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**The Effect of NovaSure Endometrial Ablation on
Premenstrual Anxiety and Emotional Irritability**

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Abstract:

A cohort of one hundred five women were interviewed prior to and one year post-NovaSure Endometrial Ablation. Questions centered on the presence and intensity of premenstrual anxiety, irritability, and upset feelings (AIU). Approximately 70% of women undergoing the NovaSure procedure reported AIU feelings, and only women with such complaints were included in the study. Participants claimed an average of 6.5 days a month of at least some degree of AIU. Asked to rate the intensity of AIU symptoms on a 1-10 basis, with “1” being “mild” or “negligible” and “10” being “severe” (Patient Subjective Severity Index, PSSI), patients claimed an average of 7.1/10 level of severity of AIU, with a range of 3/10 to 10/10. All 105 patients were interviewed during their “routine annual exams” approximately one year post-ablation, and 93% of participants stated that premenstrual AIU had completely resolved or significantly decreased. Seventy-four percent of patients reported complete resolution of symptoms while nineteen percent reported improvement of symptoms. Patients with persistent but improved AIU rated the symptoms much lower and they lasted an average of only 1.3 days per month.

Background:

It is widely accepted in popular culture that some women can experience certain symptoms prior to their periods, with the most common complaint being dysphoria or emotional irritability (AIU). Other symptoms can also occur, including fluid retention, abdominal bloating, headache, fatigue, pelvic/back/leg aches, and food cravings. While these symptoms are often referred to as “hormonal”, no specific hormonal aberration has been identified to account for these symptoms. The purpose of this study is to demonstrate that endometrial ablation results in resolution, or at least significant diminution, of one of the most common subjective complaints, premenstrual anxiety, irritability, and upset feelings.

Methods:

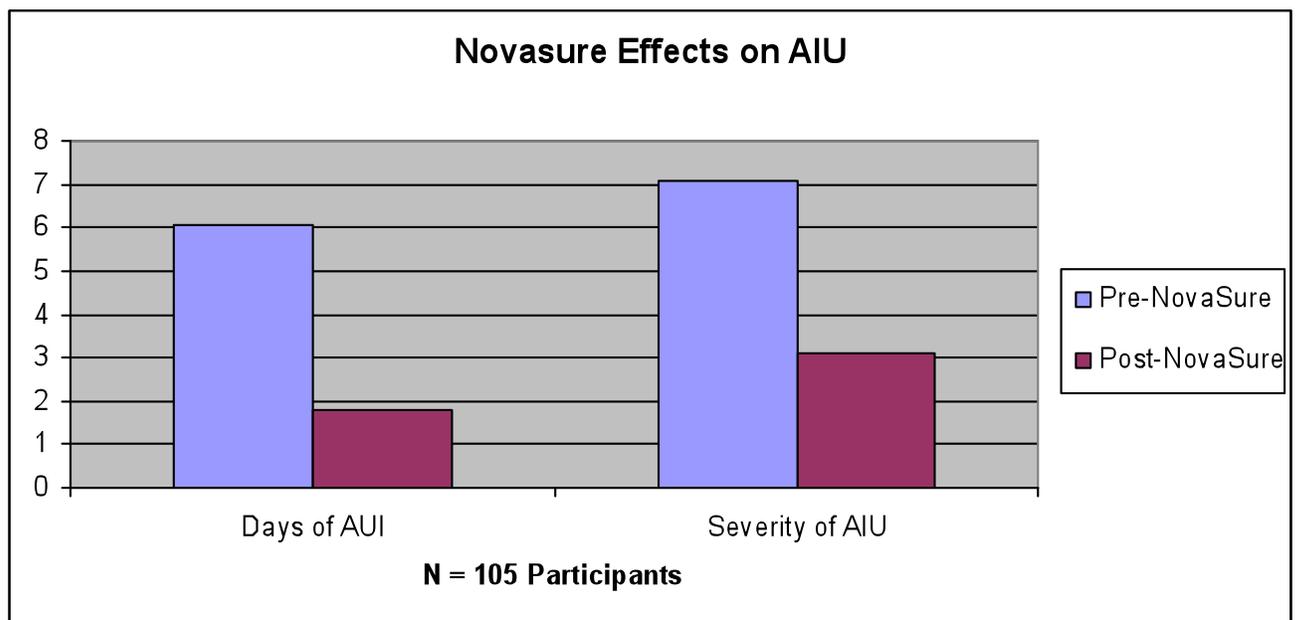
Concept: If removal of all (or most) of the endometrium using the NovaSure Endometrial Ablation system results in alleviation of one of the most common premenstrual symptoms, then it is reasonable to assume that there is some metabolite, antigen, co-factor, or “agent” that in some way causes one of the principal premenstrual symptoms, anxiety/irritable/upset feelings (AIU).

Implementation: Patients who were candidates for endometrial ablation based on a history of menorrhagia were asked to complete a questionnaire regarding whether they experienced certain symptoms leading up to their periods. One of the questions was whether they generally had AIU before their periods over the previous one year. They were also given the opportunity to express in their own words if they felt “rattled”, “not on their game”, or “if things bothered them that would not ordinarily bother them”.

Venue and Locale: All patients were either existing gynecologic patients or referred patients of a solo gynecologist in Athens, GA, a medium sized college town about 50 miles east of Atlanta, GA.

Data Processing: Data was entered into an EXCEL spreadsheet, and results were computed, also producing graphs.

Results:



Summary: Despite general acceptance of the existence of the phenomenon of “PMS” or “PMDD”, there are few formal studies documenting its scope and frequency, and there are no widely accepted theories regarding its pathogenesis. This current study documents with a high degree of confidence that the phenomenon of premenstrual AIU exists and is widely prevalent, frequently being labeled by patients as 8/10 on the 10-point scale. This study further documents that, with patients serving as their own controls, AIU symptoms significantly decrease after the endometrium is removed, or mostly removed, using the NovaSure Endometrial Ablation system.

Implications: Further study is needed to carefully document the prevalence and intensity of premenstrual symptoms, not just AIU but other symptoms as well. Furthermore, it would be very helpful to understand more about age and demographic distributions of the symptoms to help define possible genetic factors of causation. Finally, it would seem

warranted to investigate possible mechanisms related to the late stage secretory (i.e. degenerating) endometrium.