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## Review Article

# Endometrial ablation for treatment of heavy menstrual bleeding: For whom it may not work?

## Abstract

Endometrial Ablation (EA) refers to a group of minimally invasive approach that produces irreversible destruction of the endometrium. These procedures provide a satisfactory alternative to hysterectomy when medical treatment is contraindicated or unsatisfactory. While EA has become longstanding in practice, variable failure rates were reported, that seem to relate, in part, to time since intervention. Identification of predictors of long-term outcomes allows better patient selection and lowers the probability of reintervention. This review discusses determinants of EA failure and how to improve patient selection based on available evidence.

## Introduction

Heavy Menstrual Bleeding (HMB) is the most prevalent form of abnormal uterine bleeding, a complaint that affects approximately 14% of reproductive aged women and presents both a health and financial burden [1]. For decades, hysterectomy had been the only treatment approach when medical treatment is contraindicated or ineffective. Endometrial ablation (EA) has been introduced as an alternative to radical treatment since late 80's and early 90's and has gained substantial popularity as a convenient procedure of less cost and high safety profile. Thereafter, evidence from the literature has supported EA as a second line treatment if medical treatment fails or is contraindicated [2]. Second generation EA devices (also known as global EA) have been well-established in gynecologic care and are offered to all eligible women. Because second generation devices allow office-based treatment under local anaesthesia, EA has become widely acceptable by both patients and health care providers and has become the most common treatment of HMB in the United States [3].

Although EA provides fewer complications and significantly costs less than hysterectomy [4], treatment failure, defined as recurrence of symptoms that necessitates reintervention, presents a major concern. Treatment failure is time-dependent and accordingly, the incidence of reintervention has been increasingly recognizable while 2-3 decades passed since EA was introduced [5]. Failure of EA reached up to 26% after 8 years of treatment [3]. Because failure of EA doubles treatment burden in terms of morbidity and costs and because EA failure seems to vary widely among reports, identification of

determinants of treatment success had become imperative to improve patient selection and counselling [6].

In this review, our objective is to present available evidence on predictors of long-term failure of EA. We also aim to explain the mechanisms by which these predictors may contribute to recurrence and to recommend strategies that could improve treatment outcomes and minimize the need for intervention.

## Endometrial ablation: An overview

EA refers to a set of procedures that aim to destroy the endometrium beyond its natural capacity to regenerate. Although the term seems to be relatively recent, trials on endometrial destruction were initiated many decades ago. One of the oldest trials was conducted by Droegemuller et al., who treated 11 women with dysfunctional uterine bleeding using cryosurgery of the endometrium based on a Frigitrionics nitrous oxide cryosurgical system [7]. One decade later, ND: YAG Laser was first introduced by Goldrath et al., as a method of vaporization of the endometrium. This study presented the actual introduction of EA to the literature; results from Goldrath et al., study supported both the efficacy and safety of endometrial destruction over 20 months of follow-up. Twenty one out of 22 responded to this approach and no major events were reported [8]. In 1987, hysteroscopic resection of the endometrium was introduced by DeCherney et al., using modified urologic hysteroscope. Destruction of endometrial lining was achieved using coagulating current. The procedure was highly successful and no complications were reported [9].

These techniques were gradually established as treatment

options and in the 90's, evidence from the literature was reviewed and these modalities were considered in clinical guidelines as an alternative to hysterectomy [10]. Nineteen ninety six and afterwards, new modalities of endometrial ablation, that do not necessitate direct visualization of the uterine cavity, have emerged and have been known as second-generation EA or global EA [11]. Because older methods (first generation) require special training and are associated with risk of uterine perforation and fluid overload, new EA modalities have provided obvious privilege in terms of safety and feasibility [12]. US Food and Drug Administration (FDA) currently approves thermal balloon ablation (ThermaChoice® Uterine Balloon Therapy; Johnson & Johnson, New Brunswick, NJ, USA [FDA approval obtained in 1997]), cryoablation (Her Option™; Cooper Surgical, Trumbull, CT, USA [FDA approval obtained in 2001]), heated free fluid (Hydro ThermAblator [HTA™] System; Boston Scientific, Natick, MA, USA [FDA approval obtained in 2001]), bipolar REA (NovaSure®; Hologic, Inc, Bedford, MA, USA [FDA approval obtained in 2001]), and microwave ablation (MEA® System, [FDA approval obtained in 2003]). These modalities can be provided under local anesthesia in an office setting.

#### Failure of endometrial ablation: Incidence and time factor

Many studies provide information on probability of failure of EA particularly on long-term followup. However, data were predominantly inconsistent. Some of these studies are summarized in Table 1 [13–21]. The rate of EA failure, which denotes subsequent interventions, ranges widely between 8% and 29%. Although it has been perceived that failure is primarily influenced by followup length, these studies did not convey this perception while the lowest rate (8%) was reported after 84 months and the highest rate (29%) was reported after 24 months of followup [16,18]. However, this information does not reject the significance of treatment–followup interval. Among studies that included larger sample sizes (816–3,681),

failure rates had tighter ranges (13.4% – 21%) and were parallel increasing with the length of followup [18–20]. Apparently, older studies tended to present higher failure rates than more recent evidence. This may suggest a higher probability of failure among women treated with first generation EA particularly endometrial resection; failure rates in studies including endometrial resection consistently exceeded 20% [13,15,16,18]. Furthermore, microwave EA yielded a significantly lower failure rate compared to studies conducted at that time [14]. Second generation EA devices were generally associated with less than 20% failure rates. However, there is no evidence that second generation EA provides more favorable outcomes than first generation devices [22]. Accordingly, this discrepancy may reflect a change in attitude of patient selection that copes with emerging evidence that particular characteristics may increase the chance of failure. Many gynecologists believe that an older age group may respond better to EA than younger women even before this has become evident in the literature. Therefore, it is difficult to assume a single failure rate while many confounders could play a role. Identification of predictors of treatment failure is prioritized to achieve the lowest of this failure range which seems to be principally acceptable.

#### Endometrial ablation: Baseline predictors of failure

Identification of baseline characteristics that would increase the probability of treatment failure poses an appropriate strategy to reduce the rate of surgical reintervention and improve patient counselling. However, baseline predictors of failure seem to widely vary among studies. Some of these predictors are summarized in Table 2 [5,18–20,23–26]. A younger age at EA has been the most consistent predictor of failure among most of these studies [18–20,23–26]. The impact of age may be ascribed to procedure–menopause interval; failure of EA is time dependent and accordingly, older women may get to menopause within few years and avert failure. While approaching menopause, bleeding pattern also tends to be irregular rather than heavy. A younger age also predicted

**Table 1:** Failure rates following Endometrial Ablation (EA).

Study	Country	Study period	Sample size	Type of ablation	Average follow-up duration	Failure rates
[13]	Canada	August 1990 to May 1995	301	Rollerball ablation or a combination of rollerball and endometrial resection	60 months	27%
[14]	UK	October 1994 to April 1995	43	Microwave endometrial ablation	36 months	16.3%
[15]	UK	between June 1994 to August 1996	188	Resectoscopic endometrial ablation	60 months	24.5%
[16]	USA	January 1998 to June 2003	109	Resectoscopic endometrial ablation and thermal balloon ablation	24 months	29.1%
[17]	Hungary	1997 to 2000	75	Radiofrequency endometria ablation	84 months	8%
[18]	USA	Between January 1999 to December 2004	3,681	Resection and ablation first-generation endometrial ablation procedures (no Laser endometrial ablation), Thermal balloon endometrial ablation, hydrothermal endometrial ablation and radio-frequency endometrial ablation	96 months	21%
[19]	USA	January 1998 to December 2005	816	Radiofrequency and thermal balloon endometrial ablation	60 months	16%
[20]	USA	January 2003 to June 2010	1,169	Rollerball, thermal balloon, radiofrequency, cryoablation	39 months	13.4%
[21]	UK	July 2007 to August 2011	200	thermal balloon, radiofrequency endometrial ablation	50 months	16%

**Table 2:** Predictors of long-term failure of Endometrial Ablation (EA).

Study	Country	Study period	Sample size	Type of ablation	Predictors of failure	Average follow-up duration
[5]	USA	April 1998 to December 2011	1,178	Radiofrequency ablation	Uterine length, procedure duration, and radiofrequency ablation (RFA) index	51.6 months
[20]	USA	January 2003 to June 2010	1,169	Rollerball, thermal balloon, radiofrequency, cryoablation	Age and type of ablation	39 months
[23]	USA	July 2005 to February 2008	142	Hydrothermal ablation	Younger age, tobacco products, menometrorrhagia	12.4 months
[19]	USA	January 1998 to December 2005	816	Radiofrequency and thermal balloon endometrial ablation	Age <45 years, parity of 5 or greater, prior tubal ligation, history of dysmenorrhea	60 months
[18]	USA	Between January 1999 to December 2004	3,681	Resection and ablation first-generation endometrial ablation procedures (no Laser endometrial ablation), Thermal balloon endometrial ablation, hydrothermal endometrial ablation and radio-frequency endometrial ablation	Age <40 years	96 months
[24]	Egypt	September 2000 to September 2001	45	Thermal balloon ablation	Younger age, greater uterine depth, inadequate balloon pressure	24 months
[25]	The Netherlands	January 1995 to September 1998	130	Thermal balloon ablation	Young age, retroverted uterus, endometrial thickness of at least 4 mm, prolonged duration of menstruation + Uterine depth and dysmenorrhea reduced treatment effectiveness	24 months
[26]	USA	January 1990 to January 2000	174	Rollerball ablation	Previous tubal ligation, age <35 years	49 months

postablation pain; perhaps due to a longer exposure to higher estrogen levels that would stimulate estrogen dependent lesions [27]. Although predictability of age variable seems to be universally accepted among different ablation devices, a cutoff point has not been settled yet with 30 and 45 being the most frequently adopted. A cutoff point of 45 years and 40 years were associated with adjusted hazard ratios (HR) of 2.6 (95% confidence interval [CI] 1.3–5.1) [19] and HR 3.2 (95% CI 2.4–4.2), respectively [18]. Accordingly, CIs are overlapping and the differences do not seem to convey a strong clinical predilection. Age less than 35 years was associated with future bleeding but hysterectomy rate was not higher than other age groups [26]. Accordingly, establishing patient selection of women between 40 and 45 years may be influenced by other clinical circumstances.

Tubal ligation has been also recognized as a potential predictor of treatment failure [19,26]. Although it has not been defined as a predictor in all studies, tubal ligation was recognized as a risk factor for postablation cornual and tubal hematometra (postablation syndrome) which necessitates intervention [28–30]. The syndrome was not restricted to a particular ablation device [19,29,30]. It is, therefore, justifiable that women with prior tubal ligation be counselled for the risk of reintervention particularly for postablation pain. Women were also at risk of significant postoperative pain if they were less than 40 years old or if they experienced preablation dysmenorrhea [27]. Dysmenorrhea is another risk factor that has been considerably recognized both in practice and in the literature. Preablation dysmenorrhea was defined as a predictor of EA failure and is commonly addressed during counselling in current practice [19,25,27]. The presence of dysmenorrhea may signify underlying endometriosis or adenomyosis which cannot be definitely excluded prior to EA. Therefore, EA will not largely relieve patient complaint.

The role of tobacco use was addressed in 2 previous studies specially as predictors of postablation pain [23,27]. However, this association was not explained given the anticipated relation between smoking and hypoestrogenism [31]. Although the relation between smoking and pain perception is debatable, there is evidence that smoking may increase pain intensity in women with chronic pain owing to central mechanisms [32]. Nevertheless, evidence on smoking contribution in EA failure or its mechanism is lacking and interpretation of this information in practice is still limited. Other predictors of failure were described in individual studies.

### Endometrial ablation: Perioperative predictors of failure

While most studies primarily assessed how baseline characteristic would impact treatment success, few studies address the role of perioperative measurements including premedications, preprocedure sonographic findings, uterine measurements, and procedure parameters. However, it is generally accepted that a particular uterine length would not allow EA; one of the earliest guidelines for EA, published in 1995, stated that EA should be performed for uterine length <12cm [10]. Although this cutoff point was considered in many studies, A greater success was recognized when a lower cutoff is used [33,34]. A cutoff point of 10cm is now widely adopted [35]. This explains why uterine depth was not frequently evaluated as a predictor of failure in most studies. According to El-Nashar et al., a uterine length ≥9cm was not connected to failure. However, women with uterine lengths <9cm were more prone to amenorrhea [19]. Shaamash and Sayed found that uterine depth would predict EA failure in women treated with thermal balloon EA. The range of uterine depth was 7.5–12cm but no particular cutoff was defined [24]. A recent study found that uterine length >10.5cm was associated with REA failure particularly those caused by post-ablation bleeding [5].

On the other side, there is no much information in the literature on the role of uterine width. Uterine length and width could be measured sonographically prior to the procedure and automatically at the time of REA procedure. Shazly et al., found that failure of REA is higher if uterine width exceeded 4.5cm [5]. This is particularly predictive of postablation pain and may indicate an undiagnosed uterine adenomyosis or a uterine width that extends beyond ablation zone leaving active peripheral endometrial tissue behind a central obliterated cavity. A radiofrequency ablation (RFA) index was thus established as: REA procedure duration divided by uterine surface area (uterine length multiplied by uterine width). This equation seemed to be more predictive than uterine length, width, or duration alone [5]. Other perioperative predictors include uterine retroversion and endometrial thickness which were found significant by one study on thermal balloon EA and were not significant by another larger study that included a mixed a cohort of thermal balloon EA and REA [19,25]. Premedications were not given in the latter study.

### Endometrial ablation failure: Conclusion

Although the probability of further intervention following EA is considerable, EA remains an appealing alternative to hysterectomy. It is anticipated that proper patient selection would substantially lower the rate of reintervention. Unfortunately, potential predictors have not been meta-analyzed to data owing to the wide heterogeneity of available studies. However, it seems that age is the most acceptable predictor to date. Using either 40 or 45 years as a cutoff is not definite and it should be made according to other clinical circumstances. Tubal ligation and dysmenorrhea should also be considered. Perioperatively, women should be advised that EA success would be lower if uterine length is greater than 10 to 10.5cm. RFA index is a novel index that considers uterine surface area rather than uterine length alone. However, further studies are needed to validate its use. There is currently no evidence that uterine position, endometrial thickness, and premedication change long-term outcomes. Although adoption of a selective strategy is justifiable, further research on the impact of its implementation on long-term outcome is recommended.

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