

# Comparison of Bipolar Ball Endometrial Ablation and Transcervical Resection of the Endometrium in the Treatment of Heavy Menstrual Bleeding: A Randomized Clinical Trial

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## Abstract

**Objectives:** To compare the operative time, effectiveness, and patient satisfaction between ball endometrial ablation and transcervical resection of the endometrium (TCRE) using a bipolar resectoscope.

**Materials and Methods:** Forty-four women with heavy menstrual bleeding who were unresponsive to at least 3 months' medical management were included in this randomized, controlled clinical trial. After randomization, patients underwent either TCRE or ball endometrial ablation using a bipolar resectoscope. The operative time, fluid deficit, and postoperative pain were recorded. The patients were evaluated postoperatively at 3, 6, and 12 months after surgery. Patient satisfaction, amenorrhea rate, reintervention rate, and pictorial blood-loss-assessment chart (PBAC) score were compared between the two groups.

**Results:** The mean operative time in ball endometrial ablation group was  $11.17 \pm 2.24$  min and in TCRE group was  $22.33 \pm 5.26$  min ( $P < 0.001$ ). There was no significant difference in the postoperative PBAC score, amenorrhea rates, patient satisfaction, and need for reintervention between the two groups.

**Conclusion:** Operative time with ball endometrial ablation is significantly less when compared to TCRE when using a bipolar resectoscope.

**Keywords:** Ball endometrial ablation, bipolar resectoscope, heavy menstrual bleeding, pictorial blood-loss-assessment chart, transcervical resection of the endometrium

## INTRODUCTION

Heavy menstrual bleeding (HMB) is a common problem in premenopausal women and has a significant effect on their medical and psychological well-being.<sup>[1]</sup> Abnormal uterine bleeding due to an underlying endometrial dysfunction ( $P_0A_0L_0M_0-C_0O_0E_1I_0N_0$ ) is an important cause of HMB. Medical therapy is usually used as first-line therapy in these patients, but they are not effective in all of them. Endometrial ablation has emerged as an alternative to hysterectomy in these patients. First-generation endometrial ablation devices (transcervical resection of the endometrium [TCRE] and rollerball) require

cervical dilatation under anesthesia and have been almost completely replaced by second-generation devices in Western countries.<sup>[2]</sup> However, these second-generation devices which are disposable devices are not commonly used in developing countries. On the other hand, first-generation devices are still widely used in developing countries.<sup>[3,4]</sup>

There are few studies comparing individual first-generation devices such as TCRE and rollerball ablation.<sup>[5,6]</sup> These studies were done using monopolar resectoscope. Bipolar

### Article History:

Submitted: 17 June 2020

Revised: 29 October 2020

Accepted: 11 January 2021

Published: 3 August 2021

### Access this article online

#### Quick Response Code:



Website:  
www.e-gmit.com

DOI:  
10.4103/GMIT.GMIT\_88\_20

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**How to cite this article:** Subbaiah M, Selvest N, Maurya DK. Comparison of bipolar ball endometrial ablation and transcervical resection of the endometrium in the treatment of heavy menstrual bleeding: A randomized clinical trial. *Gynecol Minim Invasive Ther* 2021;10:143-7.

resectoscopes have replaced monopolar resectoscopes in many centers as they have been found to be safer, with lower incidence of hyponatremia and hyposmolarity.<sup>[7]</sup> Bipolar resectoscopes have different electrode, current setting, and distension media when compared to monopolar resectoscopes.<sup>[8]</sup> Ball end coagulation electrodes in bipolar resectoscopes are similar to rollerball electrodes used with monopolar electrodes. Endometrial ablation using these ball end coagulation electrodes has not been evaluated in any study. This study was done to compare this ball endometrial ablation with TCRE using a bipolar resectoscope.

## MATERIALS AND METHODS

This was a randomized controlled trial done in the Department of Obstetrics and Gynaecology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry and included women with HMB who were unresponsive to at least 3 months' medical management. Only women who had completed the family size and had a pictorial blood-loss-assessment chart (PBAC) Score >150 were included in the study.<sup>[9]</sup> All the patients had ovulatory type of abnormal uterine bleeding (P<sub>0</sub>A<sub>0</sub>L<sub>0</sub>M<sub>0</sub>-C<sub>0</sub>O<sub>0</sub>E<sub>1</sub>I<sub>0</sub>N<sub>0</sub>) and an endometrial biopsy was done to rule out endometrial malignancy and hyperplasia in all the patients. Patients with uterine cavity length >12 cm, history of dysmenorrhea, and those not using a reliable contraceptive were excluded from the study. The study enrollment was from January 2017 to July 2018. This study was done as per the ethical standards set by the Institute Scientific Advisory and Ethical Committee (Human Studies), in accordance with the 1964 Helsinki declaration and its later amendments. Protocol for this study was approved by the Institute Ethics Committee for human studies (JIP/IEC/2016/27/902, approval date May 25, 2016) and was registered under Clinical Trials Registry India (CTRI/2016/11/007503).

After taking written informed consent, patients were randomized into two groups: TCRE group or ball ablation group. Block randomization with fixed block size of four was used to randomize the patients in the study arms in the ratio of 1:1. Sequentially numbered, sealed, opaque envelopes were used for concealment. These envelopes were opened in the operation theatre. Patients were blinded to the type of endometrial ablation. All the surgeries were done by a single surgeon experienced in operative hysteroscopy. No premedications were used for endometrial thinning or cervical priming and all the procedures were done immediately after menstruation.

All the procedures were done under spinal anesthesia and fluid deficit during the procedure was calculated every 5 min by a resident. After cervical dilatation, a 26F continuous-flow Bipolar resectoscope (Karl Storz, Germany) was introduced

into the uterine cavity. Normal saline (0.9%) was used for uterine distension and continuous irrigation. During TCRE, a 24F cutting bipolar loop was used to resect the endometrium and superficial myometrium. Resected bits of tissue were removed with a curette. The same 24 F bipolar loop was used for coagulation of oozing surface and ablation of the cornual region. During ball ablation, coagulation electrode (bipolar, ball end; 24F) was used to ablate the entire endometrium from cornua to the isthmus. A drag speed of around 1 cm/s was used; slower drag speed was used if necessary, depending on the tissue effect observed. Autocon II 400 high-frequency unit (Karl storz, Germany) was used and the effect setting was five for cut and six for coagulation.

Postoperative pain was assessed at 1 and 4 h after the procedure using visual analog scale. Any need for additional analgesia and postoperative bleeding was also documented. They were discharged the same day and were told to follow-up after 2 weeks. They were told to complete the PBAC score for 1 year and were followed up at 3, 6, and 12 months after the procedure. At 12 months follow-up visit, the level of satisfaction with the procedure was assessed (satisfied, partially satisfied, and not satisfied). Any history of chronic pelvic pain or new-onset dysmenorrhea was documented. Primary outcome measure was operative time difference between the two groups. Secondary outcome measures were postoperative PBAC score, amenorrhea rate, postoperative pain, reintervention rate, and patient satisfaction at the end of 12 months.

## Statistical analysis

Based on our retrospective hospital data, we found the time taken for TCRE with bipolar resectoscope to be 30 ± 14 min. We considered 30% difference in operative time to be clinically important. With an  $\alpha$  error of 0.05 and power of 80% with 1:1 ratio between the two study groups, the minimum sample size required was 38 patients in each group. The sample size was calculated using open Epi, Version 3. However, an interim analysis with total sample size of 44 revealed a significant difference in the primary outcome.

Categorical variables were expressed as frequency and percentage and the comparison between these groups was carried out using Chi-square or fisher exact test. The distribution of data on continuous variables was expressed as mean with standard deviation. The comparison between the continuous variables was done with independent Student's *t*-test or Mann-Whitney U-test.  $P < 0.05$  was considered as statistically significant. Statistical analysis was performed using IBM SPSS software version 21.0 (IBM Corp.Armonk, NY).

## RESULTS

A total of sixty patients were assessed for eligibility, and 44 patients were included in the study. No patients were

lost to follow-up. Twenty-two patients were randomized for TCRE and 22 patients for ball endometrial ablation using bipolar resectoscope [Figure 1]. Baseline demographic features of patients are shown in Table 1. There was no significant difference in endometrial thickness, uterine cavity length, and other demographic data between the two groups. The intraoperative variables and immediate postoperative outcome are shown in Table 2. Although the fluid deficit was higher in the TCRE group when compared to ball endometrial ablation group, this was not statistically significant. There was no significant difference between the two groups with respect to postoperative pain. Operative time in the ball endometrial ablation group was significantly less when compared to TCRE group ( $11.17 \pm 2.24$  min vs.  $23.33 \pm 5.26$  min;  $P < 0.001$ ). More patients in the TCRE group reported postoperative vaginal spotting compared to ball endometrial ablation group (27.3% vs. 9.1%). However, this difference was not statistically significant. This mild vaginal spotting usually lasted for 2–3 days in both groups and did not need any further treatment. None of the patients in both groups needed any additional analgesia in the postoperative period. There were no intraoperative complications noted in both

groups. PBAC score and patient satisfaction at 12 months follow-up are reported in Table 3. There was no significant difference in postoperative PBAC score, amenorrhea rates, patient satisfaction, and need for reintervention between the two groups. All the patients who needed reintervention were offered repeat endometrial ablation, further medical therapy, or hysterectomy. Three patients needed reintervention (two in TCRE group; one in ball ablation group), and all of them opted for hysterectomy. None of the patients reported new-onset dysmenorrhea or chronic pelvic pain.

### DISCUSSION

Forty-four patients with ovulatory type of abnormal uterine bleeding were included in this study and underwent either TCRE ( $n = 22$ ) or ball endometrial ablation ( $n = 22$ ) using bipolar resectoscope. Operative time in ball endometrial ablation group ( $11.17 \pm 2.24$  min) was significantly less when compared to TCRE group ( $23.33 \pm 5.26$  min;  $P < 0.001$ ). There was no significant difference between the two groups with respect to fluid deficit and postoperative pain. At 12 months follow-up, both groups were found to have similar PBAC score, patient satisfaction, and reintervention rates.

Endometrial ablation techniques involve either ablation or resection of the basal layer of the endometrium along with superficial myometrium. These procedures are less invasive when compared to hysterectomy. First- and second-generation endometrial ablation approaches have equal efficacy in the management of HMB, with similar rates of amenorrhea.<sup>[10]</sup> However, second-generation approaches have shorter operating times and do not require general anesthesia. They can be performed as an office procedure and have no learning curve unlike first-generation devices. For these reasons, second-generation devices are more commonly used in Western countries. First-generation endometrial ablation devices such as TCRE and rollerball are still in common use in resource-poor countries.<sup>[11]</sup>

Bipolar resectoscope has been found to be safer than monopolar resectoscope in several studies.<sup>[7,12]</sup> For this reason, bipolar

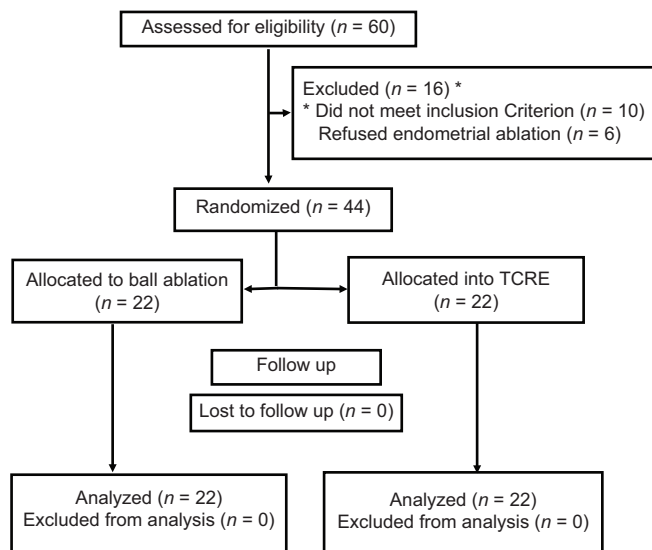


Figure 1: Consort flow diagram

Table 1: Baseline patient characteristics

Patient characteristics	Ball ablation (n=22)	TCRE (n=22)	P
Mean age (year)±SD	41.9 (4.11)	42.2 (4.91)	0.82
Mean body mass index (kg/m <sup>2</sup> )±SD	23.32 (3.48)	24.18 (3.65)	0.43
Parity, mean±SD	2.41 (0.85)	2.45 (0.67)	0.85
Prior LSCS, n (%)	8 (36.4)	3 (13.6)	0.162
Prior tubal sterilization, n (%)	19 (86.4)	18 (81.8)	1
PBAC score, mean±SD	363 (95.75)	342.27 (122.66)	0.52
95% CI	328.1-410.5	258.56-413.1	

CI: Confidence interval, SD: Standard deviation, LSCS: Lower segment cesarean section, PBAC: Pictorial blood-loss-assessment chart, TCRE: Transcervical resection of the endometrium

**Table 2: Intraoperative and immediate postoperative outcome**

	Ball ablation (n=22)	TCRE (n=22)	P
Operative time (min)±SD	11.17 (2.24)	23.33 (5.26)	<0.001
95% CI	10.18-12.16	20.99-25.67	
Fluid deficit (ml)±SD	795.45 (371.3)	920.45 (119.2)	0.14
95% CI	630.9-960	867.61-973.3	
Postoperative VAS at 1 h	3.45 (1.18)	3.27 (1.2)	0.62
Postoperative VAS at 4 h	2.64 (0.85)	2.68 (0.95)	0.87
Vaginal spotting, n (%)	2 (9.1)	6 (27.3)	0.24

CI: Confidence interval, SD: Standard deviation, VAS: Visual analogue scale, TCRE: Transcervical resection of the endometrium

**Table 3: Bleeding pattern and patient satisfaction at the end of 12 months follow-up**

	Ball ablation (n=22)	TCRE (n=22)	P
PBAC score, mean±SD	75.87 (63.11)	75.38 (53.53)	0.98
95% CI	40.92-110.81	43.04-107.73	
PBAC <100, n (%)	18 (81.8)	19 (86.4)	1
Amenorrhoea, n (%)	7 (31.8)	8 (36.4)	0.75
Reintervention, n (%)	1 (4.5)	2 (9.1)	1
Patient satisfaction, n (%)			
Satisfied	17 (77.3)	14 (63.6)	0.64
Partially satisfied	2 (9.1)	3 (13.6)	
Not satisfied	3 (13.6)	5 (22.7)	

CI: Confidence interval, SD: Standard deviation, TCRE: Transcervical resection of the endometrium, PBAC: Pictorial blood-loss-assessment chart

resectoscope was used to perform TCRE and ball endometrial ablation in this study. The most used first-generation technique is TCRE. However, there is no evidence to support superiority of TCRE over roller ball.<sup>[13]</sup>

There are several studies which have compared TCRE with rollerball ablation using monopolar resectoscope.<sup>[14,15]</sup> A randomized controlled trial done to compare monopolar TCRE and rollerball ablation in 120 women did not find any significant difference with respect to bleeding reduction and patient satisfaction in the two groups.<sup>[14]</sup> However, they did not compare the operative time between the two groups. No significant difference between the two groups with respect to amenorrhea rates and reduction in PBAC score (at 12 months follow-up) were found in the present study.

TCRE may be associated with higher rate of uterine perforation especially at the cornual region when compared to rollerball ablation.<sup>[6]</sup> There were no uterine perforations in either group in the present study.

In a randomized study, 82 patients with HMB were subjected to either TCRE or rollerball ablation using monopolar

resectoscope.<sup>[15]</sup> They reported that ablation group had a shorter operative time, lower reintervention rates, and higher satisfaction rates at 2 years follow-up when compared to TCRE group. In the present study also, operative time was found to be shorter with the ball endometrial ablation group. During TCRE, resected bits of endometrium must be removed to improve visualization during the procedure. Further, TCRE requires more time to achieve hemostasis as small blood vessels in the superficial myometrium are cut during the procedure and need coagulation. These factors may be responsible for the longer operative time with TCRE compared to ball endometrial ablation.

It is well established that longer operative time is a risk factor for fluid overload and related complications such as pulmonary edema.<sup>[16,17]</sup> In the present study, there was significant reduction in operative time in the ball endometrial ablation group.

### Strength and limitation

To the best of our knowledge, this is the first RCT comparing two first-generation ablation techniques using bipolar resectoscope. Ball end coagulation electrode was used for endometrial ablation in this study, unlike earlier studies where roller ball electrodes were used. Ball end coagulation electrodes have not been evaluated in earlier studies. PBAC, which is an objective way of assessing HMB was used in this study unlike the earlier studies done using monopolar resectoscope.

The main limitation of the study is the small sample size. Sample size in this study was not powered to compare reintervention rates and complications. Because the expected difference between the two groups in these parameters is less; the required sample size would be very large. Multicentric studies, involving larger sample size and longer follow-up are needed to compare these outcomes. Another limitation of the study is noninclusion of quality of life as an outcome parameter.

### CONCLUSION

Operative time with bipolar endometrial ball ablation is significantly less when compared to TCRE. Larger trials with longer follow-up period are needed to confirm the findings, especially with respect to complication rates and reintervention rates.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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