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Female Tubal Sterilization

The Time Has Come to Routinely Consider Removal

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Female sterilization, one of the most effective forms of pregnancy prevention, can be performed remote from pregnancy (interval sterilization) or around the time of delivery. Modern methods for sterilization include tubal interruption, salpingectomy, and transcervical sterilization. Tubal interruption has been the primary method for interval sterilization for decades, developing as a means of rapid intra-abdominal laparoscopic surgery at a time when instrumentation and operating systems were less sophisticated than today. New evidence that the most common ovarian cancer, serous adenocarcinoma, frequently may start in the Fallopian tube, has increased research and clinical use of salpingectomy as a preferred method for sterilization. With studies showing that the surgical risks with tubal interruption and salpingectomy are likely equivalent, even when performed at cesarean delivery, the rationale seems to be in place to change our clinical practice. However, we should ask why this revelation has not occurred sooner, even though surgical techniques have advanced and salpingectomy, unlike tubal occlusion or hysteroscopic sterilization, does not leave patients at risk for future intrauterine or ectopic pregnancy. We should not have started thinking about salpingectomy for female sterilization only once a decrease in ovarian cancer risk became part of the equation. Providers' failure to offer this option means that women and their true desires were not part of the conversation. If we had included the patient in the discussion, perhaps the higher efficacy of salpingectomy would have been what women desired all along.

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Female sterilization is one of the most commonly used contraceptive methods in the United States, used by 38% of women who have children.¹ Interestingly, having a prior unintended pregnancy is a significant predictor for a woman to choose sterilization as a contraceptive method.² Accordingly, avoiding future unintended pregnancy is vitally important to women who choose sterilization.

Female sterilization can be performed remote from pregnancy (interval sterilization) or at the time of delivery (postpartum tubal sterilization), typically at the time of cesarean delivery or within 24 hours after a vaginal delivery. Procedures at both times are highly effective, although postpartum tubal sterilization is slightly more effective (Table 1). Nationally, approximately half of all sterilizations are postpartum tubal sterilization procedures, which number approximately 350,000 annually and occur after 8–9% of all deliveries.³ Postpartum tubal sterilization is more frequent among women having a cesarean as compared with a vaginal delivery.

Modern methods for interval sterilization include laparoscopic tubal interruption and salpingectomy, as well as transcervical sterilization. Tubal interruption has been the primary method for decades, developing as a means of rapid intra-abdominal laparoscopic surgery at a time when instrumentation and operating systems were less sophisticated than today. The most common methods in use currently for interval procedures interrupt the Fallopian tube using either a silicone ring, the Filshie clip, or bipolar cauterization.

The U.S. Collaborative Review of Sterilization was a long-term prospective cohort study designed to understand efficacy and complication rates of female sterilization.⁴ The study enrolled 12,138 women from 1978 to 1987; the report detailing efficacy included 10,685 women with follow-up for up to 14 years. The methods evaluated included all laparoscopic procedures currently used in practice today except for the Filshie clip. The Filshie clip was approved for use based on prospective trials demonstrating efficacy



Table 1. Life-Table Cumulative Probability of Pregnancy per 1,000 Procedures

Age (y)	1 Year			5 Years			10 Years		
	Bipolar Cautery	Silicone Band	PPTS	Bipolar Cautery	Silicone Band	PPTS	Bipolar Cautery	Silicone Band	PPTS
18–27	3.0	9.5	1.5	26.4	18.2	7.8	54.3	33.2	11.4
28–33	2.6	4.3	0.0	18.7	9.0	5.6	21.3	21.1	5.6
34–44	1.3	4.5	0.0	6.3	4.5	3.8	6.3	4.5	3.8

PPTS, postpartum tubal sterilization.

Modified from 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, with permission from Elsevier.

equal to that of other methods at 2 years.⁵ Overall, the Collaborative Review of Sterilization data show that laparoscopic sterilization is highly effective (Table 1), with failure rates that are age-dependent, most likely because a procedure that interrupts the Fallopian tube has the potential to allow the body's natural tendency to heal to result in recannulation of the tube or fistula formation. Accordingly, failure rates are dependent on potential years of remaining fertility.

Hysteroscopic sterilization developed as an attempt to provide a less invasive yet highly effective alternative to the laparoscopic approach. Current methodologies, unfortunately, have limitations that make the procedure less promising than expected. Although two products have become clinically available, only one remains today. Essure first became available in the U.S. in late 2002. Pivotal clinical trials reported pregnancy rates only for those women who were able to complete the multiple steps required to prove sterilization. Because these steps occurred over multiple months, clinical experience began to demonstrate significant loss to follow-up for confirmation of sterilization success. A recent decision analysis estimated that the multi-step process with Essure results in significantly more failures than conventional laparoscopic tubal interruption, with pregnancy rates of 96 and 24–30, respectively, per 1,000 women over a 10-year period.⁶ Currently, it appears that transcervical sterilization is a method that may be better suited for the individual for whom a laparoscopic or abdominal approach should be avoided and is reliable both to use as alternative contraception and return for confirmatory imaging studies.

Salpingectomy as a primary method of sterilization has not been considered routinely until the past few years. Interestingly, for individuals in whom sterilization fails, it has been long been considered that bilateral salpingectomy is the preferred method to ensure definitive treatment.⁷ Recent discussions about salpingectomy for sterilization have been driven by new evidence that the most common ovarian cancer, serous

adenocarcinoma, frequently may start in the Fallopian tube.⁸ Although ovarian cancer traditionally was thought of as one disease process, ongoing research suggests that there is not one single site or cell type from which these cancers arise. Some serous tumors appear to originate from dysplastic lesions in the distal Fallopian tube,⁹ with recent evidence suggesting that as much as 60% of high-grade pelvic (nonuterine) serous carcinomas are associated with serous tubal intraepithelial carcinoma.¹⁰ Therefore, what we traditionally have considered “ovarian” cancer may in fact be tubal in origin.

It has long been noted that bilateral tubal interruption confers some protection toward developing ovarian cancer. Proposed mechanisms include effects on ovarian function and mechanical barriers against ascending vaginal carcinogens and ascending proximal tubal or endometrial cells.¹¹ A meta-analysis of 13 studies noted a 34% risk reduction in the development of ovarian cancers after “tubal ligation,” with a sub-analysis finding significance only for endometrioid and serous epithelial tumors.¹² However, a recent pooled analysis of 13 case-control studies, including approximately 24,000 women (10,157 ovarian cancer cases and 13,904 controls), has provided even more information about tubal sterilization practice and ovarian cancer.¹³ Women who had undergone tubal sterilization had a 29% decreased risk of all epithelial ovarian cancers. However, the protective effect was most significant for clear cell (odds ratio 0.52; 95% confidence interval 0.40–0.67) and endometrioid (odds ratio 0.48; 95% confidence interval 0.40–0.59) ovarian carcinomas as compared with serous adenocarcinoma. Thus, the protection afforded by tubal occlusion may affect cancers related to ascending cells but likely does not affect more common serous tumors, which are believed to originate at the fimbriated end of the Fallopian tube. A recent case-control study supports this finding; data on 194 cases and 388 age-matched controls over a 45-year period found that the risk of serous ovarian cancer



or primary peritoneal carcinoma after salpingectomy was reduced by more than 60% as compared with a group of women who were either not sterilized or had a tubal interruption sterilization procedure.¹⁴

Gynecologists would need to change clinical norms if salpingectomy were to be used widely for sterilization because of the potential to prevent serous ovarian carcinoma in high-risk (BRCA mutation carriers) and low-risk women. An Irish study surveyed gynecologists and found that 96% currently performed tubal interruption but 73% were willing to consider salpingectomy for sterilization for women with BRCA mutations.¹⁵ More recent literature indicates that such practice is being more widely considered as an alternative to bilateral salpingo-oophorectomy in high-risk premenopausal women.^{16,17} The bigger question, however, is whether gynecologists would change practice for women without BRCA mutations. A Canadian ovarian cancer prevention initiative educated obstetrician-gynecologists in British Columbia during September 2010 about the potential link between tubal and ovarian cancer. A retrospective analysis of the effect of this effort demonstrated an increase in salpingectomy at the time of hysterectomy, interval tubal sterilization, and postpartum tubal sterilization.¹⁸ The number of sterilization procedures decreased overall during the 4-year analysis period, which included the 2 years before the intervention and the 2 years after (2008, n=3,948; 2009, n=3857; 2010, n=3,730; 2011, n=3,351). Whereas 0.3–0.4% of procedures were performed as salpingectomies in the 2 years before the intervention, the rates increased to 11.4% and 33.3% in the 2 subsequent years. Data from these procedures showed an increase in operative time of approximately 10 minutes with performance of salpingectomy compared with tubal occlusion and no differences in complication rates, including when salpingectomy was performed during cesarean delivery.

Although bilateral salpingectomy conceptually would confer 100% efficacy for women desiring sterilization, there is still a very rare chance of pregnancy, potentially related to cornual fistula, with at least one case report in the English literature.¹⁹

Unfortunately, although surgical technology has advanced since the introduction of laparoscopic sterilization, no studies have addressed whether complete tubal removal should now be offered to women who undergo sterilization given the ability of salpingectomy to provide the best immediate and long-term efficacy. The recent discoveries of a link between the Fallopian tube and ovarian cancer have brought this issue to the forefront; however, women have not been included in the discussion about their desires, specifically around

pregnancy prevention. If failure (pregnancy) is considered a major morbidity, how much more complicated is a bilateral salpingectomy as compared with laparoscopic tubal interruption? The evidence from the large retrospective cohort in British Columbia, Canada, mentioned above suggests that the morbidity is no different with today's surgical technology.¹⁸ Therefore, the question should not be focused only on ovarian cancer prevention; rather, the more important question should be why we are not offering women a chance for near 100% efficacy by removing the Fallopian tube completely for sterilization.

Just as importantly, non-cancer benefits of salpingectomy, such as avoidance of future surgery for complications of occlusion (such as ectopic pregnancy or hydrosalpinx), should be considered. Some providers still may worry about the potential need for a larger incision for salpingectomy after vaginal delivery, large vessels present when postpartum tubal sterilization is performed during cesarean delivery, increased cost with salpingectomy owing to a 10 minute increase in operating time and the risk of regret as a reason to minimize damage or removal of the Fallopian tubes at the time of sterilization. Future studies can continue to address these concerns as well as include cost-benefit analyses to evaluate salpingectomy for both sterilization failures and ovarian cancers prevented. Information on regret is harder to understand for women today because the majority of these data were accumulated more than a decade ago, when use of intrauterine devices and contraceptive implants, collectively called long-acting reversible contraceptives (LARC), in the United States was very low. These older data suggest that women who are age 30 years or younger at the time of sterilization are about twice as likely as those older than 30 years to express regret and eight times as likely to actually undergo reversal or an evaluation for in vitro fertilization.²⁰ However, the proportion of contraceptors currently using LARC increased significantly, from 2.4% in 2002 to 3.7% in 2007 and 8.5% in 2009.²¹ The reality is that sterilization is intended to be permanent. For women who are not certain, LARC methods offer equal to or greater efficacy than tubal interruption procedures. Women who are not certain about sterilization should be counseled more carefully about LARC rather than a less effective sterilization method that also has a risk of ectopic pregnancy that does not exist with salpingectomy.

The link between salpingectomy and ovarian cancer risk undoubtedly will change how we approach permanent sterilization and maybe all contraceptive counseling for women who have completed childbearing. However, regardless of the



strength of the link, maybe it is time we reassess how we perform sterilization. Our technology has advanced such that salpingectomy may have no greater risk than tubal occlusion. The information is coming at us quickly; most importantly, let's not forget to truly include women in the conversation by offering salpingectomy as an option simply because it is the most effective method. Knowing the safety and efficacy of salpingectomy today, we wonder whether women would have been choosing to remove the Fallopian tubes all along.

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