Introduction
Abnormal uterine bleeding (AUB) affects approximately 1 in 3 women in their lifetime and approximately 10 million women per year.1-3 In addition, women who suffer from AUB are noted to have health-related quality of life scores (HRQoL) in the bottom 25th percentile of women of similar age due to a negative impact on sexual functioning, mental well-being, and overall health. The direct economic healthcare cost of AUB is estimated to be between $1 billion to $1.55 billion and the indirect cost associated with work absence and feminine products is estimated to be between $12 billion to $36 billion per year.5

Of the more than 500,000 hysterectomies performed per year, approximately 100,000 are performed for AUB alone. In approximately 38% of these women, no other treatment options such as oral contraceptives, progesterone, hormonal intrauterine devices, or ablation prior were offered to the patient prior to hysterectomy.4

This article will review existing literature to evaluate global endometrial ablation (GEA) for the treatment of AUB with respect to success rates across various populations, the overall effect on cancer detection, and the cost effectiveness of this treatment option.

Treatment of Abnormal Uterine Bleeding
After appropriate evaluation, patients may be offered several treatment options for AUB. Hormonal therapies have been the mainstay of treatment for disorders of the menstrual cycle with variable effectiveness, with as few as 25% of women continuing this treatment long-term.5 Hormonal intrauterine devices (LNG-IUS) have been shown to be superior to systemic hormones but have demonstrated a discontinuation rate of up to 50% at 3 years.5 Hysterectomy is a definitive treatment option but requires surgical skill that may vary across practice settings with inconsistent clinical outcomes. Risk for injury to bladder, ureters, bowel, spleen, or vessels resulting in poor patient outcome, re-intervention, or long-term morbidity is a major concern for both patients and physicians alike.

Endometrial ablation with rollerball or bipolar resection has been available to patients for decades but requires significant hysteroscopic skills likely resulting in higher patient risk. Fluid overload, perforation, and inadequate
endometrial removal are some of the potential risks associated with these techniques. In 1997, the Food and Drug Administration (FDA) approved the first GEA technology and thereafter several GEA devices have been approved (Table 1).

GEA technologies offer women a low-risk, noninvasive method to treat abnormal uterine bleeding with high effectiveness and reduction of risk over hysterectomy, with no hormonal risks or hormone-associated side effects. Risks of endometrial ablation include thermal injury to surrounding organs, infection, continued bleeding, and post-endometrial ablation pain related to hematometra. However, the risks of these adverse events of GEA are small, the learning curve is typically low, and the procedure can often be performed in an office setting to lower healthcare costs.

### Success Rates for Global Endometrial Ablation

The success rate with endometrial ablation can be attributed to the type of technology utilized and the surgeon’s level of experience. Success of endometrial ablation can be defined clinically with several different parameters, such as amenorrhea rates, reintervention rates, or patient satisfaction.

Gimpelson in 2014 systematically reviewed the literature to assess the 10-year experience with radiofrequency endometrial ablation. In this article, several randomized, prospective studies with head-to-head comparisons were reported and reviewed (Table 2). Radiofrequency GEA was consistently shown to have superior outcomes. These findings are supported by another large cohort study of 114,910 women who had undergone ablation in the United Kingdom and found that radiofrequency GEA was associated with a lower risk of subsequent surgery compared to all other technologies (both first and second-generation). Furthermore, in a separate meta-analysis of second-generation GEA devices, Daniels et al. reported that the radiofrequency GEA procedure had higher amenorrhea rates at 12 months compared to other GEA procedures.

Minerva is the newest GEA ablation technology to be approved for use in the United States (US) and uses radiofrequency-heated argon plasma inside a silicone balloon anchored on a NovaSure-like frame to produce the endometrial ablation. Only one peer-reviewed article is available and is based on a prospective, single-arm study of 105 intent-to-treat patients in a pre-market analysis trial conducted outside the United States. In this small cohort, success rates for reducing bleeding to normal and amenorrhea rates were 96.2% and 69.5%, respectively. Limitations to this data include: a small cohort of treated patients, all sites being located outside the United States, and the lack of a traditional, standardized control group rather than a mathematically modeled statistical control. Therefore, the actual comparative success of this technology over other approved methods for endometrial ablation cannot be known. Minerva has reported no peer-reviewed data from the FDA clinical trial with 153 patients (102 Minerva, 51 rollerball), long-term data greater than 12 months, post-ablation syndrome rates, reintervention rates, compatibility with Essure inserts, or Asherman’s syndrome (see the Minerva IFU).

Recognizing the changes to the NovaSure radiofrequency device since FDA approval in 2002, along with increased surgeon experience, clinical outcomes may differ from the original data reported in the initial pivotal trials for NovaSure. Therefore, a systematic review of the literature was undertaken to assess the clinical outcomes associated with radiofrequency GEA utilizing only prospective, single-arm, or comparative studies as inclusion. The goal was to aggregate rates of amenorrhea, clinical success, and patient satisfaction so this pooled data could be utilized to determine “modern” NovaSure success rates to compare radiofrequency ablation with emerging GEA technologies.

A search of the English medical literature from 2000-2015 was conducted to identify peer-reviewed, prospective studies that reported outcomes after radiofrequency GEA with parameters of amenorrhea, patient satisfaction, and surgical re-intervention rates. Ten prospective trials were identified including 3 single-arm trials and 7 RCTs comparing NovaSure GEA to other GEA or first-generation ablation technologies. Amenorrhea was defined as either a pictorial blood loss chart (PBLAC) of 0 or patient report of complete menstrual cessation. Success was defined as PBLAC≤75 or subjective reduction in menstrual flow including amenorrhea, hypomenorrhea or eumenorrhea. Patient outcomes were reported for success and amenorrhea in all studies in the intent-to-treat (ITT) population. Patient satisfaction was based on the evaluable patient population.

### Table 1: Current FDA-approved endometrial ablation technologies

<table>
<thead>
<tr>
<th>Device</th>
<th>Mechanism of Action</th>
<th>Year FDA Approved</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Themachoic® Uterine Balloon Therapy</td>
<td>Heated water within a balloon</td>
<td>1997</td>
<td>Johnson &amp; Johnson, NJ</td>
</tr>
<tr>
<td>Her Option™ cryotherapy</td>
<td>Refrigerant gas cooling system</td>
<td>2001</td>
<td>Cooper Surgical, CT</td>
</tr>
<tr>
<td>HydroThermAblator System (HTA™)</td>
<td>Freeing flowing heated water</td>
<td>2001</td>
<td>Boston Scientific, MA</td>
</tr>
<tr>
<td>NovaSure® Radiofrequency Ablation</td>
<td>Radiofrequency mesh system</td>
<td>2002</td>
<td>Hologic, Inc, MA</td>
</tr>
<tr>
<td>MEA® microwave</td>
<td>Microwave heat system</td>
<td>2003</td>
<td>Microlis Medical LTD, UK</td>
</tr>
<tr>
<td>Minerva endometrial ablation system</td>
<td>Radiofrequency heating of an argon gas within a silicone balloon</td>
<td>2015</td>
<td>Minerva Surgical, CA</td>
</tr>
</tbody>
</table>
for heavy bleeding, Sabbah et al\textsuperscript{20} desire NovaSure GEA treatment in patients with uterine fibroids who were successfully treated with most GEA technologies.\textsuperscript{7} Obesity can be an underlying uterine pathology to patients without significant adenomyosis as imaging modalities can be beneficial.\textsuperscript{26-28} While adenomyosis has been found in many hysterectomy specimens after failed ablation and has been proposed to be a major factor in ablation failure, few studies have investigated this association. In 2011, Carey et al\textsuperscript{29} reported, after 7 years of follow-up, a post-ablation hysterectomy rate of 9.7% with a pathological diagnosis of adenomyosis in 28% of the specimens. This rate is consistent with the underlying prevalence of this disease in the general population. In a study by Mengerink et al,\textsuperscript{30} the prevalence of adenomyosis in hysterectomy patients after failed ablation was similar to that of a control group of women undergoing hysterectomy for menorrhagia and/or dysmenorrhea (45.5\% vs. 42.8\%). In women who had a pre-ablation ultrasound suggestive of adenomyosis, El-Nashar and colleagues did not identify an increased risk of GEA failure with NovaSure (OR 1.7, 95\% CI 0.6-4.8).\textsuperscript{31} The literature does not support withholding ablation therapy for women with suspected adenomyosis as imaging modalities define as subjects that returned for questioning 12 months after their procedures. Pooled data (Table 3) reveal an objective and subjective amenorrhea rate in 732 total patients of 47.6\% (range 33.3-75.8\%), a success rate in 515 total patients of 85.0\% (range 54.8-97.0\%) and a rate of patient satisfaction in 430 total patients of 93.7\% (range 90.4-100\%).

Menstrual outcomes based on PBLAC and subjective reporting are presented in Figure 1. Findings from this Mean Mathematic Assessment across the variety of data and large number of patients suggest that overall rates of amenorrhea, success, and patient satisfaction are excellent for NovaSure.

<table>
<thead>
<tr>
<th>Device</th>
<th>Amenorrhea Rate</th>
<th>Hysterectomy Rate</th>
<th>Patient Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>NovaSure\textsuperscript{®}</td>
<td>43-56%</td>
<td>2-5.3%</td>
<td>87-94%</td>
</tr>
<tr>
<td>Thermachoice\textsuperscript{®}</td>
<td>8-11%</td>
<td>0-9.3%</td>
<td>77-83%</td>
</tr>
<tr>
<td>HTA\textsuperscript{™}</td>
<td>23-24%</td>
<td>3-10%</td>
<td>68%</td>
</tr>
</tbody>
</table>

Table 2: Amenorrhea, hysterectomy, and patient satisfaction rates after 12 months of follow-up for NovaSure, Thermachoice, and HTA GEA technologies.\textsuperscript{7}

Special Circumstances

Most studies reviewing endometrial ablation outcomes are limited to patients without significant underlying uterine pathology or systemic disease. However, patients with uterine fibroids, previous cesarean section (CS), coagulopathy, adenomyosis, severe dysmenorrhea, anovulatory bleeding, Essure implants, and obesity can be successfully treated with most GEA technologies. In patients with uterine fibroids who desire NovaSure GEA treatment for heavy bleeding, Sabbah et al\textsuperscript{20} reported in a prospective, single-arm study on 65 patients with type I or II submucous fibroids up to 3 cm with or without polyps. At 12 months, 69\% of patients reported amenorrhea and 95\% of patients reported reduction of bleeding to normal or less. With respect to CS and ablation, women with previous low transverse CS can proceed to ablation with low risk and good outcomes. Khan et al\textsuperscript{21} reported on 162 patients undergoing either NovaSure or Thermachoice ablation with at least one previous CS and compared outcomes to 542 patients with no history of CS. With a mean follow-up of 5 years, outcomes for non-CS and CS groups were not statistically significant for amenorrhea rates (20.8\% vs. 19.8\%, \textit{P}=0.76) or treatment failure (11.3\% vs 11.7\%, \textit{P}=0.81). No bladder injuries or fistula were reported in this cohort. Similarly, Adkins et al\textsuperscript{22} reported on 100 women with previous CS and 94 women with vaginal delivery who underwent NovaSure endometrial ablation. No uterine perforations, bowel or bladder injury were encountered in women with or without CS.

Women with coagulopathy and AUB (AUB-C) represent an interesting group of patients for which avoidance of major surgery can be beneficial.\textsuperscript{23} El-Nashar et al\textsuperscript{24} reported on 41 patients with known coagulopathy due to an intrinsic bleeding disorder or anticoagulation therapy compared to 111 patients without coagulopathy undergoing either NovaSure or Thermachoice endometrial ablation. At 2-year follow-up, no significant difference was found in intraoperative or post-operative complications, which were minor and infrequent (6\%). Overall, 84\% experienced amenorrhea or light bleeding. There was no difference in rates of reintervention with hysterectomy or repeat ablation (5\% coagulopathy vs. 7\% no coagulopathy, \textit{P}=0.728). A follow-up study by El-Nashar et al\textsuperscript{25} of this cohort revealed health quality-of-life improvements were similarly improved and durable in both groups over time.

Adenomyosis is a uterine condition that causes menstrual pain and/or heavy uterine bleeding in women (AUB-A). In patients with AUB, the prevalence of adenomyosis is as high as 91.3\% and noted to have an overall prevalence of approximately 21-28\%. Furthermore, the identification of adenomyosis with ultrasound or magnetic resonance imaging has been shown to have a sensitivity ranging from 66-81\%. However, these sensitivities have been achieved in centers with highly trained technicians and physicians calling into question the ability to detect this disease in a general radiologic or gynecologic practice.\textsuperscript{26-28}
may not be accurate in diagnosing this condition, and the underlying prevalence of adenomyosis or ablation success rate does not appear to be dissimilar from control group or the general population.

Dysmenorrhea is a common complaint associated with AUB. By reducing the menstrual blood loss with GEA, dysmenorrhea might be reduced or eliminated as well.32 Alternatively, patients with abnormal uterine bleeding and associated severe dysmenorrhea may be at higher risk for adenomyosis or endometriosis and endometrial ablation may be less successful in this patient population. Multiple studies have shown significant benefit of NovaSure on rates of dysmenorrhea.7,18 Nonetheless, patients with dysmenorrhea may be particularly challenging to treat. One study analyzed the outcome of patients with AUB and dysmenorrhea treated with LNG-IUS and NovaSure (23 women) vs GEA alone by NovaSure or ThermaChoice (65 patients). After 4 years of follow-up, LNG-IUS with GEA was superior in outcome to GEA alone with failure rates of 8.7% and 29.2%, hysterectomy rates of 0% and 24%, post-ablation pelvic pain of 4.3% and 12.3%, and persistent heavy bleeding of 4.3% and 23.1%.33 The combined action of endometrial suppression and ablation with LNG-IUS and GEA appears to be effective in treating women with AUB and dysmenorrhea, though further studies are needed to confirm these findings.

NovaSure, ThermaChoice, and HTA are all FDA-approved devices deemed safe to use after implantation with Essure implants (Essure IFU). A single study reported on 117 consecutive patients undergoing NovaSure ablation after implantation of Essure with no significant adverse events.34 Additionally, both Bayer (Essure) and Hologic (NovaSure) are currently involved in FDA post-market trials to confirm the safety of performing the NovaSure procedure after Essure inserts have been placed. Cryoablation or Minerva currently do not have approval for use after placement of Essure implants as these combinations have not been studied or reviewed by the FDA for safety.

Non-cyclic menstrual bleeding due to ovulatory dysfunction (AUB-O) can be a major underlying cause for women over the age of 40, women with polycystic ovarian syndrome (PCOS), and obese women due to a hyperestrogenic state.1,35 Concerns about treatment of AUB-O with endometrial ablation have been raised due to potential future risk for endometrial cancer and increased risk for failure. However, the recommendation to limit this treatment option in the AUB-O population is not based on data but rather Level C evidence of consensus opinion.1 Some recent studies have in fact proven that use of GEA for the treatment of AUB in women with AUB-O is a safe and effective option. Smithling et al36 reported on outcomes in 968 women with regular (36%), irregular (30%), or unspecified (30%) menstrual cycles after radiofrequency endometrial ablation with 3 years of follow-up. No difference was observed in treatment failure (13% vs 12%, \(P=0.9\) or subsequent procedures.

### Table 3: Objective and Subjective Outcomes for NovaSure Radiofrequency Endometrial Ablation at 12 months based on Peer-Reviewed Prospective Studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Amenorrhea*</th>
<th>Success**</th>
<th>Patient Satisfaction***</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Single Arm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fulop - 2007</td>
<td>43</td>
<td>75</td>
<td>57.30%</td>
</tr>
<tr>
<td>Gallinat - 2008</td>
<td>62</td>
<td>107</td>
<td>57.90%</td>
</tr>
<tr>
<td>Busund - 2003</td>
<td>26</td>
<td>46</td>
<td>56.50%</td>
</tr>
<tr>
<td>RCT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abbott - 2003</td>
<td>16</td>
<td>37</td>
<td>43.20%</td>
</tr>
<tr>
<td>Athanatos - 2015</td>
<td>25</td>
<td>33</td>
<td>75.80%</td>
</tr>
<tr>
<td>Clark - 2011</td>
<td>14</td>
<td>42</td>
<td>33.30%</td>
</tr>
<tr>
<td>Bongers - 2004</td>
<td>34</td>
<td>83</td>
<td>41.00%</td>
</tr>
<tr>
<td>Cooper - 2002</td>
<td>63</td>
<td>175</td>
<td>36.00%</td>
</tr>
<tr>
<td>Penninx - 2010</td>
<td>35</td>
<td>82</td>
<td>42.70%</td>
</tr>
<tr>
<td>Penninx - 2016</td>
<td>29</td>
<td>52</td>
<td>55.80%</td>
</tr>
<tr>
<td>Total Single Arm + RCT</td>
<td>347</td>
<td>732</td>
<td>47.40%</td>
</tr>
</tbody>
</table>

* Amenorrhea defined as PLBAC=0 or patient reported absence of menses; n-value based on intent-to-treat population
**Success defined as PBLAC≤75cc or patient reported reduction in menstrual flow
***Based on the evaluable patient population defined as subjects that returned for questioning 12 months after their procedures
(16% vs 18%, \( P=0.7 \)) between women with regular and irregular bleeding. Hokenstad et al\(^3\) reported outcomes in 320 women with regular cycles (AUB-endometrial[E]) and 169 women with irregular cycles (AUB-O) who underwent either NovaSure ablation or Thermachoice ablation. Five-year cumulative treatment failure rates were 11.7% (95% CI, 6.5%-16.9%) for AUB-O and 12.3% (95% CI, 8.4%-16.2%) for AUB-E (\( P=0.62 \)). Amenorrhea rates were 11.8% for AUB-O and 13.8% for AUB-E. No cancers were observed in this cohort. Of note, in this study patients who underwent NovaSure were 11.5 times more likely to have amenorrhea at 12 months than patients who underwent Thermachoice ablation. Though hormonal treatment remains a common therapy for AUB-O, hormones may be contraindicated in some women and not desired by many. In addition, hormonal options may not provide sufficient control of bleeding as observed in other populations of women who desire ablation therapy.

In the AUB-O population, many women are obese with underlying anovulation due to a hyperestrogenic state or PCOS; or older with anovulation. Avoiding major surgical intervention in the obese patient and older patient with systemic disease may be advantageous as higher morbidity and mortality are a concern. To underscore the success of ablation in a group more likely to have AUB-O, one study demonstrated that women over the age of 45 years have a significantly increased likelihood of success with endometrial ablation with amenorrhea rates approaching 89% and the lowest rate for reintervention with hysterectomy or repeat ablation.\(^4\) With respect to obesity and treatment of AUB, Madsen et al\(^3\) compared outcomes in 263 obese patients with a BMI >30 and 403 patients with normal BMI after both NovaSure and Thermachoice endometrial ablation. No difference was observed in treatment failure at 5 years between the obese and non-obese cohorts (11.6% vs 9.7%) with an adjusted hazard ratio of 0.96 (95% CI, 0.60–1.53; \( P=0.878 \)). The crude 12-month amenorrhea rate was higher among non-obese than obese women (24.3% vs 17.5%); however, this difference was not significant after adjusting for known predictors of amenorrhea. The odds ratio was 1.28 (95% CI, 0.75–2.19; \( P=0.366 \)). Adverse events were rare and comparable between the cohorts.

### Endometrial Cancer and GEA

A long-standing concern of many clinicians is the risk of missing a diagnosis of endometrial cancer due to inability to evaluate the uterine lining post-GEA secondary to intrauterine synechiae. However, several recent studies have been reported that contradict this assumption. In 2011, AlHilli et al\(^3\) systematically reviewed the English literature for post-GEA cancer and reported on 22 cases. Time to cancer diagnosis was 2 weeks to 10 years following GEA and 76.5% were diagnosed at Stage I, similar to the percentage of endometrial cancer staging in women without previous endometrial ablation.

Dood et al\(^4\) undertook a review of a United Kingdom clinical database of 234,721 female patients receiving care for AUB. The authors investigated whether endometrial ablation is associated with increased risk or delayed diagnosis of endometrial cancer compared to women who received medical management alone. In this cohort, 4,776 women underwent GEA for treatment of AUB while 229,945 women received medical management with a median 4.08 years and >1 million women-years of follow-up. In the medical management arm, 30,731 women received combination oral estrogen-progestins, 40,457 received progestins only, and 3,588 had an LNG-IUS. An equivalent percentage

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\( \text{Figure 1: Menstrual outcomes based on PBLAC and subjective reporting in an ITT population.} \)
of women with polycystic ovarian disease were in each group but a statistically higher percentage of obese women were in the GEA group. No significant difference in cancer rates (0.06% in the GEA group vs 0.26% in the medical treatment group) was observed between the two groups. In addition, no delay in diagnosis of cancer was observed in the GEA group (237 days, range 155-1350 days) compared to the medically managed group (299 days, range 144-1133 days) (P=0.99). Lastly, Argall et al in 2015,41 reported on 6 patients with endometrial cancer after endometrial ablation. Interestingly, 4 women underwent ablation after a negative office endometrial biopsy performed 1-17 months prior to the procedure. However, immediately preceding the ablation procedure a curettage was performed and endometrial cancer was detected. Follow-up hysterectomy revealed no residual cancer seen. In 2 other patients, endometrial cancer was diagnosed remote from the ablation therapy and both were found to have stage IA adenocarcinoma. All remained disease-free. The authors also reported that the histology of the uteri were not compromised; the interface of the endometrium to the myometrium was intact post-ablation allowing the pathologist to accurately access depth of disease.

While post-GEA synechiae do occur, no studies have shown a difference in scarring between different GEA technologies or first-generation techniques.22 In fact, the cornerstone of a successful endometrial ablation relies on scarification of the endometrial lining in conjunction with destruction to achieve amenorrhea. Reassuringly, the preceding data would suggest that the presentation of endometrial cancer is not delayed or hidden over time. As a further reassurance, in 77% of women, clinicians can obtain a pipelle biopsy post-ablation13 and with skilled hysteroscopic techniques and ultrasound access, 100% of cavities can be accessed and sampled. However, if appropriate sampling cannot be obtained in light of persistent abnormal uterine bleeding, careful discussion with the patient about the potential for hysterectomy may be warranted.

Economic Benefit of GEA

Determination of economic benefit of each treatment option for women suffering with AUB is a difficult and complicated issue. Some studies have suggested that hysterectomy is the most cost-effective therapy and should be the first-line treatment option for women with AUB over LNG-IUS or endometrial ablation.54 However, in some of these studies, underlying assumptions call into question the veracity of some conclusions. These assumptions include: stating hysterectomy has equivalent risk compared to endometrial ablation, inadequate follow-up failing to account for additional surgery for incontinence or prolapse in the calculations, exclusion of potential treatment costs from bone loss/myocardial infarction/hormone replacement complications from premature loss of estrogen production after hysterectomy, lost time from work, additional potential savings from office-based procedures, and potential increased effectiveness of certain GEA technologies over others. In addition, this conclusion overlooks that many women do not desire an invasive surgical procedure as a frontline option.

In a study by Bonafe de et al in 2014,45 a Medicaid database was used to identify 1880 women with AUB who underwent GEA or hysterectomy with a minimum of 12 months of follow-up. Hysterectomy was nearly 3-fold more expensive than an ablation for the treatment of AUB due to more treatment-related complications. A second study evaluated the cost effectiveness of NovaSure compared to other GEA technologies and hysterectomy in both a commercial insurance setting and Medicaid setting. The model was developed utilizing an insurance claims database to collect initial procedure information, follow-up interventions, and HRQoL data for quality of life improvements, and costs associated with each variable. Results of the analysis revealed that at the 5-year time frame, NovaSure endometrial ablation showed a substantially lower direct and indirect cost compared to other GEA technologies ($578 to $4,372 less per patient) and hysterectomy ($6,208 to $9,259 less per patient) in both the commercial and Medicaid settings.46

Cost effectiveness of ablation is improved when the best technologies available are utilized for patient care and when an office setting is chosen, if possible.

Conclusion

Endometrial ablation with global techniques is an important treatment option for women who suffer from AUB. Several factors play a role in successful outcomes for patients and include surgical skill, appropriate patient selection, and choosing effective technology based on the body of peer-reviewed clinical data. Successful outcomes with endometrial ablation appear to be durable with high patient satisfaction and it has the potential to reduce the need for future hysterectomy in women suffering from AUB by 80-95%.7 NovaSure offers long-standing evidence of both safety and efficacy.

References


Understanding Abnormal Uterine Bleeding (AUB)

**AUB:** A gynecological condition marked by heavy, excessive, or extended menstrual bleeding.

AFFECTS MORE THAN 10 million US women each year.

**NATIONAL ECONOMIC IMPACT**

- **DIRECT Annual Healthcare Costs:** $1.55 billion
- **INDIRECT Annual Costs Due to Work Absence:** $12-36 billion

†D&C alone may not provide improvement. 7

*Providers prioritize least invasive options over more invasive options.*

About 1 in 3 women will be impacted at some point in their life.

EFFECT ON QUALITY OF LIFE

Scores for women with AUB are below the 25th percentile of national norms.

The Continuum of Care

**THE TREATMENT**

**NON-SURGICAL**
- Hormone Therapy (postmenopausal)
- Hypothyroidism
- Intrauterine Device (IUD)

**PROCEDURAL**
- Dilation & Curettage (D&C)
- Endometrial Ablation (GEA)
- Radiofrequency

**SURGICAL**
- Partial Hysterectomy
- Total Hysterectomy

The Overutilization of Hysterectomy

Benign hysterectomies performed annually in the US:

>530,000

100,000

19% are done for AUB.

GEA is a Safe, Cost-effective Alternative

**WHO IT’S FOR**

Premenopausal women who have no desire for future fertility.

**HOW IT WORKS**

Stops or reduces menstrual flow by destroying the lining of the uterus.

**Forms of GEA**

- Electrosurgery
- Laser Therapy
- Cryotherapy
- Radiofrequency

Clinical and Patient Benefits

**SETTING**

- **IN-PATIENT**
  - Hysterectomy
- **OUT-PATIENT/IN-OFFICE**
  - GEA

**AVERAGE RECOVERY TIME**

- **LONG**
  - Hysterectomy
- **SHORT**
  - GEA

**RATE OF COMPLICATIONS**

- **Hysterectomy**
  - 41%
- **GEA**
  - 9%

**ANNUAL WORK DAYS LOST**

- **Hysterectomy**
  - 26 FEWER WORK DAYS LOST
- **GEA**
  - 2X FEWER WORK DAYS LOST

**ECONOMIC BENEFITS**

**Cumulative DIRECT COSTS PER PATIENT**

- **Hysterectomy**
  - 30-DAY: $12,615
  - 1-YEAR: $13,539
  - 5-YEAR: $14,768
- **GEA**
  - 30-DAY: $6,094
  - 1-YEAR: $7,352
  - 5-YEAR: $9,751

Cumulative indirect costs are 46% LESS with GEA.

*Can lead to loss of days, premenopausal hysterectomy and postmenopausal hysterectomy.*

†Combined number of days lost from work due to absence and from short-term disability leave.

§Combined number of days lost from work due to absence and from short-term disability leave.

All data derived from Truven Health MarketScan database analyses. 30 costs for commercial payers, in 2014 US dollars (USD).

<table>
<thead>
<tr>
<th>Year</th>
<th>Hysterectomy</th>
<th>GEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Day</td>
<td>$12,615</td>
<td>$6,094</td>
</tr>
<tr>
<td>1-Year</td>
<td>$13,539</td>
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</tr>
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<td>5-Year</td>
<td>$14,768</td>
<td>$9,751</td>
</tr>
</tbody>
</table>

$6,094

$7,352

$9,751

52% LESS

46% LESS

34% LESS

Cut per-patient cost by nearly 1/2 with GEA.