar SA, Hopkins MR, Creedon DJ, Cliby WA, Famuyide AO. Efficacy of bipolar radiofrequency endometrial ablation vs thermal balloon ablation for management of menorrhagia: a population-based cohort. J Minim Invasive Gynecol 2009; 16: 692-9.
4. Penezic L, Riley K, Harkins G. Long-term patient satisfaction with thermal balloon ablation for abnormal uterine bleeding. JSLS: J Soc Laparoendoscopic Surg 2014; 18: e2014.00325.
5. Bouzari Z, Yazdani S, Azimi S, Delavar MA. Thermal balloon endothermic ablation in treatment of heavy menstrual bleeding. Med Arch 2014; 68: 411-9.

6. Bouzari Z, Ganjoei TA, Yazdani S, Bijani A, Azimi S. Complications, bleeding and satisfaction of patients with abnormal uterine bleeding through the integration of endometric degradation and thermal balloon therapy. JBUMS 2015; 17: 22-7.

7. Daniels J, Middleton L, Champaneria R, et al. Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. BMJ 2012; 344: e2564.

8. Ahonkaiie S, Martikainen H, Santala M. Endometrial thermal balloon ablation has a beneficial long-term effect on menorrhagia. Acta Obst Gynecol Scand 2008; 87: 107-10.

9. Julian S, Habiba M. Factors affecting the outcome of endometrial ablation using Cavaterm TM plus. Euro J Obstet Gynecol Reprod Biol 2005; 123: 92-7.

10. El-Nashar SA, Hopkins MR, Barnes SA, et al. Health-related quality of life and patient satisfaction after global endometrial ablation for menorrhagia in women with bleeding disorders: a follow-up survey and systematic review. Am J Obstet Gynecol 2010; 202: 348. e1-7.

11. Vitagliano A, Bertin M, Conte L, et al. Thermal balloon ablation versus transcervical endometrial resection: evaluation of postoperative pelvic pain in women treated for dysfunctional uterine bleeding. Clin Exp Obstet Gynecol 2014; 41: 405-8.

12. Gangadharan A, Revel A, Shushan A. Endometrial thermal balloon ablation in women with previous cesarean delivery: pilot study. J Minim Invasive Gynecol 2010; 17: 358-60.

13. Ajao O, El-Nashar SA, Khan Z, Hopkins MR, Creedon DJ, Fanyuyide AO. non resectoscopic endometrial in high risk surgical patients: a cohort study. J Minim Invasive Gynecol 2013; 20: 487-91.

14. Chapa HO, Venegas G, Antonetti AG, et al. In-office endometrial ablation using a third-generation uterine balloon therapy system: 12-month prospective follow-up on menstrual patterns and dysmenorrhea impact. J Reprod Med 2009; 54: 678-84.

15. Dickersin K, Munro MG, Clark M, et al. Hysterectomy compared with endometrial ablation for dysfunctional uterine bleeding: a randomized controlled trial. Obstet Gynecol 2007; 110: 1279-89.

16. Higham JM, O’Brien P, Shaw R. Assessment of menstrual blood loss using a pictorial chart. Br J Obstet Gynaecol 1990; 97: 734-9.

17. Drippd DR, Lamint A, Eckenhoff JE. the role of anaesthesia in surgical mortality. JAMA 1961; 178: 261-6.

18. Nieboer TE, Johnson N, Lethaby A, et al. Surgical approach to hysterectomy for benign gynaecological disease. Cochrane Database Syst Rev 2009; 3:CD003677.

19. Mäkinen J, Johansson J, Tomas C, et al. Morbidity of 10 110 hysterectomies by type of approach. Hum Reprod 2001; 16: 1473-8.

20. Brummer TH, Jalkanen J, Fraser J, et al. FINHYST, a prospective study of 5279 hysterectomies: complications and their risk factors. Hum Reprod 2011; 26: 1741-51.

21. Fergusson RJ, Lethaby A, Shepperd S, Farquhar C. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. Cochrane Database Syst Rev 2013; 11: CD000329.

22. Lethaby A, Shepperd S, Farquhar C, Cooke I. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. Cochrane Database Syst Rev 1999; 2. Available at: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000329/information

23. Aldape D, Chudnoff SG, Levie MD. Global endometrial ablation in the presence of Essure® microinserts. Rev Obstet Gynecol 2013; 6: 80-8.

24. Candiotii K, Sharma S, Shankar R. Obesity, obstructive sleep apnoea, and diabetes mellitus: anaesthetic implications. Br J Anaesth 2009; 103: i23-i30.

25. Ingrande J, Lemmens HJ. Anesthetic pharmacology and the morbidly obese patient. Curr Anesth Rep 2013; 3: 10-7.

26. Bray GA. Pathophysiology of obesity. The Am J Clin Nutr 1992; 55: 488S-94S.

27. Talab HF, Zabani IA, Abdulrahman HS, et al. Intraoperative ventilatory strategies for prevention of pulmonary atelectasis in obese patients undergoing laparoscopic bariatric surgery. Anesth Anal 2009; 109: 1511-6.

28. Adams J, Murphy P. Obesity in anaesthesia and intensive care. Br J Anaesth 2000; 85: 91-108.

29. Vella M, Galloway DJ. Laparoscopic adjustable gastric banding for severe obesity. Obes Surg 2003; 13: 642-8.
30. Todd DW. Anesthetic considerations for the obese and morbidly obese oral and maxillofacial surgery patient. J Oral Maxillofacial Surg 2005; 63: 1348-53.
31. Tuteja L, Vanarase M, Deval D. Anaesthetic management of a morbidly obese patient. J Postgraduate Med 1996; 42: 127-8.
32. Balakrishnan D, Dibyajyoti G. A comparison between non-descent vaginal hysterectomy and total abdominal hysterectomy. J Clin Diagn Res 2016; 10: QC11-4.
33. Aniuliene R, Varzgaliene L, Varzgalis M. A comparative analysis of hysterectomies. Medicina (Kaunas) 2007; 43: 118-24.
34. Napolitano LM. Preoperative anemia. Surg Clin North Am 2005; 85: 1215-27.
35. Musallam KM, Tamim HM, Richards T, et al. Preoperative anaemia and postoperative outcomes in non-cardiac surgery: a retrospective cohort study. Lancet 2011; 378: 1396-407.
36. Wu WC, Schiffner TL, Henderson WG, et al. Preoperative hematocrit levels and postoperative outcomes in older patients undergoing noncardiac surgery. JAMA 2007; 297: 2481-8.
37. Löfgren M, Poromaa IS, Stjerndahl JH, Renström B. Postoperative infections and antibiotic prophylaxis for hysterectomy in Sweden: a study by the Swedish National Register for Gynecologic Surgery. Acta Obstet Gynecol Scand 2004; 83: 1202-7.
38. Peipert JF, Weitzen S, Cruickshank C, et al. Risk factors for febrile morbidity after hysterectomy. Obstet Gynecol 2004;103: 86-91.
39. Kjølhede P, Halili S, Löfgren M. The influence of preoperative vaginal scrub on postoperative infectious morbidity in abdominal total hysterectomy on benign indications. Acta Obstet Gynecol Scand 2009; 88: 409-16.
40. Aletebi FA, Vilos GA, Eskandar MA. Thermal balloon endometrial ablation to treatment menorrhagia in high-risk surgical candidates. J Am Assoc Gynecol Laparosc 1999; 6: 435-9.