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Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization☆,☆☆

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Abstract

Objective: To compare the expected probability of pregnancy after hysteroscopic versus laparoscopic sterilization based on available data using decision analysis.
Study design: We developed an evidence-based Markov model to estimate the probability of pregnancy over 10 years after three different female sterilization procedures: hysteroscopic, laparoscopic silicone rubber band application and laparoscopic bipolar coagulation. Parameter estimates for procedure success, probability of completing follow-up testing and risk of pregnancy after different sterilization procedures were obtained from published sources.
Results: In the base case analysis at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women opting for hysteroscopic than either laparoscopic band or bipolar sterilization. The expected pregnancy rates per 1000 women at 1 year are 57, 7 and 3 for hysteroscopic sterilization, laparoscopic silicone rubber band application and laparoscopic bipolar coagulation, respectively. At 10 years, the cumulative pregnancy rates per 1000 women are 96, 24 and 30, respectively. Sensitivity analyses suggest that the three procedures would have an equivalent pregnancy risk of approximately 80 per 1000 women at 10 years if the probability of successful laparoscopic (band or bipolar) sterilization drops below 90% and successful coil placement on first hysteroscopic attempt increases to 98% or if the probability of undergoing a hysterosalpingogram increases to 100%.
Conclusion: Based on available data, the expected population risk of pregnancy is higher after hysteroscopic than laparoscopic sterilization. Consistent with existing contraceptive classification, future characterization of hysteroscopic sterilization should distinguish "perfect" and "typical" use failure rates.
Implications: Pregnancy probability at 1 year and over 10 years is expected to be higher in women having hysteroscopic as compared to laparoscopic sterilization.

Keywords: Female sterilization; Hysteroscopic sterilization; Laparoscopic sterilization; Tubal ligation; Pregnancy after sterilization; Sterilization failure

1. Introduction

Female surgical sterilization is the most popular method of pregnancy prevention worldwide and is the most commonly used method of contraception among women age 35 years and older in the United States (U.S.) [1,2]. Each year, 345,000 U.S. women undergo sterilization procedures and a total of 10.3 million U.S. women rely on female sterilization for pregnancy prevention [3,4].

Since the introduction of a hysteroscopic approach in 2001, an increasing number of women are undergoing hysteroscopic sterilization instead of laparoscopic sterilization [5–7]. Hysteroscopic sterilization has several advantages over laparoscopic sterilization: it avoids abdominal entry, can be performed as an office procedure and may avoid general anesthesia [5]. More than 650,000 hysteroscopic sterilization procedures have been performed worldwide [5]. One U.S. academic center reported that the proportion of interval sterilization performed laparoscopically from 2002 to 2006 decreased by 50% with a

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corresponding increase in the proportion of procedures performed by hysteroscopic sterilization by 50% [6].

However, hysteroscopic sterilization has limitations as well. The likelihood of achieving successful bilateral coil placement on first attempt varies from 76% to 96% [8–22]. In addition, unlike laparoscopic sterilization, hysteroscopic sterilization is not immediately effective; at least 3 months is required for tubal fibrosis and occlusion to occur for the procedure to be effective. During these 3 months, women need to use alternative contraception until they can undergo a post-procedure hysterosalpingogram (HSG) to confirm bilateral tubal blockage [23]. Prior research has shown that some (6–87%) women never return for their HSGs [8,10,12–14,16–19,24] and that blockage does not occur in 5–16% of HSG evaluations 3 months post-procedure [8,12–14,16–19]. The multiple steps involved in hysteroscopic sterilization, including the 3-month delay in possibly achieving sterilization, can increase the risk of patient non-compliance with this clinical care protocol and subject women to contraceptive failures (unintended pregnancies) during the process [23].

For any new method of contraception or sterilization, the most important variable to scrutinize is effectiveness. Unfortunately, the literature on hysteroscopic sterilization is limited by lack of such data [2,25–27]. Most studies of its efficacy have excluded women who failed initial microinsert placement did not return for HSG or who became pregnant before their HSG [23]. Furthermore, there are no prospective studies comparing the effectiveness of hysteroscopic and laparoscopic sterilizations. Most studies that do retrospectively report pregnancies after hysteroscopic sterilization are limited by small study numbers, short follow-up duration, lack of reporting follow-up duration and high loss to follow-up [27,28].

We sought to gain a more objective and comprehensive understanding of hysteroscopic sterilization outcomes, based on the published literature. In the absence of a prospective study directly comparing short- and long-term probability of pregnancy after hysteroscopic and laparoscopic sterilization procedures, the best way to understand the consequences of the two contraceptive approaches is through a decision analytic model. Decision analysis can account for the complexity of the multi-step process for coil placement and follow-up, can incorporate the variability in clinical outcomes reported in the literature and can compare the expected probability of pregnancy after hysteroscopic and laparoscopic sterilization. Also, by mapping out the clinical pathway of these procedures, it provides a unique opportunity to identify knowledge gaps in the current literature and help set priorities for future research.

2. Materials and methods

2.1. Study design

We developed a Markov state-transition model (Fig. 1) to estimate the probability of pregnancy following three sterilization strategies: hysteroscopic, laparoscopic with silicone rubber band application (falope rings) and laparoscopic with bipolar coagulation. Laparoscopic sterilization was chosen as the comparator for the newer hysteroscopic sterilization procedure, since it is the standard of care for interval (not related to pregnancy) female sterilization [2]. Using yearly cycles, the Markov model mapped health states (major clinical events) and clinical pathways between those states following each strategy. These health states and pathways included successful or failed sterilization attempts, follow-up procedures and their outcomes and progression to alternative procedures if prior procedures were unsuccessful and their outcomes. Fig. 1 depicts this complex model that incorporates the probabilities of the health states and pathways (Table 1) to estimate the risk of pregnancy.

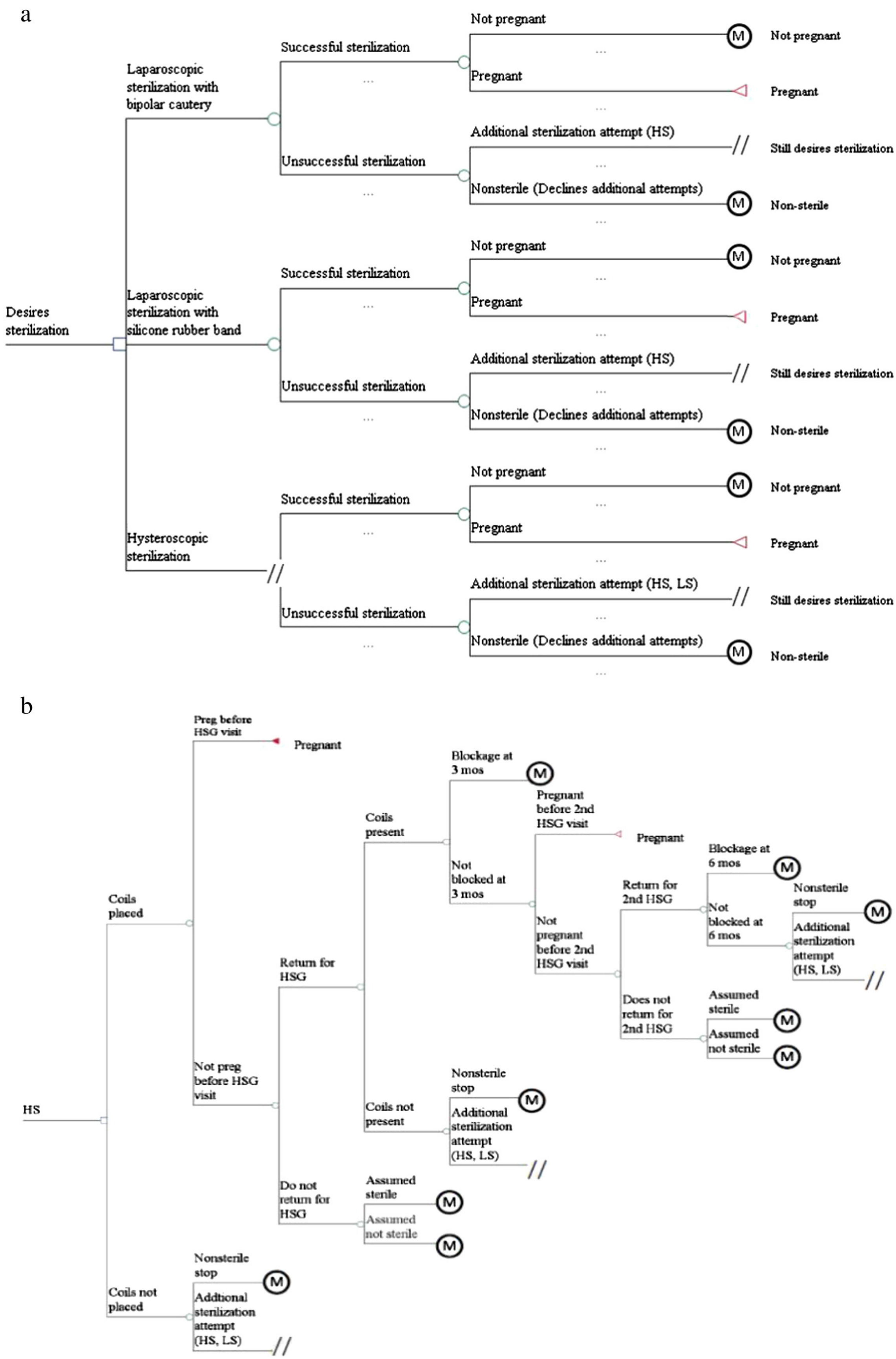
We estimated the expected probability of pregnancy in hypothetical cohorts of women based on available data. Sterilization success was defined in accordance with standard clinical practice. A successful hysteroscopic sterilization was defined as having bilateral blockage of fallopian tubes on follow-up HSG. A successful laparoscopic sterilization was defined as physical fallopian tube obstruction at surgery.

Procedure characteristics and follow-up testing probabilities were estimated from published sources (Table 1). Resultant sterilizations and pregnancies within each cohort were attributed to the initial procedure. Thus, women undergoing hysteroscopic sterilization who ultimately received laparoscopic sterilization were counted as hysteroscopic successes. Cohorts were followed in the model for 10 years. In the absence of published data, assumptions from a previous and similar model [25], where relevant, were carried over to this analysis. Data not obtainable from published literature were acquired from our practice's active database, initiated in July 2003. Standard decision analysis software (TreeAge Pro Suite 2012) was used.

2.2. Data sources for hysteroscopic sterilization

For hysteroscopic sterilization, we used data on Essure® hysteroscopic sterilization, as it is the only method available. Base case values and reported ranges of the relevant parameters (Table 1) came from a comprehensive literature search of all pertinent studies in English in PubMed and Ovid last searched September 20, 2013, and by reviewing the bibliographies of identified references. All published studies that reported more than 50 subjects were included. Base case values are weighted by study sample size averages from those studies. Data from studies not using HSG to evaluate hysteroscopic sterilization success as required by the U.S. Food and Drug Administration (FDA) were not included.

Scant data are available regarding pregnancy risk after hysteroscopic sterilization [2,25–27]; the most recent available data are from the Essure package insert, updated between April and August 2012. From 2001 to 2010, 748 pregnancies following an Essure procedure were reported to the manufacturer, the FDA, or in published reports; the company also reported sales of 497,306 Essure kits during that time period [30]. To calculate the risk of pregnancy after a confirmatory HSG shows bilateral occlusion, we excluded


a
Desires sterilization
Laparoscopic sterilization with bipolar cautery
Laparoscopic sterilization with silicone rubber band
Hysteroscopic sterilization
Successful sterilization
Unsuccessful sterilization
Not pregnant
Pregnant
Additional sterilization attempt (HS)
Additional sterilization attempt (HS, LS)
Nonsterile (Declines additional attempts)
Still desires sterilization
Non-sterile
b
HS
Coils placed
Coils not placed
Preg before HSG visit
Pregnant
Not preg before HSG visit
Return for HSG
Do not return for HSG
Coils present
Coils not present
Blockage at 3 mos
Not blocked at 3 mos
Pregnant before 2nd HSG visit
Not pregnant before 2nd HSG visit
Return for 2nd HSG
Does not return for 2nd HSG
Blockage at 6 mos
Not blocked at 6 mos
Nonsterile stop
Additional sterilization attempt (HS, LS)
Addtional sterilization attempt (HS, LS)
Assumed sterile
Assumed not sterile

Q2

Fig. 1.

t1.1 Table 1
t1.2 Parameter values for model

	Probability of	Baseline value (%)	Range (%)	Reference or assumption
t1.3	Probability of	Baseline value (%)	Range (%)	Reference or assumption
t1.4	Laparoscopic sterilization			
t1.5	Successful LS	99	99–100	8, 29
t1.6	Choosing HS if LS failed	20	10–50	Author consensus
t1.7	Hysteroscopic sterilization			
t1.8	Successful coil placement on first attempt	92	76–96	8–22
t1.9	Returning for HSG at 3 months	79	13–94	8, 10, 12–14, 16
t1.10	HSG: coils present at 3 months	96	95–99	14, 17–19
t1.11	HSG: blockage at 3 months	95	84–100	8, 12–14, 16–19
t1.12	Returning for HSG at 6 months	79	13–94	Assume same as for 3 months
t1.13	HSG: blockage at 6 months	94	93–100	12, 14, 16–18
t1.14	Assumed sterile if do not return for HSG	91 (95% of 96%)	84–100	Assume same as women returning at 3 and 6 months
t1.15	Additional sterilization attempts			
t1.16	Choosing another procedure (HS or LS) after one failed HS attempt (unable to place coils)	63	21–100	8–11, 14, 16, 21
t1.17	Choosing LS after one failed HS attempt	79	33–100	9–11, 14, 16, 21
t1.18	Choosing LS after two failed HS attempts	92	72–100	19, Practice database
t1.19	Successful coil placement on second HS attempt	68	67–100	8, 9, 11, 16, 18, 21, 22
t1.20	If HSG at 3 months shows no coils or HSG at 6 months shows non-occlusion			
t1.21	Choosing another procedure	30		Practice database
t1.22	Choosing second HS	50		Practice database
t1.23	Occlusion with second HS	48	45–100	19, Practice database
t1.24	Pregnancy after hysteroscopic sterilization			
t1.25	Among women using contraception (after HS and before HSG)			
t1.26	During 3 months waiting period after HS	4.2	0.05–20	31, 32
t1.27	Incremental pregnancy months 3–6	3.1		
t1.28	During 6 months waiting period after HS	7.3	0.05–20	31, 32
t1.29	Incremental pregnancy months 6–9	2.6		
t1.30	During 9 months waiting period after HS	9.9	0.05–20	31
t1.31	Incremental pregnancy months 9–12	2.5		
t1.32	Annually, years 2–10	12.4	0.05–20	3, 31, 32
t1.33	Among women not using contraception (after HS and before HSG)			
t1.34	During 3 months of no contraception	21		32
t1.35	Incremental pregnancy months 3–6 no contraception	22		
t1.36	During 6 months of no contraception	43		32
t1.37	Incremental pregnancy months 6–9 no contraception	21		
t1.38	During 9 months of no contraception	64		32
t1.39	Incremental pregnancy months 9–12 no contraception	21		
t1.40	Annually, years 2–10	85		32
t1.41	After HSG			
t1.42	Annually if bilateral occlusion not confirmed	12.4	0.05–20	3, 31, 32
t1.43	Annually if bilateral occlusion confirmed[a]	0.004	0–0.5	30
t1.44	Monthly risk after occlusion confirmed	0.0003		Calculation from above
t1.45	Pregnancy after laparoscopic sterilization[b]			
t1.46	Pregnancy after silicone band application			
t1.47	Year 1	0.59	0.33–0.85	33
t1.48	Year 2	0.17	0–0.73	33
t1.49	Year 3	0.07	0.03–0.69	33
t1.50	Year 4	0.07	0–0.73	33
t1.51	Year 5	0.10	0–0.78	33
t1.52	Year 6	0.00	0–0.71	33
t1.53	Year 7	0.30	0–1.21	33
t1.54	Year 8	0.31	0–1.55	33
t1.55	Year 9	0.00	0–1.39	33
t1.56	Year 10	0.16	0–1.62	33

Table 1 (*continued*)

Probability of	Baseline value (%)	Range (%)	Reference or assumption
Pregnancy after bipolar coagulation			
Year 1	0.23	0.03–0.42	33
Year 2	0.23	0–0.72	33
Year 3	0.21	0–0.84	33
Year 4	0.64	0–1.50	33
Year 5	0.34	0–1.45	33
Year 6	0.18	0–1.41	33
Year 7	0.24	0–1.77	33
Year 8	0.13	0–1.52	33
Year 9	0.13	0–1.69	33
Year 10	0.15	0–1.81	33

Abbreviations: LS, laparoscopic sterilization; HS, hysteroscopic sterilization.

[a] The manufacturer reports 748 pregnancies following an Essure procedure and sales of 497,306 HS kits during the same time period [30]. To estimate the rate of pregnancy after confirmatory HSG, we excluded the following pregnancies: (1) 32 luteal phase pregnancies that should not differ between laparoscopic and hysteroscopic sterilization, (2) 229 pregnancies due to patient non-compliance, (3) 95 pregnancies due to perforation, (4) 45 pregnancies due to unsatisfactory placement and (5) 35 pregnancies due to physician non-compliance. The latter four categories were excluded because they more likely occurred prior to HSG confirmation of tubal blockage. An additional 240 pregnancies were reported as "insufficient information." We assumed half of these pregnancies occurred before HSG testing. This resulted in a total of 192 pregnancies (748 total pregnancies minus 556 pregnancies before HSG) occurring after HSG testing among 496,750 sterilizations over 10 years, i.e., 0.4 pregnancies per 1000 sterilizations over 10 years [or 0.004% annual pregnancy rate, which was calculated as $1-(1-0.0004)^{(1/10)}$].

[b] To calculate the annual rate of pregnancy after LS, we used the cumulative pregnancy rate reported in CREST [33] to denote the point estimate of the cumulative pregnancy rate for year t as $P(t)$, upper bound of the 95% confidence interval of the cumulative pregnancy rate in year t as $P_u(t)$ and the lower bound of the 95% confidence interval of the cumulative pregnancy rate in year t as $P_l(t)$. For year t after LS, we calculated the annual pregnancy rate as $P(t)-P(t-1)$, the upper bound of the annual pregnancy rate as $P_u(t)-P_l(t-1)$ and the lower bound of the annual pregnancy rate as $P_l(t)-P_u(t-1)$ (but restricted to ≥ 0).

32 luteal phase pregnancies, which should not differ between laparoscopic and hysteroscopic sterilization, and 524 pregnancies that occurred prior to HSG (e.g., patient non-compliance, perforation, unsatisfactory placement, physician non-compliance). This provided a conservative estimate of pregnancy risk after HSG of 192 per 496,750 over 10 years (0.4 per 1000 sterilizations) and an annual pregnancy rate of 0.004% after HSG testing (Table 1).

2.3. Data sources for laparoscopic sterilization

Data from the U.S. Collaborative Review of Sterilization (CREST), the largest prospective study (n=12,138) of laparoscopic sterilization, were used for base case values and ranges of pregnancy risk after laparoscopic sterilization [33]. The study, which enrolled women during 1978–1987, included all procedures currently used in practice today except for the Filshie clip. Because of a lack of long-term Filshie clip follow-up data, this method was not included in the current model. We modeled pregnancy risk after laparoscopic sterilization using silicone rubber band application and bipolar coagulation.

2.4. Interventions and measures

Sterilizations via hysteroscopy, laparoscopy with silicone rubber band application and laparoscopy with bipolar coagulation were tested in identical hypothetical cohorts. The model used estimated probabilities of women undergoing a second or third sterilization attempt after one failed attempt from the published literature (Table 1). Pregnancy following hysteroscopic sterilization may occur at four different time points: (1) during the 3- or 6-month waiting period when patients rely on alternative contraception before confirmatory HSG testing, (2) after HSG fails to confirm bilateral occlusion, (3) after HSG confirms bilateral occlusion and (4) after a failed hysteroscopic sterilization attempt when no further sterilization attempts occur. While the probability of hysteroscopic sterilization success was assumed to be identical whether or not women completed follow-up HSG testing, the risk of pregnancy differs. This is because women who did not have a follow-up HSG would not know if they were still at risk for pregnancy and may not be using additional necessary contraception, hence resulting in a higher risk of pregnancy (Table 1).

Cohorts were followed for 10 years, consistent with the analysis of pregnancy risk in the CREST study [33]. Finally, to simulate real patient experiences, we also used published data on contraceptive use and pregnancies from Cycle 6 of the U.S. National Survey of Family Growth and calculated weighted average pregnancy risk over time among U.S. women using reversible contraception [31]. These calculations for contraceptive failure were used to determine pregnancy risk for women awaiting a confirmatory HSG and for women who stop pursuing sterilization and rely on routine contraception instead [32] (Table 1). We conducted both one-way and two-way sensitivity analyses to assess the impact on findings when varying the value of a single parameter (one-way sensitivity analysis) and the values of two parameters simultaneously (two-way sensitivity analysis) in the model. The plausible range for each parameter is listed in Table 1.

3. Results

In the base case analysis at all points in time after the sterilization procedure (ranging from 1 year to 10 years after procedure initiation), the expected cumulative risk of pregnancy after sterilization is higher in women opting for hysteroscopic than laparoscopic sterilization using silicone band application or bipolar coagulation. Pregnancy risk after hysteroscopic sterilization is primarily accrued in the first year after initiating the process. The expected pregnancy rates per 1000 women at 1 year are 57, 7 and 3 for hysteroscopic sterilization, laparoscopic silicone rubber band application and laparoscopic bipolar coagulation, respectively. At 10 years, the cumulative pregnancy rates per 1000 women are 96, 24 and 30, respectively (Fig. 2).

One-way sensitivity analyses suggest that pregnancy risk after hysteroscopic or laparoscopic sterilization is most influenced by the probability of the following events: pregnancy during 3 months of routine contraception use after successfully performed hysteroscopic sterilization, choosing a second procedure after one failed hysteroscopic sterilization attempt, returning for mandated HSG, the assumption of sterility among women who do not return for HSG, pregnancy after confirmed bilateral occlusion in hysteroscopic sterilization, probability of successful coil placement on first hysteroscopic sterilization attempt and successful laparoscopic sterilization procedure.

Results from our two-way sensitivity analyses also informed us of which variables would need to change and by how much they would need to change to create equal effectiveness between hysteroscopic and laparoscopic sterilization. To reach equivalency, the probability of successful band or bipolar laparoscopic sterilization would need to decrease below 90% (base case, 99%) and one of three improvements in hysteroscopic outcomes would need to occur: (1) the probability of successful bilateral coil placement on first hysteroscopic sterilization attempt would need to increase to 98% (base case, 92%), (2) the probability of choosing a second procedure after one failed hysteroscopic sterilization would need to increase to $\geq$93% (base case, 63%) or (3) the probability of returning for the mandated HSG would need to increase to 100% (base case, 79%). Under these circumstances, the three procedures would have an equivalent pregnancy risk of approximately 80 per 1000 women at 10 years.

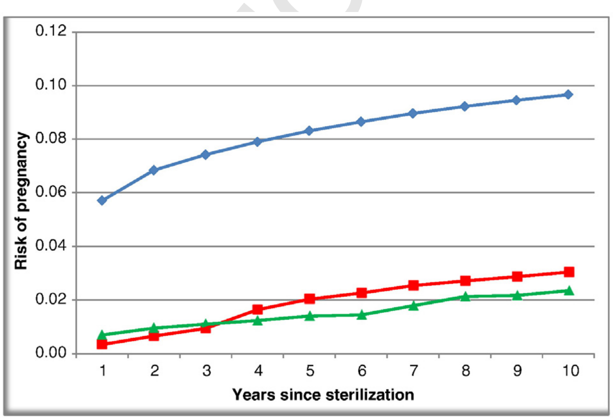


Fig. 2.

4. Discussion

Based on best data currently available, our model suggests that hysteroscopic sterilization is not as effective as laparoscopic sterilization in preventing pregnancy when the complete clinical pathways of the procedures are considered. Our analysis improves upon prior studies of hysteroscopic sterilization by taking into account uncertainties in successful placement of coils, return for HSG and successful blockage of tubes. Reflecting these real-life circumstances, our base case estimates showed that a woman undergoing hysteroscopic sterilization is expected to have a pregnancy risk of 96 per 1000 women after 10 years, compared to 24 and 30 per 1000 women for laparoscopic sterilization with silicone rubber band and bipolar cautery, respectively.

This analysis expands upon our previous study that compared the likelihood of successful bilateral tubal occlusion after hysteroscopic versus laparoscopic sterilization procedures [25]. By estimating the risk of pregnancy after both sterilization procedures over a 10-year period, our current study provides important new data on expected long-term outcomes. This information is essential for patients and clinicians.

Our findings have important implications for future development of hysteroscopic sterilization products. The higher pregnancy rate over 10 years with hysteroscopic compared to laparoscopic sterilization is primarily driven by first-year failures because the subsequent failure per year is similar between hysteroscopic and laparoscopic methods. Future efforts to improve hysteroscopic sterilization need to focus on its higher first-year failure risk, which is primarily influenced by the rate of successful placement of both coils on first attempt, lack of immediate effectiveness and need for follow-up evaluations.

Even if certain steps of the hysteroscopic sterilization procedure are optimized (e.g., 98% bilateral coil placement), laparoscopic sterilization remains superior unless the probability of successfully performing a laparoscopic sterilization procedure also drops below 90%, which is not clinically probable. Thus, the expected higher failure rate of hysteroscopic sterilization needs to be considered and communicated to patients, in conjunction with its benefits when counseling patients about female sterilization options. Unintended pregnancy resulting from sterilization failure can have serious consequences for both women's quality of life and maternal and neonatal health outcomes and should be considered a significant adverse event.

We recognize that although we have used the best evidence available, our analysis is limited by the quality of the data used in the model. There are no prospective studies on pregnancy risk after hysteroscopic sterilization [2,25–27], let alone studies directly comparing the effectiveness of hysteroscopic and laparoscopic sterilizations [2,25–27]. Of the retrospective studies of pregnancy after hysteroscopic sterilization, most are limited by small study numbers, short follow-up duration, lack of reporting follow-up duration, high loss to follow-up, reliance on X-ray instead of HSG for confirmation, passive reporting of pregnancy or estimates of the number of procedures performed [25–27,30,34]. For example, one large retrospective study of 4306 women from Spain reported 7 (0.16%) pregnancies over 7 years, but only 20% of the original cohort had follow-up for 7 years, and abdominal X-ray was used primarily instead of HSG [28]. Hence we estimated the pregnancy rate after hysteroscopic sterilization based on passive (not mandatory) pregnancy reporting data to FDA and the manufacturer and the manufacturer's estimates of the number of Essure kits sold (rather than the number of devices actually implanted). The inability to account for unused kits, failed procedures or multiple attempts could have resulted in an underestimated pregnancy rate for hysteroscopic sterilization [30].

Similarly, the CREST data, which provided the pregnancy rates after laparoscopic sterilization for our analysis, have limitations too. The CREST was a longitudinal prospective study of laparoscopic sterilization procedures performed 26–34 years ago, early in the "learning curve" of laparoscopic surgery [2,35]. Consequently, our estimated pregnancy outcome may be biased in favor of hysteroscopic sterilization.

Nevertheless, our analysis is a useful first step to understand the full impact of hysteroscopic sterilization on pregnancy risk, based on currently available data. The finding that laparoscopic is superior to hysteroscopic sterilization occurred despite a bias in favor of hysteroscopic sterilization in the analysis. That is, the study assessed outcome by initial method of sterilization attempted, including 6% of women starting with hysteroscopic sterilization that are ultimately sterilized laparoscopically [25]. Thus, women undergoing hysteroscopic sterilization who ultimately received laparoscopic sterilization, which had a higher success rate, were counted as hysteroscopic successes. Future research from a prospective cohort of women undergoing hysteroscopic and laparoscopic sterilization procedures with high long-term follow-up rates would enhance our understanding of hysteroscopic sterilization effectiveness.

Contraceptive methods are ranked by effectiveness and characterized by "perfect" and "typical" use failure rates. Methods requiring multiple steps (i.e., frequent compliance) like combined hormonal contraceptive pills have higher typical use failure rates than the corresponding perfect use failure rates and are significantly less effective than one-step methods such as intrauterine devices and contraceptive implants [32,33]. This difference in perfect and typical use failure rates is also important to consider when assessing the effectiveness of multi-step hysteroscopic sterilization. However, most rankings do not differentiate hysteroscopic from laparoscopic sterilization and do not ascribe different failure rates for perfect and typical sterilization use. Our findings suggest that it is time to rethink this characterization.

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References

[1] EngenderHealth. Contraceptive sterilization: global issues and trends. New York, NY: EngenderHealth; 2002, pp. 17–64.
[2] Peterson HB. Sterilization. Obstet Gynecol 2008;111:189–203.
[3] Jones J, Mosher W, Daniels K. Current contraceptive use in the United States, 2006–2010, and changes in patterns of use since 1995. Natl Health Stat Rep 2012;60:1–5.
[4] Mosher WD, Jones J. Use of contraception in the United States: 1982–2008. Vital Health Stat 23 2010:1–4.
[5] Conceptus. Essure permanent birth control. Available at: , http://www.essuremd.com/about-essure Retrieved March 25, 2013.
[6] Shavell VI, Abdallah ME, Shade Jr GH, Diamond MP, Berman JM. Trends in sterilization since the introduction of Essure hysteroscopic sterilization. J Minim Invasive Gynecol 2009;16:22–7.
[7] Connor VF. Essure: a review six years later. J Minim Invasive Gynecol 2009;16(3):282–90.
[8] Duffy S, Marsh F, Rogerson L, Hudson H, Cooper K, Jack S, et al. Female sterilisation: a cohort controlled comparative study of ESSURE versus laparoscopic sterilisation. BJOG 2005;112:1522–8.
[9] Ubeda A, Labastida R, Dexeus S. Essure: a new device for hysteroscopic tubal sterilization in an outpatient setting. Fertil Steril 2004;82:196–9.
[10] Shavell VI, Abdallah ME, Diamond MP, Kmak DC, Berman JM. Post-Essure hysterosalpingography compliance in a clinic population. J Minim Invasive Gynecol 2008;15:431–4.
[11] Shavell VI, Abdallah ME, Diamond MP, Berman JM. Placement of a permanent birth control device at a university medical center. J Reprod Med 2009;54:218–22.
[12] Savage UK, Masters SJ, Smid MC, Hung YY, Jacobson GF. Hysteroscopic sterilization in a large group practice: experience and effectiveness. Obstet Gynecol 2009;114:1227–31.
[13] Levie M, Chudnoff SG. Prospective analysis of office-based hysteroscopic sterilization. J Minim Invasive Gynecol 2006;13:98–01.
[14] Sinha D, Kalathy V, Gupta JK, Clark TJ. The feasibility, success and patient satisfaction associated with outpatient hysteroscopic sterilisation. BJOG 2007;114:676–83.
[15] Levie M, Chudnoff SG. A comparison of novice and experienced physicians performing hysteroscopic sterilization: an analysis of an FDA-mandated trial. Fertil Steril 2011;96:643e1–8e1.
[16] Chen BA, Hayes JL, Reeves MF, Creinin MD. Outcomes of transcervical hysteroscopic sterilization in an urban academic medical center. Contraception 2009;80:205.
[17] Kerin JF, Carignan CS, Cher D. The safety and effectiveness of a new hysteroscopic method for permanent birth control: results of the first Essure pbc clinical study. Aust N Z J Obstet Gynaecol 2001;41:364–70.
[18] Kerin JF, Cooper JM, Price T, Herendael BJ, Cayuela-Font E, Cher D, et al. Hysteroscopic sterilization using a micro-insert device: results of a multicentre Phase II study. Hum Reprod 2003;18:1223–30.
[19] Cooper JM, Carignan CS, Cher D, Kerin JF, Selective Tubal Occlusion Procedure 2000 Investigators Group. Microinsert nonincisional hysteroscopic sterilization. Obstet Gynecol 2003;102:59–67.
[20] Nichols M, Carter JF, Fylstra DL, Childers M, Essure System U.S. Post-Approval Study Group. A comparative study of hysteroscopic sterilization performed in-office versus a hospital operating room. J Minim Invasive Gynecol 2006;13:447–50.
[21] Andersson S, Eriksson S, Mints M. Hysteroscopic female sterilization with Essure in an outpatient setting. Acta Obstet Gynecol Scand 2009;88:743–6.
[22] Miño M, Arjona JE, Cordón J, Pelegrin B, Povedano B, Chacon E. Success rate and patient satisfaction with the Essure sterilisation in an outpatient setting: a prospective study of 857 women. BJOG 2007;114(6):763–6.
[23] ACOG Committee on Gynecologic Practice. ACOG Committee Opinion No. 458: hysterosalpingography after tubal sterilization. Obstet Gynecol 2010;115:1343–5.

[24] Thiel JA, Carson GD. Cost-effectiveness analysis comparing the essure tubal sterilization procedure and laparoscopic tubal sterilization. J Obstet Gynaecol Can 2008;30:581–5.
[25] Gariepy AM, Creinin MD, Schwarz EB, Smith KJ. Reliability of laparoscopic compared with hysteroscopic sterilization at 1 year: a decision analysis. Obstet Gynecol 2011;118:273–9.
[26] Hurskainen R, Hovi SL, Gissler M, Grahn R, Kukkonen-Harjula K, Nord-Saari M, et al. Hysteroscopic tubal sterilization: a systematic review of the Essure system. Fertil Steril 2010;94:16–9.
[27] Cleary TP, Tepper NK, Cwiak C, Whiteman MK, Jamieson DJ, Marchbanks PA, et al. Pregnancies after hysteroscopic sterilization: a systematic review. Contraception 2013;87(5):539–48.
[28] Povedano B, Arjona JE, Velasco E, Monserrat JA, Lorente J, Castelo-Branco C. Complications of hysteroscopic Essure(®) sterilisation: report on 4306 procedures performed in a single centre. BJOG 2012; 119(7):795–9.
[29] Destefano F, Greenspan JR, Dicker RC, Peterson HB, Strauss LT, Rubin GL. Complications of interval laparoscopic tubal sterilization. Obstet Gynecol 1983;61:153–8.
[30] Conceptus. Essure permanent birth control. Available at: , http://www.essuremd.com/about-essure/clinical-data Retrieved March 25, 2013.
[31] Kost K, Singh S, Vaughan B, Trussell J, Bankole A. Estimates of contraceptive failure from the 2002 National Survey of Family Growth. Contraception 2008;77:10–21.
[32] Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.
[33] Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. Am J Obstet Gynecol 1996; 174:1161–8.
[34] Levy B, Levie MD, Childers ME. A summary of reported pregnancies after hysteroscopic sterilization. J Minim Invasive Gynecol 2007;14: 271–4.
[35] Peterson HB, Xia Z, Wilcox LS, Tylor LR, Trussell J. Pregnancy after tubal sterilization with bipolar electrocoagulation. U.S. Collaborative Review of Sterilization Working Group. Obstet Gynecol 1999;94: 163–7.

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