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Review Article

Late-onset Endometrial Ablation Failure—Etiology, Treatment, and Prevention

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ABSTRACT This review summarizes the history and demographics of nonresectoscopic endometrial ablation and global endometrial ablation procedures as well as the presentation, etiology, risk factors, treatment options, and prevention of late-onset endometrial ablation failures. Journal of Minimally Invasive Gynecology (2015) 22, 323–331 © 2015 AAGL. All rights reserved.

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Nonresectoscopic endometrial ablation (NREA) and global endometrial ablation (GEA) are minimally invasive techniques to manage intractable uterine bleeding in women who are unresponsive to medical therapy. The intent of these procedures is to offer appropriate candidates a less invasive alternative to hysterectomy. Long-term follow-up data indicate that several types of late-onset endometrial ablation failures (LOEAFs) cause at least 25% of women to undergo subsequent hysterectomy [1,2]. This review summarizes the history and demographics of NREA and GEA procedures as well as the presentation, etiology, risk factors, treatment options, and prevention of LOEAF.

The authors declare no conflict of interest.

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History of Endometrial Ablation

Synopsis

Endometrial ablation (EA) refers to a series of techniques originating in the 19th century that were blind and used various energy sources to affect thermal destruction to the endometrium. The late 20th century brought an important paradigm shift when a rod lens hysteroscope was colocated to an energy source permitting EA under direct visualization. However, the complexity and morbidity associated with early hysteroscopic and resectoscopic techniques soon gave way to a series of user-friendly methods known as nonresectoscopic EA or GEA. These devices and techniques boast improved safety with acceptable outcomes—features critical to the widespread adoption of EA.

The First Generation: "Blind" Techniques

In 1898, Dührssen [3] reported the first case of EA in the treatment of a 37-year-old woman "exhausted by profuse and persistent menorrhagia by introducing steam in the

uterine cavity for 2 minutes." Dührssen noted that "as a result, the uterus underwent complete atrophy" [3]. The next EA technique involved the blind introduction of electrosurgery. In 1936, Bardenheuer [4] published *Elextrokoagulation (ELK) der Uterusschleimhaut* (electrocoagulation of the endometrium) with the introduction of a unipolar *Kungelsondenelktrode* featuring a 5- to 8-mm diameter steel ball mounted on a 12- to 16-cm shaft (Fig. 1). The system required an electrosurgical generator and a lead or aluminum grounding plate placed under the patient's buttocks. Bauman [5] reported a series of 387 patients using Bardenheuer's technique in an office setting employing "light narcosis." The subjects were divided into groups (i.e., women with menorrhagia, postmenopausal bleeding, endometrial polyps, and leiomyomas). The most common complication was infection, which occurred in 4 subjects (1.29%). Bardenheuer recognized the importance of avoiding electrocoagulation of the internal os to prevent subsequent hematometra formation and pain, providing the first report of LOEAF.

Another blind technique was reported by Schultze in 1937 [6] who reported the results of 204 women who had undergone intrauterine insertion of radium with a follow-up period of 2 to 20 years. The dosage (1200–1500 mCi/h hours) produced many undesirable side effects including atrophic vulvitis and subsequent endometrial cancer, causing this form of therapy to be abandoned. However, Schultze was the first to show the direct relationship between patient satisfaction and age.

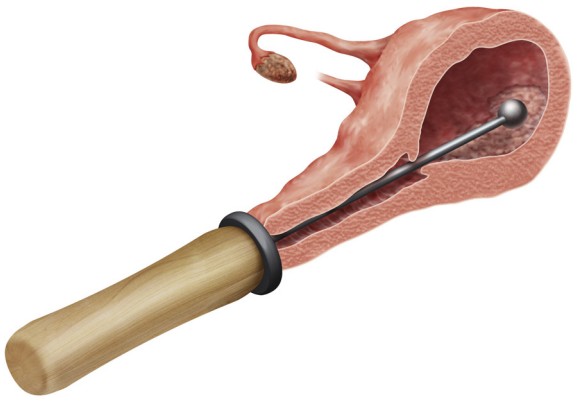
The blind introduction of a cryoprobe to accomplish EA was first reported by Cahan and Brockunier [7] in 1967. In 1971, Droegemueller et al described a similar technique using both Freon (Dupont, Deepwater, NJ) and nitrous oxide probes [8]. Despite some success, these cumbersome devices never gained acceptance in the gynecologic community.

The Second Generation: The First "Visual" Techniques

A paradigm shift occurred when Goldrath et al [9] and DeCherney et al [10] colocated a rod lens endoscope with an energy source (laser and electrosurgery, respectively) to perform EA under direct visualization. The use of the Nd:YAG laser was associated with both economic and technical challenges. DeCherney et al's technique, although significantly more affordable, suffered the technical inconveniencies of a noncontinuous flow system. In 1989, after the introduction of the first Food and Drug Administration (FDA)-approved continuous flow gynecologic resectoscope, Vancaillie [11] reported the first hysteroscopic EAs using a ball-end electrode. Inexpensive acquisition costs and excellent visualization caused the technique to gain some degree of acceptance within the gynecologic community. However, early reports of fatal complications attributable to excessive fluid absorption and hyponatremic encephalopathy [12] led to a search for safer methods of EA.

Fig. 1

Kungelsondenelktrode (ball-end electrode) used by Bardenheuer.



The Third Generation: The "Return" of "Blind Techniques"

The next paradigm shift in EA began in 1997 with the introduction of the first NREA or GEA devices or systems. These are often referred to as "second-generation" devices—a term that belies their historic context. Presently, there are 5 FDA-approved NREA devices or systems: the thermal balloon (ThermaChoice Uterine Balloon System; Johnson and Johnson, New Brunswick, NJ), the cryoablation system (Her Option; Cooper Surgical, Trumbull, CT), a heated free fluid system (Hydro ThermAblator or HTA System; Boston Scientific, Natick, MA), a bipolar radiofrequency ablation device (NovaSure EA; Hologic, Inc, Bedford, MA), and a microwave ablation system (MEA System; previously produced by Microsulis Medical Limited, Denmead, UK). These devices and systems, receiving FDA approval between 1997 and 2003, have been responsible for the widespread expansion of EA in the United States and Europe. With the exception of the Hydro ThermAblator System, these modalities all involve the blind introduction of a thermally active device into the uterine cavity in order to accomplish EA. Compared with resectoscopic endometrial ablation (REA), GEA devices offer technical simplicity, shorter operating times, comparable results, and greater safety [13,14]. Additionally, reminiscent of the first blind techniques of the early 20th century, they are well suited for an office setting.

Demographics of EA

In 2008, GEA procedures were the most common treatment for heavy menstrual bleeding with some 312 000 performed across the United States. The market was dominated by Hologic's NovaSure device, which was responsible for 66% of all GEA devices used [15] that year. By 2010, the US GEA device market was valued at $407 million [16]. In 2012, Hologic led the US GEA systems market with sales of its NovaSure device and related products, garnering 54.9% of the market. Figure 2 reviews the 2012 GEA device