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Essure microinsert hysteroscopic tubal sterilization: eight-years follow-up results

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Summary

Objectives: To evaluate the effectiveness and reliability of microinsert hysteroscopic sterilization method at short- and long-term. *Materials and Methods:* In the period between January 2004 and December 2005, 34 patients who submitted to the present gynecology outpatient clinic seeking for permanent contraception and accepted tubal sterilization with microinsert method were included in this prospective, interventional study. *Results:* Bilateral microinsert placement was successful in 28 (87.5%) of 32 patients that underwent the procedure. In all of the 30 patients (100%) in whom the placement procedure was attempted, bilateral tubal occlusion was documented by hysterosalpingogram (HSG) including the two patients in whom unilateral placement was carried out. First three procedures were performed under general anesthesia. Local or general anesthesia was not administered in any other cases (97.5%). The mean visual analogue scale score for pain felt during the procedure was 3.1. The mean procedure time was 11.5 ± 4.88 (5-22) minutes, the average time from beginning the procedure to discharge of the patients was 41.7 ± 18.5 (15-94) minutes . One intrauterine pregnancy was detected in one of the patients nine months after cessation of the alternative contraceptive period. This patient was excluded from the follow-up. At short-term all patients rated their microinsert-wearing tolerance as good or excellent. At eighth year, three patients were lost to follow-up. Mean follow-up time was 83.4 ± 15.0 (36-103) months. During 2,420 woman-months of follow-up, no other pregnancies were detected. Almost all of the patients were happy with the procedure and recommended it to a friend. *Conclusion:* Essure microinsert is a safe, effective, minimally invasive sterilization method which can be performed in outpatient settings without any anesthesia requirement. It appears to be a good alternative to laparoscopic tubal sterilization. The procedure time and the time to discharge are brief. Patient tolerance during the procedure and at long-term is very good.

Key words: Hysteroscopy; Tubal sterilization; Microinsert; Long-term results.

Introduction

In most of the countries, the vast majority of sterilization procedures are performed under general anesthesia by laparoscopy or mini-laparotomy [1]. As expected, these surgical procedures create potential complications of anesthesia. Even they are uncommon, there are some complications as vascular, intestinal, bladder, and uterine damage that necessitate a shift from laparoscopy to laparotomy [2]. The risk is higher in the event of the former abdominal surgery and pelvic adhesions. Additionally, postoperative pain and morbidity are other unintended states [3, 4].

Transcervical tubal sterilization or in other words, hysteroscopic tubal sterilization, eliminates the need for surgical incision or general anesthesia. Transcervical approach favors less pain and shorter time for recovery. Nevertheless, it was not straightforward to define a safe and effective transcervical method. For this purpose, electrocauterization (hot, cold), chemical materials (tissue glues, sclerotic agents), mechanical obstructive devices and polymer corks have already been suggested since mid 1970's. Unfortunately, none of these methods were not used in daily practice because of the absence of their adequate safety and effectivity [5, 6]. Today, Essure Permanent Birth Control System with microinsert and Adiana with polymer matrix system are the two solely hysteroscopic FDA approved (2002 and 2009, respectively) sterilization methods in routine gynecological practice [7].

In this prospective-interventional study, the authors aimed to evaluate the reliability and effectiveness of Essure microinsert hysteroscopic tubal sterilization procedure with short- and long-term follow-up of the patients.

Materials and Methods

Thirty-four patients who submitted at the present gynecology outpatient clinic desiring permanent contraception and accepted tubal sterilization with microinsert method were enrolled in this prospective, interventional study in the period between January 2004 and December 2005. The study had been approved by the Institutional Review Board of Hacettepe University Medical Faculty and all women who accepted to take part gave written informed consent before enrollment to the study. The inclusion criteria for

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the study were: willingness for permanent birth control method, ages between 28-46 years, with regular menstrual periods, a desire to complete the family (at least two or more children), and to accept using an alternative contraceptive method (barrier or oral) after placement of the device for three months. Exclusion criteria were: presence of a known anatomical anomaly precluding tubal cannulation, ambivalence towards permanent contraception, medical history of chronic pelvic pain, severe dyspareunia, severe dysmenorrhea, unexplained abnormal uterine bleeding, presence of any tubal, ovarian, cervical or endometrial pathology, and history of any allergic reaction against contrast agent. Detailed anamnesis was taken from all the participants and physical and pelvic examinations were performed. Cervical smears were obtained if not present during the last one year. A blood pregnancy test was obtained before the procedures. As far as possible, the procedures were scheduled during the proliferative phase of the menstrual cycle between days 7-14 to facilitate the visualization of tubal ostia and to rule out a luteal pregnancy.

Hysteroscopy procedures were performed by the same operator (M. Sakinci) using five-mm, continuous-flow, 30^0 hysteroscopy device, patients set in dorsal lithotomy position. All but three patients who were operated under general anesthesia were only given a premedication consisting of five mg diazepam and 100 mg flurbiprophen orally, one to two hours before the procedure. No prophylactic antibiotics were administered before the procedure. Hysteroscopies were carried out by vaginoscopic approach without using a tenaculum or speculum not to cause more pain or disturbance in the patients. As far as possible, mechanical dilatation of the cervix was avoided. Uterine cavity distention was provided with automatically controlled electronic irrigation/ absorption device enabling 80-150 mm-Hg intrauterine pressure. All stages of the procedure were also visualized by the patient via the monitor of the hysteroscopy system. Tubal cannulation was performed through five Fr (inner diameter 1.7 mm) operative channel of the hysteroscopy. Optimal positioning of the microinsert in the fallopian tube was considered when the proximal end of the insert seen at the tubal ostium measured about five to ten mm. All hysteroscopy procedures were carried out in outpatient settings. The main purpose of the procedures was placement of the microinserts bilaterally in optimal position. A direct pelvic X-ray was obtained one day after the procedure for the first evaluation of the positions of the inserts. Procedure duration and the time to discharge from the beginning of the procedure was noted in all cases. The severity of the pain felt during the procedure was assessed through a questionnaire, assessing the level of pain as no pain, minimal pain, moderate pain, and severe pain and using a ten-cm visual analog scale (VAS). The participants were also contacted by telephone at the procedure day, one day after, and one week after the procedure to ask if there was any complaint of pain, bleeding, cramping, if they were happy or satisfied with the procedure, and the return to daily activities. They were reminded to continue an alternative contraceptive method and not to rely on microinserts until the hysterosalpingography (HSG) which would be performed three months later.

Three months after the microinsert placement procedure, all the patients underwent HSG for evaluation of tubal occlusion and position of microinserts. After HSG procedure patients were again asked if there were happy with the procedure, recommended it to a friend, which alternative contraceptive method they used, and if there was any significant complaint related with the procedure. If the device location was satisfactory and complete tubal obstruction was present on HSG, participants were advised to rely on the microinserts as permanent contraceptive method and to discontinue the alternative contraceptive method.

After cessation of alternative contraceptive period, patients were contacted by telephone to enquire about the efficiency of microinsert method for pregnancy prevention, if they solely relied on microinsert for contraception, if they encountered an adverse effect or symptom, to what extent they were satisfied with the method, and if they recommend the method to anybody else.

Table 1. — *Demographic characteristics of the patients.*

Properties	n = 32*
Age (year)	38.3 ± 4.5
Weight (kg)	67.5 ± 10.8
BMI[£] (kg/m^2)	26.6 ± 3.7
Gravida	4.4 ± 1.8
Parity	2.8 ± 1.0

* The patients microinsert placement procedure was not attempted are not included in the table. All values are given as mean ± standard deviation.
[£] Body mass index

Table 2. — *Causes for failure to bilaterally place the device.*

Reasons	Frequency
Previously blocked tube	1 (2.9%)
Uterine synechia	1 (2.9%)
Laterally placed tubes	1 (2.9%)
Tubal spasm	1 (2.9%)
Nonvisualization of tubal ostia	1 (2.9%)
Obesity	1 (2.9%)

Results

The mean age of the study population, mean gravida, mean parity, and mean body mass index (BMI) were respectively, 38.3 ± 4.48 (28-46), 4.4 ± 1.79, 2.8 ± 1.00 (2-6), and 26.6 ± 3.72 (20.4 - 33.6) kg/m^2. Demographic characteristics of the participants are summarized in Table 1.

Placement of Essure microinsert system was attempted in 32 patients out of 34. No attempts were tried in two patients. The tubal ostia were not visualized in two separate hysteroscopy sessions in one of these patients. This patient underwent tubal ligation by laparoscopy. To reach the tubal ostia was impossible in the other patient due to obesity.

For the first three patients (7.5 %) who underwent the procedure, intravenous sedation anesthesia was provided by masked ventilation without endotracheal intubation. The reasons for using general anesthesia were: as this procedure was applied for the first time in the present center for the first two patients and due to the patient's request in the third patient. Excluding premedication with flurbiprophen and diazepam, no local anesthetic agents or intravenous sedation were administered to the other patients (92.5%).

Tubal cannulation was not possible in two out of 32 patients who underwent a bilateral intervention of microinsert placement (attempted bilateral tubal cannulation). Tubal ostia were placed in an extreme lateral position in one of the patients, as it was impossible to line them onto

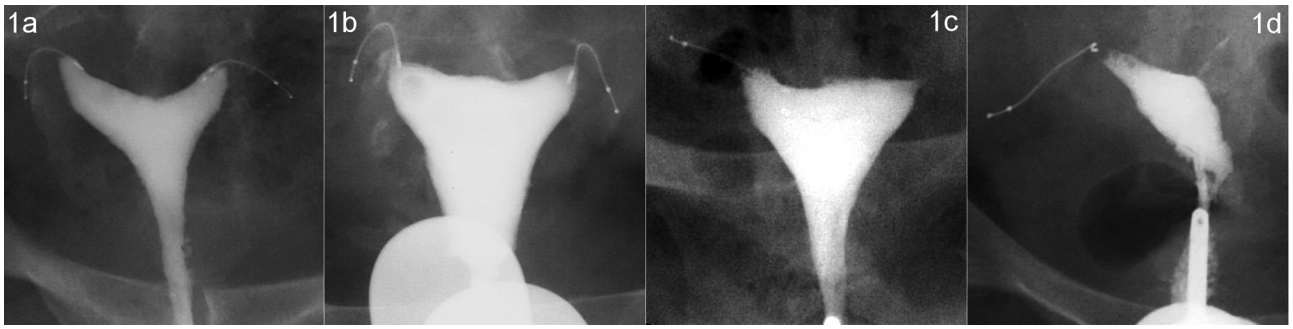

Figure 1. — 1a-1b: Normal symmetrically-located bilateral microinserts, bilaterally no contrast passage; 1c: Normally placed unilateral microinsert, unilateral cornual block; 1d: Normally located unilateral microinsert, severe synechia obliterating totally left side of the cavity and causing a unicornuate uterus appearance; minimal passage from left uterine cornu.

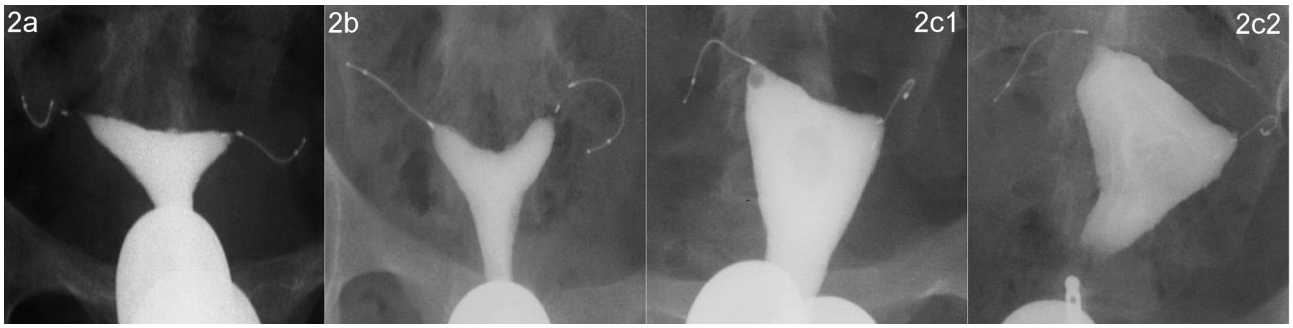

Figure 2. — 2a-2b: HSG views showing assymetrically-placed microinserts not allowing any contrast passage; 2c1-2: HSG views obtained one year apart in which no passage, despite assymetrical microinsert location can be seen, belonging to the patient who conceived at follow-up.

the direction of the microinsert catheter, whereas in the other patient the catheter failed to proceed inside the tubes bilaterally due to a previous tubal occlusion or cornual spasm. Tubal ligation was performed in both of these patients by laparoscopy, as a result of their own request.

Microinserts were placed in a total number of 30 patients. Unilateral placement was performed in two patients. Accordingly, bilateral microinsert placement was achieved in 28 out of 32 (87.5%) patients. Positions of the devices were assessed by viewing direct pelvic X-rays of patients during the postoperative day one. All but four patients out of 28 who underwent a bilateral placement procedure (24 women), had positions of the microinserts that were bilaterally optimal and symmetric and bilateral cornual block was documented in their HSGs (Figure 1a, 1b). In one patient out of two who underwent unilateral placement, a microinsert was successfully placed in the right tube during the first session, however the authors failed to cannulate the left tube. After the primary procedure, cannulation process was also attempted during two other sessions, but unfortunately it was not possible. HSG was obtained three months later, and demonstrated no passage of the contrast agent bilaterally in both tubes with and without microinsert and was assessed as bilateral cornual blockage (Figure 1c). Possible pregnancy risk was explained, however the patient insisted that she would not use any contraceptive methods while trusting bilateral blockage. In the other patient, during hysteroscopy, right tubal ostium was monitored while the left tubal ostium was not. The cavity demonstrated a likewise unicornuate uterus appearance. In HSG, synechia totally obliterating the left side of the cavity in a form similar to the unicornuate uterus and unilateral block due to microinsert in the other tube was detected (Figure 1d). After the patient was informed, laparoscopic ligation was performed to the tube at the side where the synechia was present. No intervention was performed on the right tube which was already occluded due to the microinsert. The reasons related with the failure to place microinserts bilaterally are displayed on Table 2. Bilateral placement was performed in a single session in 24 patients out of 28. The remaining four patients underwent a successful microinsert placement procedure in the second session.

As mentioned above, positions of microinserts were evaluated as asymmetric in four patients. No passage of contrast agent bilaterally in HSGs were observed in three of them at third month (Figure 2a, 2b, 2c1). The first two patients who showed asymmetric placement and no passage on their HSGs demonstrated no significant problems during

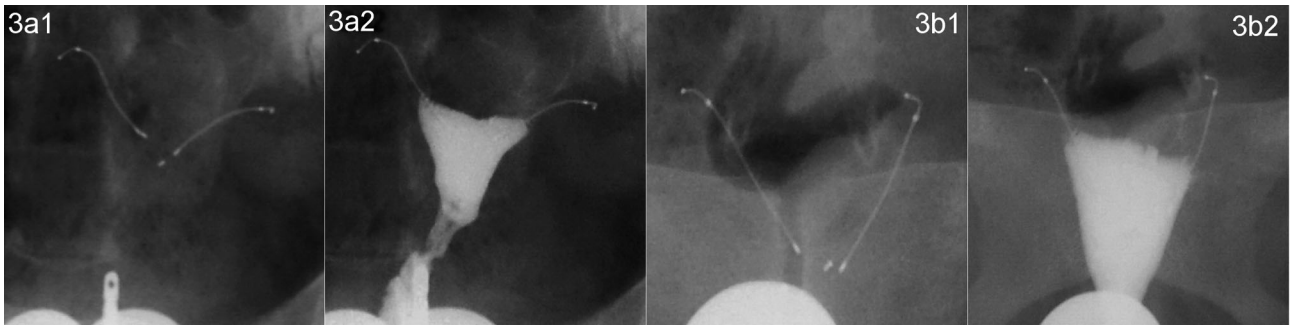

Figure 3. — 3a1-2, 3b1-2: Direct X-ray and HSG views showing too proximally located microinserts bilaterally belonging to two different patients. No passage can be seen in HSG views.

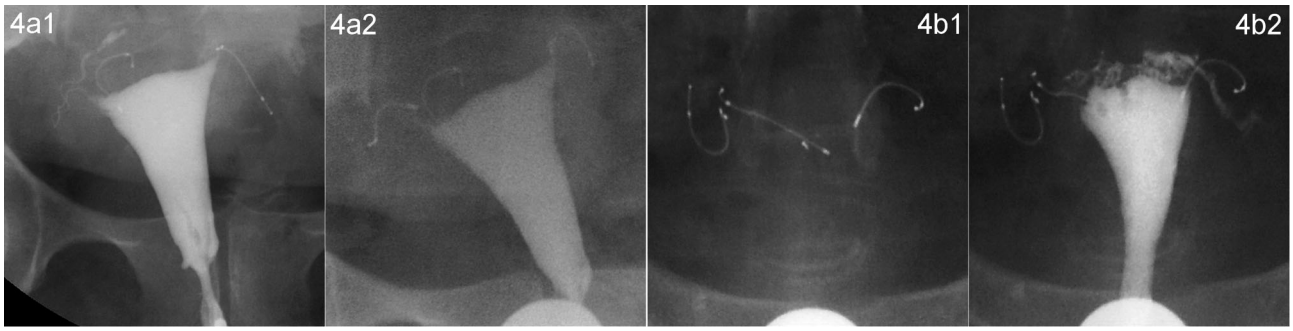

Figure 4. — 4a1: Contrast passage is seen through the right tube. Right microinsert is considered to be located intramyometrially. 4a2: HSG view of the patient in Figure 4a1 after correct placement of a new microinsert: Normal and symmetrically-located bilateral microinserts not allowing contrast passage, third microinsert at right side located myometrially. 4b1-2: Second microinsert at right tube placed due to too distal placement of the first, total three microinserts, bilaterally no passage is seen, venous intravasation of the contrast is seen at fundus.

their eight years follow-up period (Figure 2a, 2b). The third patient who displayed a HSG film that demonstrated no passage bilaterally is shown in Figure 2c1, became pregnant at month nine of abandoning the alternative contraception method. A six-week pregnancy with positive fetal cardiac activity was detected by transvaginal sonography. The pregnancy was terminated due to the request of the patient and she underwent hysteroscopy again six weeks after her curettage. The tail length of the right and left microinserts were two and six coils, respectively, and both two tails were monitored aligned at the tubal ostium. Despite this, to eliminate myometrial placement, bilateral cannulation of the tubes was re-attempted, unfortunately this attempt had failed. One day after office hysteroscopy a second HSG was performed. It was very interesting that no bilateral passage was monitored in the new HSG (Figure 2c2). Although passage could not be monitored by HSG, the authors thought that the tubal occlusion at the left asymmetric microinsert had not been completed or that the microinsert was placed intra-myometrially located at the cornual region, and therefore laparoscopic tubal sterilization was applied upon request by the patient. No perforating microinsert, extending towards the abdominal cavity from the myometrium was monitored during laparoscopy. Thereby patient ratio that trusted microinsert-insert as the contraceptive method reduced from 100% to 96.7%. This patient was withdrawn from the follow-up.

After bilateral microinsert was placed, the number of coils located inside the uterine cavity was counted and recorded for all the patients. In all but two patients, minimum three and maximum nine coils were left inside the uterine cavity. An excess proximal placement occurred in two patients due to difficulty during bilateral cannulation. Tail length counted in the right ostia was 11 and 12 coils while this number was 12 in the left ostia for both patients. The pelvic X-ray obtained at day 1 demonstrated too proximally but symmetrically located microinserts which were thought as satisfactory positions. Also, bilateral tubal occlusion was detected on HSGs of both patients obtained three months after (Figures 3a1-2 and 3b1-2). No pregnancies or any adverse effects were encountered in these two patients during their eight years follow-up.

In the fourth patient who had asymmetric microinsert placement, the right tube was detected as patent in three month-HSG (Figure 4a1). The authors assumed that the microinsert at the right side was located intra-myometrially.

Thus uterine perforation was encountered in one of the patients (3.3 %). This patient was absolutely asymptomatic during and after the procedure. Two days after HSG was obtained, a microinsert was placed again. The right ostium was carefully monitored and the microinsert was successfully placed. The location of the new device was viewed symmetrical and no bilateral passage was monitored on HSG at month 3 (Figure 4a2) and the patient was advised to abandon the alternative contraception method. No adverse intra-abdominal effect was detected in this patient related with perforation. No significant problems were encountered during the eight years follow-up period.

In the present series, additional to the patient mentioned above, three microinserts were placed in a second patient. However, the reason of the third device in this patient was excess distal placement in the right tube during the initial attempt. The trailing coils of the right microinsert had not been monitored in the uterine cavity. The authors assumed that the microinsert had migrated towards the ampulla section of the tube and therefore decided to perform cannulation again to this tube at the same session. A second microinsert was placed in the right tube in a satisfactory position. The trailing length of the device in the cavity was nine coils. No bilateral passage was monitored in the HSG obtained at month 3. No problems were encountered during the eight years terms of follow-up (Figure 4b1-2).

Obesity and previous abdominal surgical history which both can be accepted as a relative contraindication for laparoscopy did not lead to any negative impact during the placement of bilateral microinserts. Bilateral placement was performed in seven out of eight (26.7 %) patients with a BMI more than 30; however unilateral placement was performed in one of the patients due to unilateral tubal occlusion. Fifteen (50%) patients demonstrated a previous history of intra-abdominal surgery. Eighteen (56%) patients had one or more medical problems that may compose a contraindication for anesthesia and laparoscopy, such as diabetes mellitus, hypertension, goiter, asthma, hearth valve disease, and Behcet's disease.

The average duration regarding the procedures (hysteroscopy procedure, placement of microinserts, and finalization of hysteroscopy procedure) was calculated as 11.5 ± 4.88 (5-22) minutes . The mean duration starting from the beginning of the procedure until the time of discharge was calculated as 41.7 ± 18.5 (15-94) minutes .

Patients were requested to score their pain levels during the procedure and right after the procedure, using a ten-cm VAS. The mean pain score during procedure was 3.1 ± 2.4 (0-8) and 1.6 ± 1.5 (0-5) right after the procedure. Accordingly, 16.6% of the patients (five patients) stated that they felt almost no pain during the procedure while 56.7% of the patients (17 patients) felt a mild pain, 23.4% of the patients (7 patients) felt a moderate pain, and finally one patient (3.3%) felt severe pain. No postoperative analgesics were necessary in 83.4% of the patients. No negative symptoms were observed in patients during discharge and no analgesics were prescribed to any of the patients.

Patients were asked if they experienced complaints such as bleeding, pain, cramps, fever, nausea or dizziness, etc. during the first week of their follow-up period and 27% of the patients (8 patients) stated no bleeding events while 73% (22 patients) informed the authors they experienced bleeding in the form of minimal spotting. This spotting symptom easily recovered within approximately two days. Symptoms such as fever, nausea or dizziness was not observed in any of the patients. Patients were asked to classify the pain they felt as no pain, minimal pain, moderate pain, severe pain, and extreme pain considering the pain felt during their menstruation was classified as moderate pain as a reference point. Accordingly, 36.7% of the patients stated that, they felt no pain during their first week of follow-up while 56.6% felt a minimal pain, and 6.7% felt moderate pain.

When the patients were asked about the degree of satisfaction they felt from the procedure and the level of their happiness during the post-operative period, 97% of the patients found the procedure more simple than they thought and they were very happy of the outcome. Only one patient stated that she felt more pain during the procedure than estimated. After three-months follow-up period, HSG was obtained. 90% of the patients (27 patients) were very happy and 10% were happy with the procedure. All of the patients stated that they have recommended or would recommend the procedure to their friends or relatives. Excluding only one patient, all patients stated that they were able to continue their normal daily activities at the same day with the procedure while one patient had to rest at home for two days.

The mean follow-up period in the present study was 83.4 ± 15.0 (36-103) months. Twenty-six patients completed a eight-year follow-up time. Three patients were lost to follow up during the various times of the eight years follow-up (two patients were lost at month 60 telephone call and one patient at month 90). Since 2004, excluding the intrauterine pregnancy in only one patient, no pregnancy was detected in 2,420 women-year follow-up period. In one patient, vaginal hysterectomy was performed 73 months after the procedure due to uterine prolapsus. One patient entered menopause during follow-up.

During the long term follow-up after the procedure, four patients (13.3%) stated an increase in the amount of their menstrual bleeding while five patients (16.7%) stated a decrease. No patients suffered from persistent pelvic pain, including the patients who had more than two microinserts placed. Only two (6.7%) patients stated that they felt a slight groin pain from time to time and they were not sure if the pain was related with the microinsert. All the patients interviewed informed the authors that they were quite happy with the result of the procedure and they have recommended it to their friends.

Discussion

To the authors' knowledge, this is the first study evaluating the efficacy of sterilization and long term data by using Essure microinsert in Turkey. During the follow-up of 2,420 woman-months, no pregnancies except one, which was mentioned above, were detected in this study. In another trial conducted by Arjona *et al.*, 1,630 women were examined for 42 months and three unintended pregnancies were reported [8]. Consistent with the literature, the present rate of tubal occlusion was almost 100% through the correct placement of devices with proper technique [9, 10]. On the other hand, one new gestation had occurred in one patient despite the documentation of tubal block twice via HSG performed one year apart in the same patient. Compared to the first HSG, the microinsert at right tube seemed to locate more distally at the second year HSG. Interestingly, the laparoscopy procedure of this participant revealed no myometrial perforation by Essure and unintended gestation may be due to the inadequate fibrosis of tuba uterina.

Adiana polymer matrix, another hysteroscopic sterilization method, has similar mechanisms for contraception like Essure, but, the main difference between the two is due to the success rates. In a study about Adiana evaluating the follow-up of 570 patients for five years, 12 unintended gestations were reported [7]. However, Essure, even after the inclusion of all unintended pregnancies in the literature, seems to be the most effective contraceptive method [11].

In this study, all the procedures were carried out in office conditions using only two per oral drugs (ibuprofen and diazepam) due to the minimally invasive nature and short duration of the procedure except in the first three patients. The absence of requirements like general anesthesia, incisions, and narcotic analgesics resulted in markedly decreased postoperative morbidity rate and very short recovery time. Previously reported time for hysteroscopic application of Essure was around 13 minutes in most of the studies [12-14]. Concordant with this data, the mean procedure duration in the present study was 11.5 minutes. The authors also found that the time between the beginning of the procedure and office discharge was only 42 minutes.

Another major advantage of this method was the absence of a marked pain during the procedure. In the present study, vast majority of the participants denied any pain or felt minimal pain at the time of procedure and 3.1 ± 2.4 were the mean pain score detected by using 10-cm VAS. Only five (16.6%) patients that demanded analgesics, underwent intramuscular diclofenac sodium injection. Neither of the patients needed narcotic analgesics nor suffered from postoperative nausea and vomiting. Also, majority of the patients returned to their daily activities at the same day.

Essure system seems as a perfect alternative, particularly for the patients who have unfavorable characteristics either for general anesthesia or laparoscopy. In the present study, the system was successfully performed in a woman with a cardiac arrest history during general anesthesia and another with serious mitral stenosis. Additionally, the number of patients suffering from co-existent diseases that created further risks was high. The procedure was also accomplished with success in patients with relative contraindications for laparoscopy (e.g. previous history of abdominal surgery, obesity).

Two of the disadvantages of Essure system was the necessity of a supplemental contraceptive method in the course of postoperative tubal occlusion for three months and the need for radiologic studies (HSG, X ray, and ultrasonography) in order to diagnose the blockage of tuba uterina. When this method was initially performed, HSG was solely used for the affirmation of intratubal correct placement and tubal blockage, at the end of the third postoperative month. Recent approach recommends an early subsequent pelvic X-ray, and in the event of bilateral symmetrical placements, withdrawal of alternative contraceptive method without a control HSG at the third postoperative month. To this approach, HSG is only indicated if the procedure is difficult, painful, and/or the placement of devices is unsatisfactory or asymmetrical on pelvic X-ray [12].

Complications are rarely seen during the implementation of Essure system, if seen these are expected to be minor and clinically insignificant. These can be classified under two headings; complications associated with hysteroscopy (fluid overload, cervical lacerations, and uterine rupture) and complications associated with the system itself (expulsion of device, rupture, and improper placement). The short duration of procedure and the use of small-sized hysteroscopies favor a low complication rate. In a retrospective study including 4,306 Essure microinsert procedure by Povedano *et al.*, the complication rate was reported to be 2.7%. Additionally, the most common complication was vasovagal syncope (1.9%). Device expulsion was seen in 19 (0.4%) cases and 14 of these expulsions were within the first three months [15].

Fortunately, there were no expulsions in the present study. Although proximal placements were seen on control HSG in two cases, complete tubal obstruction was detected in both. A third device was introduced in two cases. First case was the patient with uterine perforation as a result of myometrial placement of one microinsert and the other case was due to the distal placement of one microinsert.

One of the limitations of hysteroscopic sterilization by microinsert method is the inability of bilateral successful placement of the devices due to unpredictable intrauterine or tubal pathologies or anatomic impediments. In this study, bilateral proper placements of devices were achieved in 87.5% of participants. The reasons for failure of bilateral placement of microinserts were formerly obstructed or stenotic tuba uterina, tubal spasm, intrauterine synechia completely occluding tubal ostium, and laterally placed tubal ostia in which the microinsert catheter and tubal os-

tium could not be brought in the same direction. In a prospective study by Mino *et al.*, 99% of 857 patients had successful placements; on the other hand 15% of procedures were reported as "difficult" by the operators. Anatomical tubal abnormality or tubal spasm were the major reasons of these difficulties [16].

The absence of persistent pelvic pain and low rate of any menstrual cycle changes associated with the procedure and the Essure system itself in follow-up were among the long-term advantages of the microinsert method.

In conclusion, the authors wish to emphasize that hysteroscopic tubal sterilization with Essure system is a minimal invasive and effective method which can be performed without any anesthesia and incisions in office conditions. Additionally, patients having contraindications for general anesthesia and laparoscopy are ideal candidates for Essure system.

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