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Hysteroscopic tubal occlusion system - two case report

Key words:

hysteroscopy,
tubalocclusion,
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Abstract

Objective: To review Hysteroscopic Essure Microinsert Sterilization (HEMS) technique of our first applications and to evaluate their 5-years follow-up.

Method: HEMS was performed to two women asking for permanent sterilization in the department of obstetrics and gynecology, in our institute (İzmir Atatürk Training and Research Hospital, Turkey), in January 2007. Three months after the procedure and 5 years after the procedure, patients were evaluated using imaging technique.

Results: There had been no complications in perioperative and postoperative period. The procedure was successfully performed. The placement of the system and total tubal occlusion were confirmed postoperatively. Five years after the procedure patients had no complaints, and they were evaluated by transvaginal ultrasonography.

Conclusion: HEMS procedure is safe, easy, well-tolerated and highly effective. Although it has many advantages compared to the traditional methods, it is not performed often, because of inexperience in our country.

Introduction

Worldwide, more than 100 million women undergo sterilization by tubal occlusion or ligation. Although laparoscopic method is still the most common method under general anesthesia, the hysteroscopic methods are getting popular day by day in all over the world as a less invasive procedure, with about 200.000 women sterilized using this method¹. Hysteroscopic tubal occlusion system (Essure microinsert, Conceptus, Inc, Mountain View, Ca) was first described in 2001, as a transcervical sterilization procedure.

In the Essure procedure, a microinsert is placed into the interstitial portion of each fallopian tube under hysteroscopic guidance. The insert consists of an inner coil of stainless steel and polyethylene tetrapholate (PET) fibers and an outer coil of nickel -titanium (nitinol). The device is placed into the fallopian tube using a standard hysteroscope (< 5 mm) with a

French size 5 working channel with continuous physiologic saline flow. When released from the delivery system, the outer coil expands to 1.5-2.0 mm to anchor the microinsert to the fallopian.

The optimal placement of the insert is with 3 to 8 coils remaining in the uterus to prevent migration toward to the peritoneal cavity².

Over a 3-month period the PET fibers elicit inflammatory response and it results in intramural fibrosis and total permanent tubal occlusion³.

Essure microinsert system can be inserted under local anesthesia, with or without intravenous sedation as well as using oral analgesics alone². It makes the procedure easier and enables to perform in the office conditions, eliminating complications related to general anesthesia.

Tubal ligation, both by laparoscopy and minilaparotomy, requires approach into the abdominal cavity and have some

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risks related with the surgical procedure in itself. In hysteroscopic procedure there is no need for abdominal incision so there are no scars or cosmetic problems and no postoperative complications, such as pain and infection. It is well-tolerated by the patients and related to decreased hospitalization.

The total occlusion must be confirmed by histerosalpingography (HSG), 12 weeks after microinsert placement. Until the positive confirmatory test, another form of contraception must be used. Pelvic X-Ray and ultrasonography (USG) are required for confirming of microinsert placement⁴.

National Institute for Health and Clinical Excellence (NICE) guidance concluded that current evidence on safety appeared adequate, although the evidence of long-term efficacy is not adequate for the procedure to be used without special arrangements for consent and for audit or research⁵.

In 2007, Hysteroscopic Essure Microinsert System (HEMS) was performed in Atatürk Education and Research Hospital, Department of Obstetric and Gynecology, İzmir, Turkey; for 2 patients who asked for sterilization. The objective of this report is to review these patients on their 5 years post-procedure control.

Method

In our Institute, HEMS was performed in 2 patients asking for a procedure of sterilization. Both of the patients were at the age of 43 and multiparous. The patients were informed about all procedures and they chose hysteroscopic tubal ligation.

HEMS procedure was performed in operating room conditions, and there had been no complications in the perioperative and postoperative period.

Control examination of both patients was performed after 3 months, using X-Ray, transvaginal ultrasonography (TVUS) and HSG. Both patients were followed for the 5 years after the procedure.

Results

There have been no complications were recorded in the perioperative period. Control examination was performed 3 months after the procedure. On the pelvic X-Ray, the microinserts were symmetric and bilateral. HSG revealed total tubal ligation had seen. And on TVUS, the echo of microinsert system at the location of the uterine horn and proximal ovarian tube was recorded.

Five years after the procedure the microinserts were controlled by TV-USG, and were seen at the same location, symmetrical and bilateral. None of the patients had complaints such as pelvic pain.



Figure 1



Figure 2

Discussion

In this article, we have presented 2 patients who had hysteroscopic sterilization in our institute in 2007 by Essure microinsert system, and their 5 years follow up period.

There are many new studies about this procedure in literature. Essure hysteroscopic sterilization system is an effective, safe and well-accepted method of permanent sterilization. Contraceptive effectiveness is nearly 99.8% and at follow up visits, good or excellent satisfaction and comfort were reported in 96 and 99% of women, respectively⁶.

It is an easy procedure that can be performed in the office conditions. There are no incisions, no relation with abdominal cavity and no need for general anesthesia. As a result, this procedure is less complicate compared with the

traditional procedures. Cooper et al. evaluated satisfaction in a cohort of 464 women with bilateral Essure microinsert placement. The comfort was rated as 99% at all follow up visits. In this study total procedure time was compared to laparoscopy. Time from room entry to discharge from the facility was 80 minutes for laparoscopy, and average hysteroscopy time was less than 15 minutes, in both operating room and office settings³.

Procedure is easy to perform, and learning curve for the physicians is short. In the study performed with 464 women, only one procedure of bilateral placement was successful in 96% of patients, and in 4% a second placement procedure was required. Adverse factors for bilateral hysteroscopic occlusion are uterine anomalies and proximal tubal occlusion, tortuosity, spasm or stenosis^{3,6}. Physician experience does not have a significant impact on efficacy. In Cooper's study³, and a large retrospective study involving 884 women⁷, the success of procedure was high (95%), although physicians had no previous experience.

To determine its contraceptive efficacy, in 2007, Levie et al reviewed the reported pregnancies after Essure sterilization to date that estimated 50,000 Essure procedures performed worldwide between 1997 and 2005. There were 64 unintended pregnancies reported to the manufacturer. The causes of the pregnancies were reported as related with the physician and manufacturer staff. And also Levie et al addressed patient satisfaction in a 2010 publication⁸. The results revealed high satisfaction correlated to low pain scores. The most common reported symptoms were cramping (30%), pain (13%) and nausea (9%)³.

The adverse events related to the Essure procedure are rare, and include vasovagal response, hypervolemia from uterine distention and severe emesis secondary to the pain medications³. There were no major complications.

In our cases, we have seen no complications in our 5 years follow up. The patients had no complaints in the recovery period and no pregnancies at the follow-up period. We controlled the patients by TV-USG on the 5th year and saw the microinserts in proximal tubas symmetrically.

Established Facts

Known fact 1: The hysteroscopic methods (especially office hysteroscopy) are getting popular day by day in all over the world.

Known fact 2: Office hysteroscopy is a less invasive procedure.

Novel Insights

New information 1: Essure microinsert system can be done under local anesthesia, with or without intravenous sedation as well as using oral analgesics alone. It makes the procedure easier and enables performing in the office conditions, with no complications related to the general anesthesia.

New information 2: In hysteroscopic procedure there is no need for abdominal incisions and no cosmetic problems, and less post-operative complications such as pain and infection. It is well-tolerated by the patients, and related with less hospitalization.

New information 3: Essure™ hysteroscopic sterilization is an effective, safe, and well accepted method of permanent sterilization.

Conclusion

HEMS procedure has a high rate of efficacy. It is safe, easy and well-tolerated. Although the microinsert is expensive; anesthesia, operating room costs, postoperative recovery maintenance and period should be considered while choosing the appropriate procedure for the patient. It is less invasive and facilitates moving the procedure to the office from the operating room.

Hysteroscopic Essure Tubal Sterilization is quite new procedure in Turkey. There are no adequate reports about the performance. We need large further studies to detect effectiveness and effects of this system.

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Систем за хистероскопску тубарну оклузију – приказ два случаја

Кључне речи:

хистероскопија,
оклузија туба,
Essure

Сажетак

Циљ рада. Приказ наших првих случајева хистероскопске Essure микроинсерт стерилизације (HEMS), и провере стања пацијената после 5 година.

Метод. HEMS је извршен код две жене које су захтевале трајну стерилизацију, на одељењу за гинекологију и акушерство на нашем институту (İzmir Atatürk Training and Research Hospital, Turska), у јануару 2007. Контрола пацијената визуелизационим техникама извршена је после 3 и после 5 година од поступка

Резултати. Није било компликација ни у периоперативном нити у постоперативном периоду. Поступак је успешно проведен. Положај микроинсерт система и потпуна оклузија туба, потврђени су постоперативно. Пет година после поступка пацијенти немају тегобе, а преглед је извршен трансвагиналном ултрасонографијом.

Закључак. HEMS техника је безбедна, лако се примењује и веома је ефикасна. Иако има многе предности у односу на традиционалне методе, не изводи се често, због неискуства у нашој земљи.

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