Women treated with the NovaSure® system reported higher amenorrhea rates than those treated with Minerva

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This study was published in 2018 in the International Journal of Women's Health. *Efficacy and patient satisfaction after NovaSure and Minerva endometrial ablation for treating abnormal uterine bleeding: a retrospective comparative study*. All authors were principal investigators in the current study and received compensation from Hologic for participation. Dr. Scordalakes is a speaker for Shionogi & Co., Ltd and a share-holder of The Women's Hospital (Newburgh, IN). Dr. del Rosario is on the speakers' bureau for Minerva Surgical, Inc. Dr. Stankiewicz is a consultant for Ethicon and for Myriad Genetics

Objectives

Compare amenorrhea rate, menstrual symptoms, patient satisfaction, and adverse events in women who underwent endometrial ablation with the NovaSure versus the Minerva radiofrequency ablation systems.

Methods

Study Type

- Retrospective case series chart review
- Prospective telephone survey: assessed amenorrhea rate and bleeding severity changes, re interventions, perioperative AE and patient satisfaction

Patients

- 189 premenopausal women (40.8 +/- 6.2 years)
- 4 private GYN clinics in the US
- Follow-up patient survey at ≥3 months post procedure
- AUB intervention with the NovaSure (n=97) or Minerva (n=92) endometrial ablation systems

Evaluation Methods

- Patient reporting of their perceived menstrual bleeding burden before and after endometrial ablation
  - "No bleeding," "Spotting," "Light bleeding," "Normal menses," or "Heavy bloodflow"
- Amenorrhea rate defined as "No bleeding" at the time of survey
- Clinical success was defined the patient reporting normal-to-no bleeding

Patient Reported Results (mean follow-up post-ablation 11.3 months)

	NovaSure	Minerva	p value
Amenorrhea	64%	42%	p=0.004
Success (none-to-normal Bleeding)	97%	92%	p=0.2039
Reduction in sanitary product use	78%	61%	P=0.049
Incidence of menstrual pain	21%	41%	p=0.003
PMS improvement	85%	68%	p=0.019
Report some level of satisfaction with clinical outcomes	94%	78%	p=0.003
Would definitely recommend to a friend	92%	78%	p=0.013
Adverse events (number of subjects)*	10	5	p=0.284
Reintervention rates	5 procedures in 4 subjects	4 procedures in 3 subjects	p> 0.05

*Pain, fever, nausea, vomiting, vaginal bleeding, acute renal failure, urinary tract infection and and vaginosis, with onsets occurring within 14 days after ablation.

- Mean days per cycle with any reported bleeding were comparably reduced in both groups, from 9.0–9.5 days per cycle before treatment to 4.8–5.5 days/cycle after ablation.
- Endometrial ablation lowered the impact of menstrual bleeding on subject QoL in both NovaSure and Minerva groups. The average postoperative impact score was improved (lower) in NovaSure versus Minerva subjects (0.3 points and 0.7 points, respectively; p=0.012)

NovaSure Pivotal Study Information

- Amenorrhea rate: 36.0%
- Clinical Success: 77.7%
- Patient Satisfaction: 92.8%

Pivotal study supporting FDA approval of NovaSure system (September 28, 2001). Randomized, prospective, multi-center clinical study comparing NovaSure system to a control arm of wire loop resection plus rollerball endometrial ablation (hysteroscopic endometrial ablation). Patient success based on a reduction in a menstrual diary score from ≥ 150 pre-treatment to ≤ 75 at one year post-treatment, using a validated menstrual dairy scoring system developed by Higham. Patient satisfaction assessed by administering Quality of Life (SF-12 Questionnaire) and Menstrual Impact questionnaires prior to treatment and at 3, 6 and 12 months post-treatment.

Conclusion

"While overall bleeding reduction in premenopausal women with abnormal uterine bleeding was excellent with either endometrial ablation system, NovaSure treatment resulted in a higher patient-reported 1-year amenorrhea rate, and women with residual bleeding used fewer pads and tampons than Minerva-treated women."

"Additionally, NovaSure subjects reported better menstrual-related life quality and PMS symptom alleviation, and greater satisfaction with outcomes than Minerva-treated women."

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