

Long-Term Patient Satisfaction with Thermal Balloon Ablation for Abnormal Uterine Bleeding

Lindsey Penezic, MD, Kristin Riley, MD, Gerald Harkins, MD

ABSTRACT

Background and Objective: Thermal balloon ablation is a minimally invasive surgical technique that can be used to treat abnormal uterine bleeding/heavy menstrual bleeding (AUB/HMB). Most published studies to date provide information on short-term patient satisfaction and outcomes. The purpose of this study was to determine long-term patient satisfaction after thermal balloon endometrial ablation 7 to 10 years postoperatively in a population previously surveyed at the Penn State Milton S. Hershey Medical Center at 1 to 5 years postoperatively.

Methods: Two-hundred fourteen patients were identified who underwent thermal balloon ablation at our institution between January 1, 2001 and December 31, 2004. These patients were mailed a 2-page survey asking for information on demographics, patient satisfaction, postoperative bleeding patterns, and the need for subsequent surgery. Satisfaction rates, amenorrhea rates, and the rates of women who required hysterectomy were calculated as percentages.

Results: Ninety-seven patients returned completed surveys. The survey response rate was 62%, excluding 57 surveys that were returned as undeliverable. The follow-up interval was 93 to 129 months. Eighty-seven percent of respondents were satisfied with the results of their procedure compared with 88% in the original study. Subsequent hysterectomy was required in 21.6% of women after 7 to 10 years compared with 9% after the 1- to 5-year follow-up period. Of the 76 women who did not undergo hysterectomy, 58% reported amenorrhea and 35.5% reported minimal to light bleeding.

Conclusion: This study demonstrates a consistently high patient satisfaction rate with thermal balloon ablation at our institution at 7 to 11 years postoperatively compared with 1

to 5 years postoperatively. The hysterectomy rate, however, was 2.4 times greater in the long-term follow-up period.

Key Words: Endometrial ablation techniques, Menorrhagia, Patient satisfaction, Hysterectomy.

INTRODUCTION

Abnormal uterine bleeding/ heavy uterine bleeding (AUB/HUB), previously termed *menorrhagia*, is defined as menstrual blood loss greater than 80 mL per cycle and affects 11% to 13% of women of all ages. The incidence of menorrhagia increases with age, affecting 24% of women aged 36 to 40 years.¹ The condition can be treated both medically and surgically. Although hysterectomy is considered to be the definitive surgical treatment for AUB/HMB, thermal balloon ablation (TBA) is a less invasive surgical approach for long-term control of bleeding. A study performed at the Penn State Milton S. Hershey Medical Center in 2006 reported that 89% of patients who underwent thermal balloon ablation at Hershey Medical Center between January 1, 2001 and December 31, 2004 were either satisfied or very satisfied with their procedure. In this population, 9% of patients went on to undergo a hysterectomy after their ablation procedure. The satisfaction rate for the procedure over a 13- to 60-month follow-up period was consistent with the satisfaction rates of 70% to 90% that were previously reported in the literature.²

Although patient satisfaction with TBA at our institution and in the literature is high, the follow-up period for most studies is limited. A systematic review of randomized controlled trials studying TBA published in 2008 reported follow-up periods ranging from 6 to 48 months post procedure.³ A more recent retrospective cohort study in 2012 of 1169 women undergoing endometrial ablation, including 176 TBAs, reported a 9- to 84-month follow-up period.⁴ Patient counseling before the procedure involves discussion of the risks of dissatisfaction with the procedure and the possible need for future interventions including hysterectomy.⁵ The primary goal of this study was to obtain long-term follow-up data for our institution regarding patient satisfaction rates for the TBA procedure to

Penn State Hershey Medical Center Department of Obstetrics and Gynecology, Hershey, PA, USA (all authors).

Dr. Gerald Harkins is a speaker/proctor for Intuitive and Ethicon.

Address correspondence to: Lindsey Penezic, MD, Penn State Hershey Medical Center Department of Obstetrics and Gynecology, 500 University Drive, Hershey, PA 17033. Telephone: (724) 840-4532, Fax: (717) 531-0066, E-mail: lpenezic@hmc.psu.edu

DOI: 10.4293/JSLS.2014.00325

© 2014 by JSLS, *Journal of the Society of Laparoscopic Surgeons*. Published by the Society of Laparoscopic Surgeons, Inc.

optimize patient counseling. Secondary outcomes for this study included postprocedure bleeding patterns and the need for subsequent surgery, including hysterectomy, after the TBA procedure. We hypothesized that the hysterectomy rate would increase and the satisfaction rate would decrease over the extended follow-up period.

MATERIALS AND METHODS

Institutional Review Board approval was obtained at the Penn State Milton S. Hershey Medical Center to survey all patients who underwent the TBA procedure at our institution between January 1, 2001 and December 31, 2004. Two-hundred fourteen women were identified from the *International Classification of Diseases*, 9th revision, coding on billing records as having undergone the TBA procedure in this time frame and were included in the study. This group of patients was previously surveyed in 2005 by Hazard and Harkins.²

Patients received a 2-page written survey in the mail identical to that used in the prior study. The survey included questions regarding patient demographics, indication for procedure, surgery date, therapy received before the TBA procedure, surgery required after the procedure, and bleeding patterns since the TBA procedure. Patients were also asked to rate their satisfaction with the procedure and to state whether they would recommend the procedure to family and friends. They were also allowed to write in any additional comments regarding their procedure.

All mailings and data collection were performed by the Survey Research Center at University Park in State College, Pennsylvania. Initial surveys were sent in September 2012 and all surveys were received by January 18, 2013. No further attempts were made to contact patients whose mail was returned as undeliverable because of a wrong address. Patients were sent as many as 3 reminder postcards to mail in their surveys. The final reminder postcard was accompanied by a \$2 incentive for the patients who had not yet returned their surveys. The total follow-up interval was 93 to 129 months since the time of the procedure. SPSS software was used for all data analysis (IBM, Armonk, New York). The Fisher exact test was used to compare the satisfaction rates and hysterectomy rates between studies.

RESULTS

Two-hundred fourteen surveys were mailed initially; 57 surveys were returned as undeliverable. Our response rate was 62% of the 157 surveys received by patients. Patient demog-

graphics are listed in **Tables 1 and 2**, along with those from the 2005 study by Hazard and Harkins.²

Of the 97 respondents, 88% reported that they were satisfied or very satisfied with the results of their procedure, compared with 89% in the prior study ($P = .84$) (**Table 3**). Amenorrhea was reported by 44 of 76 (57.9%) women

Table 1.
Demographics

	Penezic (N = 97)		Hazard ² (N = 178)	
	Median	Range	Median	Range
Age (y)	51	33–63	42	25–73
Height (in)	65	59–70	66	58–71
Weight (lb)	165	98–285	150	100–353
Gravity	2	0–9	2	0–9
Parity	2	0–6	2	0–6
Smoking (%)	Yes 8%	No 92%	Yes 17%	No 83%

Table 2.
Ethnicity

	Penezic (N = 97)	Hazard ² (N = 178)
	Number of patients (%)	Number of patients (%)
Caucasian	91 (93.8)	159 (91)
African American	2 (2.1)	6 (3.4)
Hispanic	1 (1)	4 (2.3)
Asian	1 (1)	2 (1)
Other	1 (1) ^a	4 (2.3) ^b

One patient did not answer the question.

^aPacific Islander.

^bPacific Islander, Greek, Native American.

Table 3.
Patient Satisfaction

	Penezic (N = 97)	Hazard ² (N = 178)
	Number of patients (%)	Number of patients (%)
Satisfied	84 (88)	158 (89)
Not satisfied	12 (12)	20 (11)

One patient did not answer the question.

Table 4.
Bleeding Patterns Postablation

	Penezic		
	No hysterectomy (n = 76)^a	All (N = 93)^b	Hazard² (N = 177)^c
	Number of patients (%)	Number of patients (%)	Number of patients (%)
Amenorrhea	44 (57.9)	50 (53.8)	70 (40)
Minimal/light bleeding	27 (35.5)	35 (37.7)	68 (39)
Moderate bleeding	8 (10.5)	4 (4.1)	26 (15)
Menorrhagia/heavy bleeding	3 (3.9)	4 (4.1)	13 (7)

^aTwo patients did not answer the question.

^bFour patients did not answer the question.

^cOne patient did not answer the question.

who had not undergone hysterectomy. An additional 27 (35.5%) reported minimal to no bleeding (**Table 4**).

Twenty-one patients (21.6%) had undergone a hysterectomy at the time of our survey, compared with a 9% hysterectomy rate in the same population in 2005 ($P = .005$). An additional 4 patients (4.1%) reported having a dilation and curettage procedure since the time of their ablation and one (1.1%) patient had undergone a repeat ablation (**Table 5**).

DISCUSSION

The patient satisfaction rate for TBA at our institution remained statistically unchanged at 8 to 11 years post procedure compared with 1 to 5 years post procedure. In contrast, the hysterectomy rate was 2.4 times higher over the same follow-up interval. Despite the significant increase in hysterectomy rate, more than 88% of our patients who underwent TBA for menorrhagia 8 to 11 years before were able to avoid hysterectomy. A consistently high satisfaction rate despite an increased hysterectomy rate suggests that many of our patients who ultimately required hysterectomy remain satisfied with the procedure.

The rate of patients with amenorrhea increased from 40% at 1 to 5 years post procedure to 57.9% of patient who retained their uterus at 8 to 11 years post procedure. This is consistent with the median age of patients increasing from 42 to 51 years over the time that elapsed between studies. Several of our patients commented on the onset of menopausal symptoms and subsequent amenorrhea since the time of their surgery.

Our survey response rate of 62% over a follow-up period of 8 to 11 years is a strength of this study; the prior study

Table 5.
Postablation Procedures

	Penezic (N = 97)	Hazard² (N = 178)
	Number of patients (%)	Number of patients (%)
Hysterectomy	21 (21.6)	16 (9)
Dilation and curettage	4 (4.1)	7 (4)
Repeat TBA	1 (1)	4 (2)

in 2005 also had an excellent response rate of 88%. This is attributable to our stable patient population at Hershey Medical Center as well as the multiple reminders sent to patients. The study design was kept identical between the two studies to allow for even comparison. The demographics between the two studies were similar and consistent with the change in time between them.

The follow-up period for this study (93–129 mo) is longer than other studies reported in the literature. A systematic review of randomized controlled trials studying TBA in 2008 reported follow-up periods ranging from 6 to 48 months post procedure, with an average follow-up period of 12 to 24 months. The patient satisfaction rate for this study ranged from 59% to 95%.³ A retrospective cohort study in 2012 reported a 9- to 84-month follow-up period. This study reported an overall hysterectomy rate of 13.4% for all ablation types and 16.4% for TBAs.⁴ Our data obtained over this extended follow-up period are consistent with these studies and are specific to our patient population. It is hoped that these will allow for improved

counseling of our patients and prediction of satisfaction and the eventual need for hysterectomy.

Weaknesses of the study include the retrospective design and the lack of data for procedures performed after 2004 or for other types of global endometrial ablation techniques. The long follow-up period, although a strength of the study, may also contribute to recall bias. In addition, our data are specific to the patient population at our institution and may not be widely applicable. Finally, our survey did not ask patients to specify the indication for their hysterectomy. One of our patients wrote on her survey that her hysterectomy was performed to treat prolapse; another stated that her hysterectomy was performed along with a bilateral salpingo-oophorectomy after a diagnosis of hormone receptor-positive breast cancer. Data regarding the frequency of hysterectomy performed specifically as a result of menorrhagia would be valuable.

CONCLUSIONS

This study demonstrates a consistently high patient satisfaction rate with TBA at our institution at 7 to 11 years

postoperatively compared with 1 to 5 years postoperatively, despite a significant increase in the hysterectomy rate over the same time period.

References:

1. Marret H, Fauconnier A, Chabbert-Buffet N, et al. Clinical practice guidelines on menorrhagia: management of abnormal uterine bleeding before menopause. *Eur J Obstet Gynecol Reprod Biol.* 2010;152(2):133–137.
2. Hazard D, Harkins G. Patient satisfaction with thermal balloon ablation for treatment of menorrhagia. *Am J Obstet Gynecol.* 2009;20(5):e21–e23.
3. Iavazzo C, Salakos N, Bakalianou K, Vitoratos N, Vorgias G, Liapis A. Thermal balloon endometrial ablation: a systematic review. *Arch Gynecol Obstet.* 2008;277:99–108.
4. Shavell VI, Diamond MP, Senter JP, Kruger ML, Johns DA. Hysterectomy subsequent to endometrial ablation. *J Minim Invasive Gynecol.* 2012;19(4):459–464.
5. Vilos G, Edris F. Second-generation endometrial ablation technologies: the hot liquid balloons. *Best Pract Res Obstet Gynaecol.* 2007;21(6):947–967.