Published in final edited form as:
Contraception. 2012 April ; 85(4): 384–388. doi:10.1016/j.contraception.2011.09.004.

Tubal risk markers for failure to place transcervical sterilization coils

Ophra Leyser-Whalen, **Mahta Rouhani**, **Mahbubur Rahman**, and **Abbey B Berenson***
Center of Interdisciplinary Research in Women's Health, Dept. of Obstetrics and Gynecology, University of Texas Medical Branch

Abstract

Background—There is a growing body of literature on placement rates of the Essure® procedure, yet prior studies have not attempted to identify tubal-associated risk factors for placement failures. The current study examines risk markers associated with the inability to deploy the Essure® coils into the tubal lumen using the new ESS305 design.

Study Design—We used electronic medical record data to assess risk markers associated with the inability to place the Essure coils in the tubal lumen using the new ESS305 design. A total of 310 attempted procedures between June 14, 2007, and April 29, 2011 were analyzed.

Results—There were 18 tubal failures (5.8%) out of the 310 attempted procedures. A history of a prior sexually transmitted infection (STI) was associated with tubal failure (OR 2.64, 95% confidence interval (CI) 1.01–6.90; p=.048).

Conclusions—We speculate that the observed association between a prior STI and an inability to place the coil was due to a past history of pelvic inflammatory disease.

Keywords

transcervical sterilization; placement rate; tubal factors; STI

1. Introduction

The Essure® (Conceptus, Inc., Mountain View, California) procedure was first approved in the US as a sterilization technique in November 2002 [1] and is increasingly being used. As Essure® rates have increased, rates of other female sterilization procedures have decreased [2]. The procedure entails guiding a hysteroscope through the cervix to the opening of each fallopian tube, where a microinsert composed of nickel and steel coils is deployed. The coil fibers initiate a benign fibrotic reaction that occludes the tubes. A follow-up hysterosalpingogram (HSG) is recommended 3 months post-procedure to verify tubal occlusion (FDA). Some advantages of this technique are the short procedure time that can be performed in the clinic setting with a same-day recovery period, and that pain medication can be administered intramuscularly or locally [3]. Further, compared to a tubal ligation, Essure® is more cost-effective [4] and has fewer potential complications [5].

*Corresponding author: Abbey B. Berenson, University of Texas Medical Branch, 301 University Blvd, Galveston, TX 77555, abberens@utmb.edu.

There is a growing body of literature on the Essure® procedure, with a subset focused on placement rates that range between 81%–99% [2, 6–33]. One area of concentration in this literature is procedure-related, such as finding higher successful placement rates in the outpatient versus inpatient setting [22,26]. Some researchers demonstrate an association between placement failure and an increased length of procedure, [2,34], but placement rates have not been significantly associated with time in the recovery area, performing a concomitant intrauterine surgical procedure [23,28], or provider experience [8,34]. Further, no association has been observed between placement rates and certain types of anesthesia or premedication [18,23,28,34] with the exception of decreased failure rates when anti-inflammatory agents are used to reduce tubal spasm [7,8,22].

Patient-level factors associated with difficulty in coil placement include having a large uterus [27] and a history of intrauterine device (IUD) use [21]. Another study observed a relationship between failure rates and body mass index (BMI) [27] while others have observed a positive relationship between failure rates most likely due to visualization and certain phases of the menstrual cycle [23,25,27]. Placement rates do not appear to be significantly associated with age, race, parity, gravidity, pain experience, tobacco or illicit drug use, history of ectopic pregnancy, history of cesarean section, or hormonal contraceptive usage [8, 12,15,18,22,23,26,28,34].

Many of these studies have attributed half of their placement failures to an inability to advance the coils into the fallopian tubes after the tubal ostia have been visualized [30,35]. Prior studies have not attempted to identify reasons for this difficulty or associated risk factors. Furthermore, few data are available on placement rates among women at risk for tubal disease as they are often excluded from the studies. In addition, few data are available on placement rates using the new ESS305 design, third-generation model which was approved for use in the US in June 2007 [24,28,32,36]. The current study adds to the literature by examining risk markers associated with the inability to deploy the Essure® coils into the tubal lumen using the new ESS305 design, third-generation model. Furthermore, this study presents data from a largely Hispanic population, for which only one smaller study exists [16].

2. Materials and methods

After obtaining approval from the Institutional Review Board at The University of Texas Medical Branch (UTMB), electronic medical record (EMR) data were collected on any patient who underwent attempted placement of Essure® coils between August 31, 2005, and April 29, 2011, at The University of Texas Medical Branch clinics. All patients were de-identified by subject number in the analysis database. Information extracted from the records included demographics, prior pregnancy, reproductive, sexual, and social histories, details of the sterilization procedure and follow-up HSG results.

For this analysis, we excluded 10 patients who were seen before the third-generation Essure® model was approved, as well as 14 women who had non-tubal factor-related failed Essure® attempts. This left 310 women available for analysis, who were sterilized between June 14, 2007, and April 29, 2011.

Our dependent variable was “tubal factor failure” as defined by the inability to insert Essure® coils in one or both fallopian tubes upon first placement attempt. This outcome was selected because clinicians continue to look for means by which to improve the success rate at first attempt [15] and because comparisons or usage of data on subsequent procedure attempts has self-selection bias because some patients choose to not re-attempt the procedure at a later visit.

Tubal factor failure can be due to either tubal stenosis or tubal spasm. With our data, there could be a reduced likelihood of tubal spasm because patients were administered both non-steroidal, anti-inflammatory drugs (Toradol 60 ml. and Ibuprofen 800 mg) and an anxiolytic (Valium 10 mg) 1 h before the procedure.

We examined the association between tubal factor failure with demographic variables of age, race/ethnicity, and parity. Moreover, a history of sexually transmitted infection (STI) was of special interest because of its link to pelvic inflammatory disease (PID) that causes tubal scarring. We used STI as a risk marker for PID because information on PID was not collected in a methodical manner in the EMR.

Bivariate comparisons were performed to compare the two groups of successful versus failed insertions, using the chi square test, Fisher's exact test, or Mann-Whitney test as appropriate. Binary logistic regression was used to identify correlates of tubal failure. All analyses were performed using SPSS 15.0 for Windows (IBM Corp., Somers, NY).

3. Results

The overall number of failures of Essure® placement for any reason in this population was 32 out of 324 (9.9%) procedures. Of these 32, tubal factors accounted for 18 (56.3%) unsuccessful coil placements. The 14 non-tubal failures excluded from our analysis were: 9 with inadequate visualization of the ostia due to endometrial tissue or excessive uterine scarring, 3 with cervical stenosis, 1 with severe uterine prolapse, and 1 woman who forgot to take her hypertension medication the day of the procedure so staff did not attempt the procedure due to her high blood pressure upon arrival at the clinic. Thus, our analysis included 310 women, of which 18 could not have the coils placed due to a tubal factor, which gave us a tubal failure rate of 5.8%.

The median age of the study population at the time of procedure was 34.0 (interquartile range 30.0–38.0) years. The racial composition of the sample was 31.6% white (n=98), 11.9% black (n=37), 53.2% Hispanic (n=165), and 3.2% Asian (n=10). Over one-third of the population (36.8%, n=114) was given at least one injection of intramuscular depo medroxyprogesterone acetate (150 mg) during their pre-procedure consultation process, with a median of 1.0 month before the procedure. The median parity was 3.0 (2.0–3.0) children. The majority of the patients (n=215, 69.4%) attended UTMB's public clinic, while 30.6% received care at a UTMB clinic for patients with public or private insurance.

Over a quarter (n=83, 26.8%) of the women reported a history of one or more STIs. These included chlamydia (17.1%), human papilloma virus (HPV, 6.5%), gonorrhea (3.5%), herpes simplex virus (3.5%), trichomoniasis (3.2%), syphilis (0.65%), and human immunodeficiency virus (0.32%). Of the 83 women with a history of STI, failure of placement occurred in 9 (10.8 %). Of the 204 women without a history of STI, failure of placement occurred in 9 (4.4 %). The difference between these two groups is significant, where the association between a history of STI and failure placement is p=.042 (Table 1).

Sample characteristics by tubal failure status are shown in Table 1. The successful and failed insertion groups are similar in terms of age, race/ethnicity, marital status, education, parity, intra-uterine contraceptive use and BMI. The failed insertion group was more likely to have a history of STIs (p=.042) than the latter group.

From our bivariate logistic regression models, we observed that having a history of any STI was associated with increased odds of Essure® tubal insertion failure (OR 2.64, 95% CI 1.01–6.90; p=.048) (Table 2). Age (p=.259), race/ethnicity (blacks, p=.222 and Hispanics,

p=.167, compared to whites), and parity (p=.708) were not associated with tubal failure rates.

4. Discussion

We observed a positive relationship between a history of STI and tubal placement failure compared to the findings of Shavell et al. [34], where no association was found. However, there are a number of differences between their study and ours that make a direct comparison of the two difficult, and may explain the difference in findings. First, they reported on 22 placement failures of which a maximum of 4 were due to tubal occlusion factors. Our study did not include all women who had a placement failure, but instead was limited to the 18 women seen during this time period who experienced a failure due to tubal factors. Second, the patient population differed between the two studies with 18 of their 22 (81.8%) placement failures observed in women with private insurance versus only 11% of our population (2 out of 18) . This could account for the difference in STI rates. Yet another difference is that 54% of the Essure® procedures in Shavell et al.'s [34] study were performed under general anesthesia, as opposed to 1.3% (n=4) of those included in this analysis. Lastly, they used the second-generation model, versus our use of the third-generation model.

We speculate that the link we observed between a prior history of an STI and an inability to place the coil in the fallopian tube is a past history of PID. When the lower reproductive tract infection ascends into the upper reproductive tract, it can cause infection of the fallopian tubes and lead to partial or total occlusion [37]. Half of our failure rate group (n=9) reported at least one prior STI, with most of the STIs having links to PID [37,38].

It cannot be determined from these data if failure to insert coils into the fallopian tubes was due to tubal occlusion or spasm. Previous studies have not attempted to differentiate between the two, as it can be a difficult task. The patients in our study were given agents shown to reduce tubal spasm that would otherwise inhibit insertion of the Essure® coils [7,8,22]. In fact, most Essure® patients are given anti-inflammatory agents and thus, some failures which have been attributed to tubal spasm in other studies may actually be due to occlusion.

An adverse outcome may result if tubal occlusion is misdiagnosed as tubal spasm during the procedure. This was demonstrated in a recent case report in which the physician encountered resistance in advancing the coil into the fallopian tube. It was assumed that the cause was tubal spasm and the physician continued to push the coil into the tube. The patient had post operative abdominal pain and the 3 month follow-up HSG showed a tubal perforation with the coil in the abdominal cavity [10].

We did not exclude patients based on their reproductive histories, so our sample population is probably representative of women who use public health clinics for the Essure® procedure. However, our data come from a largely Hispanic client population, which may under-represent patients with STI histories as national data show that Hispanics as a whole, compared to other races, have lower rates of STIs [39]. Thus, future study is needed to ascertain the association between STI and tubal occlusion in other study populations.

Our study is limited by its design because use of medical records may have led to the under-detection of some conditions. For example, history of a prior STI was obtained by self-report. Second, conditions such as bacterial vaginosis may also lead to PID [37,38], yet these conditions were not categorized in any orderly manner in the EMR and thus not entered into our database. Further, some clinicians take more meticulous notes than others,

which may result in missing data. However, the missing data were not excessively large (n=23, 7.4%) for STI, our main explanatory variable.

Prospective data are needed to confirm the relationship we observed between tubal placement failure and a prior history of STI. Future studies should also examine the relationship between Essure® success rates and a history of PID, or other conditions, such as previous tubal surgery, which could lead to tubal inflammation and scarring. Further, having a history of STI does not necessarily preclude a successful procedure as placement failure occurred in 10.8 % of patients with an STI history and 4.4% of patients without an STI history. Until more conclusive data are available, the current study suggests that physicians should increase their awareness of their patients' histories of pelvic inflammatory disease or other risks of tubal damage so that they can assess how much pressure to apply to the tubes if they encounter tubal resistance.

Acknowledgments

Federal support for this study was provided by the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) as follows: Dr. Berenson, under a mid-career investigator award in patient-oriented research (K24HD043659). Dr. Leyser-Whalen, as an NRSA postdoctoral fellow under an institutional training grant (T32HD055163; Berenson, PI).The content is solely the responsibility of the authors and does not necessarily represent the official views of the NICHD or the National Institutes of Health.

References

1. US Food and Drug Administration. [Accessed June 13, 2011] Medical Devices. Essure System - P020014. 2009 June 29. Available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm083087.htm.
2. Shavell VI, Abdallah ME, Shade GH, Diamond MP, Berman JM. Trends in sterilization since the introduction of Essure hysteroscopic sterilization. J Minim Invasive Gynecol. 2009; 16:22–27. [PubMed: 18996773]
3. Connor VF. Essure: a review six years later. J Minim Invasive Gynecol. 2009; 16:282–290. [PubMed: 19423060]
4. Levie MD, Chudnoff SG. Office hysteroscopic sterilization compared with laparoscopic sterilization: a critical cost analysis. J Minim Invasive Gynecol. 2005 Jul–Aug.12:318–322. [PubMed: 16036190]
5. Lessard C, Hopkins M. Efficacy, safety, and patient acceptability of the Essure procedure. Patient Preference Adherence. 2011; 5:207–212.
6. Arjona JE, Mino M, Cordon J, Povedano B, Pelegrin B, Castelo-Branco C. Satisfaction and tolerance with office hysteroscopic tubal sterilization. Fertil Steril. 2008; 90:1182–1186. [PubMed: 18201703]
7. Chern B, Siow A. Initial Asian experience in hysteroscopic sterilisation using the Essure permanent birth control device. BJOG. 2005; 112:1322–1327. [PubMed: 16101615]
8. Cooper JM, Carignan CS, Cher D, Kerin JF. Microinsert nonincisional hysteroscopic sterilization. Obstet Gynecol. 2003; 102:59–67. [PubMed: 12850608]
9. Duffy S, Marsh F, Rogerson L, et al. Female sterilization: a cohort controlled comparative study of ESSURE versus laparoscopic sterilization. BJOG. 2005; 112:1522–1528. [PubMed: 16225573]
10. Gerritse M, Veersema S. Incorrect position of Essure microinserts 3 months after successful bilateral placement. Fertil Steril. 2009; 91:930.e1–930.e5. [PubMed: 18945426]
11. Kerin JF, Carignan CS, Cher D. The safety and effectiveness of a new hysteroscopic method for permanent birth control: results of the first Essure (TM) pbc clinical study. Aust N Z J Obstet Gynaecol. 2001; 41:364–370. [PubMed: 11787907]
12. Kerin JF, Cooper JM, Price T, et al. Hysteroscopic sterilisation using a micro-insert device: results of a multicentre phase II study. Hum Reprod. 2003; 18:1223–1230. [PubMed: 12773450]

13. Kerin JF, Munday DN, Ritossa MG, Pesce A, Rosen D. Essure hysteroscopic sterilization: results based on utilizing a new coil catheter delivery system. J Am Assoc Gynecol Laparosc. 2004; 11:388–393. [PubMed: 15559354]
14. Langenveld J, Veersema S, Bongers MY, Koks CA. Tubal perforation by Essure: three different clinical presentations. Fertil Steril. 2008; 90:e5–e10. [PubMed: 18692813]
15. Lett C, Thiel J. The effect of menstrual phase and hormonal contraception on successful bilateral placement of the Essure micro-insert tubal coil. Gynecol Surg. 2009; 6:219–222.
16. Levie MD, Chudnoff SG. Prospective analysis of office-based hysteroscopic sterilization. J Minim Invasive Gynecol. 2006; 13:98–101. [PubMed: 16527710]
17. Litta P, Cosmi E, Sacco G, Saccardi C, Ciavattini A, Ambrosini G. Hysteroscopic permanent tubal sterilization using a nitinol-dacron intratubal device without anaesthesia in the outpatient setting: procedure feasibility and effectiveness. Hum Reprod. 2005; 20:3419–3422. [PubMed: 16085664]
18. Lopes P, Gibon E, Linet T, Philippe HJ. Hysteroscopic tubal sterilization with Essure intratubal devices: a case-control prospective with inert local anesthesia or without anesthesia. Eur J Obstet Gynecol Reprod Biol. 2008; 138:199–203. [PubMed: 17822834]
19. Mascaro M, Mariño M, Vicens-Vidal M. Feasibility of Essure placement in intrauterine device users. J Minim Invasive Gynecol. 2008; 15:485–490. [PubMed: 18602048]
20. McSwain H, Shaw C, Hall L. Placement of the Essure permanent birth control device with fluoroscopic guidance: A novel method for tubal sterilization. J Vasc Interv Radiol. 2005; 16:1007–1012. [PubMed: 16002509]
21. Mino M, Arjona JE, Cordon J, et al. Success rate and patient satisfaction with the Essure™ sterilisation in an outpatient setting: a prospective study of 857 women. BJOG. 2007; 114:763–766. [PubMed: 17516970]
22. Nichols M, Carter JF, Fylstra DL, Childers M. A comparative study of hysteroscopic sterilization performed in-office versus a hospital operating room. J Minim Invasive Gynecol. 2006; 13:447–450. [PubMed: 16962530]
23. Panel P, Grosdemouge I. Predictive factors of Essure implant placement failure: prospective, multicenter study of 495 patients. Fertil Steril. 2010; 93:29–34. [PubMed: 19022435]
24. Panel P, Grosdemouge I, Houllier M, Renouvel F, Friederich L, Le Tohic A. Bipolar hysteroscopic procedures and placement of Essure microinserts for tubal sterilization: a case control study. Fertil Steril. 2011; 95:2422–2425. [PubMed: 21497338]
25. Rosen DM. Learning curve for hysteroscopic sterilisation: lessons from the first 80 cases. Aust N Z J Obstet Gynaecol. 2004; 44:62–64. [PubMed: 15089871]
26. Savage UK, Masters SJ, Smid MC, Hung Y, Jacobson GF. Hysteroscopic sterilization in a large group practice. Obstet Gynecol. 2009; 114:1227–1231. [PubMed: 19935023]
27. Sinha D, Kalathy V, Gupta JK, Clark TJ. The feasibility, success and patient satisfaction associated with outpatient hysteroscopic sterilisation. BJOG. 2007; 114:676–683. [PubMed: 17516957]
28. Thiel JA, Lukwinski A, Kamencic H, Lim H. Oral analgesia vs intravenous conscious sedation during Essure micro-insert sterilization procedure: randomized, double-blind, controlled trial. J Minim Invasive Gynecol. 2011; 18:108–111. [PubMed: 21195962]
29. Ubeda A, Labastida R, Dexeus S. Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting. Fertil Steril. 2004; 82:196–199. [PubMed: 15237011]
30. Vellayan M, Baxter A, Connor M, Brown V. The Essure hysteroscopic sterilization procedure: initial experience in Sheffield, UK. Gynecol Surg. 2006; 3:303–307.
31. Vleugels MP, Veersema S. Hysteroscopic sterilisation in the outpatient department without anaesthesia. Gynecol Surg. 2005; 2:155–158.
32. Vleugels M, Heckel S, Veersema S, et al. Hysteroscopic sterilization with Essure device in situ: a challenge? Gynecol Surg. 2011; 8:51–55.
33. Weston G, Bowditch J. Office ultrasound should be the first-line investigation for confirmation of correct Essure placement. Aust NZ J Obstet Gynaecol. 2005; 45:312–315.
34. Shavell VI, Abdallah ME, Diamond MP, Berman JM. Placement of permanent birth control device at a university medical center. J Reprod Med. 2009; 54:218–222. [PubMed: 19438163]

35. Palmer S, Greenberg J. Transcervical sterilization: a comparison of Essure permanent birth control system and Adiana permanent contraception system. Rev Obstet Gynecol. 2009; 2:84–92. [PubMed: 19609402]

36. [Accessed May 25, 2011] Conceptus, Inc. Essure Training Manual: Milestones. Available at: http://www.essuremd.com/Portals/essuremd/PDFs/PST/CC1687_Essure_Training_Manual.pdf.

37. Soper DE. Pelvic inflammatory disease. Obstet Gynecol. 2010; 116:419–428. [PubMed: 20664404]

38. Cherpes TL, Wiesenfeld HC, Melan MA, et al. The associations between pelvic inflammatory disease, *Trichomonas vaginalis* infection, and positive herpes simplex virus type 2 serology. Sex Transm Dis. 2006; 33:747–752. [PubMed: 16691155]

39. CDC. [Accessed June 10, 2011] Sexually transmitted diseases - Interactive data 1996–2008. Available at: http://wonder.cdc.gov/controller/datarequest/D46.

Table 1

Study sample characteristics by insertion status

	Successful insertion (n=292)	Failed insertion (n=18)	p value
Age, median (IQR)	34.0 (30.0–38.0)	32.0 (30.0–37.0)	.242
Race/ethnicity n (%)[≅]			.288
White	95 (33.7%)	3 (16.7%)	
Black	34 (12.1%)	3 (16.7%)	
Hispanic	153 (54.3%)	12 (66.7%)	
Marital status n (%)			.345
Not married	98 (33.6%)	8 (44.4%)	
Married	194 (66.4%)	10 (55.6%)	
Education n (%) [±]			.953
Did not complete HS	101 (43.7%)	8 (44.4%)	
HS graduate	130 (56.3%)	10 (55.6%)	
Parity, median (IQR)	3.0 (2.0–3.0)	3.0 (2.0–3.0)	.657
STI history n (%) [‡]			.042[*]
With STI history	74 (27.5%)	9 (50%)	
Without STI history	195 (72.5%)	9 (50%)	
IUC Use n (%) [≈]			.747
Yes	47 (16.6%)	2 (11.1%)	
No	236 (83.4%)	16 (88.9%)	
BMI, median (IQR)	29.5 (25.8–34.6)	30.0 (26.9–39.1)	.273

IQR= interquartile range; HS = high school

[≅] We omitted our Asian category (n=10) because 10 had successful placement and 0 were in the unsuccessful cell.

[±] Missing data (n=61, 19.7%).

[*] Statistically significant at the p≤ .05 level.

[‡] Missing data (n=23, 7.4%).

[≈] IUC Use is defined as ever used intrauterine contraception as method of birth control. Missing data (n=9, 2.9%).

Table 2

Correlates of failure to insert the Essure devices into the tubes

Characteristics	Odds ratio (95% CI)	*p* value
Age	0.95 (0.87–1.04)	.259
Race/ethnicity[±]		
White	Reference	
Black	2.79 (0.54–14.51)	.222
Hispanic	2.48 (0.68–9.03)	.167
Parity	1.07 (0.74–1.55)	.708
STI history		
No	Reference	
Yes	2.64 (1.01–6.90)	.048[*]

Based on bivariate logistic regression analysis, we could not build multivariate logistic regression models due to the small number of failure of insertion for participants. Dependent variable: Failure to insert (no failure=0, failure =1).

Independent variables: age (continuous), race/ethnicity (non-Hispanic white, non- Hispanic black, Hispanic), parity (continuous), STI history (no STIs=0, one or more STIs=1).

CI= Confidence intervals

[±]We excluded Asian women due to the small sample size of this group

[*]Statistically significant at the p≤ .05 level.