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Reliability of Laparoscopic Compared With Hysteroscopic Sterilization at 1 Year

A Decision Analysis

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OBJECTIVE: To estimate the probability of successful sterilization after an hysteroscopic or laparoscopic sterilization procedure.

METHODS: An evidence-based clinical decision analysis using a Markov model was performed to estimate the probability of a successful sterilization procedure using laparoscopic sterilization, hysteroscopic sterilization in the operating room, and hysteroscopic sterilization in the office. Procedure and follow-up testing probabilities for the model were estimated from published sources.

RESULTS: In the base case analysis, the proportion of women having a successful sterilization procedure on the first attempt is 99% for laparoscopic sterilization, 88% for hysteroscopic sterilization in the operating room, and 87% for hysteroscopic sterilization in the office. The probability of having a successful sterilization procedure within 1 year is 99% with laparoscopic sterilization, 95% for hysteroscopic sterilization in the operating room, and 94% for hysteroscopic sterilization in the office. These estimates for hysteroscopic success include approximately 6% of women who attempt hysteroscopically but are ultimately sterilized laparoscopically. Approximately 5% of women who have a failed hysteroscopic attempt decline further sterilization attempts.

CONCLUSION: Women choosing laparoscopic sterilization are more likely than those choosing hysteroscopic sterilization to have a successful sterilization procedure within 1 year. However, the risk of failed sterilization and subsequent pregnancy must be considered when choosing a method of sterilization.

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Female sterilization is one of the most commonly used methods of contraception. Of the 38.2 million U.S. women using a form of contraceptive between 2006 and 2008, 27% used female sterilization.[1] Although this proportion has been stable since 1988, the methods used to achieve sterilization have changed.[2]

Hysteroscopic sterilization has been commercially available since 2002. Advantages of hysteroscopic sterilization include that it is a nonincisional method, avoids abdominal entry (which may be especially important in women with adhesions or comorbidities), can be performed as an office procedure, and avoids general anesthesia. A 6-year review of sterilization trends at a U.S. academic medical center from 2002–2006 showed a 50% decline in both laparoscopic sterilization and postpartum sterilizations and a corresponding 50% increase in hysteroscopic sterilization.[3] According to the manufacturer of Essure, the most popular hysteroscopic sterilization system, approximately 310,000 devices have been placed as of 2010.[4]

However, unlike laparoscopic sterilization, which conveys immediate reliability, hysteroscopic sterilization is a multistep process in which the hysteroscopic sterilization procedure is followed by a confirmatory hysterosalpingogram performed at least 3 months

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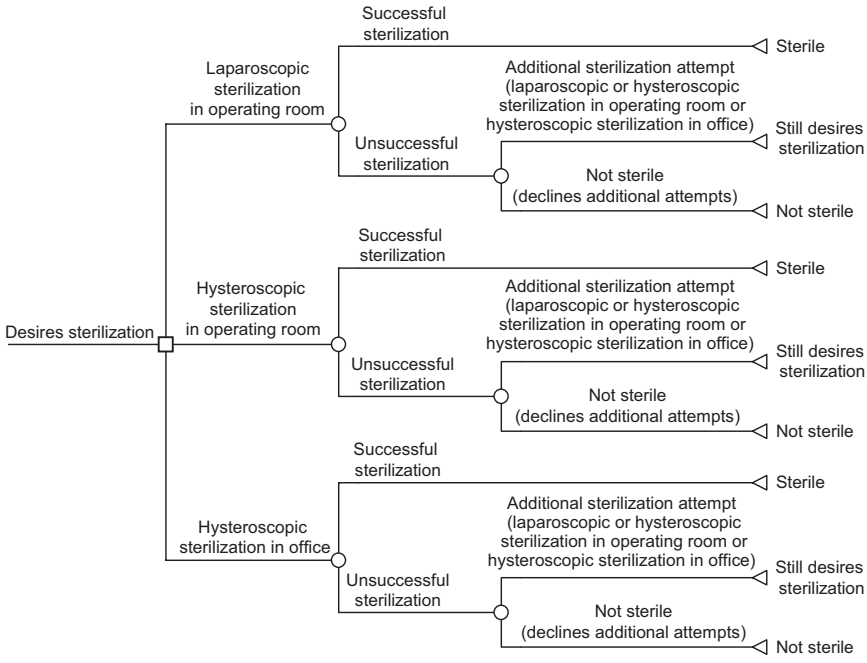

Fig. 1. The Markov model for probability of a successful sterilization procedure using the laparoscopic compared with the hysteroscopic approach.
Gariepy. Laparoscopic and Hysteroscopic Sterilization. Obstet Gynecol 2011.

after the initial procedure to prove bilateral tubal occlusion before women can rely on this method of contraception.[5] For women without occlusion but with devices present, an additional hysterosalpingogram may be indicated 3 months later. Alternative contraception must be used until occlusion is proven. Each step of this process introduces a chance of finding that the procedure failed, of noncompliance with use of alternative contraception, or loss to follow-up. Failed attempts at hysteroscopic sterilization can subject women to multiple procedures, a delay in achieving sterilization, and increase the risk of unintended pregnancy.

Current published assessments of hysteroscopic sterilization success do not adequately address these complex issues. Reported success rates often exclude women who failed initial microinsert placement or did not return for hysterosalpingogram, thereby falsely elevating the percentages of successful sterilization. Accordingly, we performed an evidence-based decision analysis that includes these complexities to better estimate the likelihood of a successful sterilization procedure after hysteroscopic sterilization or laparoscopic sterilization.

MATERIALS AND METHODS

We developed an evidence-based Markov decision model (Fig. 1) to compare the probability of a successful sterilization procedure through three strategies: laparoscopic sterilization, hysteroscopic sterilization in the operating room, and hysteroscopic sterilization in the office setting. The Markov model, using monthly cycles, contains health states and transition probabilities between those states corresponding to differing paths that could occur with each strategy, including the probabilities of successful sterilization, of follow-up procedures (and their outcomes), and of proceeding with alternative procedures (and their success) if prior procedures were unsuccessful.

The primary objective of the model was to estimate the probability of successful sterilization after hysteroscopic sterilization or laparoscopic sterilization based on available data. Hysteroscopic sterilization and laparoscopic sterilization success were defined in accordance with standard clinical practice. A successful hysteroscopic sterilization procedure was defined as having bilateral blockage of fallopian tubes on follow-up hysterosalpingogram evaluation. A successful laparoscopic sterilization procedure was defined as physical obstruction of the fallopian tubes at the time of surgery.

For the model, women were maintained in groups based on the original attempted procedure. Thus, women in hysteroscopic sterilization strategies who ultimately received laparoscopic sterilization were counted as an hysteroscopic sterilization success, biasing against the laparoscopic sterilization strategy. Cohorts were followed for 1 year. Standard decision analysis software was used (TreeAge Pro Suite 2009).

Table 1. Parameter Values Used in the Model

Probability of	Baseline Value (%)	Range (%)	Reference or Assumption
Laparoscopic sterilization			
Successful LS	99–100	99–100	6, 7
Choose HS in OR if LS failed	20	10–50	Expert opinion
Major complication	1	0.098–1.7	7–11
Minor complication	0.5	0.26–1	10, 11
Probability of death	0		7, 8, 12
HS in OR			
Successful coil placement on first attempt	90	85–95	12–19
Major complication	0.13	0–0.4	12, 14, 16
Minor complication	5	4–7	12–14, 16
Choose second OR procedure	70	41–100	13, 17–19
Choose LS after one failed HS in OR	83	67–100	13, 17–19
Successful coil placement on second attempt	84	67–100	12, 13, 17, 19
Probability of death	0		12
HS in office			
Successful coil placement on first HS attempt	90	76–96	6, 15, 20–23
Major complication	0		20, 24, 25
Minor complication	5	2–8	20, 24, 25
Choose second procedure after one failed	70	21–100	6, 20, 24
Choose HS	33	0– 67	20, 24
Successful coil placement on second attempt	80	67–100	6, 20, 22
Probability of death	0		15
HSG outcomes			
Returning for HSG at 3 mo	69	13–94	6, 13, 18, 21, 23, 24
HSG: coils present	97	95–99	12, 14, 16, 24
HSG: blockage at 3 mo	96	84–100	6, 12–14, 16, 21, 23, 24
Returning for HSG at 6 mo	69	13–94	Assume same as for 3 mo
HSG: blockage at 6 mo	98	93–100	12–14, 24
Assumed sterile if do not return for HSG	96	84–99	Assume same as for women who do return at 3 and 6 mo
If HSG at 3 mo shows nonocclusion			
Initial procedure in OR			
Choosing another procedure	30		Practice database
Choosing second HS in OR	50		Practice database
Occlusion with second HS in OR	73	45–100	16, Practice database
Initial procedure in office			
Choosing another procedure			Assume same as OR
Choosing second HS in office			Assume same as OR
Occlusion with second HS in office			Assume same as OR
If two failed HS attempts			
LS after two failed HS in OR	87		16, Practice database
LS after two failed HS in office	100		20

LS, laparoscopic sterilization; HS, hysteroscopic sterilization; OR, operating room; HSG, hysterosalpingogram.

Procedure and follow-up testing probabilities were estimated from published sources (Table 1). This model used data pertaining to Essure hysteroscopic sterilization only as a result of its dominance of the market. The major sources for base case values (and the ranges of lowest and highest reasonable values) were identified through a comprehensive literature search of all pertinent studies in English in PubMed and Ovid (last searched April 13, 2011) and by reviewing the bibliographies of identified references. All published studies that reported more than 50 patients were included. However, some studies did not provide complete information for every outcome in the model. The base case values and ranges used in the model as well as the studies referenced to provide this information are described in Table 1. The values themselves are a mathematical average of the results from the referenced studies. When data were missing from published literature, we used data from our own practice's active database, which was initiated in July 2003. Outcome data from studies that did not evaluate the success of hysteroscopic sterilization

using hysterosalpingogram, as required by the U.S. Food and Drug Administration (FDA), were not included in this analysis.

Follow-up rates of hysterosalpingogram at 3 months vary widely (Table 1) with the highest follow-up rates reported in the original hysteroscopic sterilization clinical trials performed by the manufacturer. The base case values used in this analysis were limited to subsequent case series or cohort analyses in an effort to avoid bias. However, we did include the manufacturer's follow-up rates of 98% to 100% in the sensitivity analyses.[12,14,16]

In the absence of published data, the following assumptions were made for the model: 1) 20% of women who failed laparoscopic sterilization would accept hysteroscopic sterilization; 2) the probability of choosing another hysteroscopic sterilization procedure after one failed hysteroscopic sterilization (defined as a negative hysterosalpingogram) would be the same after hysteroscopic sterilization performed in the operating room or office; 3) the probability of choosing a repeat hysteroscopic sterilization procedure (as opposed to choosing a laparoscopic sterilization procedure) after a failed hysteroscopic sterilization in the office (defined as a negative hysterosalpingogram) would be the same as is reported for the operating room; 4) a second hysteroscopic sterilization had similar success regardless of operating room or office location; 5) the probability of returning for hysterosalpingogram at 6 months is similar to the probability at 3 months; 5) women would not want a third hysteroscopic sterilization attempt; and 6) hysteroscopic sterilization success was identical whether or not women completed follow-up testing.

A schematic diagram of the Markov model is shown in Figure 1. Sterilization through laparoscopic sterilization, hysteroscopic sterilization in the operating room, and hysteroscopic sterilization in the office setting were tested in identical hypothetical cohorts of women. Complications related to hysteroscopic sterilization and laparoscopic sterilization are also included in the model but are not shown in Figure 1. Using published data, the model also calculates the number of women who pursue a second or third attempt after a failed sterilization and the number of women who stop pursuing sterilization after one failed attempt. One-way sensitivity analysis was performed for the reasonable range of values identified for all parameters.

RESULTS

In the base case analysis, the percentage of women able to rely on their method of sterilization at 3 months postprocedure (without having any other procedures done) is 99% for laparoscopic sterilization, 86% for hysteroscopic sterilization in the operating room, and 85% for hysteroscopic sterilization in the office. The reliance rate at 6 months postprocedure (without having any other procedures done) is 99%, 88%, and 87%, respectively.

The probability of having any successful sterilization procedure within 1 year is 99% for women starting with laparoscopic sterilization, 95% for women starting with hysteroscopic sterilization in the operating room, and 94% for women starting with hysteroscopic sterilization in the office. However, the method by which the woman was ultimately sterilized sometimes differs from the method initially chosen. In the base case analysis, 7.0% and 5.3% of women who undergo an initial hysteroscopic sterilization procedure in the operating room or office, respectively, actually achieve sterilization through laparoscopic sterilization. Of the women who experienced one failed attempt at an hysteroscopic sterilization procedure, approximately 5% will decline any further sterilization attempts.

In sensitivity analyses, we found that the model is most strongly influenced by the high probability of success with laparoscopic sterilization (Fig. 2). However, even if the model is biased against laparoscopic sterilization by using the highest probability of success for hysteroscopic sterilization (97.9% for hysteroscopic sterilization in the operating room and 97.2% for hysteroscopic sterilization in the office) and the lowest probability of success for laparoscopic sterilization (98.3%), we found that laparoscopic sterilization would still outperform hysteroscopic sterilization and 0.4% more women would have successful sterilization procedures if they initially chose laparoscopic sterilization. In contrast, if we use the highest probability of success for laparoscopic sterilization (99.6%) and the lowest for hysteroscopic sterilization (89.5% for hysteroscopic sterilization in the office), the difference in successful sterilization procedures within 1 year is as large as 10%.

DISCUSSION

Women seeking permanent sterilization deserve an accurate assessment of the likelihood of success for both hysteroscopic sterilization and laparoscopic sterilization. The time required to achieve sterilization before women can rely on it must also be included as part of the informed consent process. According to this model, 85–86% of women who chose hysteroscopic sterilization will have a successful sterilization procedure by 3 months. This finding is consistent with the results from the Essure Pivotal clinical trial.[26]

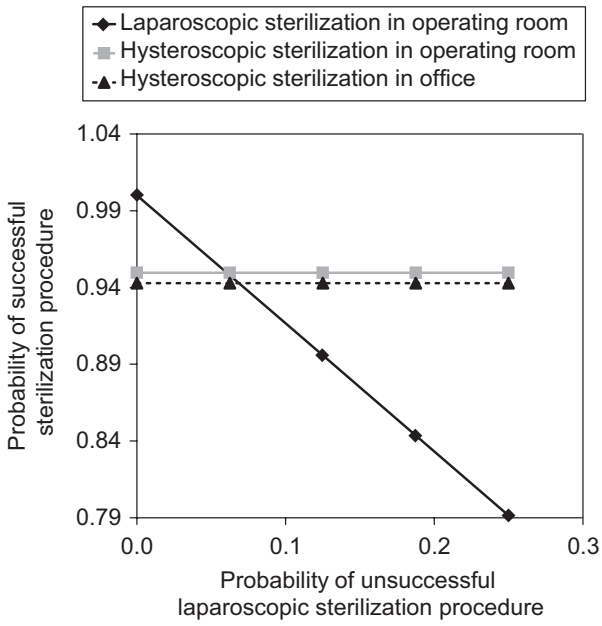

Fig. 2. Sensitivity analysis of the probability of a successful sterilization procedure using the laparoscopic compared with the hysteroscopic approach.

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By 12 months, 95% of women who chose hysteroscopic sterilization in the operating room will have a successful sterilization procedure. However, the additional percentage gained by 1 year is mostly the result of subsequent successful sterilization through laparoscopic sterilization. Seven percent of women choosing hysteroscopic sterilization in the operating room and 5% of women choosing hysteroscopic sterilization in the office will ultimately require laparoscopic sterilization to be sterilized and may only reach their goal of sterilization after multiple attempts at microinsert placement, hysterosalpingograms, office visits, time missed from work, insurance copays, and need for other reliable interim contraception.

In the base case analysis, the large majority of women choosing hysteroscopic sterilization in the office or operating room will have a successful sterilization procedure. However, women choosing hysteroscopic sterilization are less likely to have a successful sterilization procedure than women choosing laparoscopic sterilization. In this analysis, this difference in success rates between the two approaches could be as large as 10%, although the true difference will vary by patient population.

In the United States, 345,000 women undergo sterilization annually.[1] If all female sterilizations in the United States were performed only by hysteroscopic sterilization, this model predicts that approximately 31,050 women would not achieve actual sterilization within 1 year of their initial hysteroscopic sterilization procedure. This estimate is comprised of the 5% of women who experience one failed attempt at hysteroscopic sterilization and decline any further sterilization attempts and the 4% of women (99% minus 95%) who do not achieve sterilization by hysteroscopic sterilization as compared with those choosing laparoscopic sterilization.

Failed attempts at sterilization can result in unintended pregnancies. In a recent analysis of outcomes after unfulfilled postpartum sterilization, the risk of pregnancy within 1 year was twice that of women not requesting sterilization.[27]

Failed sterilizations resulting in unintended pregnancy can also occur after a successful procedure. Data on pregnancy after successful hysteroscopic sterilization are reported to be zero by the manufacturer of Essure and are currently limited to case reports. For laparoscopic sterilization, the CREST (Collaborative Review of Sterilization) study showed a cumulative pregnancy rate at 1 year of 0.68%.[28] At 1 year, if we assume a pregnancy rate of zero after hysteroscopic sterilization and 0.68% after laparoscopic sterilization, the likelihood of being able to rely on sterilization at 1 year is still lower with hysteroscopic sterilization than laparoscopic sterilization.

The Adiana system, another multistep method of hysteroscopic sterilization, was approved by the FDA in 2009. In the pivotal clinical trial for Adiana, the number of patients able to ultimately rely on Adiana at 1 year after placement was similar to that reported for Essure.[29] Thus, the findings of this model are likely applicable to Adiana.

This model and its findings are limited by the uncertainty of the data it is based on. The biggest limitation of published hysteroscopic sterilization data is that the majority comes from observational case series or cohort designs and the lack of any randomized trials directly comparing hysteroscopic sterilization and laparoscopic sterilization.[30] Published studies are also limited by low follow-up rates and possible conflicts of interest because most hysteroscopic sterilization studies are performed by the manufacturer.[12,16] Also, we could not incorporate the results of 5 years of postapproval data collection that were presented by the manufacturer to the FDA in the spring of 2010 because they have not been published (as of PubMed and Ovid search April 13, 2011).

Limitations with published laparoscopic sterilization data do not take into account women who were never offered laparoscopic sterilization as a result of

comorbid conditions that were relative contraindications for general anesthesia or Trendelenburg positioning required for laparoscopic sterilization or as a result of knowledge of significant adhesive disease. Although the same argument could be applied to women who were not offered hysteroscopic sterilization, the absolute and relative contraindications to hysteroscopic sterilization are less frequently encountered than for laparoscopic sterilization.

However, contraindications to hysteroscopic sterilization may be difficult to identify preoperatively. According to the package insert, Essure should not be used for any patient "for whom only one micro-insert can be placed (including patients with apparent contralateral proximal tubal occlusion and patients with a suspected unicornuate uterus)."[31] Uterine anomalies and tubal scarring are often asymptomatic.

Comparative trials are needed to assess true long-term efficacy and costs of hysteroscopic sterilization. Reported success rates for hysteroscopic sterilization that exclude patients who failed bilateral microinsert placement, failed to return for hysterosalpingogram, or were ultimately sterilized by laparoscopic sterilization are disingenuous. For physicians and patients, reporting of hysteroscopic sterilization success rates must include the actual number of women who can truly rely on the method for its desired effect. We plan further analyses to evaluate cost and comparative pregnancy rates over time to provide additional data for women and their providers.

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