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## CLINICAL ARTICLE

## Randomized controlled trial of thermal balloon ablation versus vaginal hysterectomy for leiomyoma-induced heavy menstrual bleeding

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## ABSTRACT

**Objective:** To compare the efficacy of thermal balloon ablation (TBA) with that of vaginal hysterectomy in the treatment of leiomyoma-induced heavy menstrual bleeding (HMB). **Methods:** An open-label randomized controlled trial was conducted between November 1, 2012, and October 31, 2014, in a tertiary care hospital in Delhi, India. Eligible women with HMB (aged  $\geq 40$  years, uterus size  $\leq 14$  weeks of pregnancy, leiomyoma  $\leq 5$  cm, uterocervical length  $\leq 12$  cm) were randomly assigned (1:1) to undergo TBA or vaginal hysterectomy using computer-generated random number tables. The primary outcome was the number of women in the TBA group with HMB 6 months after surgery. Analyses were by intention to treat. **Results:** Each group contained 20 women. No women in the TBA group had HMB at 6 months. Nineteen women were amenorrheic by 6 months and one was hypomenorrheic. **Conclusion:** TBA can replace vaginal hysterectomy in some perimenopausal women with uterine leiomyomas.

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## 1. Introduction

Heavy menstrual bleeding (HMB) accounts for 30% of all gynecologic visits, increases morbidity, reduces health-related quality of life, and has a substantial economic burden on the healthcare system [1]. One cause of HMB is uterine leiomyomas (or fibroids), which are common benign neoplasms found in 20%–77% of premenopausal women, of whom 20%–25% are symptomatic [2].

Vaginal hysterectomy is considered the gold standard in the treatment of leiomyomas. According to the National Centre for Health Statistics in the USA, vaginal hysterectomy is the second most commonly performed major surgery in women of reproductive age [3]. In 2010, 433 621 vaginal hysterectomies were performed in the USA, 45% of which were due to uterine leiomyomas [4]. In India, the vaginal hysterectomy rate among women of reproductive age is 7%–9%, with the most common indication being uterine leiomyomas [5,6]. Nevertheless, although vaginal hysterectomy provides definitive treatment, it is associated with the high risks of any major surgery. Therefore, recent focus in gynecologic practice has been to reduce rates of vaginal hysterectomy by using safer alternatives to minimize both morbidity and cost. Minimally invasive endometrial ablative procedures are fairly safe and

effective options, with quick return to daily activity and similar efficacies as vaginal hysterectomy [7].

Endometrial ablation aims to destroy the entire layer of endometrial tissue, including the deep basal glands, to successfully suppress menstruation. There are currently five endometrial ablation techniques that have been approved by the US Food and Drug Administration: thermal balloon ablation (TBA), circulating heated saline, bipolar radiofrequency, cryoablation, and microwave energy ablation [7]. TBA is effective in the treatment of HMB in premenopausal women with a normal uterine cavity who have no desire for future fertility and do not wish to undergo major surgery, or in women for whom surgery is contraindicated [8,9]. Amenorrhea rates following TBA range from 15% to 60%, with low retreatment rates and high patient satisfaction [7].

Previous studies have focused on the use of TBA for heavy bleeding in women with a normal-size uterus, yet its role in leiomyoma-induced HMB has been infrequently studied [3,7,10]. According to a 2013 Cochrane meta-analysis [11], TBA and endometrial resection are safe and effective alternatives to vaginal hysterectomy for HMB, with equivalent satisfaction rates; however, its role in leiomyoma treatment has not been addressed.

The aim of the present study was to compare outcomes of TBA for the treatment of HMB induced by uterine leiomyomas—e.g. reduction in menstrual bleeding, improvement in hemoglobin, operative events, and quality-of-life measures—with those of vaginal hysterectomy. Leiomyomas cause HMB by increasing the endometrial surface area, as well as vascularity and blood flow to the uterus [12]. Therefore, the

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hypothesis was that endometrial ablation in perimenopausal women with leiomyoma-induced HMB will ablate the basal endometrial layer, resulting in decreased menstrual flow or amenorrhea until menopause, after which leiomyomas are known to regress in size.

## 2. Materials and methods

An open-label, randomized controlled trial was conducted at the Department of Obstetrics and Gynecology, University College of Medical Sciences and Guru Teg Bahadur Hospital, Delhi, India between November 1, 2012, and October 31, 2014. Women older than 40 years who had no desire for future childbearing, HMB (pictorial blood loss assessment chart [PBAC] score  $\geq 100$ ), a uterine size up to that of 14 weeks of pregnancy, leiomyomas of 5 cm in diameter or less, and a uterocervical length of 12 cm or less were eligible for inclusion. Women with acute pelvic inflammatory disease or pelvic pathology (e.g. adenomyosis, gynecologic cancers [including endometrial malignancy], atypical endometrial hyperplasia, and submucosal leiomyomas) were excluded. Ethical clearance was obtained from the institutional ethics committee. All participants provided written informed consent.

Participants were randomly allocated into two groups (TBA and vaginal hysterectomy) in a 1:1 ratio using computer-generated random number tables. Participants, investigators, and data analysts were not masked to group assignment.

A detailed history was obtained from all participants. A physical examination was also performed, along with PBAC scoring. All requisite preoperative investigations were undertaken, including hemoglobin tests, cervical smear tests, ultrasonography, endometrial histologic examinations, and pre-anesthetic evaluation. The Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire was used to assess the quality of life before and after the procedures. The UFS-QOL consists of the symptom severity score (SSS) and the health-related quality of life (HR-QOL) score. SSS includes questions pertaining to severity of symptoms, and the HR-QOL score includes questions pertaining to concern, energy, activities, control, self-consciousness, and sexual functions [13]. The SSS and HR-QOL score were applied to formulas to obtain corresponding transformed scores indicating severity (Uterine Fibroid Symptom Transformed Score [UFS-TS]) and quality of life (Health-Related Transformed Score [HR-TS]), respectively, in terms of percentages.

Both TBA and vaginal hysterectomy were performed under spinal anesthesia in the postmenstrual phase of the cycle. TBA was performed using the LiNAMenotreat system (LiNA Medical, Glostrup, Denmark), which consists of a reusable Menotreat system controller and a single-use Menotreat balloon set with an inflatable silicon balloon catheter. Thorough curettage was performed to reduce the endometrial thickness before TBA. The balloon was inflated with normal saline at  $85^{\circ}\text{C} \pm 3^{\circ}\text{C}$  with the pressure maintained at  $200 \pm 10$  mm Hg for 11 minutes  $\pm 5$  seconds. The maximal uterine cavity length for TBA was 12 cm as recommended by the manufacturer. Vaginal hysterectomy was performed using the standard technique.

Intraoperative variables—including blood loss, duration of surgery, need for blood transfusion, complications, and technical difficulty—were compared in both groups. Technical difficulty was assessed by asking the surgeon to grade the surgery as “easy,” “difficult,” or “very difficult.” Postoperative severity of pain was assessed using a visual analog scale (VAS) scored 4, 6, and 12 hours after surgery, and then on postoperative days 1 (24 hours), 2 (48 hours), and 3 (72 hours). For patients with early postoperative discharge ( $<72$  hours), subsequent VAS scoring was performed by telephone. Duration of hospital stay, and early and late postoperative complications—including infection, fever, endometritis, pneumonia, thromboembolism, hematoma, cellulitis, and abscess formation—were noted and compared in both groups. The frequency of adverse events such as hematometra and postablation tubal sterilization syndrome was noted in women who underwent TBA.

Follow-up was performed at 1, 3, and 6 months after surgery to assess menstrual blood loss (PBAC score) in women in the TBA group and hemoglobin levels in both groups. Six months after surgery, improvement of symptoms and UFS-QOL scores (SSS and HR-QOL scores) was assessed in all women. Women in the TBA group were also assessed at 12 and 24 months after surgery for recurrence of HMB.

The primary outcome measure was the number of women with HMB in the TBA group 6 months after surgery for uterine leiomyomas. Secondary outcome measures were improvement in hemoglobin levels, intraoperative and postoperative events, and UFS-QOL scores in both groups.

A sample size of 40 was considered adequate assuming that 40% of women in the vaginal hysterectomy group and 8% in the TBA group would experience adverse effects (minor and major), and a reduction in the PBAC score of 342 in women undergoing TBA, with 80% power at a 5% level of significance [10,14]. Statistical analyses were by intention to treat and were performed using SPSS version 20.0 (IBM, Armonk, NY, USA). The  $\chi^2$  test was used to study baseline variables and symptoms; the unpaired *t* test was used to compare changes in UFS-QOL. The two-way repeated measures ANOVA test was applied for VAS scoring, and the McNemar test was used to compare symptom scores. *P* values and mean differences with 95% confidence intervals (CIs) were used to determine significance.  $P < 0.05$  was considered significant.

## 3. Results

Twenty women were randomly assigned to each group (Fig. 1). None of the participants were lost to follow-up. The baseline characteristics of women in both groups were similar, other than uterocervical canal length (Table 1).

In terms of the primary outcome, no women in the TBA group had HMB at 6 months (Fig. 2). Eighteen (90%) women became amenorrheic after 1 month and continued to remain so until 6 months postoperatively. One of the other two women was hypomenorrheic (PBAC score 74) after 1 month and became amenorrheic after 6 months. The second woman in the TBA group had a PBAC score of 106 after 1 month and became hypomenorrheic by 6 months (PBAC score 80). At 12 months after TBA, 1 (5%) woman had a recurrence of HMB for which she underwent vaginal hysterectomy, 2 (10%) became hypomenorrheic, and 17 (85%) remained amenorrheic. At 24 months, of the 19 women in the TBA group who had not undergone vaginal hysterectomy, 15 (79%) remained amenorrheic and 4 (21%) had hypomenorrhea.

There was a significant increase in hemoglobin levels in both the TBA and vaginal hysterectomy groups after 6 months, rising from 108.8 g/L to 127.5 g/L and 101.9 g/L to 123.2 g/L, respectively ( $P < 0.001$  for both). There was no significant difference between the two groups at 6 months ( $P = 0.192$ ).

Operative time was significantly shorter in the TBA group than in the vaginal hysterectomy group ( $P < 0.001$ ) (Table 2). Blood loss was also significantly lower in the TBA group ( $P < 0.001$ ) (Table 2). The number

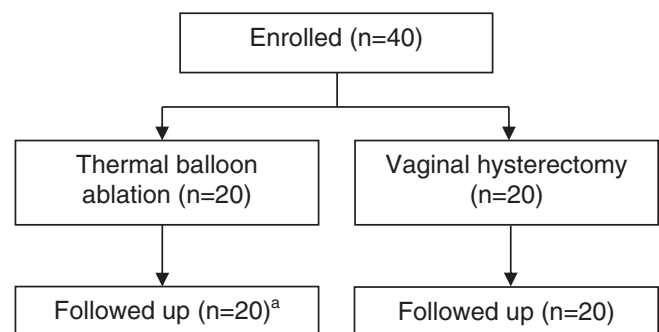


Fig. 1. Flow of patients through the study. <sup>a</sup> One woman underwent vaginal hysterectomy 12 months after thermal balloon ablation.

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