

# Long-term risk of ectopic pregnancy varies by method of tubal sterilization: a whole-population study

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**Objective:** To evaluate the risk of ectopic pregnancy (EP) associated with different methods of tubal sterilization.

**Design:** Population-based retrospective cohort study.

**Setting:** Hospitals in Western Australia.

**Patient(s):** All women aged 18–44 years undergoing tubal sterilization between 1990 and 2010 at Western Australian hospitals (n = 44,829).

**Intervention(s):** Data on tubal sterilization were extracted from hospital records.

**Main Outcome Measure(s):** Long-term risk of EP.

**Result(s):** There were 89 EPs recorded during the observation period in women previously sterilized. The 10-year and 15-year cumulative probability of EP for all methods of tubal sterilization were 2.4/1,000 and 2.9/1,000 procedures, respectively. The 10-year cumulative probability of EP was 3.5 times higher in women sterilized before the age of 28 years than in those sterilized after the age of 33 years. An increased risk of EP existed in women who received laparoscopic partial salpingectomy (adjusted hazard ratio = 14.57, 95% confidence interval 3.50–60.60) and electrodestruction (adjusted hazard ratio = 5.65, 95% confidence interval 2.38–13.40), compared with those who had laparoscopic unspecified destruction of fallopian tubes.

**Conclusion(s):** Women undergoing tubal sterilization at a young age are at particular risk for subsequent EP. The risk among younger women doubled between 5 and 15 years after sterilization. Laparoscopic electrodestruction and partial salpingectomy carried the highest risk of EP. (Fertil Steril® 2014;101:728–34. ©2014 by American Society for Reproductive Medicine.)

**Key Words:** Cohort studies, tubal sterilization, ectopic pregnancy, life tables, age

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Several case studies and series have reported ectopic pregnancy (EP) as a complication of tubal sterilization, and even bilateral and recurrent cases have been found (1–6). Of concern is the maternal risk from EP, which accounts for 5% of maternal deaths in developed

countries (7). Given the widespread use of this contraceptive method (8) and the seriousness of EP (7), there is pressing need to provide accurate long-term risk estimates of EP in women undergoing these procedures and characterize women at increased risk.

Studies of the EP risk after tubal sterilization are challenging. Cases are often reported many years after sterilization, necessitating long-term follow-up. Research in this area has been hampered by insufficient sample sizes and reliance on self-report. Only two large studies have examined the cumulative risk of EP in women previously sterilized (9, 10). The Collaborative Review of Sterilization (CREST) Working Group followed 10,685 women in the United States who underwent laparoscopic tubal sterilization from 1978–1986 (9). The cohort was surveyed annually to record new cases of EP (9). A 10-year cumulative probability of 7.3/1,000 EP, and an elevated relative risk for bipolar and unipolar coagulation, interval

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partial salpingectomy, spring-clip and silicone rubber band application, compared with postpartum partial salpingectomy was reported. However, results were prone to loss-to-follow-up. In addition, surgical sterilization procedures have changed markedly since the 1980s (due to a Filshie clip (Femcare-Nikoméd) introduction and lower invasiveness of procedures), thereby impacting the relevance of finding to current practice. Another study of 6,639 women who underwent sterilization by Falope rings (Gyrus) by laparoscopy or Pomeroy technique by laparotomy within a single center in India (from 1986–1997) reported 0.6 EP per 1,000 procedures, all of which used Falope rings and occurred within the first 12 months after sterilization (10). This study did not distinguish between interval and postpartum sterilizations, although the latter accounted for about one-third of all procedures used in that center.

Postpartum sterilizations, frequently used in the United States, are rare in Europe or Australasia (11). In contrast, Filshie clip (also known as titanium clip) has become the sterilization of choice in many developed countries during the past three decades but is yet to be evaluated by any population-based studies (12). Furthermore, no study has evaluated EP risk more than 10 years after sterilization. We used whole-population administrative health data to estimate the cumulative probability and risk of EP in a cohort of women undergoing tubal sterilization, with up to 20 years of follow-up, and considering the impact of sterilization method and age.

## MATERIALS AND METHODS

The study included all women aged 18–44 years who were admitted to hospital in Western Australia (WA) for first-time tubal sterilization from January 1, 1990, through June 30, 2010. Women were included if they had a primary or secondary hospital procedure for tubal sterilization with any of the following International Classification Diseases (ICD) codes: ICD-9 (56.62–56.65, 59.80) (13), ICD-9-CM (66.2–66.29, 66.3–66.39, 66.6, 66.63–66.64) (14), or ICD-10-AM (35638-08, 35638-10, 35688-00–35688-04, 35717-02–35717-03) (15). We restricted the analysis to women who had undergone tubal sterilization of both fallopian tubes by the same method, and who had not concurrently undergone removal of tubal pregnancy. Women with a history of EP were excluded. We used a 10-year look-back period to capture non-first-time tubal sterilization procedures.

We used linked whole-population administrative health data provided by the WA Department of Health. Migration to and from WA has been shown to be lower than in any other Australian jurisdiction, largely due to its geographic separation from other major Australian cities (16). Data were extracted from all statutorily collected midwives' notifications, hospital separation records, and death registrations from 1980–2010. Midwives' notifications contained information for all registered births in WA, which was used to identify pregnancies preceding tubal sterilization. Hospital morbidity data included diagnostic and procedural records for all hospital separations (public and private) in WA. This information was used to select the cohort, EP, and pelvic inflammatory disorders (PID), a strong predictor of EP (17), as previously

defined using the following codes (ICD-9/ICD-9-CM: 614–614.9; ICD-10-AM: N70.0, N70.1, N70.9, N73.0–N73.9) (18) and procreative management (ICD-9-CM: V26.1–V26.9; ICD-10-AM: Z31.1–Z31.9) (18). Deaths were identified from the WA Mortality Register. Socioeconomic status was derived from address recorded in morbidity data at the time of the tubal sterilization procedure. The Index of Socio-Economic Disadvantage (19) at a collection district level (200 households) was used to measure socioeconomic status.

Eleven methods of tubal sterilization were compared. We evaluated five laparoscopic approaches (partial salpingectomy, electrodestruction of fallopian tubes, salpingectomy, unspecified destruction of fallopian tubes, and occlusion using titanium clip), five minilaparotomy approaches (partial salpingectomy, other unspecified destruction or occlusion of fallopian tubes, electrodestruction, salpingectomy, and an open abdominal approach using titanium clip), and a hysteroscopic approach with the Essure device (transcervical sterilization; Conceptus).

The primary outcome was hospitalization for first-time EP after incident tubal sterilization. An EP was defined by a hospital admission with a primary or secondary diagnosis: ICD-9 (57.43) (13), ICD-9-CM (633.0–633.91) (14), or ICD-10-AM (000.0–000.9) (15, 20). Women were considered to be at risk for EP until they had a repeat sterilization procedure, a surgical reversal (tubal anastomosis), hysterectomy, undergone IVF, died, or reached age 45 years, whichever came first. Follow-up for all women still at risk was stopped (censored) on June 30, 2010.

Descriptive statistics were performed to summarize characteristics of the study cohort at the baseline. Kaplan-Meier curves and cumulative life-table probabilities of EP were calculated to assess time to EP overall and by age group (18–27, 28–33, 34–44 years), as previously categorized by the CREST study (21). We used Cox regression to calculate hazard ratios (HR) and 95% confidence intervals (CI) to investigate the association between type of surgical sterilization and EP. Additional prognostic factors for EP, including age, Indigenous status, a history of PID, and parity, were also evaluated. Data were analyzed using SAS version 9.3 (22).

The study was approved by the Human Research Ethics Committees of the Department of Health WA and the University of Western Australia.

## RESULTS

Between 1990 and 2010, 45,332 women aged 18–44 years were identified as having undergone incident tubal sterilization in a WA hospital. Of these patients, we excluded 348 women who had concurrent records for sterilization and EP on the same admission, 80 with a history of EP before their first sterilization procedure, and 75 with <30 days of follow-up, leaving 44,829 women for analysis.

Characteristics of women at time of incident sterilization procedure are shown in Table 1. Women undergoing tubal sterilization were most commonly treated with either laparoscopic unspecified destruction or occlusion (50%) or laparoscopic occlusion with titanium clip (27%). The median and mean ages of women at sterilization were both 34 years

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