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NovaSure® Endometrial Ablation:

Real-World Experience and Clinical Data

NovaSure®
Endometrial Ablation

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Important Safety Information:

NovaSure® endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous. The NovaSure procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. NovaSure endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. Inform patients to contact you if they experience a possible side effect related to use of this product. For detailed benefit and risk information, please consult the IFU.

Foreword

Endometrial ablation as a treatment for abnormal uterine bleeding (AUB) has evolved since its introduction in 1987. With the single goal of providing women with a safe and effective alternative to hormones and hysterectomy, endometrial ablation has changed the way we counsel our patients and practice medicine on a daily basis. There are currently multiple devices approved for use around the world. Each device uses unique technology to achieve destruction of the endometrium, which decreases menstrual blood loss, improves quality of life, and leads to high overall satisfaction. What differentiates these devices with respect to outcomes and functionality? How do we advise our patients on expectations and possible untoward events? Why should we choose to employ one endometrial ablation modality over another?

As clinicians, we recognize that patients differ with regard to AUB etiology and characteristics. Comorbidities, demographics, patient expectations, and underlying disorders may play a significant role in AUB and the postprocedure experience. The NovaSure® endometrial ablation system uses bipolar radiofrequency technology and has become the global leader for endometrial ablation. In the 15 years since approval, extensive data have been published demonstrating the effectiveness of NovaSure endometrial ablation in the management of AUB due to a myriad of reasons including coagulopathies, anovulatory disorders, intracavitary lesions, and adenomyosis. NovaSure endometrial ablation has been shown to be effective in women of diverse racial backgrounds from countries throughout Europe, Asia, and North America. The safety of NovaSure endometrial ablation has been established through extensive reporting over the years, peer-reviewed publications, and physicians' experience with over 2.5 million procedures. Our goal as clinicians is to offer the best in care through the practice of evidence-based medicine.

Inside the pages of this monograph are the experiences and opinions of recognized experts in the field of minimally invasive gynecology along with in-depth reviews of the most up-to-date literature related to AUB and endometrial ablation. The physician authors of these articles are paid consultants of Hologic, Inc., and editorial and financial support was provided to the authors by Hologic in connection with the development of their articles.

I hope you will take the time to read the information provided and incorporate these findings into your practice. We at Hologic are committed to our partnership with you, the women's healthcare provider, to ensure that you have the most advanced technologies and data to feel comfortable counseling and treating your patients with AUB.

Edward Evantash, MD
Medical Director
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Reasons Why I Am a Long-Term User of the NovaSure® System

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In my group practice at a teaching hospital, we see a large number of patients with abnormal uterine bleeding (AUB). Over time, our approaches to managing AUB have evolved as medical and surgical treatment options have advanced. In cases where endometrial ablation (EA) is appropriate, we use the NovaSure® system (Hologic, Inc., Marlborough, MA). We perform approximately 100 NovaSure procedures per year. We have been using the NovaSure system for over 10 years, and we and our patients continue to be satisfied with the procedure and its outcomes.

Evolution of treatment options for AUB

Abnormal uterine bleeding negatively impacts patients' quality of life and poses a high economic and healthcare burden for women with the condition.[1,2] Hysterectomy is a definitive treatment for AUB, but because of its invasive nature and associated risks, patients often prefer less invasive options first. The preferred treatment for AUB has changed over the last few decades. In the past, dilation and curettage would be performed, and if unsuccessful, would be followed by hysterectomy.[3,4] As understanding of the underlying etiologies of AUB grew, in conjunction with evidence supporting the effectiveness of medical options, medical management with hormonal treatments, nonsteroidal anti-inflammatory drugs, and antifibrinolytic agents has gained acceptance.[5] However, medical management is suitable for few women with AUB, with long-term oral medication in particular being tolerated by only a minority.[5] The decision for nonmedical management depends on the clinical condition and preference of the patient. EA, which involves destruction of the endometrium, offers a less invasive option to hysterectomy for the treatment of AUB. Although anemia and failure of medical management are important considerations, they are not a prerequisite for EA.[6,7]

First-generation EA techniques were performed under direct visualization of the uterine cavity by hysteroscopic guidance and have been largely replaced by second-generation devices that are safer, faster, and mostly non-hysteroscopic.[8,9] Fergusson et al reviewed results of 8 randomized controlled trials that compared outcomes of ablation procedures with those of hysterectomy.[10] EA procedures were found to provide a similar level of patient satisfaction as hysterectomy but were much quicker and associated with fewer complications than hysterectomy. Additionally, duration of stay and recovery times were longer with hysterectomy. Prospectively collected national data indicated that hysterectomies for benign causes are associated with a risk of venous thromboembolism, urinary tract infections, sepsis, need for blood transfusion, wound complications, return to the operating room or readmittance to the hospital, and death.[11]

There are multiple EA device options, but I choose to use NovaSure endometrial ablation

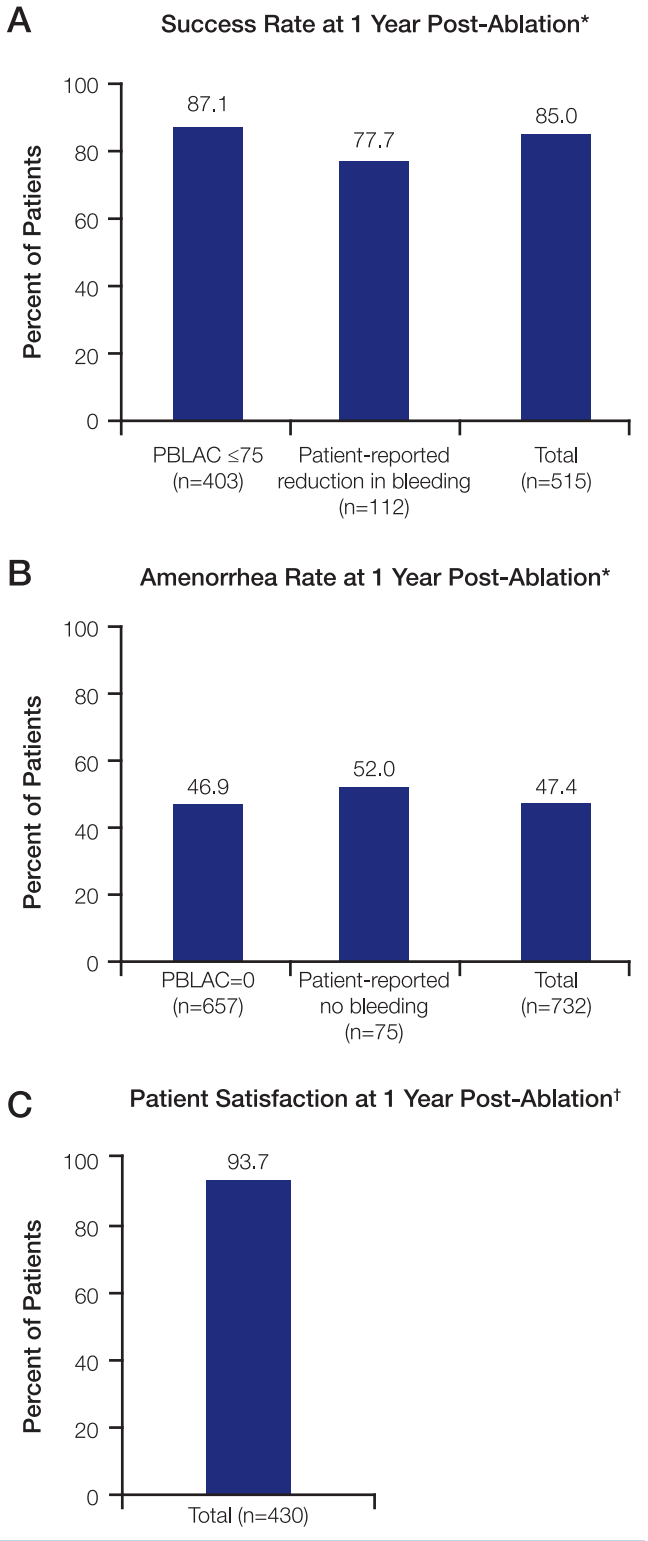
Based on patient history and symptoms and after a thorough work-up, I choose appropriate treatment to manage each of my patients. There are several devices available for performing EA, but findings from published literature support our choice of the NovaSure device. Published evidence demonstrates that the NovaSure device offers a safe, efficacious, less invasive, and cost-effective alternative to hysterectomy for the treatment of AUB in women for whom childbearing is complete.[12,13]

Consensus guidelines from the Society of Gynecologic Surgeons Systematic Review Group emphasize the importance of patient counseling to optimize decision making.[4] We make sure the patients are aware of the risks associated with the NovaSure procedure. We have found that setting realistic expectations with the patient is essential to increase patient satisfaction with the procedure. To this end, we advise patients that NovaSure endometrial ablation is very likely to result in reduction of heavy menstrual bleeding **(Figure 1)** and although the majority of women may see complete cessation of menstruation, amenorrhea is not always guaranteed and is not necessary to achieve satisfaction with the outcome.

Proven safety and effectiveness of NovaSure endometrial ablation for the treatment of AUB

Pooled aggregate data obtained from published reports of 3 single-arm studies[14-16] and 7 randomized controlled trials[17-23] demonstrated a combined treatment success rate of 85%, amenorrhea rate of 47.4%, and patient satisfaction of 93.7% at 1 year post-ablation with NovaSure endometrial ablation **(Figure 1)**. Further, prospective studies demonstrate that the rates of surgical re-intervention are low after NovaSure endometrial ablation.[12]

Figure 1. Aggregate NovaSure Outcomes Across 10 Prospective Studies



*Combined data from 3 single-arm studies and 7 randomized controlled trials; intent-to-treat analysis.

†Available data from 6 randomized controlled trials, reflecting the evaluable patient population (ie, those subjects who provided responses at 1 year).

PBLAC=pictorial blood loss assessment chart.

Long-term follow-up studies have shown that NovaSure endometrial ablation continues to be a safe and effective procedure. In a follow-up of over 100 women who underwent the NovaSure procedure, rates of amenorrhea increased over time from 46.2% at 6 months[16] to 75% at 5 years.[24] Similarly, in another study that evaluated long-term outcomes of the NovaSure procedure, amenorrhea rates increased from 59.1% at 1 year to 88.9% at 7 years after the procedure.[15] In a 10-year follow-up of a randomized study comparing the NS and TC procedures, the amenorrhea rate with NS was 73% and patient satisfaction was 81%.[26] Meta-analyses of published studies comparing second-generation devices have shown that the NovaSure procedure achieved higher rates of amenorrhea than other second-generation EA devices.[8,25]

Additionally, the NovaSure procedure is demonstrated to be safe, quick, and convenient to perform successfully in an office or outpatient surgical setting using local anesthesia.[20,27,28] In accordance with the available evidence, we have found the NovaSure procedure to be very convenient and easy to perform in our practice, and we have achieved good long-term outcomes. In my years of experience with the NovaSure procedure, I have encountered only 2 patients who required a hysterectomy after undergoing the NovaSure procedure.

Hologic has made performance of EA with the NovaSure device very user-friendly **(Figure 2)**. They have a Technical Support team that is readily available via phone giving us access to knowledgeable personnel whenever needed. The quick reference guide provided by the Hologic representative has been very helpful to us in becoming comfortable with the device. Given our role as a teaching hospital, it is important that the NovaSure device has features to facilitate physician ease-of-use and built-in safety features to protect patients.

Figure 2. The NovaSure Device

NovaSure endometrial ablation in clinical practice

In our practice, we have successfully used the NovaSure procedure to treat patients with AUB associated with a variety of conditions other than primary endometrial disorder (AUB-E) and with other clinical features that could conceivably impact the effectiveness of the procedure.

AUB due to ovulatory dysfunction (AUB-O)

For women with AUB-O, medical management with progestin or combined hormonal contraception is often the treatment of choice. For those with inadequate response or a contraindication to medical management, or based on treatment goals, EA may be an option.[29] We have successfully performed EA with the NovaSure device in women with AUB-O. If women complain of spotting after the ablation, we give them Depo-Provera at the follow-up visit, which helps achieve amenorrhea, and patients have been very satisfied with the results.

Evidence for the efficacy of the NovaSure procedure for women with AUB-O has been demonstrated in a large retrospective study of 489 women who underwent EA with the NovaSure device or thermal balloon.[30] At the 12-month follow-up, 11.8% of 169 women in the AUB-O group and 13.8% in the AUB-E group had amenorrhea. By univariable or multivariable analysis, patients with AUB-O were no more or less likely than those with AUB-E to have amenorrhea or require hysterectomy in the 12 months after the ablation. Another retrospective study showed similar treatment success rates between AUB-O and AUB-E groups.[31] These studies concluded that EA is a safe and effective option and alternative to hysterectomy in women with AUB-O who are unable or unwilling to use hormonal treatment.

Patients with leiomyomas (AUB-L)

We have also successfully treated AUB with the NovaSure procedure in patients with fibroids up to 2 cm. Our experience is consistent with published results from a prospective single-center study evaluating the NovaSure procedure in women with AUB caused by leiomyomas up to 3 cm.[32] At 12 months after the procedure, 69% of patients reported amenorrhea, and 95% were satisfied with the outcome.

Coagulopathy (AUB-C)

In our practice, we have achieved good outcomes using the NovaSure procedure for patients with AUB presenting with coagulopathies. There is published evidence showing that EA can be an effective treatment option for AUB in women with coagulopathy. In a retrospective comparative study, El-Nashar and colleagues demonstrated that EA with either the NovaSure or thermal balloon procedures significantly reduced bleeding in women with or without coagulopathy.[33] The probability of treatment failure was no different between women with and without coagulopathies. Similarly, an observational study showed comparable global outcomes with the NovaSure procedure between a high-risk group of patients, which included women with coagulopathy, and a low-risk group that did not have coagulopathy.[34]

History of cesarean delivery

In patients with prior classical cesarean delivery, potential weakening of the myometrium is thought to increase the risks associated with EA;[6] the EA procedure is therefore contraindicated in such patients. However, 2 cohort studies have shown that EA is safe and effective in patients with a history of low transverse cesarean delivery.[35,36] In a retrospective study assessing adverse events associated with EA, women with a history of cesarean delivery were shown to tolerate the NovaSure procedure well, and there were no reports of bowel or bladder injury.[35] The safety and efficacy of EA were also evaluated retrospectively in a large study involving 704 patients, of whom 162 had a history of cesarean deliveries. At 5 years after EA with either the NovaSure or thermal balloon ablation procedure, amenorrhea and cumulative treatment failure rates were similar for women with prior cesarean and vaginal deliveries.[36] The incidence of uterine perforation, the only intraoperative complication observed, was not statistically significantly different between groups. Of note, uterine perforations identified were not associated with the cesarean delivery scar.

In our practice, a history of cesarean delivery does not preclude treatment with the NovaSure procedure. We have not encountered any complications in women with a history of cesarean delivery who underwent the NovaSure procedure.

Conclusion

With long-term clinical evidence as support, we continue to be very satisfied overall with the outcomes of the NovaSure procedure. We offer this option to patients with a variety of conditions associated with AUB. The safety, convenience, effectiveness, and user-friendliness of the procedure are the reasons we plan on continuing to use the NovaSure device for performing EA.

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Moving From Thermachoice to the NovaSure® Endometrial Ablation Procedure in the Office

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We are a private practice that recently became part of the multispecialty Dupage Medical Group. We provide comprehensive obstetric and gynecologic services and we routinely perform in-office endometrial ablation (EA).

Experience with Thermachoice

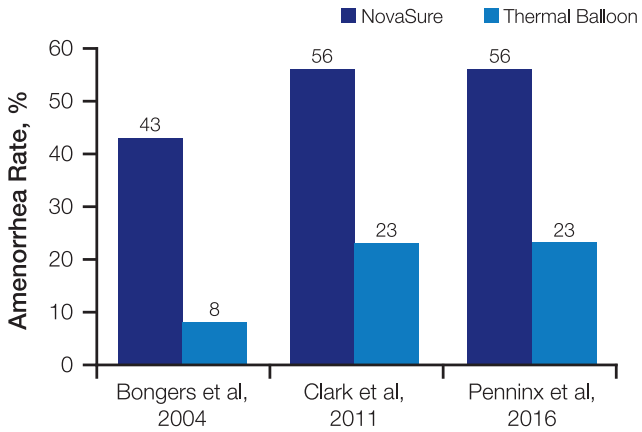
For approximately 4 years, we used the Thermachoice Uterine Balloon Therapy System for performing EA, most often under local anesthesia with oral analgesics. Treatment outcomes were favorable, and patient satisfaction was about 80%. However, we were not entirely satisfied with Thermachoice for several reasons, including the relatively long duration needed to perform the procedure compared with other devices. Additionally, ablation with Thermachoice relies on direct contact of the balloon with the endometrial lining. Therefore, its success is dependent upon sufficient distension of the balloon to fill the uterine cavity, which was particularly challenging for large uteri. In these cases, the timeout mechanism on the device would end the procedure if not completed within a certain time frame, which would require the procedure to be restarted and compound the time and inconvenience. On several occasions, we found ourselves heating water in the microwave to beat the timeout mechanism. Finally, during postablation hysteroscopic examination, we sometimes did not see a complete and uniform ablative effect on the endometrium after the Thermachoice procedure.

The Thermachoice device was recalled and discontinued by the manufacturer in 2016; since then, we have been using the NovaSure® endometrial ablation device from Hologic, Inc. (Marlborough, MA).

Comparing the benefits of the NovaSure procedure with Thermachoice

Clinical evidence demonstrates that the NovaSure procedure compares favorably with Thermachoice. In a prospective, multinational, head-to-head study, pain experienced during NovaSure and Thermachoice procedures was assessed using both the visual analog scale and the numeric rating scale. Mean ratings on both scales indicated that the NovaSure procedure was associated with statistically significantly lower (P<0.001) intraoperative and postoperative pain compared with Thermachoice.[1] The study also found that the NovaSure procedure took significantly shorter time (2.5 ± 1.1 minutes) than Thermachoice (11.9 ± 2.1 minutes; P<0.0001). Other studies directly comparing the NovaSure procedure with Thermachoice have shown similar results, with significantly shorter procedure times, lower risk of failure, and significantly higher amenorrhea rates associated with NovaSure.[2,3] The superior efficacy of the NovaSure procedure in achieving amenorrhea rates versus thermal balloon modalities, including Thermachoice and Thermablate EAS (Idoman Teoranta Limited, County Mayo, Ireland), has been well established in clinical studies[4-6] **(Figure 1)**. Further, a meta-analysis of 19 articles comparing various EA techniques demonstrated greater efficacy and higher patient satisfaction rates with radiofrequency ablation compared with thermal balloon ablation.[7]

Figure 1. Higher Amenorrhea Rates Achieved at 12 Months With the NovaSure Procedure Compared With Thermal Balloon Ablation Techniques in Randomized Controlled Studies



Bongers et al and Clark et al compared NovaSure with Thermachoice. Penninx et al compared NovaSure with Thermablate.

Evidence from randomized controlled trials also demonstrates high patient satisfaction rates with the NovaSure procedure. Bongers et al compared outcomes of 83 and 43 women who underwent NovaSure and Thermachoice procedures, respectively. Besides superior amenorrhea rates (43% vs 8%), patient satisfaction at 12 months was higher in the NovaSure group (90%) compared with Thermachoice (79%).[6] Similarly, in other studies, patient satisfaction rates of about 90% have been observed with the NovaSure procedure.[6,8,9] Penninx et al recently compared NovaSure with Thermablate, a newer balloon ablation device, in a randomized trial in an in-office setting under local anesthesia.[4] Twelve months after the procedure, amenorrhea rates were 56% and 23% in the NovaSure and Thermablate groups, respectively. More patients were completely satisfied after undergoing EA with NovaSure (40/52, 77%) versus Thermablate (29/52, 56%; relative risk, 0.5; 95% CI, 0.3–0.9). Quality of life, measured using the Shaw score, was significantly better in the NovaSure group. Thus, the NovaSure procedure showed superior performance overall as an in-office procedure than Thermablate thermal balloon ablation.

Switching to the NovaSure procedure

When switching to the NovaSure procedure, we took advantage of the training programs offered by Hologic, which we found helpful in increasing our confidence in performing NovaSure endometrial ablation. Hologic arranged a live demonstration of the procedure performed by a peer physician. Their representatives are available to provide hands-on support any time, even during a procedure for live trouble-shooting.

As an office-based practice, we were interested in performing EA in the office under local anesthesia. Not only is office-based use of second-generation EA devices convenient, it also yields overall economic benefit.[10] Evidence shows that in-office performance of the NovaSure procedure is associated with cost savings versus those performed under general anesthesia in an operating room, particularly regarding resource use.[11] In addition, recovery from the NovaSure procedure is quick, which benefits both the patient and healthcare provider. In an observational study, 94% of patients undergoing NovaSure procedure under local anesthesia were discharged the same day.[8]

As reported in literature, we find that performing the NovaSure procedure in an office setting eliminates the costs associated with the operating room and general anesthesia. It also increases efficiency; in the time it would take to prepare the operating room, we can complete 3 NovaSure procedures in the office.

Several studies have demonstrated the feasibility of performing the NovaSure procedure under local anesthesia with minimal patient discomfort.[5,8,9,12] Based on the observation that the NovaSure procedure was associated with low levels of pain and short procedure time,[1] Penninx et al first evaluated the feasibility of performing the NovaSure procedure in an office setting under local anesthesia to save time and costs associated with the operating room.[9] The procedure was performed under a paracervical block (PCB) with Ultracaine or 1% prilocaine without sedation. The majority of patients (94%) found the procedure acceptable, and all procedures were completed successfully. Although patients reported minimal pain 24 hours after the procedure, some patients still experienced pain during active ablation. The median pain score for the procedure was 5.1 on a scale of 1 to 10. Other studies have evaluated a combination of PCB with a fundal block involving hysteroscopic injection of a local anesthetic into the myometrium to further reduce pain experienced by patients. Such a combined protocol has been shown to substantially reduce the perception of pain during EA.[13,14] In a case-control study involving 83 women who underwent the NovaSure procedure in the office with the combination of PCB and intramyometrial block of the uterine fundus, 69% rated pain during the procedure as 0 (on a scale of 1–10), and 92% rated pain as ≤2. The average pain score was significantly lower with combined block compared with PCB only (0.6 vs 4; $P<0.0001$).[14] All of the women said that they would recommend the procedure to a friend. Substantial pain control during the procedure with the combined PCB/fundal block has recently been further demonstrated in a randomized controlled trial.[15]

Taking into consideration the published data, our own clinical experience, and discussions with peer physicians, we have refined our in-office local anesthesia procedure for using NovaSure endometrial ablation. We use a combination of oral nonsteroidal anti-inflammatory drugs and an opioid, anxiolytics, and misoprostol leading up to the procedure, and then PCB with ropivacaine in the myometrium during the procedure **(Table)**. Overall, our patients report feeling very comfortable during the in-office NovaSure procedure and experience minimal pain. Most of our patients are discharged the same day, and they express satisfaction with the procedure and its results. Contraindications to the NovaSure procedure in our practice include previous ablation, anticoagulant therapy, low pain tolerance, and high anxiety. We perform the NovaSure procedure in obese women in the office under local block recognizing that tolerability to general anesthesia is a concern in these patients.

To summarize, we have found that the NovaSure procedure is convenient to perform in the office, takes much less time than Thermachoice, provides a more uniform destruction of the endometrium, and results in high success rates.

"Overall, our patients report feeling very comfortable during the in-office NovaSure procedure and experience minimal pain."

Table. Anesthesia Protocol for Endometrial Ablation Using NovaSure

Medication	Dosage	Time Course
Preprocedure		
Ibuprofen	800 mg PO	Q8h for 48 h prior to procedure
Misoprostol (Cytotec®)	200 mg vaginally	6 AM and 6 PM day prior to procedure
Alprazolam (Xanax®)	1 mg PO X 1	60 – 90 min before procedure
Oxycodone/acetaminophen (Percocet®)	5/325 2 tabs PO X 1	60 – 90 min before procedure
Promethazine (Phenergan®)	25 mg PO X 1	60 – 90 min before procedure
Ketorolac (Toradol®)	30 mg IM	45 – 60 min before procedure
Procedure		
*0.5% ropivacaine (Naropin®) 30 cc mixed with 20 cc saline. Use a 10- or 20-cc syringe with 22-gauge needle with an extender to inject 10 cc at 4, 8, 10, and 2 o'clock. Try to avoid 3 and 9 o'clock as they are proximal to uterine vessels. The block is placed just medial to the cervico-vaginal reflection and is to be placed deep into the uterine musculature.		

*Paracervical block to be administered 20 min before the NovaSure procedure.
IM=intramuscular; PO=by mouth; Q8h=every 8 hours.

NovaSure ADVANCED device

In January 2017, Hologic introduced the NovaSure ADVANCED device **(Figure 2)**, providing surgeons with unique device features and advantages for performing EA. The diameter of the NovaSure device has been reduced to a nominal 6 mm, which I believe will help with the cervical dilation component of the procedure. Rounded smooth access tips have been added, which are associated with less force during insertion of the device. Additionally, the cervical seal has been updated resulting in an increased sealing surface that may be beneficial during the cavity integrity assessment test and application of vacuum during the ablation cycle. In my opinion, all of these features will greatly improve my ability to continue to perform the NovaSure procedure in the office setting.

Figure 2. NovaSure ADVANCED

Conclusion

We plan to continue performing the NovaSure procedure in the future. We are encouraged by our experience in the clinic and by the cumulative evidence reported in a 10-year review of clinical data showing sustained long-term benefits and safety of the NovaSure system.[16] I am also looking forward to utilizing the next-generation NovaSure ADVANCED® device, which has enhancements that further improve the patient and physician experience in the office setting.

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Moving From Hysterectomy to NovaSure® Endometrial Ablation for Managing Abnormal Uterine Bleeding

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Shrewsbury and Telford Hospital NHS Trust is the main provider of district general hospital services in Shropshire, Telford & Wrekin, and mid Wales. As a hospital-based practice, we have performed transcervical resection of the endometrium (TCRE) in the past for managing abnormal uterine bleeding (AUB) and have been mostly using the NovaSure® device (Hologic, Inc., Marlborough, MA) for about 4 years. All of our NovaSure endometrial ablations are performed under local anesthesia in an outpatient ambulatory care setting.

Hysterectomy is a definitive treatment, but is associated with risks

Management options for AUB include both pharmacologic and surgical treatments. Hysterectomy has traditionally been the definitive option for controlling AUB.[1,2] However, with the increasing use of less invasive alternative treatments such as endometrial ablation (EA), the rates of hysterectomies are declining.[3] This is reflected in our practice as well; although we are performing far fewer hysterectomy procedures than in the past, our use of EA procedures has increased.

Although the success rates with hysterectomy are high, as expected,[4] the procedure is invasive and is associated with risks. As reported in several studies including a Cochrane systematic review, hysterectomy is associated with higher incidences of intraoperative and perioperative events than EA, such as injury to surrounding structures (bowel, bladder, and ureters), wound infection, urinary tract infection, and hematoma.[4-7] In a large retrospective cohort study, Cooper et al found that women who underwent hysterectomy were more likely than those who had EA to require pelvic floor repair, insertion of tension-free vaginal tape for urinary incontinence, or fistula repair.[8] Other retrospective studies have demonstrated that complication rates from hysterectomy ranged from 4% to 23%.[9,10] A US database review of 49,331 cases of hysterectomies performed for benign causes identified a death rate of 0.02% with the procedure.[10] Wound complications and urinary tract infections were the most commonly reported complications, and sepsis occurred in 0.53% of cases. Hysterectomy is also associated with long recovery times; return to normal activity after a hysterectomy can take up to 8 weeks.[11] An additional drawback of hysterectomy, even when sparing the ovaries, is that it can cause premature menopause,[12] which is associated with multiple health concerns.[13]

We perform vaginal, abdominal, and total laparoscopic hysterectomies. Our hospital does not offer robotic hysterectomy, although the use of robotic hysterectomy as a minimally invasive approach to hysterectomy has become popular in the past few years. Available data do not support better outcomes or fewer complications when compared with the laparoscopic procedure, and in addition, robotic procedures are found to be costly and require technical expertise.[14-16]

EA with NovaSure as an alternative to hysterectomy

In premenopausal women for whom childbearing is complete, EA with the NovaSure system[17] has been shown to be an effective, less invasive, and safe option for the management of AUB.[18] In addition, the NovaSure device has advantages over other devices. Women undergoing the NovaSure procedure were less likely to have a subsequent procedure or a hysterectomy compared with first-generation techniques in a large retrospective study of 114,910 EA procedures.[19] A network meta-analysis of 19 randomized controlled trials demonstrated the NovaSure device to be more effective than other second-generation devices in inducing amenorrhea.[20] In prospective studies, need for subsequent surgical reintervention at long-term follow-up after the NovaSure procedure remained low.[18]

In our experience, <5% of patients have required a subsequent re-intervention after NovaSure procedure. We perform about 120 procedures per year, and no major complications have

occurred to date, nor have we encountered any perforations. Additionally, compared with hysterectomy, the NovaSure procedure takes a much shorter time, typically about 12 minutes including anesthetic preparation time, and can be performed under local anesthesia. Recovery is also faster, which resonates well with the patients. They are discharged within an hour and can return to work within 48 hours with the NovaSure procedure, whereas we have seen that return to normal activities takes 6 to 12 weeks after hysterectomy.

High patient satisfaction rates with the NovaSure procedure have been demonstrated in multiple studies.[21-24] Likewise, in our practice, patient satisfaction is high with the NovaSure procedure. We offer a "Friends and Family" survey to our patients who undergo the NovaSure procedure, asking them how likely they are to recommend the procedure to a family member or a friend. Based on the results from last year, 98% of our patients who have undergone the NovaSure procedure say that they would recommend the procedure to family and friends.

"98% of our patients who have undergone the NovaSure procedure say that they would recommend the procedure to family and friends."

In today's healthcare environment, there is increasing emphasis on reducing hospital-acquired infections and total costs.[25] The proven safety and feasibility of performing NovaSure ablation as an outpatient procedure[22,24] is therefore a notable advantage. EA is also a cost-effective option. Data from a commercial medical database showed that overall costs associated with hysterectomy were approximately twice those of EA for the procedure and related expenses over the following year.[26] Additionally, consistently lower direct costs were observed with EA compared with hysterectomy for up to 5 years after the procedure in an economic modeling study[27] **(Table)**.

Table. Cost Benefits of EA Versus Hysterectomy

	Direct Costs of Treatment*, US $		
Procedure	**1-Year**	**3-Year**	**5-year**
Hysterectomy	13,539	14,173	14,768
EA	7,352	8,508	9,751
Difference vs hysterectomy	–46%	–40%	–34%

*From the commercial payer perspective. EA=endometrial ablation

Clinical experience in patients with different etiologies of AUB

In our practice, ~90% of patients with AUB are suitable candidates for the NovaSure procedure. Contraindications for the NovaSure procedure are the presence of endometrial hyperplasia or malignancy and a uterine cavity that is too small for the device, which is not encountered often in our practice. Otherwise, our practice offers the NovaSure procedure to patients with AUB resulting from a variety of conditions including adenomyosis (AUB-A), endometrial dysfunction (AUB-E), underlying coagulopathy (AUB-C), and ovulatory dysfunction (AUB-O), which is supported by published literature.[18]

A predictive model using retrospective cohort-based data demonstrated that prior ultrasound suggestive of adenomyosis was not predictive of failure with NovaSure endometrial ablation.[28] In another study, Mengerink and colleagues retrospectively assessed adenomyosis in a population who had hysterectomy after undergoing NovaSure endometrial ablation.[29] The prevalence of adenomyosis was comparable between those who had previously undergone NovaSure endometrial ablation and the control group, and a link between adenomyosis and EA failure was not established.

Previously we preferred hysterectomy in patients with suspected AUB-A, but now we prefer to use NovaSure endometrial ablation for these patients. We combine NovaSure endometrial ablation with use of the levonorgestrel intrauterine system (LNG-IUS), Mirena® (Bayer, New Jersey), in patients with adenomyosis. NovaSure endometrial ablation reduces or stops the bleeding and Mirena®, which is inserted directly after the ablation, helps with the cyclical discomfort. We also offer Mirena® or a copper coil to patients who require contraception following the ablation. This approach is supported by published research. Papadakis et al documented the efficacy of combining LNG-IUS with EA in patients who had AUB and dysmenorrhea. In women treated with the combination of LNG-IUS and EA, the rate of treatment failure was lower compared with patients in the EA-only group.[30]

For patients with AUB-O, the recommended first-line treatment is hormonal.[1,2] However, EA is a viable option for those who experience treatment failure or do not desire medical treatment. Indeed, the rates of amenorrhea and treatment failure after EA were similar between patients with AUB-O and those with AUB-E in a retrospective cohort study of 489 women.[31] Similarly, in a study examining preoperative bleeding patterns, heavy irregular bleeding (AUB-O) did not increase the odds of treatment failure with EA versus heavy regular bleeding.[32] The authors inferred that "EA may be an appropriate treatment for women with heavy and irregular bleeding (AUB-O) who have failed or do not accept medical treatment and want to avoid the increased morbidity of a hysterectomy."

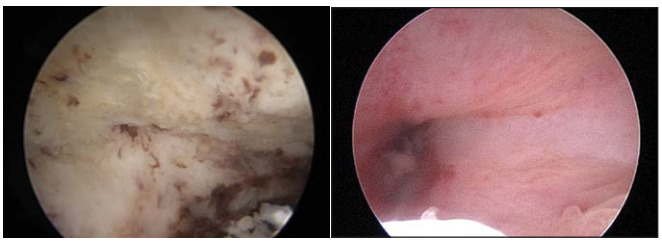
EA and the diagnosis of endometrial cancer

Although it has been suggested that EA can delay the diagnosis of cancer by masking malignant cells or compromising endometrial assessment due to scarring,[1] results from multiple studies provide evidence against this hypothesis. A systematic review of 17 published studies demonstrated that endometrial sampling after EA was often feasible to perform to evaluate AUB.[33] Additionally, for a majority of women (76.5%) who received an endometrial cancer diagnosis after undergoing EA, the cancer was stage I, which is consistent with the presenting stage in the general population of women. In the largest follow-up study reported to date comparing 234,721 women who underwent medical management or EA for AUB, EA did not result in a delay in diagnosis or an increase in the incidence of endometrial cancer compared with medical management.[34] Likewise, no patient received a diagnosis of endometrial cancer after endometrial ablation in a recent long-term retrospective study of 1521 women who underwent various ablation procedures.[35]

"We are not aware of any patients who have been diagnosed with endometrial cancer following a NovaSure ablation in our practice."

At our center, we have been performing EA for 25 years, the last 4 years with NovaSure endometrial ablation, and we are not aware of any patients who have been diagnosed with endometrial cancer following a NovaSure ablation or TCRE in our practice. A small number of patients have returned with bleeding complaints; however, we have been able to access the uterine cavity and manage the bleeding with reoperative hysteroscopy in the majority of cases **(Figure)**. Consistent with our observations, Wortman et al showed that ultrasound-guided reoperative hysteroscopy can be used to effectively assess the uterine cavity after EA and manage complications related to EA in an office setting.[36] None of the 50 patients in that study required a hysterectomy. We have been unable to access the uterine cavity in only 2 patients over the last few years who needed a hysterectomy after undergoing a prior TCRE. The final pathology in these cases did not show any evidence of malignancy.

Figure. Hysteroscopic Visualization of the Uterine Cavity in a Patient Right After NovaSure Ablation (A) and 2 Years After NovaSure Ablation (B)



The patient returned with a complaint of bleeding 2 years after undergoing endometrial ablation using the NovaSure device. The uterine cavity was hysteroscopically assessed and the histology was found to be benign.

Conclusions

Although hysterectomy is an effective treatment for AUB, we have moved to using EA, with NovaSure endometrial ablation as the preferred option for our patients. Hysterectomy is associated with greater risks and longer recovery times than EA. In contrast, NovaSure endometrial ablation can be performed in the office under local anesthesia, providing convenience, flexibility, and reduction in resource use. The rates of treatment failure are very low, allowing most women to avoid the disadvantages of hysterectomy. In our experience, and supported by clinical research, NovaSure endometrial ablation can be successfully performed in patients with different etiologies of AUB and does not preclude subsequent hysteroscopic visualization of the cavity if needed. Multiple studies have now clearly demonstrated that NovaSure endometrial ablation does not mask or delay the diagnosis of endometrial cancer, nor does it increase the incidence of cancer.[8,33-35,37] We have found that our patients are satisfied and success is consistently high with NovaSure endometrial ablation.

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Safety of Global Endometrial Ablation: Why I Continue to Use the NovaSure® Device

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Although endometrial ablation (EA) has become widely adopted as a safe and effective alternative to hysterectomy in women with abnormal uterine bleeding, there are several known risks associated with the procedure, including infection, bleeding, and possible perforation of the uterus or bowel.[1] Newer EA devices that simplify and minimize the procedure's invasiveness have been developed to lower these associated risks.[2] I have participated as a primary investigator in several clinical trials evaluating existing and emerging endometrial ablation technologies including NovaSure, Minerva, AEGEA, and Cerene devices. The results from the Minerva® Endometrial Ablation System (Minerva Surgical, Inc., Redwood City, CA) clinical trial have previously been reported.[3] I have not, however, chosen to adopt Minerva now that it is commercially available until I have a better understanding of the safety profile of this device. Based on published long-term data and my personal experience, I believe the NovaSure® endometrial ablation device (Hologic, Inc., Marlborough, MA) has the most extensive track record of safety and continue to use it routinely in my practice.

NovaSure safety profile

NovaSure has a long and robust record of safety among the available EA devices, with approximately 2.5 million treated cases, 14 years on the market,[4] and very few serious adverse events reported from experience in both clinical trial and commercial use.[5] Gimpelson conducted a review of literature published over a 10-year period, identifying 10 prospective studies (6 single-arm and 4 randomized controlled trials) that demonstrate the favorable safety profile of NovaSure endometrial ablation with few complications reported.[5] Several large studies have followed women over long durations postprocedure and consistently demonstrate safe outcomes. Of 200 women treated in a prospective observational study of NovaSure endometrial ablation, 146 were observed 1 to 4 years following the procedure.[6] Intraoperative and postoperative complications in this study were limited to 2 cases of antibiotic treatment for postoperative endomyometritis and 1 laparoscopy to rule out bleeding in a patient with uterine perforation that occurred during pretreatment hysteroscopy. A retrospective observational study in 368 women who underwent the NovaSure procedure found no major intraoperative or postoperative complications.[7] Likewise, in a 5-year follow-up of a prospective pilot study of 107 women treated with NovaSure endometrial ablation, Gallinat et al reported no intraoperative or postoperative complications.[8]

Adverse event rates with the NovaSure procedure have also been low in shorter-term, controlled studies. In the pivotal randomized controlled trial comparing NovaSure (n=175) with rollerball ablation (n=90), a lower percentage of adverse events was observed in the NovaSure group over 12 months of follow-up (13%, NovaSure; 25.3%, rollerball), none of which were reported to be serious.[9] In a more recent randomized controlled trial comparing NovaSure with balloon endometrial ablation, no complications occurred in either treatment group.[10]

This large body of data is consistent with my own findings that the NovaSure procedure is both safe and effective. In a retrospective study that I personally conducted with colleagues, we reviewed 117 consecutive cases in which the NovaSure procedure was performed and found, over an average follow-up of 9.4 months, that 61% of the patients had amenorrhea, 13% had "occasional spotting," an additional 23% had decreased bleeding, and the failure rate was 3%.[11] The satisfaction rate in this cohort was 97%, and no bowel injuries were observed.

Minerva safety profile

In a prospective, single-arm observational study in which 104 premenopausal women received treatment, no intraoperative or postoperative serious device-related adverse events were reported over the 12-month follow-up period.[12] To increase scientific rigor, a randomized controlled trial, in which I participated, compared Minerva to rollerball ablation.[3] Safety outcomes for the 102 women treated with Minerva in the trial were consistent with those in the previously reported uncontrolled clinical trial. A total of 14 patients (13.7%) experienced intraoperative or postoperative adverse events in this controlled clinical trial setting, including 1 event of pelvic

inflammatory disease that was considered serious. Although this study offers additional information regarding the safety profile of Minerva, there are limitations to extrapolating results from a controlled clinical trial setting to real-world practice. Though the US Food and Drug Administration (FDA) may determine that a device is effective and safe for marketing, until introduced into a broad patient population (both in terms of numbers, as well as demographics and clinical characteristics), it is difficult to assess the true risks associated with a new technology.

Bowel injury risk

Among the adverse outcomes associated with EA, bowel injury is the most serious. The risk of bowel injury with new EA devices is generally considered to be low relative to more invasive procedures. The MISTLETOE study, which included 10,686 women treated with a first- (rollerball; loop; or rollerball and loop used together) or second-generation EA device, reported a bowel injury incidence of 1 in 1700.[13] Based on close monitoring of reportable complications and tracking of shipped devices, Hologic has estimated the rate of bowel injury with NovaSure endometrial ablation to be less than 1 event per 10,000 treated cases.[5]

Minerva was approved by the FDA on July 27, 2015. Through December 7, 2016, 9 cases of EA-associated bowel injury using the Minerva device were reported through the Manufacturer and User Facility Device Experience (MAUDE) database **(Table)**.[14] One of these events occurred in a patient with a significant collagen-elastin deficiency (case 6) and was determined by the manufacturer to be unlikely related to Minerva, and another case was reported as a suspected bowel injury (case 7) that did not require surgical intervention to repair. There are well-recognized limitations with interpreting the MAUDE database including duplicate reports, absence of details related to the adverse events, and (despite being mandatory), underreporting of events is also known to occur.[15] Although the Minerva device has been available for over 16 months, the total number of treated patients over this period has not been reported, precluding estimation of the rate of injury or comparison of risk of injury to other devices. Until we have a better idea of the denominator, I am unable to appropriately assess this, so I will remain cautious until more information becomes available regarding the number of devices sold.

As with any new technology, one must consider the potential role of operator error as users begin to become comfortable with procedural differences between devices. Notably, investigators in the Minerva randomized controlled trial were required to have significant experience with resectoscope surgery, and the average length of experience in performing EA was approximately 23 years, emphasizing the experience that has accumulated over the >15 years since newer EA devices were introduced.[3] Comparatively fewer physicians were skilled with EA devices at the time NovaSure was first approved, and technology and techniques have been refined over this period. Minerva uses a radiofrequency heating method with operational features that are similar to the NovaSure radiofrequency device.[16,17] However, given this similarity, increased vigilance is warranted, as the 2 devices are different, and details of the procedural techniques used for each are unique. Without recognizing such differences, misuse of EA devices outside the labeled Instructions for Use could increase the risk of serious injury.[2] Indeed, several of the bowel injuries associated with Minerva that were reported through MAUDE were noted to possibly involve user error **(Table)**. Only long-term studies and close monitoring of post-marketing outcomes will ultimately determine the real world safety profile of the device.

Conclusion

Accumulation of additional long-term safety data will help clarify the true risk of bowel injury associated with Minerva. At this time, I am confident with the impressive, well-documented, long-term safety record of NovaSure endometrial ablation, with a less than 1 in 10,000 risk of bowel injury. In my personal experience, I have treated more than 1800 patients with the NovaSure procedure, have had no bowel injuries, and have observed amenorrhea/success rates equivalent to those reported for Minerva. For these reasons, I will continue to use NovaSure endometrial ablation.

Table. Postmarketing Bowel Injuries Reported With Minerva

Case	Event Date	Event Description	Outcome	Potentially Related Circumstances
1	12/27/2015	Uterine, small and large bowel perforations	End-to-end small bowel anastomosis and colostomy on large intestine	Minerva procedure appeared to be "uneventful."
2	12/30/2015	Uterine perforation (fundal); small bowel perforation	End-to-end bowel anastomosis	Anteverted uterus with some difficulty opening device on initial insertion; on second attempt, device opened.
3	3/1/2016	Uterine perforation; small bowel thermal injury	End-to-end bowel anastomosis	Difficulty placing device when attempted by resident; attending physician subsequently inserted device and performed procedure.
4	3/11/2016	Uterine perforation (fundal); small bowel thermal injury	Hysterectomy and end-to-end bowel anastomosis	Previous EA with another device; "snug fit" during device insertion with inability to confirm device deployment, although UIT passed.
5	4/7/2016	Small bowel thermal injury with adhesion to fundus; no uterine perforation	End-to-end bowel anastomosis	Abnormally thin myometrial wall and uterine hypoplasia.
6	4/18/2016	2 perforations of the colon; no evidence of uterine perforation or thermal injury	Bowel resection complicated by abnormal, highly fragile tissue; fatal MI during extubation several days after surgery	Event believed to occur as a result of mechanical tearing of highly fragile intestinal tissue, related to underlying collagen/elastin deficiency and a "frozen pelvis."
7	4/22/2016	Uterine perforation, possible bowel injury	Inpatient observation, discharged and doing well	Hysteroscopic morcellation procedure followed by Minerva; first few attempts with UIT unsuccessful but later passed. Suboptimal distention of uterine cavity during posttreatment hysteroscopy, uterine perforation suspected and confirmed during laparoscopy.
8	8/4/2016	Uterine perforation (fundal) thermal injury, damage to rectum and small intestine (adhered to uterus)	End-to-end bowel anastomosis	"Unusually difficult" Minerva procedure, but no details available.
9	9/21/2016	Uterine perforation (fundal), damage to rectum and small intestine (adhered to uterus)	End-to-end anastomosis and ileostomy of small bowel	Uterine length initially sounded at 13 cm; repeated and sounded at 11.5 cm (outside labeling of ≤10 cm).

EA=endometrial ablation; MI=myocardial infarction; UIT=uterine integrity test.

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New Device for Endometrial Ablation, But Better Outcomes?

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My private, solo practice is located in a small town, Portsmouth, Ohio, where I see an increasing number of women suffering from abnormal uterine bleeding (AUB). I have been performing endometrial ablation (EA) for approximately 10 years, and I treat 2 to 3 patients per week on average. Over the years, the facilities available to me at Southern Ohio Medical Center have enabled use of a variety of EA devices. I initially performed the procedure using the Gynecare Thermachoice III Uterine Balloon Therapy System, but long before this device was removed from the market, I switched to primarily using the NovaSure® (Hologic, Inc., Marlborough, MA) procedure because I saw better outcomes. With recent approval of the Minerva® Endometrial Ablation System (Minerva Surgical, Inc., Redwood City, CA), another alternative option has become available. I have offered my patients the opportunity to try this new device; however, when considering the superior outcomes I observe with NovaSure, this more established device continues to be the primary one I use.

NovaSure endometrial ablation experience

In my practice, all EA procedures are performed at the local hospital with general anesthesia provided by an anesthesiologist. As a routine, I perform hysteroscopy before the procedure. In my experience, proper seating with the NovaSure device can be achieved quickly and with ease. The design of the equipment allows for simple maneuverability, and the procedure is typically completed in about 3 minutes.

Over my 10 years in practice, I have experienced outstanding results following EA with NovaSure. As stated in the product labeling and reported in clinical trials,[1-3] a serosanguineous discharge may occur after the procedure that generally resolves within a few weeks; however, my patients experience very little discharge postprocedure. The most impressive result, however, is the rate of amenorrhea I have seen following the NovaSure procedure, which approaches 90%. Although this rate is much higher than that reported in the labeling and published in the literature, the NovaSure device has a robust, long-term post-approval track record of high success rates across published clinical trials.[4] A retrospective observational study in a large cohort of 368 women with a variety of clinical characteristics found an overall amenorrhea rate of 59% with the NovaSure procedure.[5] Similarly, the amenorrhea rate from a prospective clinical trial reported by Gallinat was 65% (67 of 103) at 3 years,[6] increasing to 75% (77 of 103) at 5 years.[7] In the 5-year follow-up of 103 patients, 98% reported a reduction in bleeding.[7]

In a retrospective cohort study in which success was defined as a reduction in excessive uterine blood loss, Elmardi and colleagues reported a 90.5% success rate among 105 patients at 18 months following NovaSure endometrial ablation.[8] This success rate, which considers overall reduction in bleeding, is closer to the amenorrhea rate that I see with the NovaSure procedure in my practice. There are many variables that determine the amenorrhea and success rates of EA devices in clinical trials; most notably, in addition to the technology itself, the skill and experience of the different surgeons in the trial is crucial. Likewise, I believe the very high amenorrhea rate that I see reflects the exceptional performance achievable with NovaSure endometrial ablation combined with the skill sets I have developed in using the device.

"The most impressive result is the rate of amenorrhea I have seen following the NovaSure procedure, which approaches 90% in my practice."

A common concern when selecting the optimal EA device is the potential need for future re-intervention. Consistent with my experience, published rates of re-intervention following the NovaSure procedure are low. According to product labeling, the post-ablation hysterectomy rate with NovaSure endometrial ablation is 6.3%.[3] Campbell and colleagues reported a total post-ablation hysterectomy rate of 7.6% among the 368 women included in their retrospective observational study of NovaSure endometrial ablation outcomes.[5] A similar rate of hysterectomy (6.8%) was found among 146 women who were observed for ≥1 year following the NovaSure procedure in a prospective observational study.[9] Additionally, hysterectomy was performed in 2.8% of 103 patients who completed 3 years of follow-up in a prospective, single-arm trial with NovaSure endometrial ablation.[6] At 5-year follow-up in this cohort, hysterectomy (2.9%) and surgical reintervention (3.8%) rates were low.[7] In a 10-year follow-up analysis from a randomized controlled trial comparing NovaSure with balloon ablation,

hysterectomy was required in 10 of 69 women (14.5%) following NovaSure endometrial ablation compared with 5 of 35 women (14.3%) following balloon; there was no significant difference between the 2 EA methods (relative risk, 1.0; 95% CI, 0.69–1.49).[10]

Finally, when considering the risk of complications with EA, the potential for uterine perforation is a key concern and has been reported with a variety of devices.[11,12] However, personally, I have not experienced perforations using the NovaSure device. Likewise, very few perforation events have been reported in published clinical trials using NovaSure endometrial ablation. Campbell and colleagues' retrospective study of 368 women who underwent the NovaSure procedure identified no cases of uterine perforation.[5] A small number of cases have been reported in clinical trials that enrolled patients with prior cesarean delivery[13] and underlying coagulopathy.[14] In the study reported by Khan et al, 2 perforations each were observed in the study cohorts with (n=162) and without (n=542) prior cesarean delivery, suggesting no increased risk of uterine perforation in this patient population.[13] Likewise, in the trial reported by El-Nashar and colleagues, there was only 1 perforation among the 41 women with coagulopathy, and none in the 111 women without this underlying condition.[14]

Minerva experience

Following the approval of Minerva last year, the device quickly became available at my facility, and I began offering it to my patients as a treatment option. With the support of representatives from the manufacturer, I adjusted to the technology and was able to confirm proper operation of the device. However, despite verifying correct technique, the outcomes I have observed with Minerva have not compared favorably with those I see with NovaSure endometrial ablation. Among the 12 patients at my practice who were treated using the Minerva procedure, all have had prolonged discharge, still present at their 6-week follow-up visit, and none have experienced amenorrhea.

These results appear to be inconsistent with published data. Current evidence on outcomes with Minerva comes from two published clinical trials. The first was a multicenter, prospective, single-arm study that compared Minerva with an objective performance criteria (OPC) control and led to US Food and Drug Administration approval of the device based on the superiority of Minerva compared with the OPC control.[15] Of 105 premenopausal women included in an intent-to-treat analysis from the study, 96.2% had successful outcomes at 1 year, with success defined as a patient diary-based Pictorial Blood Loss Assessment Chart (PBLAC) score ≤75, and the amenorrhea rate (PBLAC=0) was 69.5%. None of the patients in the trial required reintervention in 1 year of follow-up, and no intraoperative adverse events, such as uterine perforation, were reported.

In the second study, a randomized clinical trial design was used to improve scientific rigor, with rollerball ablation used as the comparator.[16] Results confirmed outcomes from the prior study, with an observed 1-year success rate of 93.1% among the 102 patients treated with Minerva, and an amenorrhea rate of 71.6%. Also consistent with results in the previous trial, the rate of reintervention was low, at 2.9%, and there were no serious intraoperative complications.

In the Minerva randomized controlled trial, the alkaline hematin (AH) method was used to evaluate blood loss.[16] Notably, the AH method has been shown to overestimate amenorrhea compared with the menstrual pictogram, a method similar to that more commonly used in clinical trials today.[17,18] As a result, our ability to compare the amenorrhea rate from this trial with those in clinical trials of other second-generation EA devices is limited. Another limitation relevant for most minimally invasive OB/GYN surgeons is that only 5 of 153 women (3.3%) in the trial (Minerva group, n=3; rollerball group, n=2) were African American.[16] Therefore, it is unclear how results might differ in this patient population, which also frequently seeks care for menstrual disorders.[19]

Not surprisingly, the efficacy outcomes I have observed with Minerva are not comparable to those demonstrated in these clinical trials, as the selected patient populations and methodologies used to determine outcomes in a clinical trial setting differ from those encountered in real-world clinical practice. Given the high rates of amenorrhea observed in these trials, it remains unclear to me why I have not observed amenorrhea in my Minerva-treated patients, despite using appropriate technique with this new device.

Conclusion

In view of the evidence and my own experience performing EA in approximately 400 patients, the ease of use with NovaSure facilitates optimal performance, and I have ultimately observed excellent clinical outcomes using this device. Based on the experience of my patients who were treated with Minerva and were dissatisfied with their results, NovaSure continues to be the preferred EA treatment option among the women I manage with AUB. As a result of the high rates of amenorrhea I observe with this device, 99% of my patients prefer to have their EA procedure performed with NovaSure. I am confident that my patients will continue to experience the excellent outcomes I have seen over the past several years using NovaSure endometrial ablation.

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Return to NovaSure® Endometrial Ablation After Participation in a Minerva Clinical Trial

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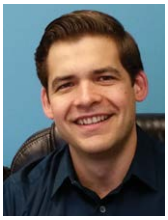

Our academic center has been involved in several clinical trials evaluating endometrial ablation (EA) devices, including the Channel Medsystems Device for Endometrial Cryoablation (Channel Medsystems, Emery, California)[1] and the NovaSure® Endometrial Ablation Procedure (Hologic, Inc., Marlborough, MA).[2] Most recently, we participated in a randomized controlled trial comparing the Minerva® Endometrial Ablation System (Minerva Surgical, Inc., Redwood City, CA) to rollerball ablation.[3] As a result, I am familiar with each of these EA devices.

Minerva clinical trial evidence

The Minerva versus rollerball trial[3] was conducted across 13 sites in the United States, Canada, and Mexico, with 153 patients treated (Minerva, n=102; rollerball, n=51), 96% of whom were white. Interestingly, no African American patients were included in the only other previously published Minerva clinical trial, which supported US Food and Drug Administration (FDA) approval.[4] Menstrual blood loss in the Minerva randomized controlled trial was measured using the alkaline hematin (AH) method,[5,6] with success defined as a reduction in menstrual bleeding to ≤80 mL at 12 months postintervention.[3] Consistent with other EA studies,[2] enrolled patients had a uterine length ≤10 cm;[3] those with uterus-distorting fibroids or underlying coagulopathies were excluded. In most cases, either intravenous sedation and cervical block (Minerva, 48.0%; rollerball, 52.9%) or general anesthesia (Minerva, 18.6%; rollerball, 19.6%) was used; none of the Minerva procedures in the study were conducted using cervical block only. The 1-year success rate with Minerva was 93.1%, including 71.6% with amenorrhea, and no serious intraoperative adverse events were observed during the study.

Several limitations of the trial are noted by the authors.[3] The lack of a racially diverse patient sample is problematic, as it fails to clarify the utility of the procedure in nonwhite populations. This is a significant point for our gynecology practice because a very large proportion of our patients are First Nations women. It is an equally important limitation for most US clinicians, given data demonstrating that black patients seek emergency care for menstrual disorders 3 times more often than white patients.[7] Likewise, the exclusion of patients with coagulopathies leaves unanswered the question of whether Minerva can be used in patients who require anticoagulation or who have an underlying coagulopathy. In addition, although the authors state that patients with fibroids distorting the uterine cavity or with polyps >2 cm were excluded from the trial, there is no mention of whether any patients had intrauterine lesions, or what outcomes could be expected in the presence of any cavitary pathology.

The Pictorial Blood Loss Assessment Chart (PBLAC) is typically used in EA device studies to diagnose heavy menstrual bleeding when determining eligibility for inclusion and to assess menstrual outcomes after treatment.[8] The scoring method used for PBLAC assigns values ranging from 0 to 10 or 20, depending on whether a tampon or sanitary napkin is used, with 1 representing light staining regardless of the type of product[9] and 0 indicating amenorrhea. Prior to validation of PBLAC, the AH method was considered a gold standard clinical trial technique for determining blood loss;[5] the AH method was used in the Minerva randomized controlled study. Interestingly, Burnett et al have presented data showing that volumes counted as <2.5 mL or <5.0 mL and recorded as amenorrhea with the AH method could instead have blood loss values ranging from 1 to 5 mL using the modified PBLAC, menstrual pictogram (MP, **Table**).[5,10] Considering that only a score of 0 would represent amenorrhea using PBLAC or MP, use of the AH method may have led to an apparently higher amenorrhea rate in the Minerva clinical trial compared with amenorrhea rates in trials using the more common PBLAC method.[8] In addition, because follow-up data are currently limited to 12 months, conclusions regarding long-term outcomes including treatment success, patient satisfaction, and amenorrhea in patients undergoing Minerva cannot be made.[3,4]

Table. Menstrual Pictogram–Determined Blood Volumes From a Prospective Clinical Trial for Samples Below the Threshold for Amenorrhea Using the AH Method

AH Volume (mL)	MP Volume (mL)
<5.00	5
<2.50	1
<2.50	1
<2.50	0
<2.50	2
<2.50	2
<2.50	1
<2.50	2
<2.50	1
<2.50	4
<2.50	3
<2.50	3
<2.50	4
<2.50	3
<2.50	0

AH=alkaline hematin assay; MP=menstrual pictogram.

Data are listed in order of increasing AH volume. Yellow shading indicates agreement between the AH and MP methods, and blue shading indicates discordant results.

Table adapted from Burnett PE, Chudnoff S, Turner L, Dadgar D. Comparison of menstrual pictogram scoring to the validated alkaline hematin assay as techniques for measuring blood loss on feminine hygiene products. Available at: http://kcasbio.com/wp-content/uploads/2014/02/AlkalineHematinComparisonPoster.pdf. Accessed December 13, 2016.[10]

Evidence and experience with NovaSure endometrial ablation

Though no comparative data between Minerva and NovaSure endometrial ablation exist, reflecting on the noted limitations of the randomized controlled trial with Minerva, there are several reasons I continue to use NovaSure endometrial ablation as my preferred EA method. Most notably, compelling data are available for NovaSure endometrial ablation, including long-term outcomes over periods of 5 years[11,12] and 10 years,[13] including a remarkable reintervention rate of ~20% reported at 10 years following the procedure.[13] The safety record with NovaSure endometrial ablation has been well documented, with substantial rates of amenorrhea across a number of clinical trials.[14] Robust data supporting excellent clinical outcomes have been reported by several investigators. The most recent of these data come from a randomized controlled trial conducted in an office-based setting, demonstrating a 56% amenorrhea rate after 12 months among 52 women treated with NovaSure endometrial ablation;[15] similar results have been observed in larger and longer-duration prospective studies. For example, Gallinat found that 75% of 103 patients who completed 5 years of follow-up after NovaSure endometrial ablation had amenorrhea.[11] These rates are consistent with my practice, as approximately two thirds of patients I treat report complete cessation of bleeding following the NovaSure procedure, and the remainder have lighter and often shorter flow. High rates of satisfaction have been reported with NovaSure endometrial ablation, ranging from 85% to 94% in prospective single-arm studies with 6 months to 4 years of follow-up[16-18] and from 87% to 94% in randomized controlled trials.[15,19-21] This parallels my own experience in that approximately 90% to 95% of my patients express satisfaction with the results of NovaSure endometrial ablation. In contrast to the number of cases using general anesthesia in the Minerva trial, in my practice, NovaSure endometrial ablation has become a routine outpatient ambulatory clinic procedure using nurse-led conscious sedation.

"90% to 95% of my patients express satisfaction with the results of NovaSure endometrial ablation."

Another reason I prefer to use the NovaSure procedure for EA is because of the favorable outcomes across a number of clinical situations that can complicate the endometrial ablation procedure, including the presence of some intrauterine pathologies.[22] In my experience, NovaSure endometrial ablation can routinely be performed in patients with fibroids <2 cm;[23,24] for those with more extensive intracavitary disease including polyps and type 0 fibroids, NovaSure endometrial ablation can successfully be performed following hysteroscopic tissue removal with the MyoSure procedure, as reported by Rubino et al.[25] In addition, consistent with published literature,[26] I have found that patients with abnormal uterine bleeding related to ovulatory dysfunction (AUB-O) and those with a primary endometrial disorder (AUB-E) have similar outcomes with NovaSure endometrial ablation. Likewise, similar outcomes and high patient satisfaction have been demonstrated among obese and non-obese patients undergoing the NovaSure procedure.[27,28]

Consistent with my experience, the NovaSure procedure can be used without serious complications in patients with previous Essure® (Bayer, New Jersey) insertion for permanent contraception, provided that proper Essure® micro-insert placement and bilateral tubal occlusion are confirmed.[23,29] Although not indicated in FDA-approved labeling, my colleagues and I have reported using NovaSure endometrial ablation in patients with larger uterine lengths.[2] Other studies have shown NovaSure endometrial ablation to be effective among patients with an underlying coagulopathy (AUB-C).[30,31] Consistent with these data,[30,31] the NovaSure procedure has been safely performed at our academic center in patients on anticoagulant therapy. **Box 1** highlights an example case scenario for which our gynecology service received an emergency consult. In this case, we performed the NovaSure procedure in a patient with past Essure® micro-insert placement and AUB-C, with subsequent complete resolution of AUB despite ongoing anticoagulant therapy.

Box 1. Use of NovaSure Endometrial Ablation in a Patient With Essure Implants and Acute Heavy AUB While on Anticoagulant Therapy

Case scenario

A 45-year-old woman with a history of heavy abnormal menstrual bleeding (AUB) was admitted for inpatient treatment of deep vein thrombosis and pulmonary embolism resulting from an underlying coagulopathy (Factor V Leiden mutation; AUB-C). The patient was initiated on rivaroxaban for anticoagulation, which significantly worsened her AUB. As a result, she became severely anemic, with hemoglobin dropping from 11.1 g/dL (111 g/L) at admission to a nadir of 7.4 g/dL (74 g/L), necessitating transfusion of 2 units packed red blood cells. Our gynecology service was consulted, and an emergency hysteroscopy with biopsy revealed a secretory endometrium with early menstrual changes, fragments suggestive of a benign endometrial polyp, and otherwise unremarkable cavity. The patient had previously undergone placement of Essure micro-inserts with prior hysterosalpingogram confirming correct placement and bilateral tubal occlusion. We performed global endometrial ablation using NovaSure endometrial ablation, and subsequent hysteroscopy revealed complete ablation to fundus and bilateral cornua. The AUB resolved immediately with recovery of hemoglobin to 10.1 g/dL (101 g/L). At 3-month follow-up, the patient remained amenorrheic despite ongoing treatment with rivaroxaban and reported being 100% satisfied with the NovaSure procedure.

Conclusion

As suggested by the authors of the Minerva trial publication, success rates in clinical practice can be expected to be lower than those observed in the highly selected patient population in their randomized controlled trial.[3] The proven track record for NovaSure endometrial ablation and my experience with satisfied patients following the procedure are key reasons I am committed to using this device.

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Transition From Hydro ThermAblator to the NovaSure® Procedure

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As is true for most physicians, time is a valuable commodity in my large, busy group practice. Finding efficient ways to accommodate patient needs is crucial for delivering the best care to the largest number of patients. One example that stands out in my mind is technology that has revolutionized the treatment options available for our patients with menorrhagia. Newer, second-generation endometrial ablation (EA) devices enable us to more easily perform EA procedures, with less risk for complications and an easier recovery since local anesthesia can be used.[1] These devices have provided patients and clinicians a way to avoid more invasive procedures such as hysterectomy. Having access to a device that simplifies the process adds even further to the efficiency of this procedure. Because I perform only about a dozen EA procedures each year, I have found this benefit to be particularly important. Two EA devices that I have used most extensively are the Hydro ThermAblator System (Boston Scientific Corporation, Marlborough, MA) and the NovaSure® endometrial ablation system (Hologic, Inc., Marlborough, MA). Of these two, I have found NovaSure to be the quickest and easiest to use. As a result, I have switched to using only NovaSure.

Key features of the NovaSure device

I have found the NovaSure device to be exceptionally easy to use. The 3 key pieces involved in operating the device are the disposable ablation electrode array (with suction line desiccant), portable radiofrequency generator (RF controller), and a carbon dioxide canister.[1-3] Handling of the disposable electrode array has a "bow-and-arrow" feel, and the device is remarkably light in weight yet sturdy, so it is exceptionally easy to handle.

As the procedure begins, a Cavity Integrity Assessment test that operates through the RF controller enables detection of any perforations that may have occurred during uterine sounding or dilation, prior to transmitting RF energy to the uterus.[1,2] The device automatically performs this assessment by allowing carbon dioxide to flow from the RF controller through the disposable ablation device lumen and into the uterine cavity; integrity of the cavity is confirmed if a pressure of 50 mmHg can be reached and maintained for 4 seconds.[1] The moisture transport system feature of the NovaSure device draws the uterine cavity against the array for more uniform contact, and removes steam, fluid, and byproducts during the procedure. Although not required, I always perform a hysteroscopy right before the ablation. Hysteroscopic visualization during the procedure would be helpful, but NovaSure endometrial ablation has many proactive safety features that help to reduce the risk of injury. Some of the features include the cavity integrity assessment test that ensures an intact uterus prior to beginning the procedure, and the self-terminating feature, which stops the procedure once a target tissue impedance of 50 ohms or the maximum procedure time of 2 minutes has been reached.[2]

In my experience, the entire NovaSure procedure can be completed in less than 3 minutes. This is a key advantage of the device because it provides the opportunity to treat more patients over a shorter time frame; in fact, one could easily perform 3 procedures within 1 hour, which in turn improves efficiency for the surgical support staff. This advantage, combined with the fact that NovaSure endometrial ablation can be performed under local anesthesia, enables safe implementation in an office-based setting. I perform EA in a surgery center with an anesthesiologist and use intravenous sedation and paracervical block. However, if I performed a higher volume of these procedures, I would prefer to do them in my office because of the convenience offered to patients, as well as the avoidance of additional remuneration incurred by both the patient and physician when performed at a surgery center, where more staff are needed. The ability to perform EA in the office allows more flexibility in scheduling around office hours, and patients do not need to take an entire day off for the procedure. In addition, payments received for the procedure, including a facility fee, can be retained by the physician.

Indeed, evidence from multiple prospective trials has demonstrated that the NovaSure procedure can be safely performed in the outpatient setting. The feasibility of performing the NovaSure procedure in the outpatient setting using paracervical block was assessed in a prospective cohort study.[4] The average duration of the procedure in this study was 110 seconds (range: 63–120), and the median pain score during the procedure was 5.1 (range: 0.0–10.0), with 94% of the patients finding the NovaSure procedure to be acceptable under local anesthesia. These investigators found an amenorrhea rate of 60.6% at 6 weeks postprocedure.

In another prospective, observational study, office-based ablations using the NovaSure procedure were completed successfully in all patients; 94% were discharged home the same day.[5] The majority tolerated the procedure well, and postoperative pain was effectively treated in most patients (88%) using simple analgesics. In a single-center, randomized controlled trial comparing the NovaSure procedure with another procedure (thermal balloon ablation), the duration of the NovaSure procedure was significantly shorter (mean difference, 6.2 minutes; 95% CI, 4.6–7.8; *P*<0.001) and resulted in a significantly higher amenorrhea rate at 12 months (relative risk, 2.4; 95% CI, 1.1–5.3; *P*=0.02).[6] This evidence combined with my own experience convinces me that the NovaSure procedure is the optimal device for busy physicians when performing EA in women with indicated clinical features.

Key features of the Hydro ThermAblator device

Performing EA with the Hydro ThermAblator system is achieved through a microprocessor unit that uses heated saline to ablate the endometrial lining of the uterus.[7] The device employs concurrent hysteroscopy to maintain continuous visualization of the uterine cavity.[7] The probe used in performing the technique must be attached to a rigid hysteroscope between 2.8 and 3.0 mm in size. A cervical stabilizer allows better control in sealing the cervix over the sheath, which is inserted into the cavity and consists of a telescopic inner and outer tube involved in thermal insulation and circulation of the heated saline, and also includes a port for the hysteroscope.[7,8] The system does not require direct contact of an instrument with the endometrial surface, making it possible to perform EA in patients with irregular uterine cavities,[7] although its safety and efficacy have not been evaluated in patients with uterine cavities >10.5 or <6.0 cm, submucosal myomas >4 cm, or a bicornuate or full septate uterus.[9] It is also interesting to note that a retrospective cohort study, in which 142 charts were reviewed, showed that EA with Hydro ThermAblator failed in 24% of patients with menorrhagia and suggested that this device is less likely to be effective in younger women, those who use tobacco, and those with menometrorrhagia.[10]

It should be noted that if dilation and curettage is performed directly before using the Hydro Thermablator, there is a risk that endometrial byproducts will clog the Hydro ThermAblator system, and persistent bleeding could make it difficult to maintain visualization during the procedure.[7,9] In contrast to NovaSure endometrial ablation, in which no pretreatment is required and the procedure can be performed at any phase of the cycle, the Hydro ThermAblator procedure must be performed with a thinned uterine lining (ie, during the early proliferative phase of the cycle or by pretreating with danocrine or gonadotropin-releasing hormone (agonists).[3,9]

The technique used with the Hydro ThermAblator system involves completing a diagnostic step to rule out any perforation or previously undetected pathology before starting the ablation process, which begins following the time period needed to heat the saline medium.[7,8] I have found that the total time to complete EA with this device is approximately 15 minutes. This is significant not just because of the additional time spent in comparison to the NovaSure procedure, but because the equipment is relatively heavy and cumbersome to handle; in my experience, holding the Hydro ThermAblator apparatus in place for the time necessary to complete the procedure is tedious.

The Hydro ThermAblator device has been shown in a prospective clinical trial to be effective for use in the outpatient setting with select patients.[8] The average procedure duration for Hydro ThermAblator in this study was 25 minutes (range: 20–35). Only 88% of patients considered the procedure to be acceptable, and fewer indicated they would recommend it to a friend (81%). The study population was limited to women who elected to have the procedure in this setting after being informed regarding the techniques used and availability of local anesthesia only. This fact led the authors to conclude that use of the device may be appropriate in the outpatient setting only in selected patients.

Clinical evidence: NovaSure versus Hydro ThermAblator devices

The NovaSure and Hydro ThermAblator devices have been compared in a double-blind, randomized controlled trial that included 160 women (NovaSure group, n=82; Hydro ThermAblator group, n=78).[11] After 12 months, 87% (65 of 75) of patients in the NovaSure group were completely satisfied with results from the treatment compared with 68% (48 of 71) in the Hydro ThermAblator group (relative risk [RR], 1.3; 95% CI, 1.0–1.6); the amenorrhea rates were 47% (35 of 75) and 24% (17 of 71), respectively (RR, 2.0; 95% CI, 1.2–3.1).[11] Reintervention was less likely to be required over the 12 months following NovaSure endometrial ablation compared with the Hydro ThermAblator (RR, 0.29; 95% CI, 0.12–0.67), including a lower risk for hysterectomy following NovaSure endometrial ablation (RR, 0.49; 95% CI, 0.15–1.5).[11] Results were consistent at 5 years of follow-up in this study, when the RR of surgical reintervention was 0.43 (95% CI, 0.23–0.80), favoring NovaSure endometrial ablation.[12] Similarly, in a meta-analysis, NovaSure endometrial ablation was 3 times more likely than Hydro ThermAblator to lead to amenorrhea; patients treated with Hydro ThermAblator were 9 times more likely to be dissatisfied and nearly 5 times more likely to have persistent heavy bleeding compared with NovaSure endometrial ablation **(Table)**.[13] This evidence suggests that NovaSure endometrial ablation is more likely to lead to better outcomes compared with Hydro ThermAblator when considering patient satisfaction, efficacy, and the potential need for re-treatment.

Table. Comparative Outcomes at 12 Months Postprocedure With Hydro ThermAblator Versus NovaSure

Outcomes	OR	(95% CI)	*P* value	Comparison
Amenorrhea rate	0.36	(0.18–0.73)	0.005	NovaSure > Hydro ThermAblator
Heavy bleeding	4.8	(1.3–18.1)	0.02	NovaSure < Hydro ThermAblator
Patient dissatisfaction rate	9.4	(1.1–77.2)	0.04	NovaSure < Hydro ThermAblator

CI=confidence interval; OR=odds ratio. OR <1.0 represents greater rate with NovaSure than Hydro ThermAblator; OR >1.0 represents greater rate with Hydro ThermAblator than NovaSure.

Adapted from Daniels JP, et al. Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. *BMJ.* 2012;344:e2564.

Conclusion

Although published clinical data suggest better outcomes with NovaSure endometrial ablation, the primary reason I switched to this device from the Hydro ThermAblator relates to ease of use and the much faster, simpler technique with the NovaSure procedure. I can complete an EA procedure in less than 3 minutes using the NovaSure procedure, whereas the Hydro ThermAblator technique takes approximately 15 minutes to complete. In addition to the longer-duration procedure using the Hydro ThermAblator, the equipment with this device is heavier and more cumbersome to operate, so maintaining a good grip on the apparatus throughout the procedure can be uncomfortable. The combination of these factors necessitates use of more clinical staff to provide assistance and more anesthesia to get through the duration of the procedure. For these reasons, NovaSure endometrial ablation will continue to be my preferred device for EA.

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Summary

As demonstrated in the articles here, endometrial ablation (EA) is a safe and effective minimally invasive alternative to hysterectomy for the treatment of abnormal uterine bleeding (AUB) in premenopausal women. Several device options are available for performing EA. Published cumulative evidence from clinical studies and 15 years of real-world physician experiences such as that reported by these authors have established the clinical benefit of the NovaSure® system in treating AUB.

The physician authors of these articles discussed the current published literature and their real-world clinical practice experience with the NovaSure system, which together indicate that the NovaSure procedure: (1) achieves high treatment success rates, (2) has low surgical re-intervention rates, (3) is simple, quick, and user-friendly, and (4) can be performed in an office setting under local anesthesia. All physician authors reported high patient satisfaction rates in their practice with the NovaSure procedure, which is supported by evidence from clinical studies. Drs. Thieu, Underwood, and Arrington show that, although hysterectomy is a definitive treatment for AUB, physicians increasingly prefer EA with the NovaSure system because it provides comparable treatment outcomes, with added advantages of lower complication rates, shorter recovery times, and lesser resource use. Drs. Goldberg, Basinski, Adams, and Rattray also currently prefer the NovaSure system over other devices, such as the Hydro ThermAblator and Minerva, based on its long-term record of safety and patient satisfaction. Corroborating the evidence in literature, Dr. Underwood did not observe a delay in diagnosis or an increase in the incidence of endometrial cancer post NovaSure endometrial ablation in his clinical practice. In addition, Drs. Thieu and Underwood provide evidence that the NovaSure procedure has demonstrated success in women with AUB caused by multiple factors such as coagulopathy (AUB-C), leiomyoma (AUB-L), and an ovulatory disorder (AUB-O).

Overall, substantiated by robust evidence in published literature, the physician authors of these articles endorse the NovaSure endometrial ablation procedure as their preferred method of ablation for women with AUB. The authors find that the NovaSure endometrial ablation procedure offers physicians and their patients a safe, simple, and minimally invasive option for the treatment of AUB, with durable and successful outcomes. It is hoped that fellow clinicians will draw on insights and data gleaned from this monograph to support their confident use of the NovaSure procedure in clinical practice.

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Important Safety Information:

NovaSure® endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous. The NovaSure procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. NovaSure endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. Inform patients to contact you if they experience a possible side effect related to use of this product. For detailed benefit and risk information, please consult the IFU.