

Next-generation NovaSure[®] device for endometrial ablation: assessing ease-of-use among physicians

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Objective: To compare physician assessment of the next-generation NovaSure[®] device to the original NovaSure device.

Design: Prospective open-label, unblinded survey utilizing Likert scales.

Setting: Community-based obstetrician and gynecology practices.

Patients: There were 270 evaluations completed by 168 physicians for women undergoing endometrial ablation with the next-generation NovaSure device compared to the previous model.

Interventions: Physician survey across multiple community-based obstetrician and gynecology practices.

Measurements and main results: In general, 53.7% of women had a normal uterus, with an average cavity length of 5.3 cm \pm 0.9 cm, and 44.7% of women had a normal cervix. Overall, 98.7% of physicians agreed or strongly agreed that they were satisfied with the performance of the next-generation NovaSure device compared with the previous device. Additionally, 89% of physicians rated the next-generation NovaSure device as superior to the previous device. The best rated features were the SureFit[™] Cervical Seal, Smooth Access[™] Tips, and the thumb-pusher. No adverse events were reported in this study.

Conclusion: Community-based physicians rated the next-generation NovaSure device as superior to the previous model in a general population of women.

Keywords: NovaSure, menorrhagia, endometrial ablation, hysterectomy

Introduction

For women, normal menstrual bleeding patterns occur at an interval of 21 to 35 days, with bleeding lasting 1 to 7 days.¹ This equates to less than one tampon or pad, or <80 mL of blood, for every 3-hour period.¹ Menorrhagia is defined as excessive but regular cyclic bleeding of more than 7 days, passage of clots, or iron deficiency anemia.¹ Prolonged bleeding over 12 days should be considered abnormal regardless of cyclic pattern.¹ Pain and heaviness are the most frequently reported bothersome aspects of excessive or very excessive periods.² In Western countries, up to 35% of women report excessive or very excessive bleeding.^{3,4} However, only 5% of women seek medical help for menorrhagia annually.⁴ Among women with excessive menstrual bleeding, 53% reported that their periods interfered with their life, compared with 23% of community controls.⁵

Pharmacotherapy treatment options for excessive bleeding include oral contraceptives, danazol, progestens, etc.⁶ Surgical treatment options for excessive bleeding include endometrial ablation and hysterectomy. Hysteroscopic endometrial ablation offers an effective, less invasive alternative to hysterectomy. Physicians and patients should work

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together to decide the best treatment option for an individual patient. For patients who wish to avoid major surgery and in whom childbearing is complete, endometrial ablation is a reasonable and effective alternative to hysterectomy.⁷ The NovaSure® (Hologic, Inc, Marlborough, MA) endometrial ablation procedure is intended to ablate the endometrial lining of the uterus in premenopausal women with excessive bleeding due to benign causes for whom childbearing is complete.⁸ To date, more than one million women have undergone the NovaSure procedure. Although widely accepted by physicians for use in endometrial ablation procedures, an initiative was undertaken to understand which features could be revised or enhanced to further improve the surgeons experience with the device. The manufacturer made several enhancements to the original device and a next-generation NovaSure device was released for commercial use in 2010. Here we present community-based, physician-reported data evaluating the ease-of-use of the newly designed next-generation NovaSure device compared with the prior model.

Methods

The data presented here represent the findings of community-based, physician-reported assessments on the ease-of-use of the next-generation NovaSure device. The objective was to compare physician assessment of the original NovaSure device to the next-generation NovaSure device. Physicians were asked to participate in the study based upon their use and experience with the NovaSure device and respondents were not compensated for their participation in this study. Participating physicians represented a diverse group that was representative of general, community-based practices. Their procedure volumes ranged from very low (a few per month) to multiple procedures per week. The study was a prospective open-label, unblinded survey utilizing Likert scales to

Table 1 Assessment of uterus type

| Uterus type | Frequency (n) n = 257 | Valid percent |
|-------------|--------------------------|---------------|
| Normal | 138 | 53.7 |
| Anteverted | 56 | 21.8 |
| Retroverted | 36 | 14.0 |
| Verted | 8 | 3.1 |
| Anteflexed | 6 | 2.3 |
| Retroflexed | 7 | 2.7 |
| Flexed | 5 | 1.9 |
| Midline | 1 | 0.4 |
| Total | 257 | 100.0 |

Table 2 Assessment of cavity length

| Cavity length (cm) | Frequency (n) n = 263 | Valid percent |
|--------------------|--------------------------|---------------|
| 3.0 | 1 | 0.4 |
| 4.0 | 37 | 14.1 |
| 4.5 | 38 | 14.4 |
| 5.0 | 63 | 24.0 |
| 5.5 | 44 | 16.7 |
| 6.0 | 45 | 17.1 |
| 6.5 | 29 | 11.0 |
| 7.0 | 2 | 0.8 |
| 8.0 | 1 | 0.4 |
| 8.5 | 1 | 0.4 |
| 9.0 | 2 | 0.8 |
| Total | 263 | 100.0 |

determine whether the updated next-generation NovaSure device design was perceived better than the previous model in ease-of-use or component features. A 5-point Likert scale was used to assess ease-of-use items. Physicians rated the performance of the next-generation NovaSure device (1 = strongly disagree to 5 = strongly agree) and also compared it with the previous model of the device (1 = inferior, 2 = equal, and 3 = superior). Anatomic variability (cervix, uterine position, and cavity length) and procedural information was also collected.

Subjects with benign endometrial pathology, uterine sound <10 cm, intracavitary fibroids <2 cm, and complete childbearing were evaluated. Ease-of-use during endometrial ablation using the new, revised design of the next-generation NovaSure device was compared with the previous NovaSure device.

Internal reliability of the survey was assessed via Cronbach's alpha. Cronbach's alpha is defined as: $\alpha = K/K - 1(1 - \sum_{i=1}^k \sigma_{Y_i}^2 / \sigma_X^2)$ where K is the number of components σ_X^2 is the variance of the observed total test scores, and $\sigma_{Y_i}^2$ is the variance of component i for the current sample of persons. Cronbach's alpha is a measure of internal consistency, that is, how closely related a set of items are as

Table 3 Assessment of cervix type

| Cervix type | Frequency (n) n = 257 | Valid percent |
|----------------|--------------------------|---------------|
| Stenotic | 19 | 7.4 |
| Typical nulip | 13 | 5.1 |
| Normal | 115 | 44.7 |
| Typical multip | 88 | 34.2 |
| Patulous | 22 | 8.6 |
| Total | 257 | 100.0 |

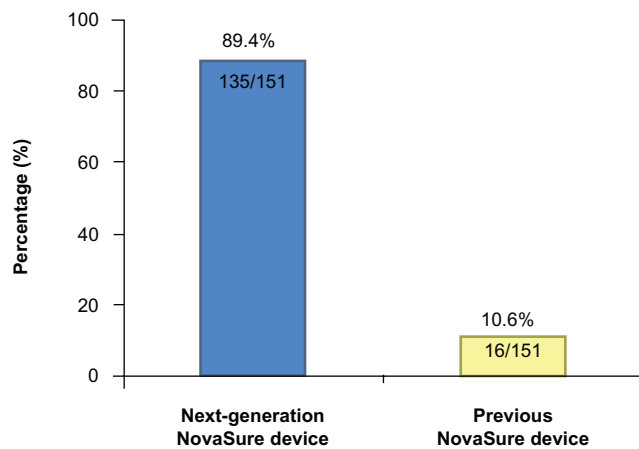


Figure 1 Community-based physician survey: Preference.

a group. Higher alpha scores (>0.80) are more desirable and indicate better reliability.

Results

Ease-of-use assessed by a community-based survey

Physicians ($n = 168$) from community-based obstetrics and gynecology practices rated six specific components of the next-generation NovaSure device. In total, 270 evaluations were completed, with 245 fully completed; 56 physicians completed two evaluations, and 26 physicians completed three or more evaluations. Patients included women undergoing endometrial ablation with the next-generation NovaSure device. In general, 53.7% of women had a normal uterus and 21.8% had an anteverted uterus (Table 1). The average cavity length of women was $5.3 \text{ cm} \pm 0.9 \text{ cm}$ with 55.1% of women having a cavity length between 4.5 cm and 5.5 cm (Table 2). Approximately 45% of women had a normal cervix and 34.2% had a typical multip cervix (Table 3).

Overall, 98.7% (155 of 157) of physicians agreed or strongly agreed that they were satisfied with the performance of the next-generation NovaSure device compared with the previous device. Additionally, 89% (135 of 151) of physicians rated the next-generation NovaSure device as superior to the previous device (Figure 1). Physicians also assessed the overall device and specific components of the next-generation NovaSure device compared with the previous model (Figure 2A and B). Overall satisfaction of the next-generation NovaSure device was evaluated in patients with cavity lengths ranging from 4–9 cm. Additionally, 100% (149 of 149) of physicians agreed that the thumb-pusher on

the next-generation NovaSure device was superior in patients with cavity lengths of $> 7 \text{ cm}$. The next-generation NovaSure device was perceived as easier to insert in uterine cavities $>7 \text{ cm}$ ($P = 0.16$). More than 99% of physicians said that overall, the next-generation NovaSure device was similar or superior to the previous model in patients with a normal cervix. All physicians (100%) agreed that the next-generation NovaSure device was similar or superior to the previous model in patients with stenotic, typical nulip, typical multip, and patulous cervixes.

Physicians prefer the next-generation NovaSure device over the earlier design, regardless of patient anatomy. A few features were considered advantageous, including the redesigned cervical collar to provide a more complete seal and improve the ability to pass cavity integrity assessment, Smooth Access™ Tips to enhance array deployment, and a thumb-pusher to overcome a long vaginal canal (Table 4). Results of this survey are considered valid, as the Cronbach's alpha was ≥ 0.80 , indicating good reliability. This survey showed a high validity and reliability based on Cronbach's alpha calculation for ease-of-use (Cronbach's alpha = 0.841) and comparison items (Cronbach's alpha = 0.823).

Discussion

Excessive menstrual bleeding can have a direct impact on a woman's quality of life. Performing endometrial ablation is a viable treatment alternative to hysterectomy, and the goal of treatment is to improve the patient's quality of life.⁹ The NovaSure endometrial ablation system is intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete. The current data demonstrate that recent enhancements made to the NovaSure device have been well-received by physicians. The next-generation NovaSure device was designed based on surgeon feedback with the goal to enhance features that would further improve the surgeons experience with the device. Several enhancements were made to the original device, and a next-generation NovaSure device was released for commercial use in 2010.

In the community-based survey, 98% of physicians were satisfied with the performance of the next-generation NovaSure device, and 89% considered it as superior to the previous model. It is important to note that the data based on anatomic variability support the use of the next-generation NovaSure device in many patient types, which is relevant for general

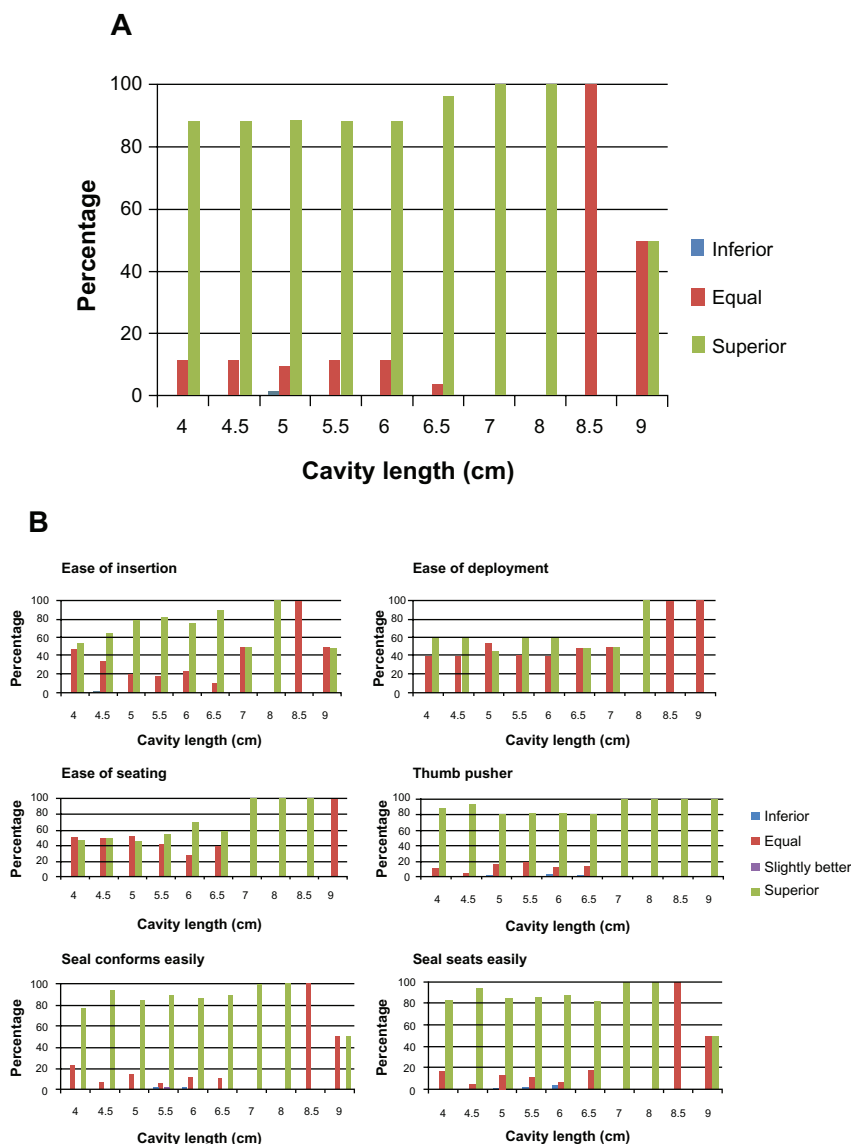


Figure 2 Community-based physician survey comparing the Next-Generation NovaSure device with the previous model. **(A)** Overall satisfaction. **(B)** Ease-of-use. **Notes:** Survey was completed giving physicians four options for rating (inferior, equal, slightly better, or superior).

practitioner use. In this survey, more than 50% of women had a normal uterus and almost 22% had an anteverted uterus. The average cavity length in the women was 5.3 cm and 55.1% of women had a cavity length of 4.5 cm, 5.0 cm, or 5.5 cm. Cervix type also indicated that these women were representative of a general population as 44.7% had a normal cervix and 34.2% had a typical multip cervix. Regardless of anatomy, physicians preferred the next-generation device, and did not identify an anatomic configuration for which the prior device would have been preferred. Physicians considered the thumb-pusher, the SureFit™ Cervical Seal, and Smooth Access Tips as the best features of the next-generation device.

The thumb-pusher allows more leverage and control over the cervical collar. The next-generation NovaSure SureFit Cervical Seal is larger, designed from softer material, provides a 70% greater coverage area, and may improve the procedure efficiency and patient comfort. Finally, the Smooth Access Tips allow for easier insertion of the device.

The results presented here are encouraging and support the changes and enhancements made in the next-generation NovaSure device. These data were collected among community-based physicians and appear to be representative of a general population of women based upon their type of uterus and cervix and cavity length. Advantages with the next-generation NovaSure device include a procedure that can be

Table 4 Community-based physician survey: physician-rated best features

| Feature | Frequency (n) n = 245 | Valid percent |
|--------------------|--------------------------|---------------|
| Cervical seal | 79 | 32.2 |
| Smooth Access Tips | 70 | 28.6 |
| Thumb-pusher | 66 | 26.9 |
| Cervical collar | 11 | 4.5 |
| Ease-of-use | 6 | 2.4 |
| All | 4 | 1.6 |
| Seating | 3 | 1.2 |
| Deployment | 2 | 0.8 |
| Easier to sheath | 2 | 0.8 |
| Distal sheath | 1 | 0.4 |
| Ease-of-use | 1 | 0.4 |
| Total | 245 | 100 |

performed in-office, and is quicker than many other hysteroscopic procedures and less invasive than a hysterectomy.

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Disclosure

The authors report no conflicts of interest in this work.

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