NovaSure GEA Technology Overview

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Summary

The NovaSure GEA is a system developed to treat women suffering from menorrhagia due to benign causes. This technology allows for a customized, controlled, contoured endometrial ablation, without the need for hysteroscopic visualization and endometrial pre-treatment. Average treatment time is ninety (90) seconds. Active bleeding, at the time of treatment, is not found to be a limiting factor for use of this technology. The safety features employed (Perforation Detection System and Device Position Feedback) combined with a high level of effectiveness and patient satisfaction qualifies this system for consideration as the treatment modality of choice in patients that qualify for endometrial ablation. Technical aspects and the steps of the NovaSure GEA procedure are described and summarized in this publication.

Introduction

Hysterectomy is currently the leading treatment method for patients symptomatic for menorrhagia. Over 600,000 hysterectomies are performed every year in the U.S. alone. This aggressive method of treatment was found to be efficacious, but is associated with a number of well-known and analyzed serious drawbacks. Hysterectomy has a relatively high morbidity and mortality rate, and direct and indirect costs associated with the procedure are also found to be quite significant[1].

Ablation of the endometrial lining of the uterus as an alternative to hysterectomy was found to be a less invasive and aggressive method. A large number of clinical trials, as well as retrospective analysis of clinical and financial data has shown that endometrial ablation allows for a lower morbidity and mortality rate and significantly lower procedure

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costs[2]. Endometrial ablation is increasingly being adopted by the gynecological community worldwide[3]. The risks associated with the hysteroscopic approach are well known. Among these are uterine wall perforation, intravasation of fluid distention media, hyponatremia, encephalopathy, and death[4,5,6,7,8]. Technical challenges, requirement for a very well developed hand-eye-foot coordination, potential risks and other drawbacks of this treatment modality do not allow for a successful adoption of this procedure by the vast majority of gynecologists. In fact, only 15% of practicing gynecologists in the United States offer this treatment method.

This particular fact and an alarming rate of hysterectomies performed the triggered the development of other, less challenging methods of endometrial ablation. A variety of methods were and are continuously developed. Tissue destruction is achieved using Nd: YAG Laser, monopolar RF energy (Vest DUB), Diode Laser (ELITT), Heated Balloons (Therma Choice, Cavaterm), heated free circulating saline (HTA), super-low temperatures (Her Option) and microwave energy (MEA). Treatment modalities are as different as the technology employed. Each of the above named treatment methods has a number of advantages over the "Gold Standard" Resection-Rollerball ablation, most importantly ease of use. Most of them are found to be quite effective. Randomized controlled studies have been and continuously are conducted to evaluate safety and effectiveness of each treatment modality.

Nevertheless, each of these technologies has several drawbacks associated with them. All of these technologies require a endometrial pretreatment of some kind (i.e. D&C, drug pre-treatment, timing). The length of the procedure is still relatively long. Depending on the technology used it varies from 3 to 15 minutes. Most of these methods cannot be used when the patient is actively bleeding, which results in a logistical problem with respect of scheduling. Intra-and post-operative pain is still quite significant, therefore compatibility with the office setting remains questionable. Most of these technologies are lacking a good reliable safety mechanism that would prevent energy delivery in the event of a perforation of the uterine wall.

The NovaSure Global Endometrial Ablation (GEA) System (Novacept, Palo Alto, USA) successfully addresses many of the drawbacks of other global ablation devices.

Description of the Novasure GEA System

The NovaSure GEA System (Picture 1) consists of a single use, 3-Dimensional bipolar ablation device and Radio Frequency Controller that enables a controlled endometrial ablation in an average of 90 sec-

Picture 1 - NovaSure GEA System

onds without the need for concomitant hysteroscopic visualization.

Endometrial "pre-treatment" of any kind (mechanical, hormonal, or cycle timing) is not required when using NovaSure GEA. The technology is easily employed in the actively bleeding patient.

Novasure GEA Disposable Ablation Device

The NovaSure GEA disposable ablation device consists of a conformable, bipolar, gold-plated, porous, fabric mesh, mounted on an expandable metal frame. Integral to the hand-held device is the Intrauterine Measuring System (IMD) used to determine uterine cavity width (cornu-to-cornu distance). The unique geometry of the electrode allows for a controlled depth of ablation. It is characterized by a more shallow depth of miometrial penetration (2 mm) at the cornu and lower uterine segment, and a deeper (5 mm) ablation in the mid-body of the uterus. The NovaSure GEA device can treat uteri with sounding lengths up to 12 cm. During insertion into the uterine cavity, the ablation electrode is housed in a protective sheath (similar to an IUD) with an outside diameter (OD) of 7.2-mm. During electrode deployment the sheath is withdrawn into the endocervical canal, allowing for full and proper intrauterine deployment of the fan-shaped bipolar electrode. During the ablation procedure, the protective sheath that occupies the full length of the cervical canal, assuring an effective protection of the endocervix from thermal injury.

Novasure GEA Controller

The NovaSure GEA Controller contains a constant power output genera-

tor with a maximum power delivery of 180 watts. Measurement of uterine cavity length (determined during sounding and cervical dilation), and width (measured by the GEA device at the time of device deployment), are key-entered into the controller, which automatically calculates the unique power output required to assure an optimal, confluent endo-myometrial ablation. Throughout the short procedure, the depth of ablation is continuously controlled by monitoring tissue impedance (resistance). Vaporization of the endometrial layer is a low impedance process owing to a high concentration of conductive liquid (saline) present in the endometrial tissue. As a result, the endometrial tissue is not slowly ablated, but vaporized instead. The vaporization front is continuously moving deeper and closer to the edge of the myometrium. Once the ablation process reaches the myometrial layer, the content of the saline becomes significantly lower. Tissue impedance (resistance) rises rapidly during myometrial tissue desiccation process and reaches 50 Ohms which is equivalent to the impedance of the ablated superficial myometrium. This signals the NovaSure™ generator to automatically terminate the ablation process. This automatic feedback mechanism is a key aspect of the NovaSure GEA technology and differentiates it from other global ablation technologies. With the NovaSure™ GEA, the ablation process is based, not on temperature and time, but on specific, well-analyzed physical characteristics (electrical conductivity) of tissues that are continuously changing during the ablation process. This approach allows for an effective ablation independently of the endometrial layer thickness. Treatment time, basically, equates to the length of time that is necessary to vaporize an endometrial layer of a certain thickness. The ablation procedure usually is longer in patents with thick endometrium (100-120 seconds) and is shorter in patients with thin endometrium (30-100 seconds). This unique approach allows for a well-controlled, tailored, consistent and rapid ablation process.

An important component, unique to the NovaSure™ GEA, is a vacuum pump, contained within the RF Controller. This pump provides continuous suction during the procedure, thus allowing for the removal of steam, blood and other by-products of ablation from the cavity. As opposed to balloon ablation technologies, in which pressure distends the uterine cavity, the NovaSure™ GEA system's use of constant vacuum assures intimate contact between the ablation electrode and the endometrium.

Another valuable aspect of the NovaSure™ GEA system is its portability and lightweight, allowing the system to be easily stored in an office cabinet.

Safety Features

A Cavity Integrity Assessment System (Perforation Detection System) is another integral part of the NovaSure GEA System. This auto-

matic safety feature assists the physician in the timely detection of a uterine perforation, and prevents energy delivery in such cases. The Cavity Integrity Assessment System utilizes the same technology employed by conventional hysteroflators, in which there is an inverse relationship between flow rate and pressure. CO_2 is delivered into the uterine cavity at a safe flow rate (max 100 cc/min) and pressure (max 100 mm Hg). The goal is to generate and maintain an intrauterine pressure of 50 mm Hg for a period of 4 seconds. The pressure of 50 mm Hg was chosen in order to avoid false positive results due to leakage of CO_2 through the Fallopian tubes (cracking pressure of the Fallopian tube is 75-80 mm Hg). Once the controller determines that this pressure is maintained, thus confirming uterine wall integrity, it signals the generator to proceed with the ablation process.

Another very helpful safety feature of the NovaSure GEA is the Device Position Feedback System. This system was designed and implemented in order to allow the physician to track and control the process of opening of the device electrode in the uterine cavity. It will also prevent RF energy delivery in the event of inadvertent placement of the device into a false passage.

The list of features that make the physician's life easier and the procedure safe is quite extensive, but how does it translate into ease of performing the procedure itself? Based on extensive clinical data (~1000 patients treated worldwide) it was found out that the procedure is very easy to perform, does not require special skills and has a very short (1-2 clinical cases) learning curve. Only knowledge and experience with intrauterine manipulations (i.e. D&C, IUD insertion) is required.

Steps of the Novasure GEA Procedure

The NovaSure GEA Procedure is performed as follows:

Following a pelvic examination, a vaginal speculum is inserted. The cervix is grasped with the tenaculum. The cavity is sounded and the uterine sound measurement is recorded. The length of the cervix is assessed during cervical dilation to 7.5-8 mm by measuring the distance between the internal and external cervical os. In most of the patients, cervical dilation is associated with a resistance during the passage of the distal tip of the Hegar dilator through the internal cervical os. As soon as this resistance is felt, advancement of the dilator should be stopped and a finger should be placed at the point of contact between the external cervical os and Hegar dilator. Hegar dilator is then withdrawn and the length from its tip to the noted location on the shaft of the dilator is measured. The cavity length (sound measurement minus length of the cervix) is entered into the RF Controller (Picture 2). The NovaSure GEA

Picture 2 - Uterine cavity size measurements are key-entered into the RF Controller

device is inserted, deployed and properly seated in the uterine cavity. The cornu-to-cornu measurement is determined by the Intrauterine Measurement Device (IMD) (Picture 3.) and key-entered into the RF Controller to allow a precise automatic calculation of the power setting required

Picture 3 - Measurement of the uterine cavity width.

for an optimal treatment of the cavity of this size. The RF Controller is activated by pressing the foot switch and perforation detection cycle is followed by the ablation cycle. At the end of the ablation cycle the RF Controller automatically terminates energy delivery and the device is closed and withdrawn from the uterine cavity. The tenaculum and vaginal speculum are removed to conclude the procedure.

Conclusions

1. The NovaSure GEA system employs a unique customized approach to achieve the optimal ablation depth and profile. It provides consistent results in patients with uterine cavities of different sizes.
2. Endometrial pre-treatment is not required when using NovaSure GEA system.
3. Active bleeding at the time of the operative visit was not found to be a limiting factor when using the NovaSure GEA system.
4. The performance of the procedure does not require special training and is not associated with a long learning curve.
5. The treatment time averages 90 seconds.
6. Based on clinical data the NovaSure GEA procedure can be easily performed in an office setting under local anesthesia (PCB) with or without IV sedation.
7. The long list of safety features employed allows this system to be considered safe.
8. The high success and patient satisfaction rate associated with this procedure qualifies the NovaSure GEA procedure to be considered a procedure of choice for patients suffering from menorrhagia due to benign causes for whom childbearing is complete.

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