Comparison of Hysteroscopic Sterilization Methods: Essure Permanent Birth Control System and Adiana® Permanent Contraception

A Case Review: David B. Schwartz, MD FACOG

Funding to support the preparation of this supplement was provided by Hologic, Inc.

INTRODUCTION

In the U.S., female sterilization is the most common form of contraception for women aged 35 to 44 years, and the second most common choice for women aged 15 to 44[i] years. Each year, nearly 700,000 women undergo sterilization procedures.[ii]

Methods of female sterilization have changed significantly over time. With the advent of hysteroscopic sterilization, permanent female sterilization is a much less invasive procedure. This paper examines the first two devices approved for hysteroscopic sterilization – Essure® Permanent Birth Control System and Adiana® Permanent Contraception – and compares patient comfort, ease of use and efficacy based on the clinical experience of David B. Schwartz, MD, FACOG, an OB/GYN practicing in Cincinnati, Ohio.

EVOLUTION OF FEMALE STERILIZATION

Female sterilization began in the late 19th century with the use of open laparotomy to achieve tubal ligation. In the 1930s, laparoscopic tubal ligation was introduced and quickly became the standard of care, eliminating the need for hospitalization and decreasing recovery time. Although less invasive than open laparotomy, laparoscopic sterilization has its own disadvantages. Serious complications requiring unintended major surgery occur in .9 per 100 patients and include significant risks such as death, burning and/or perforation of the bowel, bladder or uterus.[iii]

In 2002, hysteroscopic sterilization was introduced following FDA approval of the Essure® Permanent Birth Control System (Conceptus Inc., Mountain View, CA) to reduce the potential for complications and increase convenience for patients. No instruments are inserted into the abdominal cavity and no incisions are required, allowing for less discomfort and a shorter recovery time. The rate of complications with hysteroscopic sterilization procedures is low, and risks are minor. With the ability to perform the procedure in the absence of general anesthesia, hysteroscopic sterilization can be performed in the convenience of the physician's office, reducing costs for patients, physicians and the healthcare system.

HYSTEROSCOPIC STERILIZATION METHODS

Essure was the first device available for hysteroscopic sterilization, and it involves the surgical implantation of a nickel titanium and polyethylene terephthalate (PET) micro-insert into the fallopian tubes. After implantation, the micro-insert expands and the PET fibers elicit a chronic inflammatory and fibrotic tissue in-growth response that permanently occludes the fallopian tubes.

In 2009, the FDA approved a new form of hysteroscopic sterilization known as Adiana Permanent Contraception (Hologic, Inc., Marlborough, MA). The Adiana procedure utilizes the delivery of radiofrequency (RF) energy to the intramural segment of the fallopian tube to promote tissue ingrowth into a silicone matrix to provide tubal occlusion.

Due to its many advantages over laparoscopic tubal ligation, hysteroscopic sterilization rapidly gained popularity following the approval of Essure in 2002. However, physician experience demonstrated that despite being a significant advance in female sterilization options, the Essure procedure had several drawbacks. In particular, concerns were raised about uterine perforation and the impact on future gynecological procedures, which led to the development and subsequent adoption of an alternative hysteroscopic sterilization method.

David Schwartz, MD, FACOG, was an early adopter of both the Essure and Adiana procedures for hysteroscopic sterilization. In 2005, he began offering Essure to patients seeking a permanent contraception method. Although it was effective, Dr. Schwartz observed several shortcomings associated with the Essure procedure. As a result, he began offering Adiana Permanent Contraception immediately upon its approval in 2009.

PATIENT COMFORT & TOLERANCE

Both the Essure and Adiana procedures require the deployment of an insert into the tubal ostia and the stimulation of tissue ingrowth to achieve tubal occlusion. The Essure micro-insert is 3.85 cm in length and placed approximately 3-3.5 cm into the fallopian tube with a portion of the insert remaining in the endometrial cavity (3-8 coils or 5-10 mm) and a portion of the insert remaining in the isthmic portion of the fallopian tube. By comparison, the Adiana silicone matrix is 3.5 mm in length and is placed entirely in the intramural segment of the fallopian tube – no portion of the matrix remains in the endometrial cavity or extends into the isthmic portion of the fallopian tube.

While clinical studies report that both procedures are well-tolerated by patients, a number of patients in Dr. Schwartz's practice experienced pelvic discomfort and/or spotting subsequent to the Essure procedure. Several patients went on to have hysterectomies to resolve the continual discomfort and bleeding. Dr. Schwartz attributes these side effects to the large size and positioning of the Essure insert, as well as the chronic inflammatory nature of the body's response to the coil. The portion of the insert that remains in the uterus can irritate the endometrial cavity, which can cause discomfort and bleeding. The insert also extends farther into the fallopian tube and requires entry as far as 3.5 cm to cannulate the tube, which can lead to tubal spasm and cramping. In contrast, the 3.5 mm Adiana matrix requires cannulation less than 1.4 cm. Dr. Schwartz has observed no adverse reactions in patients who underwent the Adiana procedure.

The Adiana matrix is a biocompatible implant composed of fully cured silicone. Unlike Essure, which contains nitinol, the Adiana matrix contains no nickel, making it an option for women with a known or potential nickel allergy. It is estimated that 10 to 30% of women are at risk for having a nickel allergy.[iii, iv, v]

Disclosure: Dr. David B Schwartz, MD FACOG is a consultant and spokesperson for Hologic, Inc. Industry and editorial support for this paper was provided by Hologic, Inc., Marlborough, MA with additional support provided by Jaclyn Landon & Associates.

ADVERSE EVENTS PREVENTING RELIANCE – ESSURE VS. ADIANA (BASED ON PIVOTAL TRIALS)

Event	Essure	Adiana
Expulsion	2.9	0
Perforation	1.1	0
Other unsatisfactory location	.6	0
Total	4.6	0

ESSURE AND ADIANA COMPARISON – DR. SCHWARTZ'S PRACTICE EXPERIENCE

#	Measurement	Essure	Adiana
1.	# Procedures	150	200
2.	% Occluded	94	93**
3.	# of Pregnancies	4	1
4.	# of Complications*	11	0

*Defined as perforations, expulsions, requests for removal.
**Based on those patients who have already returned for HSG.

EASE OF USE

Overall, the Essure and Adiana procedures are similar and the length of time required is roughly equivalent. However, Dr. Schwartz observed key differences between the Essure delivery catheter tip, which is made of metal, and the Adiana delivery catheter that reduces the risk of perforation during placement. Specifically, the Adiana catheter tip, which houses the silicone matrix prior to deployment, is soft and pliable, allowing it to flex with the contours of the patient's anatomy. In addition, the catheter tip is designed to bend when it meets resistance, which limits the amount of force that can be exerted on the tissue, thus preventing perforations. The catheter also utilizes smart technology – known as the position detection array (PDA) – that provides real-time monitoring of tip position to facilitate accurate placement of the matrix into the fallopian tube, which also reduces the risk of perforation.

EFFICACY

Based on available clinical data, efficacy rates for the Essure and Adiana procedures are comparable. The Adiana clinical trial, Evaluation of the Adiana System for Transcervical Sterilization (EASE), demonstrated safety and efficacy in 645 women aged 18 to 45, with a three-year pregnancy prevention rate of 98.4%.[v] In commercial use, the one-year pregnancy prevention rate of Adiana permanent contraception was estimated at 99.43%. Based on clinical trials of approximately 500 women, Essure has been demonstrated to be 99.74% effective at five-years of follow-up.

While Dr. Schwartz has experienced similar success in terms of bilateral occlusion rates with the Essure and Adiana procedures, the rate of pregnancy prevention in Dr. Schwartz's practice differs from current clinical data. Out of 150 patients who underwent hysteroscopic sterilization with Essure, four became pregnant – a pregnancy prevention rate of 97.3%. In comparison, Dr. Schwartz observed one pregnancy out of 200 patients who underwent Adiana hysteroscopic sterilization for a pregnancy prevention rate of 99.5%.

COMPATIBILITY WITH SUBSEQUENT INTRAUTERINE PROCEDURES

Dr. Schwartz also sought Adiana permanent contraception as an alternative to Essure for its compatibility with subsequent diagnostic and therapeutic intrauterine procedures. Given that a portion of the micro-insert remains in the uterine cavity, the presence of Essure limited Dr. Schwartz's ability to successfully perform subsequent gynecological procedures, such as endometrial ablations, hysterectomies and polypectomies. For instance, performing hysterectomies on several patients who had previously undergone the Essure procedure caused Dr. Schwartz to cut through the metal coil with a harmonic scalpel, which led to the fragmentation of the coil and shorting out of the energy source utilized for the procedure.

Based on clinical evidence and Dr. Schwartz's experience, the fact that the Adiana matrix is contained entirely within the intramural portion of the fallopian tube means that its presence does not affect a patient's ability to undergo additional common diagnostic and therapeutic intrauterine procedures, including hysteroscopy, endometrial biopsies, dilation and curettage, endometrial ablation, intrauterine device insertion and in vitro fertilization (IVF). Thus, the Adiana procedure may be a more suitable option that enables physicians to provide long-term care for patients who may require subsequent gynecological intervention.

CONCLUSION

For permanent contraception, hysteroscopic sterilization offers similar efficacy with a more favorable safety profile than laparoscopic tubal ligation, including less risk of complications, shorter recovery time, less discomfort and greater convenience. According to Dr. Schwartz, as increasing numbers of physicians develop hysteroscopic skills, transcervical sterilization will become the standard of care.

The availability of Adiana® permanent contraception can help accelerate the adoption of hysteroscopic sterilization, as it has proven to be an effective method of permanent birth control that is safe for patients and easy to integrate into clinical practice. With no hormones, metal or foreign body protruding into the uterine cavity, the Adiana system may be the preferred option for women who may require intrauterine gynecological procedures in the future. By overcoming the disadvantages of earlier forms of hysteroscopic sterilization, the Adiana procedure enables physicians like Dr. Schwartz to offer better care to patients seeking a permanent method of contraception.

COMPARISON OF LAPAROSCOPIC STERILIZATION AND HYSTEROSCOPIC STERILIZATION

Considerations	Laparoscopic Tubal Ligation	Hysteroscopic Sterilization
Effectiveness	99.5%[4]	>98%[5]
Anesthesia	General	None or local
Incisions	1-2	None
Trocar insertion	Yes	None
Typical recovery time (days)	7-14	Less than 1
Pain 4 wks post-procedure[6]	35%	None
Setting	Hospital	Office/Hospital

ADIANA BEST PRACTICES

After two years of clinical use, Dr. Schwartz provides his observations on best practices to ensure successful outcomes with Adiana® Permanent Contraception.

PATIENT PREPARATION AND FOLLOW UP

Atrophic uterine lining will maximize visualization and access to the tubal ostia during matrix placement and increase confidence in the procedure. Adiana labeling recommends timing the procedure so that it occurs during the early proliferative phase of the patient's cycle. In addition, it is helpful to the surgeon that the patient undergoes a full six weeks of progesterone treatment to sufficiently thin the endometrium prior to implantation. If the patient is not currently utilizing a continuous hormonal birth control method, administer Depo-Provera 150 mg six weeks prior to the procedure.

UTILIZING THE PDA AND BLACK MARK

The Adiana catheter provides two means to ensure that the matrix is placed in the proper location within the intramural portion of the fallopian tube. The black positioning mark provides a visual confirmation that the device is properly positioned when it can be seen at the utero-tubal junction (UTJ). When the tip is correctly positioned, the matrix is deployed approximately 1.0 cm into the fallopian tube. The tip also has a gold PDA, which consists of four sensors located in quadrants circling the catheter. When all four sensors detect full tissue contact simultaneously, the RF generator signals that the catheter is correctly positioned within the fallopian tube. The likelihood of occlusion can be maximized by visualizing the black mark at the UTJ and receiving confirmation of full tissue contact via the PDA.

MOTION DURING PROCEDURE

The RF energy delivered to the fallopian tube creates a small superficial lesion, and it is essential that the matrix is deployed where the lesion was formed.

Therefore, it is important that physicians do not move either during the 60-second application of RF energy, or immediately afterward until the matrix is deployed. Avoid turning to look at a monitor or screen, as any slight motion can move the catheter before the matrix is placed. Minimize motion by resting elbows on the waist, and positioning a finger on the button that launches the matrix prior to commencing application of the RF energy.

MINIMAL PRESSURE

To avoid displacement of the matrix, limit the amount of pressure in the endometrial cavity during device placement and the HSG confirmation test. An increase in pressure during placement may artificially enlarge the diameter of the fallopian tube, thus causing the matrix to be placed more distally than recommended. Additionally, increasing the pressure following placement of the first matrix may push the matrix in the contralateral tube beyond the area where the RF energy was delivered. In most cases, it is sufficient to rely on gravity by placing the distention medium at a height of 3-4 feet above the uterus. Do not utilize a pressure cuff or fluid system as excessive pressure is unnecessary. Reduce or turn the outflow off if adequate distention cannot be obtained.

During the HSG confirmation test, do not inject the radiopaque dye with excessive pressure as it can also cause matrix displacement.

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WP-00049-001 Rev. 001