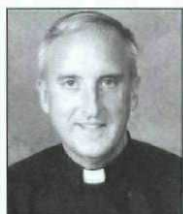


IS THE NOVASURE SYSTEM ETHICAL?

Some Have Questioned the Treatment's Use in Catholic Facilities

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Mercy Health System, Conshohocken, PA, has had inquiries concerning whether a new procedure, the NovaSure Impedance Controlled Endometrial Ablation System, can be used in a Catholic health care setting. The procedure is intended for the treatment of excessive menstrual bleeding—called menorrhagia—which sometimes occurs in premenopausal women who have completed childbearing. It is estimated that one in five women experience excessive menstrual bleeding that can result in fatigue, anemia, embarrassing accidents, and restricted activity.¹

NovaSure is the newest endometrial ablation treatment option available to such women. Following preclinical and clinical studies, the U.S. Food and Drug Administration (FDA), on September 28, 2001, declared the procedure to be safe and effective.

However, some people say that NovaSure is a form of direct sterilization. Others wonder whether it should be performed in a Catholic medical facility, since the women who undergo it are warned that future pregnancies should be avoided. Pregnancies following endometrial ablation can be dangerous to both the mother and the fetus. Accordingly, women who choose NovaSure are urged to use some form of birth control afterward.

It therefore seems appropriate to conduct a complete ethical evaluation of the procedure to determine whether it can be utilized in a Catholic health care facility. In this article, I will give a medical evaluation of the procedure and then ethically analyze it in light of the *Ethical and Religious Directives for Catholic Health Care Services*.

MEDICAL EVALUATION

CAUSES AND TREATMENTS

The word menorrhagia comes from the Greek roots *men* (meaning "month") and *rhagnyai* (meaning "to burst forth"). It is a medical term that refers to menstrual bleeding that is excessive or prolonged, or both. (The condition is also known as hypermenorrhoea.)

The menstrual cycle is not the same for every woman. Normal menstrual flow occurs about every 28 days, lasts four to five days, and produces a total blood loss of from 60 to 250 milliliters (four tablespoons to about one cup). A woman's period may be regular or irregular, light or heavy, painful or pain-free, and long or short, and still be considered normal. Statistically, although about a third of premenopausal women complain of heavy menstrual bleeding, only one in 10 experiences blood loss severe enough to be defined as menorrhagia.²

The signs and symptoms of menorrhagia include menstrual periods that last longer than seven days, menstrual flow that includes large blood clots, heavy menstrual flow that interferes with one's regular lifestyle, constant pain in the lower abdomen during the menstrual period, irregular menstrual periods, tiredness, fatigue or shortness of breath (symptoms of anemia), and a menstrual flow that soaks through one or more sanitary pads or tampons every hour for several consecutive hours.³

In some cases, the causes of heavy menstrual bleeding are unknown, but there are several conditions that may cause menorrhagia. About 80 percent result from one of two causes.

Hormonal Imbalance In a normal menstrual cycle, a balance between the hormones estrogen and progesterone regulates the buildup of the lining of

the uterus (endometrium), which a woman sheds during menstruation. If a hormonal imbalance occurs, the endometrium develops in excess and eventually sheds by way of heavy menstrual bleeding. Hormonal imbalance occurs most often in adolescent girls experiencing their menstrual periods for the first time or in women approaching menopause. Menorrhagia caused by certain conditions involving hormonal imbalance (such as thyroid disease) often can be controlled with hormone medications. However, improper use of hormone medications can itself be a direct cause of menorrhagia.

Uterine Fibroids These noncancerous (benign) tumors of the uterus appear during childbearing years. Uterine fibroids may cause heavier than normal or prolonged menstrual bleeding.⁴

Other causes of menorrhagia are polyps; ovarian cysts; dysfunction of the ovaries; adenomyosis (a condition that occurs when glands from the endometrium become embedded in the uterine muscle, often causing heavy bleeding and pain); intrauterine device (IUD) use; pregnancy complications; certain medications (including anticoagulants and anti-inflammatory drugs); and such medical conditions as pelvic inflammatory disease, thyroid problems, endometriosis, lupus, kidney disease, some uncommon blood disorders, and certain cancers; and chemotherapy.⁵

To diagnose menorrhagia, physicians take a complete medical history of the woman's menstrual cycle, perform a physical examination, and recommend one or more of the following tests: blood tests, Pap test, endometrial biopsy, ultrasound scan, sonohysterogram (an ultrasound done after fluid is injected through a tube into the uterus by way of the vagina and cervix), hysteroscopy, dilation and curettage (D & C), and a hysterosalpingography (in which, after a dye is injected into the uterus and fallopian tubes through the cervix, X-rays are taken to determine the shape and size of those organs). Excessive and prolonged menstrual bleeding can lead to other medical conditions, including iron deficiency anemia, severe pain, infertility, and toxic shock syndrome.⁶

OTHER TREATMENTS

It is estimated that as many as 7 million premenopausal women between the ages of 35 and 55 suffer from menorrhagia and that 2.5 million women seek treatment for this condition every year.⁷ A number of practices and procedures are

currently available to them.

Drug Therapy Estrogen-progestogen combinations (such as those found in oral contraceptives) or progestogens (progesterone) alone are frequently employed in the treatment of menorrhagia.

Other classes of drugs include androgens, such as Danocrine; gonadotropin-releasing hormone agonists; and nonsteroidal anti-inflammatory drugs. Drug therapy is typically the first order of treatment in alleviating excessive menstrual bleeding. Drug therapies usually require long-term treatment. They are successful for about 50 percent of patients; for others they are ineffective and may introduce unpleasant side effects. This treatment does allow the woman to maintain her fertility.

D & C This is typically the first surgical step if drug therapy is unsuccessful. In it, the cervix is dilated and the uterine contents are either scraped away or removed through vacuum aspiration. This may reduce bleeding for a few cycles. If a polyp is present and removed, the bleeding may stop. In most cases, a D & C does not provide the patient with long-term definitive results. It is useful, however, for those women who desire to maintain their fertility.

Hysteroscopic Endometrial Ablation This is a surgical procedure that uses a resectoscope or operating hysteroscope; a video monitor; a fluid distention medium such as glycine or sorbitol; and a surgical ablation device, such as an electrode loop, rollerball, or laser, to destroy the endometrium. The procedure is typically performed under general or epidural anesthesia. The cervix must be dilated to accommodate the hysteroscopic instrument, and the uterus must be properly distended. The most common risks associated with the procedure are hyponatremia from fluid overload, which is a life-threatening condition, and uterine perforation. This treatment is intended for women who no longer desire to maintain their fertility.

Thermal Endometrial Ablation In this surgical procedure, the endometrium is treated with heat for a predetermined period of time. Hot fluid may be injected directly into the uterine cavity or into a balloon-like device in the uterine cavity. The procedure may be performed under general or local anesthesia with intravenous (IV) sedation. Dilation of the cervix of from 5 to 8 millimeters may be required. This treatment is intended for women who no longer desire to maintain their fertility.

Cryosurgical Ablation In this procedure, a surgical

device is used to destroy tissues on the uterus employing extreme cold. A probe is inserted into the uterus under ultrasound guidance for predetermined periods of time, and the tip of the probe is cooled to a temperature ranging from 100 degrees to 120 degrees Celsius. The procedure may be performed under general or local anesthesia with IV sedation. Dilatation of the cervix of from 6 to 7 millimeters may be required. This treatment is intended for women who no longer desire to maintain their fertility.

Hysterectomy Historically, this is the most common and definitive surgical treatment for menorrhagia. It is, however, a major surgical procedure and one performed in the hospital under general anesthesia and associated with the risks and complications of such surgery. Among the risks are possible damage to the urinary tract, bladder, or rectum during surgery (all of which can require further surgical repair), loss of ovarian function, and early onset of menopause.⁸ Depending on the technique, a hysterectomy can require a recovery period as long as six weeks.⁹

NOVASURE

The newest endometrial ablation alternative is NovaSure. To perform it, the physician uses a RF (radio frequency) controller, carbon dioxide canister, desiccant, foot switch, power cord, and what the manufacturer calls a "Disposable Device." "The Disposable Device consists of a . . . bipolar electrode array mounted on a frame that expands into a triangle-like shape when deployed in the uterus."¹⁰ According to a spokesperson at Cytoc Corporation, Marlborough, MA, NovaSure's parent company, the RF controller costs \$16,000 and the

Disposable Device unit costs \$850.¹¹ The NovaSure System treats the entire inside of the uterus at the same time.

This procedure requires neither incisions nor hospitalization. About an hour before the therapy, a doctor may give the patient a medication to minimize cramping during and after it. After giving the patient a local anesthetic in or around her cervix, the surgeon places the Disposable Device—a sheath containing an electrode—through the

cervix. The sheath is pulled back, allowing the electrode (a wand-like device) to expand and conform to the shape of the uterine cavity. The uterus is inflated with a small amount of carbon dioxide to ensure proper placement of the device. During the ablation process, the device is activated and RF energy desiccates and coagulates the endometrium and the underlying, superficial myometrium. As tissue destruction progresses, electrical impedance of the tissue increases.

The device automatically turns off when impedance at the tissue-electrode interface reaches 50 ohms or the total treatment has lasted two minutes, whichever comes first. Usually it takes 90 seconds. The electrode is formed from stretchable, porous, silver- and gold-plated fabric or nylon and spandex. Suction drawn through the disposable device during ablation serves to maintain good contact between tissue and the electrode, and to remove liquids, steam, and other gases generated during treatment. After ablation is complete, the electrode safely retracts into the sheath for easy removal. As the name implies, the Disposable Device is then discarded. Most women are able to go home within an hour of the procedure's completion. One advantage of NovaSure is that it requires neither concomitant hysteroscopic visualization nor endometrial pretreatment.¹²

Contraindications exist for patients who:

- Are pregnant or want to become pregnant in the future. Pregnancies following ablation are possible but, because the uterine tissue has been compromised, can be dangerous for both the mother and unborn child.
- Have known or suspected endometrial carcinoma (uterine cancer) or premalignant change of the endometrium, such as unresolved adenomatous hyperplasia.
- Have any anatomic or pathologic condition, such as history of previous classical caesarian or transmural myomectomy, that could weaken the myometrium.
- Have an active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis) at the time of the procedure.
- Have IUDs in place.
- Have a uterine cavity length less than 4 centimeters, the minimum length of the electrode array. Treatment of the uterine cavity with a length less than that could result in thermal injury to the endocervical canal.
- Have active pelvic inflammatory disease.¹³

The NovaSure procedure requires neither incisions nor hospitalization.

The primary advantage of NovaSure is that it has been shown, in approximately 78 percent of the women in a randomized clinical study, to reduce menstrual bleeding to normal or below-normal levels a year after treatment.¹⁴ In approximately 36 percent of women in the study, menstrual bleeding was totally eliminated. The FDA has also certified that both preclinical and clinical data provide reasonable assurance that NovaSure is safe.¹⁵ Moreover, many women have experienced a significant reduction in painful menstruation, as well as a meaningful reduction in premenstrual syndrome (PMS) symptoms.

However, NovaSure is not without its risks. Possible surgical risks include perforation of the uterus, bleeding, infection, injury to organs within the abdomen and pelvis, and accumulation of blood within the uterus caused by scarring. The procedure may also be hazardous for women with cardiac pacemakers or other active implants. Another rare, but important, risk of any endometrial ablation procedure is that it may reduce a physician's ability to make an early diagnosis of cancer of the endometrium. That is because bleeding is one of the warning signs of endometrial cancer, and endometrial ablation procedures are of course designed to reduce or eliminate bleeding.¹⁶

It is clear that the procedure does not directly or indirectly sterilize women. Even though a woman's chances of pregnancy are reduced after it, pregnancy is still possible. Because pregnancy after ablation can be very dangerous, it is recommended that women who have had the procedure use birth control afterward.

ETHICAL ANALYSIS

POST-FDA APPROVAL RESULTS

Having approved NovaSure as both safe and effective, the FDA nevertheless asked that post-approval studies be done to follow all subjects of the original clinical study for three years after treatment, in the interest of assessing long-term safety and effectiveness.

The results thus far have been positive. Three post-approval, long-term studies, reported at the 52nd Annual Clinical Meeting of the American College of Obstetricians and Gynecologists in May 2004, describe a range of benefits that include improved patient outcomes, improved patient satisfaction rates, and reduced operating room time and recovery time.¹⁷ One study indicated that patients treated with NovaSure experi-

ence significantly less intraoperative and postoperative pain than patients treated with another system, called ThermoChoice UBT.¹⁸ A second study compared four of the commercially available endometrial devices; the results suggested that, of the devices, NovaSure yields the highest rates of clinical success and patient satisfaction.¹⁹

However, NovaSure is only one option among many that women with menorrhagia can use. As noted, women who have had the procedure may conceive afterward. Physicians therefore recommend that such women use birth control to avoid future pregnancies. I will argue that under three ethical principles—respect for persons, beneficence, and non-maleficence—the procedure is ethical and can be performed in Catholic hospitals.

RESPECT FOR PERSONS

This principle concerns a person's right to exercise self-determination and to be treated with dignity and respect. One of the fundamental elements of a physician-patient relationship is the right of a patient to receive information from physicians and to discuss with them the benefits, risks, and costs of appropriate treatment alternatives. This element includes a physician's obligation to inform patients of all current medical options available to them for a particular condition.

NovaSure is one option open to women who are experiencing menorrhagia. Because of the risks and benefits associated with the other options, the first option should always be drug therapy, using estrogen-progestogen combinations or progestogens alone. This is the safest therapy, and one that also allows a woman to maintain her fertility. However, should the drug-therapy option be unsuccessful, the D & C would be the next step. A D & C does not provide the patient with long-term definitive results; but, in combination with drug therapy, it allows women to maintain their fertility. Of the ablation methods, NovaSure appears to be the safest and most effective. It is also less risky and invasive than a hysterectomy—which should be the last option.

Birth control is an issue with NovaSure. Directive 52 of the *Ethical and Religious Directives for Catholic Health Care Services* states clearly that "Catholic health institutions

Birth control is an issue with the use of NovaSure.

Beneficence includes *non-maleficence*, which prohibits the infliction of harm.

may not promote or condone contraceptive practices but should provide, for married couples and the medical staff who counsel them, instruction both about the Church's teaching on responsible parenthood and in methods of natural family planning."²⁰

The NovaSure procedure is for women who have excessive uterine bleeding that can cause serious health problems. Many such women are celibate; birth control would not be an issue for them. Married women should be instructed about both the dangers of becoming pregnant after having had NovaSure and on the proper use of natural family planning (NFP). In good conscience, however, the physician should explain to the women that there are available to them other methods of birth control that may also reduce their chances of becoming pregnant. Patients have a right to be informed about the advantages and disadvantages

of any treatment, as well as about all viable alternatives. Unless patients are told about the other birth control options available to them, they cannot give informed consent.

Giving each person this information does not violate Directive 52 because the physician can clearly state that the Catholic Church approves only of NFP and that, if used correctly and consistently, it can help the woman avoid possible pregnancies in the future. A failure to give the woman all the options available to protect her health and that of her unborn child, should she become pregnant, would violate the basic dignity and respect that all people deserve.

BENEFICENCE

This principle involves the obligation to prevent and remove harm to a person, and to promote his or her good, by minimizing possible harms and maximizing possible benefits. Beneficence includes *nonmaleficence*, which prohibits the infliction of harm, injury, or death on others. In medical ethics, this principle has been closely associated with the maxim *Primum non nocere*: "Above all, do no harm."

We have seen that NovaSure appears to be both the most effective and the safest of the new

generation of endometrial ablation devices. As noted, drug therapy should be the first treatment option, but it is effective only about 50 percent of the time and usually must be continued in order to remain effective. The D & C procedure can be a second-tier option if drug therapy is ineffective, but it is only a temporary solution that reduces bleeding for a few cycles.

Conventional endometrial ablation removes the lining of the uterus with an electrosurgical tool or laser and effectively reduces the bleeding in approximately 85 percent of patients. However, the risks include perforation of the uterus, bleeding, infection, and even heart failure due to fluids used to open or distend the uterus.²¹ The new generation of endometrial ablation devices destroy the endometrium by using either heated fluid or freezing temperatures. These options are intended for women who no longer desire to maintain their fertility.²² NovaSure's benefits clearly outweigh those of the alternative options; the procedure is safer, more effective, less invasive, and does not destroy the endometrium and thereby cause the woman to become sterilized. In addition, women undergoing one of the other endometrial ablation procedures often need, for a month or two, to take a pretreatment drug such as Lupron to thin the lining of the uterus. No pretreatment drugs are needed with NovaSure.²³

The only other treatment alternative is a hysterectomy. As noted, a hysterectomy is a major surgical procedure performed in the hospital under general anesthesia and is associated with the risks and complications of major surgery, whereas NovaSure is minimally invasive, can be done on an outpatient basis, and is more beneficial than a hysterectomy.

Certain post-procedure complications can be associated with NovaSure, including possible fever, nausea, vomiting, shortness of breath, dizziness, bowel or bladder problems, and vaginal discharge. However, clinical studies have shown these complications to be minimal. Most women can return to normal activities within a day or two of their treatment. Sexual activity can be resumed after the patient's first checkup, usually a week to 10 days after the procedure. Possible surgical risks are perforation of the uterus, bleeding, infection, injury to organs within the abdomen and pelvis, and the accumulation of blood within the uterus due to scarring. Another important risk, as noted above, is the possibility that NovaSure will reduce

a physician's ability to diagnose cancer of the endometrium.²⁴

SAFE AND ETHICAL

The NovaSure ablation procedure is not only an effective and safe modality in the treatment of patients suffering from excessive menstrual bleeding; it also has a very low complication rate and does not require endometrial pretreatment. NovaSure treatment can be accomplished in 90 seconds under IV sedation and paracervical block anesthesia in an office setting. The procedure's medical benefits and cost-effectiveness make it a very viable option to a hysterectomy, which, under most circumstances, is the last option for a woman with menorrhagia.

It is true that women who undergo NovaSure should avoid future pregnancies, in the interest of their own health and that of the unborn child. However, pregnancy is often not an issue, particularly for celibate women. For a sexually active woman, the physician should explain the option of NFP, along with other options, to satisfy the ethical principle of informed consent. This should satisfy the birth control issue, thereby reassuring people concerned about allowing the procedure in a Catholic health care facility. Under the circumstances, it appears that the NovaSure system is not only ethical; it should be utilized in Catholic facilities for the good of women suffering from menorrhagia. ■

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