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Review Article

Hysteroscopic Permanent Female Sterilization

Esterilização Permanente Feminina por Histeroscopia

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ABSTRACT

Birth control is a necessity in society. Contraceptive methods facilitate family planning. The oral contraceptive pill (OCP) is the most popular temporary method. Female sterilization is a definitive method of contraception. The surgical approaches for female sterilization include laparotomy and minimally invasive techniques such as laparoscopy for tubal ligation (TL), and tubal occlusion by microdevices (ESSURE and ADIANA), guided by hysteroscopy, whose main advantages are: outpatient placement, no incisions and no anesthesia. ESSURE is composed of stainless steel, nitinol and Dacron. Its mechanism of action is attributed to the production of localized fibrous reaction. It is indicated for women who are secure in certain that they want definitive sterilization. It is especially beneficial to those with comorbidities that place them at increased surgical risk. It is contraindicated in pelvic inflammatory disease, steroid use and abnormal uterine bleeding. Other contraceptive methods should be used during the first three months after insertion of the microdevice, at which time an imaging test, such as hysterosalpingogram, plain radiograph (X-ray) or ultrasound should confirm tubal occlusion. The method achieves 99.8% efficacy. The most common complications are utero-tubal perforation and expulsion of the microdevice. Costs are similar to those of tubal ligation by laparoscopy and the learning curve is small.

Key words: tubal sterilization, Hysteroscopy, Intratubal microdevice, permanent contraception.

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INTRODUCTION

In modern society control of reproduction has become a necessity. Social and demographic issues compel man to seek methods that permit him to plan births. Family planning arose to respond to these issues. In Brazil family planning is regulated by Law No. 9263 enacted January 12, 1996.[1]

Contraception can be achieved by hormonal and non-hormonal methods, and by surgical sterilization. Among the non-hormonal methods the male preservative (condom) is the most used. Hormonal contraception is done with medications that contain sexual steroids (estrogen and progesterone) in the most varied formulations and routes of administration (oral, transdermal, vaginal, etc.), with the oral contraceptive pill (OCP) the most utilized.

In the second half of the last century, an American biologist Gregory Goodwin Pincus, working with an American gynecologist, John Rock, synthesized a compound, composed of estrogen and progesterone, which they called a "contraceptive pill". The Food and Drug Administration (FDA) approved this medication for clinical use in May 1960. Currently, around 80 million women around the world, and 9 million in Brazil, regularly use this medication. The oral contraceptive pill (OCP) was and continues to be, the most popular temporary contraceptive method worldwide.

With regard to efficacy, surgical contraception has a low incidence of failure, similar to the best contraceptive methods (Table 1).

The surgical approach for female sterilization can be by laparotomy (associated or not with a Caesarian section), mini-laparotomy, laparoscopy, mini-laparoscopy, vaginal (by anterior or posterior colpotomy) and, now, by a transcervical route guided by hysteroscopy (HSC).

Table 1 - Percentage of women in whom there was contraceptive failure during the first year of use and the Percentage that continued to use it at the end of the first year.

	Women who Accidently became Pregnant during the First Year of Use (%)		Women Who Continued to Use It at 1 Year (%)
Method	**Typical use**	**Perfect Use**	
No Method	85	85	
Spermicides	29	18	42
Abstinence	25		67
Rhythm method		9	
Ovulation method		3	
Symptothermal/Basal BodyTemperature		2	
Post-ovulation		1	
Coitus interrupted/Withdrawal	27	4	43
Cervical cap			
Women with children	32	26	46
Nulliparous women	16	9	57
Sponge			
Women with children	32	20	46
Nulliparous women	16	9	57
Diaphragm	16	6	57
Preservative (Condom)			
Female (Reality)	21	5	49
Male	15	2	53
Combined Pill and the Progesterone-only pill	8	0.3	68
Adhesive (Evra™)	8	0.3	68
NuvaRing	8	0.3	68
Intrauterine devices			
ParaGard[tm] (Copper T380A)	0.8	0.6	78
Myrena (Levonorgestrel T)	0.1	0.1	81
DepoProvera	3	0.3	70
Lunelle	3	0.05	56
Norplant[a] and Norplant II	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100

Source: Berek and Novak, 2008 (17).

The transvaginal route is considered minimally invasive surgery, is inexpensive, but would have a prolonged learning curve in Brazil where it is not performed frequently.

The approach most used in Brazil for tubal ligation is laparotomy, generally following Caesarian section. Since the 1950s laparoscopy has been gaining popularity as the approach for tubal ligation (TL), due to the fact that it can be used outside the context of pregnancy, and is associated with less pain, less blood loss, a shorter hospitalization, and a lower risk of infection, as well as a faster recuperation. Laparoscopy is an effective and safe technique; nevertheless the women is submitting herself to the risks of anesthesia and surgery, as well as the complications inherent in the procedure.

In the United States, the Center for Disease Control and Prevention (CDC) conducted the largest study of tubal sterilization, the Collaborative Review of Sterilization (CREST) study.[2] Jamieson and cols.

Table 2 - *Cumulative pregnancy rate in 1000 sterilization procedures performed from 1978 to 1987.*

Unipolar coagulation	7.5
Postpartum partial salpingectomy	7.5
Silastic ring (Falope or Yoon)	17.7
Interval partial salpingectomy	20.1
Bipolar coagulation (one point)	24.8
Bipolar coagulation (three points)	3.2
Hulka-Clemens Clip	36.5

analyzed 10,685 laparotomic and laparoscopic sterilizations (Table 2) performed between 1978 and 1987, with a 10 year follow-up. The accumulated failure rate of ligatures in this period was 1.85%. Among a total of 9,475 laparoscopic sterilizations, the complication rate varied between 1.17% and 1.95%. The probability was greater in patients with comorbidities (diabetes, obesity and previous surgeries) aggravated by the complications inherent with anesthesia.

Laparoscopy requires a surgical setting and general anesthesia; the efficacy approaches 99.5%, but there are intra- and post-operative complications, including 11 deaths/100,000 procedures.[3] Although minilaparoscopy using a 5 mm optic can be performed on an outpatient basis with local anesthesia and conscious sedation, both are techniques that invade the abdominal cavity.

Other techniques, such as Natural Orifice Transluminal Endoscopic Surgery (NOTES), seek access to the Fallopian tubes though natural orifices such as the vagina (anterior or posterior colpotomy). There are currently few statistics in the literature.

Hysteroscopy (HSC) is a slightly invasive method that uses the cervical canal to access the uterine cavity and the tubal ostia. The technique of hysteroscopy established itself with the work of Jacques Hamou.(3) Since 1980, there have been significant improvements in the image quality, as well as the creation of an operative canal in diagnostic hysteroscopy, that with its narrow caliber, making it possible to perform major procedures on an outpatient basis.

In the 1990s two permanent female contraception systems were developed, the ESSURE and ADIANA systems [4], that permit outpatient tubal occlusion through a transcervical route, without incisions or the need for anesthesia.

In 2002 the Food and Drug Administration (FDA) approved the first transcervical sterilization method, the ESSURE Permanente Birth Control System (Conceptus Inc., San Carlos, CA). ESSURE is a microdevice consisting of an internal spiral made of stainless steel, covered by Dacron fibers and an external dynamic spiral composed of a nickel-titanium alloy called nitinol. It is 4 cm in length and 0.8 mm in diameter, reaching 1 to 2 mm when expanded.

In 2009 the FDA approved a second transcervical sterilization method, the ADIANA Permanent Contraception System (Hologic Inc., Bedford, MA). The ADIANA sterilization method (Figure 1) combines radiofrequency-controlled cauterization, for a period of one minute, which causes a 5 mm lesion in the tubal mucosa, followed

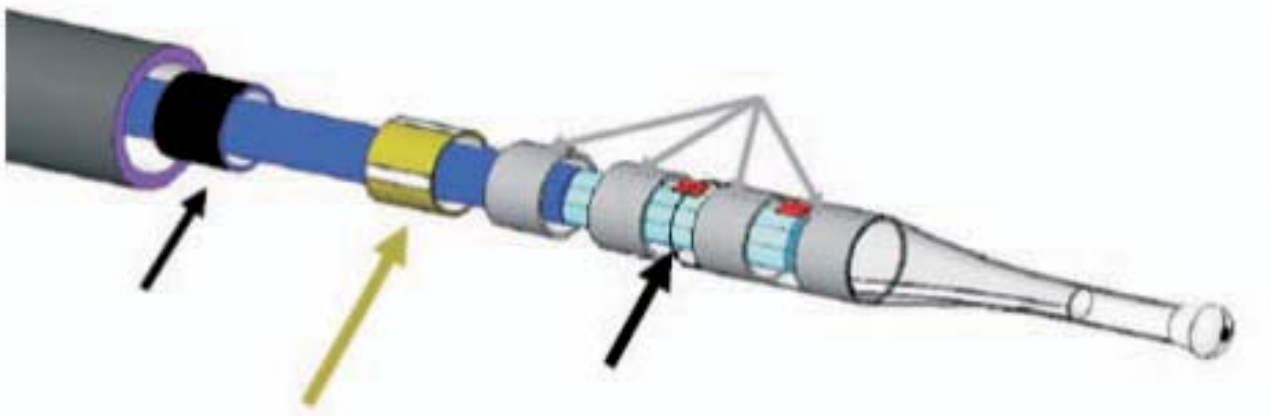

Figure 1 - *Adiana Permanent Contraception System*
Source: Reviews in Obstetrics Gynecology, 2009.

immediately by the introduction of a 3.5 mm silicone matrix that is implanted in the interior of the Fallopian tube, using a catheter inserted in the tubal ostium via hysteroscopy. Occlusion is achieved by the growth of fibroblasts around the matrix, which serves as a permanent substrate for occlusion of the tubal lumen. The occluded tube should be evaluated three months after the placement of the device by hysterosalpingogram (HSG). Such imaging actually only demonstrates where the contrast "stops", as the ADIANA itself cannot be visualized with X-rays. It can, however, be visualized with ultrasound.

The one-year and two-year accumulated failure rate for the ADIANA system is 1.08% and 1.82% respectively. In the CREST study, the failure of ADIANA was higher than all the permanent methods evaluated in the study except for the use of spring clips.[5]

Recently, the National Agency for Sanitary Surveillance (ANVISA) authorized use of the ESSURE system in Brazil. The national health care system – *Sistema Única de Saúde* (SUS) – is carrying out viability studies of intratubal microdevices for permanent sterilization. In Santa Catarina, the state legislature (Assembléia Legislativa) passed and the governor signed Law 14,870 that in its first article states: surgical procedures called tubal ligation, vasectomy, and transcervical sterilization performed in the public hospital network that are covered by SUS are free to the citizens who are residents of state of Santa Catarina.

Various publications have reported success rates for the outpatient placement of ESSURE ranging from 85% to 99.8%.[5] In the context of advances in permanent female contraception, the objective of this article is to review the literature about ESSURE. At the present time ADIANA is not available in the Brazilian market.

ESSURE'S COMPOSITION AND MECHANISM OF ACTION

The ESSURE system consists of a handle, a catheter driver, the microdevice and a "dry flow" introducer (Figure 2). The handle has a rotating control dial and a trigger button (Figure 3). The catheter houses the microdevice, which has a non-traumatic spherical tip (Figure 4). The dry-flow introducer has an anti-reflux valve which maintains the intrauterine pressure and protects the distal part of the device.

The mechanism of action is through stimulation of tissue proliferation of fibroblasts, macrophages, foreign body giant cells and plasma cells, induced by the Dacron fibers.

Table 3 - *Indications and Contra-Indications.*

ESSURE can be a true alternative for
A woman who wants definitive sterilization and complies with the family planning criteria - older than 25 years or has two children – as defined by Law No. 9263;
A woman that has experienced adverse effects with other contraceptive methods;
Healthy patient with the possibility of obstetrical problems in a future pregnancy;
Patients with comorbidities (hypertension, diabetes, heart disease, obesity, Down Syndrome, etc.) and;
A woman who does not want to subject herself to the risks of anesthesia and surgery, with their possible complications.
Patients who cannot use this method
Women who do not meet the prerequisites of Law No. 9263;Uncertainty about definitive sterilization;
Suspicion of pregnancy;
Is within six weeks of a delivery or abortion;
Recent or current acute pelvic infection;
Untreated acute cervicitis;
Metrorrhagia of unknown etiology;
Suspected or known gynecologic neoplasia;
Abnormal uterine cavity or Fallopian tubes and;
Patients using corticosteroids.

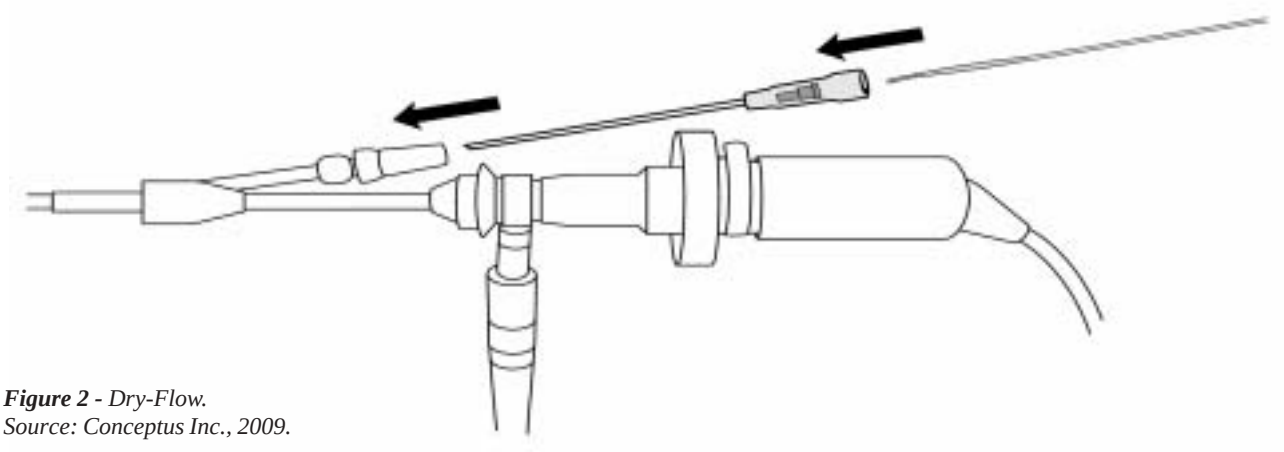

Figure 2 - *Dry-Flow.*
Source: Conceptus Inc., 2009.

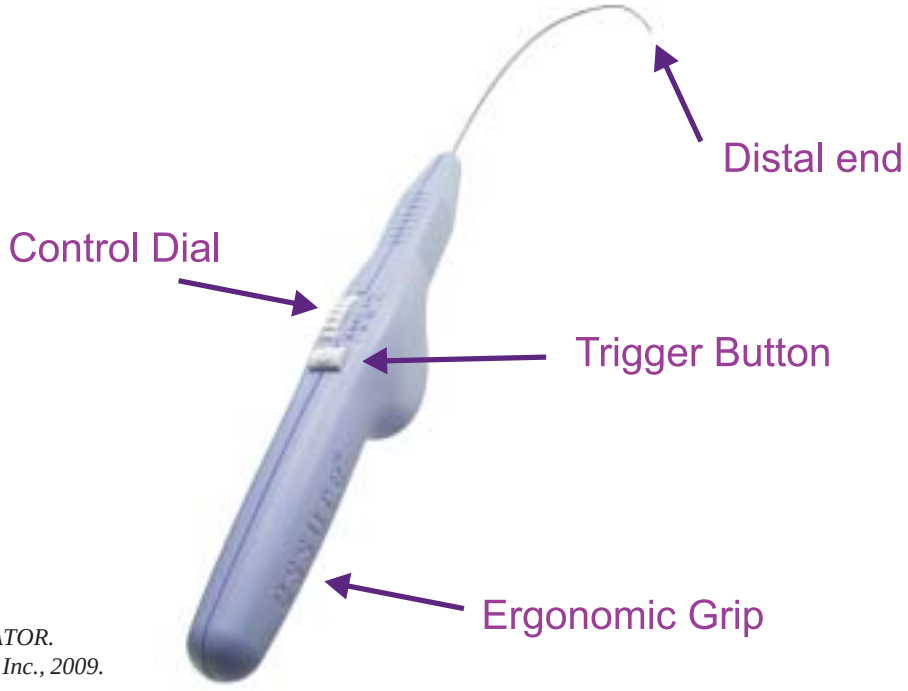

Figure 3 - *APLICATOR.*
Source: Conceptus Inc., 2009.

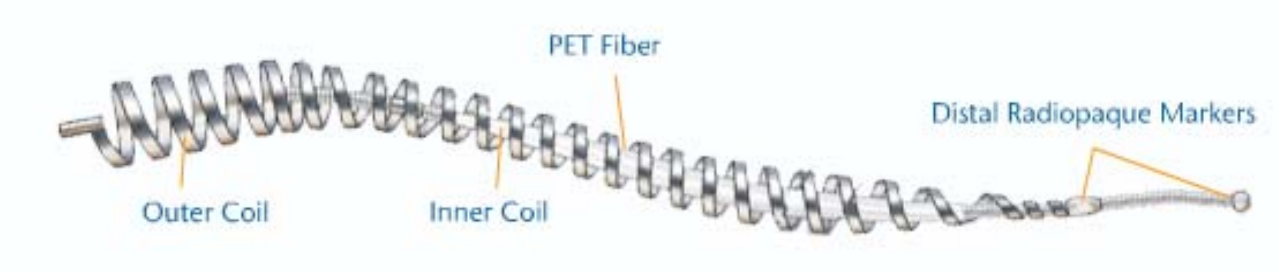

Figure 4 - *MICRODEVICE.*
Source: Conceptus Inc., 2009.

INDICATION AND CONTRA-INDICATIONS FOR THE PROCEDURE ARE STED IN TABLE 3

The placement of ESSURE should be performed during the first phase of the menstrual cycle, due to the more certain identification of the tubal ostia and the lower risk of inserting a device in a pregnant patient.

The prior use of an OCP permits the placement during any day of the cycle.

The use of a non-steroidal anti-inflammatory drug (NSAID) one hour before the procedure – administered orally or rectally – diminished uterine contractions and pain. Similarly the use of benzodiazepines (for example: 10mg diazepam given orally) reduced anxiety.

INSERTION

The advantages of the ESSURE system include the fact that it can be inserted in an outpatient setting, eliminates incisions, and does not require anesthesia. The patient is discharged after placement of the microdevice and can return to their normal work activities the same day.

For ESSURE placement a hysteroscope with an operative canal – such as equipment developed by Bettocchi – is necessary. The equipment has a oval format, with an anteroposterior dimension of 5 mm and a transverse dimension of 3.9 mm. The dry-flow introducer is first placed in the work canal of the hysteroscope; the introducer has an antireflux valve that maintains the intrauterine pressure and at the same time protects the distal part of the microdevice. The ESSURE system is guided to the tubal ostium by the introduction catheter with the proximal segment of the tube catheterized up to the black mark of the catheter. The control dial on the handle is rotated back until it locks, whereupon the outer covering of the catheter retracts displaying the gold marking that should be positioned at the opening of the ostium. At this time the trigger button is fired, and the dial is again rotated until it locks, in order to expand and disconnect the microdevice. At this point, the entire system is removed revealing the spirals in the interior of the uterus. In a good placement, there should be three to eight spirals. Repeat the procedure in the contralateral tube. A recent study demonstrated a successful rate of 99.8% ([4]).

Analyzing 1615 women who had undergone insertion of ESSURE and were premedicated with ibuprofen and oral benzodiazepines, Arjona and cols.[4] reported that 86.5% considered it “excellent” or “very good”; 10.2% felt pain similar to menstruation, and considered their ability to tolerate the placement as “good”; and only 3.1% considered it “average” or “poor,” feeling pain that was stronger than their menstrual pain. Time to return to normal activities was less than a day for 75.8%, one day for 21.3%, and more than one day for 2.9%. The degree of satisfaction with the method varied from 96.0% to 99.9%.

Duffy and cols.[6] , compared ESSURE with laparoscopic sterilization regarding pain and found double the tolerance (“good” to “excellent”) for the process of inserting ESSURE.

EXAMES POST-INSERTION DO ESSURE

It is necessary to use alternative contraceptive methods for at least three months after placement of the microdevice. Various studies in the EUA have demonstrated follow-up rates post-insertion of ESSURE that varied from 13% to 95%, depending on the education level of the patient, the medical counseling, as well as the adherence to these recommendations.[5] For post-insertion monitoring of ESSURE in the United States, the CDC requires that a hysterosalpingogram (HSG) be performed after three months to confirm the effectives of the method (Figure 5). Worldwide studies, however, have shown

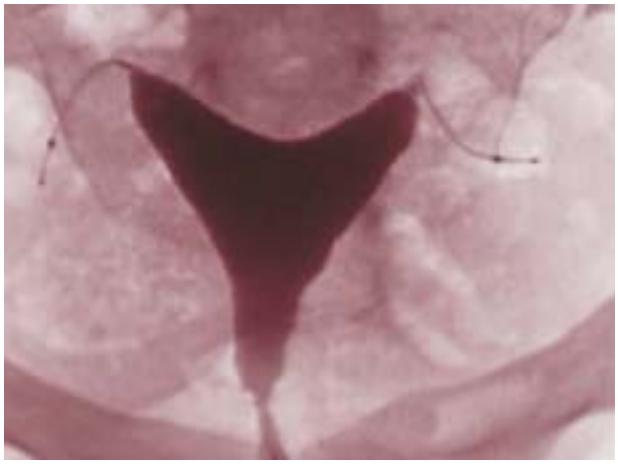

Figure 5 - *Hysterosalpingogram (HSG) after insertion of ESSURE. Source: Conceptus Inc. 2009.*

that the microdevice is well visualized by simple radiographs of the pelvis.[7]

Veersema and cols., analyzing 150 patients, concluded that the hysterosalpingogram typically performed three months after ESSURE placement could be replaced with a transvaginal ultrasound (TVUS), which is better accepted by the patient and is less expensive.[8] Kerin and Levy also validated TVUS, reserving hysterosalpingograms for atypical cases.[9]

In clinical trials, ESSURE achieved tubal occlusion in 96% of cases after three months. When this did not occur, it was recommended that patient wait as additional three months before obtaining another hysterosalpingogram (HSG); at six months tubal occlusion was 99.8%.[10]

Although several studies indicate that localization of the microdevice by transvaginal ultrasound procedure is simple and reliable in most patients, it is not part of the manufacturer's protocol. Given that the patient signs an informed consent document that outlines what should be done post-insertion, it is hard to deviate from that guidance.

RESULTS

The CREST study showed that in terms of effectiveness transcervical tubal occlusion was second only to monopolar cauterization of the Fallopian tubes, but after waiting 12 weeks to perform a hysterosalpingogram (HSG) to confirm the tubal obstruction, its effectiveness rose to 99.8%.[2]

Kerin, analyzing 37 pregnancies reported by the manufacturer that occurred between 1997 and 2004, found that six women (16%) were pregnant before the placement of the device, seven (19%) had hysterosalpingograms that were misinterpreted, and 21 (57%) had not followed the post-insertion protocol.[11] The author concluded that the majority of these pregnancies could have been avoided by placing the device during the first phase of menstrual cycle, continuing to take an OCP for several months, ensuring more accurate hysterosalpingogram results, and by strict observance of the post-insertion protocol. Levy, evaluating 50,000 procedures through December 2005 obtained results quite close to the prior studies, as shown in Table 4.[7]

Although the use of ESSURE precludes the intra-uterine device (IUD) as a temporary form of contraception, the microdevice can be placed in the presence of an IUD. In a series of 28 patients, Connor needed to remove eight IUDs (28.6%) for the proper positioning of ESSURE bilaterally; of the remaining twenty patients, 19 insertions were considered easy and one difficult.[12]

Endometrial ablation is the other procedure that can be associated with ESSURE placement, since fertile women can conceive after ablation (about 1.5%) and, of these, only 13% were absolutely normal pregnancies.[13] Follow-up three months after ESSURE placement with concomitant endometrial ablation was hampered by adhesions. The manufacturer recommends ablation after a period of three months and confirmation of tubal obstruction. Connor recommends concomitant ablation with ESSURE placement, as long as transvaginal ultrasound (TVUS) is used as a control.[14]

COMPLICATIONS

With regard to safety, a pilot study with 745 women enrolled between 1998 and 2001 showed no complications of major consequence, such as intestinal or vascular lesions or death. However, tubal perforation was observed in 2.3% of cases, though none of these evolved into significant complications.[15]

The studies found that there were no cases of pelvic inflammatory disease after placement of the

Table 4 - *Causes of pregnancy reported.*

Reason for the pregnancy	N	% of the Total
Physician or Patient did not follow the protocols	30	47
Plain radiograph of the pelvis or hysterosalpingogram (HSG) poorly interpreted	18	28
Pregnant at the time of placement	8	12.5
Defective Microdevice	1	1.5
Other	7	11
Total	64	

Table 5 - *Causes of pelvic pain after ESSURE placement.*

Device poorly positioned, including the intra-abdominal placements, excluding hysteroscopic perforations.	5
Endometrial ablation with concomitant monopolar or bipolar current, Thermachoice, NovaSure, including infection.	4
Unilateral or bilateral angular perforation.	5
More than one microdevice placed in 1 or 2 Fallopian tubes.	2
Unknown	6

microdevice. A vagal reflex occurred in about 1% of cases. The microdevice migrated into the abdominal cavity in 0.1% of cases and was expelled in 0.7%.[12]

A review by the FDA of the MAUDE (Manufacturer and User Facility Device Experience) database since the introduction of ESSURE in 2002 through 2009 found three reports of uterine perforation, with incorporation of the micro device in abdominal structures which required removal.[16] Connor [12] consulted the MAUDE database for period from 2004 to 2009 and found 22 cases of pelvic pain that required treatment (Table 5). Besides this, for the same period, the author verified five pregnancies after placement of ESSURE, of which four were in the first year after placement. One of the women with an ectopic pregnancy did not use contraception in the three months post-insertion. A second was recognized when her hysterosalpingogram revealed incorrect positioning (too proximal), a third did not have hysterosalpingogram results, and the fourth did not obtain a hysterosalpingogram.

Although it does not constitute a contraindication, the presence of an IUD increases the degree of difficulty of inserting the microdevice ([4]).

COSTS

The outpatient nature of ESSURE placement enables this method of contraception to be offered at an affordable price. Connor showed a reduction of $180 dollars per patient for procedures performed in surgical centers and a reduction of $2075 when laparoscopic sterilization was compared with outpatient ESSURE placement.[12]

FINAL CONSIDERATIONS

The ESSURE microdevice is a method of definitive female contraception that is minimally invasive, safe, and effective. It presents low rates of adverse effects and has a competitive cost-benefit ratio, when compared with other minimally invasive methods.

RESUMO

O controle da natalidade é uma necessidade da sociedade. Os métodos anticoncepcionais facilitam o planejamento familiar. O anticoncepcional oral (ACO) é o método temporário mais utilizado. A esterilização feminina é um método de anticoncepção definitiva. As vias de acesso cirúrgico para esterilização feminina incluem a laparotomia e as técnicas minimamente invasivas, como a laparoscopia (laparoscopy) para a ligadura das tubas (LT) e a oclusão tubária por microdispositivos (ESSURE e ADIANA), guiados por histeroscopia (HSC), cujas principais vantagens são: colocação ambulatorial, ausência de incisões ou de anestesia. O ESSURE é composto de aço inoxidável, dacron e nitinol. Seu mecanismo de ação se dá pela produção de reação fibrosa local, sendo indicado para mulheres que estão seguras quanto à realização de esterilização definitiva, beneficiando sobremaneira as que apresentam comorbidades, com risco cirúrgico elevado. É contra-indicado em doença inflamatória pélvica, uso de corticoesteróides e sangramento uterino anormal. Outros métodos anticonceptivos devem ser utilizados nos três primeiros meses após a inserção do microdispositivo, quando se realiza exames complementares, such as hysterosalpingogram (HSG), plain radiographs (X-ray) or ultrasound (US), the purpose of confirming tubal occlusion. com o objetivo de identificar a oclusão tubária. O method atinge 99,8% de eficácia. As complicações mais comuns são a expulsão do microdevice e a perfuração útero-tubária. Os custos são semelhantes aos da ligadura das tubas por laparoscopy e a curva de aprendizado é pequena.

Palavras-chave: Esterilização tubária, Histeroscopia, Microdispositivo Intratubario, Contracepção permanente.

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