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Update on Permanent Contraception Options for Women:

Current Opinion in Obstetrics and Gynecology

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Abstract

Purpose of review—Permanent methods are the most commonly used contraceptive options worldwide. Even with the increase in popularity and accessibility of long-acting reversible methods, there remains high demand for permanent options, especially among women in developing countries.

Recent findings—Traditional methods of permanent contraception (PC), such as post-partum tubal ligation and interval surgical tubal occlusion or electrocautery by mini-laparotomy or laparoscopy are safe and highly effective. Bilateral total salpingectomy for ovarian cancer risk reduction is currently being investigated. Hysteroscopic tubal occlusion reduces or eliminates the need for anesthesia, but requires surgical training and specialized equipment. Alternative PC methods are being explored including immediately effective hysteroscopic methods, and non-surgical permanent contraception (NSPC) methods that have the potential to improve access and reduce cost.

Summary—PC methods are an important part of the contraceptive methods mix designed to meet the needs of women who have completed desired family size or wish never to become pregnant. Current surgical approaches to permanent contraception are safe and highly effective. The development of a highly effective nonsurgical approach could simplify the provision of PC.

Keywords

permanent contraception; sterilization; tubal ligation

Introduction

Surgical permanent methods are the most commonly used forms of contraception worldwide, with the prevalence in developing countries averaging 20.6% and exceeding 35% in countries such as India, Colombia and El Salvador (1,2). In the U.S., female surgical permanent contraception (PC) is the most common method used in women over the age of 35 (1). Although the total annual number of PC procedures in the U.S. has declined slightly, from 687,000 in 1995 to 643,000 in 2006 (3), tubal ligation or occlusion is the fifth most frequently performed surgical procedure, following cesarean section (CS), abortion,

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cholecystectomy and coronary angioplasty (3–5). The wider availability and acceptance of long-acting reversible methods likely explains the decrease in procedures.

Tubal ligation or occlusion has traditionally been referred to as female sterilization. However, in some settings, the term “sterilization” can imply an involuntary or coercive process. Instead the term “permanent contraception” offers an alternative to recognize a woman’s active and informed decision to complete childbearing (6). Indeed, women today have many PC options to choose from including postpartum tubal ligation, interval surgical tubal ligation, and hysteroscopic tubal occlusion, and new methods of non-surgical PC are currently under development. This article reviews each of these methods, their risks and benefits, and potential alternatives that may soon be available to women.

Postpartum Tubal Ligation

In the U.S., postpartum tubal ligations are performed after 8–9% of all deliveries and represent approximately half of all PC procedures (3). Postpartum, PC is commonly approached by minilaparotomy, often at the level of the umbilicus, or at the time of CS using a modified Pomeroy or Parkland partial salpingectomy (PS) technique (7). These safe, simple procedures ligate and remove a mid-isthmic segment of the fallopian tube bilaterally (8). The PS failure rate is approximately 0.6/1000 in one year and 7.5/1000 in 10 years (1,9). The 10-year probability of ectopic pregnancy is lowest for postpartum PS compared to other interval techniques, at 1.5 per 1000 (10). Complications are rare and mostly related to the risks of the pregnancy, vaginal delivery or CS (1). For women delivering vaginally, the procedure can be performed immediately, or anytime prior to hospital discharge.

Use of mechanical devices, such as titanium (Filshie) clips, are less commonly used postpartum. Contrary to their use as an interval technique, titanium clips have not been shown to have equivalent efficacy with PS in the immediate postpartum period. One retrospective cohort of 290 women undergoing PC at the time of CS in the U.K. found no subsequent pregnancies in the PS group (0/203) over a median follow up of 9 years compared to one in the Filshie clip group over a median follow up of 8 years (1/87, 1.15%, $p = 0.3$) (11). Another randomized control trial of women electing postpartum PC after vaginal delivery found a significantly higher cumulative probability of pregnancy with use of the titanium clip (0.017) compared to PS (Pomeroy method) (0.004, $p = 0.04$) over 24 months of follow up (12). Although weaknesses of the two studies include small sample sizes and high loss-to-follow-up proportions, a subsequent systematic review recommended against routine use of the titanium clip for postpartum PC due to concern for decreased efficacy compared to PS (13).

Interval Laparoscopic Tubal Ligation and Occlusion

Surgical PC procedures occurring outside the postpartum period, or in women who have never been pregnant, are considered “interval” in timing. Although interval PC via minilaparotomy remains common in many low resource areas, interval procedures are typically done laparoscopically in a daypatient operating room setting. Methods include electrocoagulation, mechanical occlusion with silicone rubber bands, spring clips or titanium clips, and partial or total salpingectomy. The U.S. Collaborative Review of Sterilization

followed over 10,000 women for 8–14 years after undergoing various methods of permanent PC and found the 10-year cumulative probability of pregnancy with interval methods to be highest after spring clip procedures (36.5/1000 procedures) and lowest after unipolar coagulation (7.5/1000 procedures). The cumulative probability of pregnancy was highest in the youngest cohort of women who underwent procedures between ages 18–27 (9). Of note, this large prospective cohort did not include titanium clips, which were not introduced onto the U.S. market until 1996, and also took place at several centers where there was less experience with some of the newer procedures than the older ones.

A recent large population-based retrospective study evaluated ectopic pregnancy risk in a cohort of 44,829 women in Western Australia followed for up to 20 years after a variety of interval PC procedures (14). Five methods of laparoscopic PC were compared, including titanium clips, PS, total salpingectomy, electrocautery and unspecified destruction/occlusion of the fallopian tubes. Compared to the reference group of laparoscopic unspecified destruction of the tube (40/22,295 (0.18%) ectopic pregnancies), women who underwent laparoscopic partial salpingectomy ($<5^1/108$ (<4.63%), adjusted HR (aHR) = 14.57, (95% CI 3.50–60.60)) and electrocautery (6/789 (0.76%), aHR = 5.65 (2.38–13.4) had increased risks of ectopic pregnancy whereas the risk with laparoscopic titanium clips (19/11,858 (0.16%) a HR = 1.19 (0.68–2.06) and laparoscopic salpingectomy (0/195, aHR = 0) were not significantly different. For women undergoing PC at younger than age 28, the 10-year cumulative probability of ectopic pregnancy was 3.5 times that of women undergoing PC after age 33.

In addition to being very effective, laparoscopic PC procedures are safe. Rare but serious complications of unipolar cautery, which was associated with thermal bowel injury, led to the development of alternative techniques (15). The overall risk of complication associated with laparoscopic band, clip and bipolar cautery alternatives is very low, estimated at 0.9–1.6 per 100 procedures (15,16). Rare serious complications include unplanned major surgery required due to an intraoperative complication, blood transfusion, infection, a life-threatening event, or hospital readmission (17). Prior abdominal or pelvic surgery, obesity, diabetes, and general anesthesia are independent risk factors for complications (16).

General anesthesia is commonly used with laparoscopy in the U.S., and women may experience post-operative pain from carbon dioxide-related intraperitoneal irritation, necrosis of the fallopian tubes at the occlusion or cauterization site, or stretching of nerves. A meta-analysis of randomized, double-blind placebo-controlled trials evaluating topical application of local anesthetic during laparoscopic ring or clip procedures confirmed a benefit in patient-reported pain scores up to eight-hours post-operatively (18). This minimal intervention can help make an already simple, effective, low-risk procedure even more tolerable to the patient.

The total salpingectomy alternative

Although laparoscopic occlusion and cautery methods have become the interval PC procedures of choice for many hospitals and clinicians, there is increasing discussion about

¹Australian database rules require use of <5 to protect privacy if a data field reflects 5 or fewer individuals.

the role salpingectomy should play as an ovarian cancer risk-reducing measure for women interested in PC. There is evidence to support the hypothesis that epithelial ovarian cancers may originate from the fallopian tube (19–22). Given these data, there has been a recent call for surgeons to consider: 1) performing a salpingectomy at the time of other benign surgeries (such as hysterectomy) for ovarian cancer risk reduction; and 2) performing a salpingectomy in place of a tubal ligation for ovarian cancer risk reduction (23,24). A large retrospective study examined Ob/Gyn practices after a Canadian regional education campaign about the likely link between ovarian cancer and the fallopian tubes (25). This study found an increase in salpingectomy with hysterectomy as well as with interval and postpartum tubal ligation. For instance, only 0.3–0.4% of tubal PC procedures were salpingectomies in the two years leading up to the intervention, but salpingectomies increased to 11.4% and 33.3% in the subsequent two years respectively. They also demonstrated the operative time increased by ten minutes with salpingectomy compared to an occlusive method, and there were no statistically significant differences in complications. A recent Canadian cost-effectiveness analysis found that although salpingectomy for sterilization is slightly more expensive than tubal ligation (CAD $\$9720 \pm 3.74$ compared to $\$9339 \pm 26.74$), it is a more effective procedure with a cost-effectiveness ratio of $\$27,278/\text{year of life gained}$ (26). The model found salpingectomy to provide a 29.2% ovarian cancer risk reduction compared to standard tubal ligation. Furthermore, these authors concluded that salpingectomy would have to be \$1000 more expensive to lose cost-effectiveness. While the potential ovarian cancer risk-reducing benefits of salpingectomy are impressive, there is also the potential benefit of salpingectomy's near 100% efficacy as a PC method (23). However, we do not yet have prospectively collected data on long-term outcomes regarding surgical complication rates, failure rates, ectopic pregnancies, or ovarian cancer risk reduction. In addition, there is also evidence to support that tubal ligation/occlusion decreases the risk of epithelial ovarian cancer independent of salpingectomy (27–29). For example, population based case-control studies indicate that women with ovarian cancer are 30% less likely to have had a tubal ligation (29,30). Thus, the American Congress of Obstetricians and Gynecologists (ACOG) recommends that “randomized controlled trials are needed to support the validity of salpingectomy to reduce the incidence of ovarian cancer. The approach to hysterectomy or sterilization should not be influenced by the theoretical benefit of salpingectomy. Surgeons should continue to observe and practice minimally invasive techniques” (31).

Hysteroscopic tubal occlusion

Another alternative interval PC method is hysteroscopic tubal occlusion. This has become an increasingly popular option since the introduction of Essure[®] in the U.S. in November 2002 (32). The Essure[®] device consists of a nickel-titanium alloy outer coil and a stainless-steel inner coil wrapped in polyethylene terephthalate fibers. A disposable introducer is used to position the wound-coil insert into proximal portion of each fallopian tube under hysteroscopic or fluoroscopic guidance (1). A significant benefit of this technique is that it can be done in a clinic setting with only local paracervical anesthetic (33). In addition to reducing cost, this technique reduces the risks associated with general anesthesia and intra-peritoneal surgery (17). However, both the manufacturer and the FDA recommend a

hysterosalpingogram (HSG) three months post-procedure to confirm bilateral tubal occlusion and an alternative method of contraception during the interim (34). This confirmatory HSG requires radiation exposure, a skilled professional to perform and interpret the test, and may require the patient to travel a significant distance to the nearest radiology center, all of which add significant clinical and opportunity costs to the procedure. Together, these burdens commonly result in high proportions of women (6–87%) who do not complete the confirmatory HSG (35). Since verification of correct placement and tubal occlusion with HSG were required parts of the Essure^R clinical trials, efficacy should not be assumed in the absence of this step. Women should be counseled about the importance of the confirmatory HSG, and if it is too burdensome or inconvenient, should preferentially be counseled about methods with more immediate efficacy.

Another important counseling topic is the potential inability to successfully place coils bilaterally. The phase II trial for the Essure[®] device demonstrated 200/227 (88%) successful bilateral coil placement at the time of procedure (36). Of these women, 191/200 (96%) had satisfactory device location and bilateral tubal occlusion. An additional seven women (198/200, 99%), demonstrated bilateral tubal occlusion at six months post-procedure. Other studies have demonstrated a range of 76–96% successful bilateral coil placement on initial attempt, with 5–16% of HSGs failing to show bilateral tubal occlusion at three months post-Essure[®] (35). This can leave women at risk of unintended pregnancy. A systematic review exploring pregnancy after hysteroscopic PC found that in 22 articles there were 102 reported pregnancies after Essure[®] placement, eighteen of which occurred prior to the confirmatory HSG (37). However, most studies included had less than five years of follow-up, making long-term pregnancy risks difficult to evaluate. In a retrospective review of the Essure[®] manufacturer's commercially available data from 2001 to 2010, 748 (0.15%) pregnancies were reported out of 497,305 distributed Essure[®] kits (38). While helpful, this reporting system may underestimate the true number of pregnancies that occur after hysteroscopic PC. Garipey, *et al* used an evidence-based Markov model to estimate the typical use risk of pregnancy after Essure[®] as 57 and 96 per 1000 women at one and ten years respectively (35). Since most pregnancies are the result of noncompliance with the recommendations for contraception until imaging confirms bilateral occlusion, or misinterpretation of the HSG (37–39), Garipey, *et al* suggest discussing pregnancy risk after hysteroscopic PC in terms of “perfect” compared to “typical” use (35).

Serious complications associated with hysteroscopic tubal occlusion are rare, but there are case reports of bowel injury and obstruction due to perforated coils and infection (39). Other complications include malposition or expulsion of the coils, which may necessitate removal and replacement or use of an alternative PC method. Chronic pain has been associated with malposition or perforation, but should resolve with removal of the coils (39). However, some women will report an increase in dysmenorrhea and pelvic symptoms as they transition from hormonal contraception to the non-hormonal Essure^R. Although hysteroscopic and laparoscopic removal is technically feasible, hysterectomy may be preferable to completely remove the coils.

Women with nickel hypersensitivities should be counseled that the reported incidence of sensitivity to the Essure^R coils is very low (0.01%) (17). Screening patch tests for nickel

sensitivity are not cost-effective, but could be considered in women who have significant pre-procedure concern for allergy or post-procedure symptoms (17,39). Overall, hysteroscopic PC is a well-tolerated, safe and effective alternative method of interval PC.

New Methods of PC

Given the high demand for PC by women around the world, developing new methods of PC could help improve women's access and potentially decrease associated risks and costs. For example, hysteroscopic PC methods that are immediately effective and do not require back-up contraception nor a confirmatory HSG are being explored (40,41). An immediately effective but potentially reversible hysteroscopically placed insert is also under development in China (42). A major challenge in developing a reversible system is that epithelial destruction and collagen deposition in the transmural segment are required for effective contraception (43). Devices that occupy but do not damage the tube typically undergo expulsion or the tube will dilate and allow passage of gametes.

While improvements in hysteroscopic PC options certainly are warranted, the cost and availability of hysteroscopic equipment may still preclude availability of these methods in low-resource settings. Non-surgical PC (NSPC) methods may offer a solution for these women, as well as a more convenient and lower cost option for women in more developed regions. Chemically-induced tubal occlusion has been previously investigated, most notably with quinacrine (44–46). However, need for repeated treatments, high failure rates, and concern for potential toxicity led to alternative developments. Currently, transcervical polidocanol foam (a sclerosing agent) is under investigation in non-human primates with promising initial findings (47,48). When women's and provider's perceptions of NSPC were explored, the need for long-term safety and efficacy data were expressed as well as the desire for confirmation of successful tubal occlusion (49). Alternative confirmatory tests to HSG are needed to reduce cost and radiation exposure and to improve convenience and accessibility for women. Measurement of intrauterine pressure after NSPC is a potential option under preliminary investigation (50). Novel developments in NSPC and confirmation of tubal occlusion have the potential to greatly improve the acceptability and availability to PC methods.

Barriers to Accessing PC

The tragic deaths of sixteen women who underwent laparoscopic tubal ligation in Bilaspur, India in November 2014 reinforces the persistent need for safe and effective methods of PC (51). Women's health providers and advocates should continue to find ways to remove barriers to current methods of PC while maintaining an excellent quality of care. Strategies could include expansion of provider-types offering PC methods (52,53). NSPC methods would likely be very amenable to provision by healthcare workers in low-resource settings. In the U.S., unintended pregnancies could be reduced and public money saved by modifying existing Medicare laws that require waiting periods prior to PC and prohibit women from undergoing PC at the time of abortion (54–56).

Conclusion

Overall, PC methods continue to be highly desired by women and are generally safe and effective. Immediately effective hysteroscopic and non-surgical PC methods would add to the complement of currently available methods and increase access to PC. Finally, further funding for the research and development of novel PC methods will help ensure women in future generations have access to the contraceptive method of their choosing.

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Key points

- Permanent techniques remain popular methods of contraception around the world.
- Current methods of permanent contraception are safe and effective.
- Alternative methods of permanent contraception that are immediately effective and/or non-surgical in nature are under investigation.
- Increasing permanent contraception options available to women can help improve accessibility thus reducing unintended pregnancies and helping women achieve their family planning goals.