

# Ten-Year Literature Review of Global Endometrial Ablation with the NovaSure® Device

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## Objective

To examine the peer-reviewed literature describing prospective studies that report amenorrhea rates, patient satisfaction, and surgical re-intervention rates following the NovaSure endometrial ablation procedure.

## Materials and Methods

A search of English-language literature published from 2000 to 2011 was conducted using PubMed. Authors examined 10 prospective studies, six single-arm NovaSure trials, and four randomized controlled trials comparing NovaSure with other global endometrial ablation modalities.

## Findings

Follow-up periods ranged from **6 to 60 months**.

Amenorrhea rates for the NovaSure procedure were **30%-75%**.

Patients satisfied with the NovaSure procedure were **85%-94%**.

In a trial involving other global endometrial ablation modalities, amenorrhea rates at **12 months** with the NovaSure procedure ranged from **43-56%**; with other modalities it ranged from 8-24%.

### • NovaSure re-intervention rates

A study examining women in a single-arm clinical trials for treatment with NovaSure procedure found at a 60-month follow-up that only three hysterectomy procedures were performed among the 107 women (2.8%).

Another study found that only two of 45 women (4.4%) had hysterectomy due to bleeding at 12 months.

The study reporting the highest re-intervention rate (8.2%) showed that 10 out of 146 women observed from the 200-patient cohort had hysterectomy and two had a repeat ablation within 1-4 years of follow-up.

### • NovaSure safety, feasibility, and efficacy in an office-based setting, using local anesthesia

One study of 33 women found no intraoperative or postoperative complications, all procedures completed, median pain score of 3.0 (range of 1.0–7.0) during dilation and 5.1 (range of 0.0–10.0) for the entire procedure. At 24-hour follow-up, 23 women had a pain score of 0.

Another study of 50 women showed that 100% of patients completed the procedure; 94% were discharged the day of procedure; 14% preferred general anesthesia for future treatment; and patient satisfaction was 86% and 94% at 4 and 6 months, respectively.

### • Intraoperative and postoperative pain

Two randomized trials reported on pain during GEA. One found no statistical differences in intraoperative pain in groups treated with the NovaSure and ThermoChoice procedures; however, two (5%) balloon procedures were not completed because of patient discomfort. The other study reported NovaSure ablation to be significantly less painful than Cavaterm ablation ( $P=0.01$ ).

In a prospective multicenter clinical trial examining pain associated with the NovaSure and ThermoChoice procedures (patient choice; not randomized):

- The NovaSure group had no uterine treatment before ablation; ThermoChoice group had a three-minute suction dilation and curettage.
- Numeric pain rating scale scores were significantly better with NovaSure compared to ThermoChoice ( $P<.0001$ ).
- Postoperative pain, postoperative nausea and vomiting were significantly lower for the NovaSure procedure ( $P<.0001$ ).

### • The effect of GEA on PMS: A single-arm cohort study surveying women before and four-six months after GEA found that 97% of women reported improvement in PMS symptoms after ablation.

### • The effect of GEA on dysmenorrhea: The authors reviewed five studies evaluating the impact of GEA on dysmenorrhea.

- A randomized, multicenter trial study found that 56% of patients in both NovaSure and rollerball ablation groups experienced dysmenorrhea before ablation; at 12 months, 21% of women treated with the NovaSure procedure and 34% of those treated with rollerball reported dysmenorrhea.
- A randomized controlled trial studied women with moderate or severe dysmenorrhea; 37% were treated with the NovaSure procedure and 40% were treated with hydrothermablation. At 12 months, 21% and 14% had dysmenorrhea, respectively. This was not significantly different.
- A single-arm retrospective review of patient charts showed dysmenorrhea was present in 49.5% of women before NovaSure ablation and decreased to 21.9% at 18 months after treatment.
- The article also discusses results comparing the NovaSure and ThermoChoice procedure rates of dysmenorrhea.

- **Safety of the NovaSure procedure:** Few complications associated with endometrial ablation have been reported. Minor complications associated with the NovaSure procedure may include bleeding, infection, uterine perforation, and device failure. More serious complications may include bowel injury, cardiac arrest, urinary tract injury, carbon dioxide embolus, sepsis, and death. It is recognized that inappropriate use and physician error contribute to complications.
  - It is recognized that inappropriate use and physician error are contributors to device-related complications. Post-ablation endometritis in clinical studies ranges from 0.6%-5%. Hologic maintains post-market quality assurance tracking of all reportable complications. By applying the number of devices shipped, Hologic estimates the rate of bowel injury after endometrial ablation is less than 1 in 10,000 cases.
- **Special circumstances:**
  - **Uterine disease or pathology:** No study included women with hyperplasia or cancer of the uterus before ablation. Most studies used criteria that ensured no uterine pathology before ablation. One study using inclusion criteria of submucous fibroids up to 3 cm reported an amenorrhea rate of 69% one year after the NovaSure procedure. In another study including women with intra-cavitary lesions of 3 cm or less, submucosal fibroids were found in five women and endometrial polyps in six women treated with the NovaSure or thermal balloon procedures. No specific outcome data were reported for these women.
  - **History of cesarean delivery:** A study of 704 women found that GEA (NovaSure or thermal balloon) has similar efficacy and safety in women who had at least one low-transverse cesarean delivery compared to women with no history of cesarean delivery.
  - **Coagulopathy or use of anticoagulant medication:** A study comparing GEA (NovaSure or thermal balloon) outcomes for women who were being treated for a coagulopathy to a reference cohort concluded that GEA is an effective treatment option for women with coagulopathy and for women with coagulopathy presenting with abnormal uterine bleeding.
- **Uterine cavity and cancer risk:** A systematic literature review, including a case report of endometrial cancer diagnosed five years after NovaSure ablation, found that most patients with endometrial cancer after GEA present with symptoms such as bleeding and pelvic pain, and preoperative diagnosis of endometrial cancer can be made in most cases. This finding addresses concerns that diagnosis is delayed and may be difficult to achieve. The review found that over 75% of the women with post-ablation endometrial cancer were diagnosed in stage I, which is typical for women without a history of ablation.
- **Contraception and pregnancy:** Pregnancy after endometrial ablation is estimated at 0.7%. Pregnancy after GEA poses significant risk of major complications. More than half of these pregnancies were not carried to term because of spontaneous miscarriage or choice to terminate.

## Conclusion

Since the NovaSure procedure was FDA-approved for use in GEA 10 years ago, significant data have been generated that provide a favorable safety profile for the use of the procedure in premenopausal women for the treatment of AUB. Rates of re-intervention are low and patient satisfaction is high.

Rates of amenorrhea and reduction in heavy menstrual bleeding are consistently higher for women treated with NovaSure endometrial ablation than for women treated with other second-generation ablation devices, and these rates appear to be consistent over time.

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