

Essure: a revolution in female definitive contraception

Essure: uma revolução na anticoncepção definitiva feminina

Daniella de Batista Depes¹, Ana Maria Gomes Pereira², Salete Yatabe³, Reginaldo Guedes Coelho Lopes⁴

ABSTRACT

Tubal sterilization is the most widely used procedure in the world for definitive contraception. It is safely performed by laparoscopy, but it is an invasive procedure with potential surgical and anesthetic risks. By hysteroscopy, the Essure micro-insert assures tubal obstruction with no need of hospitalization, incision or anesthesia.

Keywords: Sterilization, tubal/methods; Sterilization, tubal/trends; Hysteroscopy/methods; Hysteroscopy/trends; Ligation; Surgical procedures, minimally invasive/methods; Surgical procedures, minimally invasive/trends

RESUMO

A ligadura tubária é o procedimento definitivo mais utilizado no mundo para controle da fecundidade. A via laparoscópica é segura, porém invasiva e com possíveis riscos cirúrgicos e anestésicos. A via histeroscópica permite a oclusão tubária de forma ambulatorial, através de um microdispositivo (Essure) inserido diretamente nas tubas, sem incisões ou necessidade de anestesia.

Descritores: Esterilização tubária/métodos; Esterilização tubária/tendências; Histeroscopia/métodos; Histeroscopia/tendências; Ligadura; Procedimentos cirúrgicos minimamente invasivos/métodos; Procedimentos cirúrgicos minimamente invasivos/tendências

The ideal method for female definitive contraception has been searched for more than 150 years. Complications from miscarriage, pregnancy and delivery are the most common causes of death among women in reproductive age, therefore, preventing unwanted pregnancy is a fundamental tool to improve woman reproductive health⁽¹⁾.

Many methods have been used for tubal occlusion. The introduction of laparoscopy brought changes in such procedure, which is no longer connected to delivery and, nowadays, represents an elective technique. In experienced hands, it has showed to be efficient and safe, but involves anesthetic and surgical risks, with all their possible complications⁽²⁾.

The CREST study (Collaborative Review of Sterilization), conducted by the Center for Disease Control (CDC), is the largest prospective, multicentric, observational study on tubal sterilization ever carried out in the United States. A total of 10.685 laparotomies and laparoscopies performed between 1978 and 1987 were analyzed in a ten-year follow-up. The accumulated failure rate of tubal ligation during this period was 1.85%⁽³⁾.

Out of 9.475 patients sterilized through laparoscopy, the complication rate ranged from 1.17 to 1.95%. The risk was even higher in patients with diabetes, obesity, previous surgeries, and abdominal or pelvic adhesions. The risk also increased with general anesthesia⁽⁴⁾.

Fatal complications occurred in one to four patients per 100 thousand procedures⁽⁵⁾.

The transcervical approach is an alternative to the transabdominal and, with the development of hysteroscopy, the direct approach of the tubal ostia was attempted.

During the 1990's, Conceptus, Inc. (San Carlos, CA, USA) developed a micro device denominated Essure. The system was initially proposed for the treatment of brain aneurysms and, after ten years of experiences, the first trials were initiated⁽²⁾.

Study carried out at Sector of Gynecologic Endoscopy, Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO – São Paulo (SP), Brazil.

¹ Master's degree; Head of the Sector of Gynecologic Endoscopy, Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO – São Paulo (SP), Brazil.

² Graduate student (Master's degree); Assistant physician at the Sector of Gynecologic Endoscopy, Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO – São Paulo (SP), Brazil.

³ Graduate student (Master's degree); Assistant physician at the Sector of Gynecologic Endoscopy, Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO – São Paulo (SP), Brazil.

⁴ Ph.D.; Director of the Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO – São Paulo (SP), Brazil.

Corresponding author: Daniella de Batista Depes – Rua Canário, 943/164 – Moema – CEP 04521-000 – São Paulo (SP), Brazil – Tel.: 11 5561-7831 – E-mail: danidepes@yahoo.com.br

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The system consists of a flexible micro device with a metallic stainless steel structure, an expandable elastic coil, (nitinol), and polyester fibers (PET). It is 4-cm long, with a diameter of 0.8 mm, and it reaches 1 to 2 mm when expanded⁽⁶⁾.

The insertion is performed as an outpatient procedure and consists in cannulating the tubes with a catheter containing the Essure system. This catheter is introduced through the operative canal of the hysteroscope which has a 5F diameter (1.7 mm)⁽⁷⁾.

The procedure should be done in the first phase of the menstrual cycle or on oral contraceptive administration, facilitating a good view of the uterine cavity and the tubal hostia. There is no need for anesthesia, for the pain during the procedure is relatively small, comparable to a menstrual colic pain and similar to the pain in diagnostic hysteroscopy⁽⁷⁾.

The Essure method has the advantages of being an outpatient procedure, with no need for incisions or anesthesia. The patient is released immediately after the placement of the device and is able to go back to her current activities in the same day⁽⁷⁾.

The efficacy of the method is of 99.9% compared to 99.5% for laparoscopic ligation. As a definitive method, the main contraindication is the woman's uncertainty about ending fertility. Shall the woman regret later, *in vitro* fertilization may be performed⁽⁸⁾.

No severe complications during or after the procedure have been described. Those reported by the many authors were system expulsion, vagal reflex and tubal or uterine perforation⁽⁷⁾.

Because of the Dacron™ fibers inside the system, there is a reaction of the surrounding tissues, followed by fibrosis, causing irreversible tube occlusion. It takes about three months and, during such period, the woman should use an alternative contraceptive method⁽⁹⁾.

Review after implanting the device is considered the final part of the procedure, being mandatory, to check whether the implant is in the pelvis and in appropriate position.

A plain pelvic film or transvaginal ultrasound is recommended three months after the insertion of the Essure. If both devices are satisfactorily placed in the uterine-tubal junction, the patient may stop the alternative method she is using for contraception. If the position seems unsatisfactory, a hysterosalpingogram should be requested⁽⁹⁾.

Even though the device is costly, the hysteroscopic procedure is less expensive than a laparoscopy, since the latter needs preoperative exams and physical assessment, hospital admission, general anesthesia, special material for laparoscopy, analgesic drugs in the postoperative period, the patient has to come back to remove the sutures and has to be away from work for some time⁽¹⁰⁾.

The ANVISA (National Health Surveillance Agency) has recently approved the device in Brazil. More than 200 thousand women all over the world already use Essure. The product has been approved in the European Union, Australia, Canada and Singapore since 2001 and, in 2002, it was approved by the FDA.

Many publications demonstrated a success rate of 85 to 99% for the insertion, performed as an outpatient procedure, in an easy and quick manner, resulting in a conceptual revolution in permanent female contraception^(7,8).

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