

## THE RISK OF ECTOPIC PREGNANCY AFTER TUBAL STERILIZATION

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### ABSTRACT

**Background** Tubal sterilization is an increasingly common method of contraception in the United States. Although pregnancy after sterilization is uncommon, it can occur and may be ectopic. We used data from the U.S. Collaborative Review of Sterilization to estimate the risk of ectopic pregnancy in women who had undergone the common types of tubal sterilization.

**Methods** A total of 10,685 women undergoing tubal sterilization were followed in a multicenter, prospective cohort study. We intended to follow all the women for 5 years by means of annual telephone interviews; for women enrolled early in the study, we attempted an additional follow-up telephone interview 8 to 14 years after sterilization. To assess the risk of ectopic pregnancy in these women, we used cumulative life-table probabilities and proportional-hazards analysis.

**Results** There were 47 ectopic pregnancies in the 10,685 women; the 10-year cumulative probability of ectopic pregnancy for all methods of tubal sterilization combined was 7.3 per 1000 procedures. The cumulative probability varied substantially according to the method of sterilization and the woman's age at the time of sterilization. Women sterilized by bipolar tubal coagulation before the age of 30 years had a probability of ectopic pregnancy that was 27 times as high as that among women of similar age who underwent postpartum partial salpingectomy (31.9 vs. 1.2 ectopic pregnancies per 1000 procedures). The annual rate of ectopic pregnancy for all methods combined in the 4th through 10th years after sterilization was no lower than that in the first 3 years.

**Conclusions** A history of tubal sterilization does not rule out the possibility of ectopic pregnancy, even many years after the procedure. (N Engl J Med 1997;336:762-7.)

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OVER 10 million U.S. women of child-bearing age have undergone tubal sterilization, and by 1990 more women had undergone tubal sterilization than were using any other method of contraception.<sup>1</sup> Pregnancy is unlikely to occur among sterilized women; when it does, however, there is a substantial risk that it will be an ectopic pregnancy.<sup>2-6</sup> In 1992, ectopic pregnancies accounted for 9 percent of all pregnancy-related deaths.<sup>7</sup> Because information on the effectiveness of tubal sterilization in preventing pregnancy is limited, it has been difficult to determine the risk of ectopic pregnancy after tubal sterilization.

The U.S. Collaborative Review of Sterilization was initiated in 1978 to evaluate the long-term safety and effectiveness of the common methods of tubal sterilization. We previously reported that the cumulative probability of pregnancy in the study cohort 10 years after sterilization was 18.5 per 1000 procedures.<sup>8</sup> In this study of the same cohort, we investigated the risk of ectopic pregnancy after tubal sterilization.

### METHODS

The methods of the U.S. Collaborative Review of Sterilization have been described in detail elsewhere.<sup>8</sup> In brief, we followed women who underwent tubal sterilization by a method chosen by the woman and her physician at medical centers in nine cities. The women were enrolled from 1978 through 1986; follow-up was completed in 1994. The study protocol was approved by the institutional review board at each medical center, and written informed consent was obtained from each study participant.

Women who were eligible to be enrolled were from 18 to 44 years of age and were undergoing tubal sterilization by a method under study at their medical center. Before the procedure, a trained nurse-interviewer obtained a detailed history from each woman who agreed to participate. The nurse also recorded the details of the sterilization, including any complications, on the basis of direct observation during the procedure or review of records thereafter. We planned to obtain follow-up information by means of telephone interviews about one month after the procedure and then annually for five years. For women enrolled from 1978 through 1983, a final telephone interview was conducted 8 to 14 years after sterilization. We used the information provided in the most recent follow-up interview in our analysis.

When a woman reported at any follow-up interview that she had had a positive pregnancy test or had been informed by a physician that she was pregnant, the interviewer asked for detailed information about the pregnancy and, if possible, obtained pertinent medical records. We classified the women's pregnancy status on the basis of the best available information on diagnosis and outcome. When we were uncertain whether a pregnancy was a luteal-phase pregnancy (in this case, one in which conception occurred before sterilization but that was identified after sterilization) or a true failure of sterilization, we classified it as a luteal-phase pregnancy, thus potentially underestimating the risk of true failure of sterilization.

We excluded women from further follow-up if, at any time after the procedure, they died, became pregnant, had any of three operations (tubal anastomosis, second tubal sterilization, or hysterectomy), were lost to follow-up, or declined to be interviewed.

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Each woman was considered to be at risk for pregnancy until the date of one of these events, if known, or, if the date was unknown, until the midpoint between the last interview before and the first interview after the event.

We restricted our analysis to women who had undergone tubal occlusion of both fallopian tubes by the same method. We evaluated four laparoscopic methods of tubal occlusion; two of these — bipolar coagulation and unipolar coagulation — use electric current to occlude the fallopian tube, and the other two — silicone rubber-band application and spring-clip application — are mechanical methods. We also evaluated one method of occlusion performed by laparotomy — partial salpingectomy (defined as including modified Pomeroy-type ligation and other methods of partial salpingectomy) and total salpingectomy. We further classified each partial-salpingectomy procedure as either postpartum partial salpingectomy (performed after vaginal delivery or at the same time as cesarean section) or “interval” partial salpingectomy (performed in women who had not recently been pregnant).

When a pregnancy reported after sterilization was classified as a failure of sterilization (i.e., any pregnancy other than a luteal-phase pregnancy, a pregnancy resulting from tubal anastomosis or in vitro fertilization, or a pregnancy that could not be classified because the available information was insufficient), it was classified further as an intrauterine or ectopic pregnancy. We reviewed the findings from the clinical examination, reports of ultrasonography or surgery, and pathological evaluation in classifying the pregnancies when these findings were available. We used a standard life-table technique and Cox proportional-hazards analysis to analyze ectopic pregnancies with the SAS statistical package.<sup>9</sup>

RESULTS

We enrolled 10,863 women in this study. Of these, 178 were excluded: 34 because they had a

luteal-phase pregnancy, 116 because they could not be located for the one-month follow-up interview or thereafter, 17 because they declined to be interviewed at the one-month follow-up, 3 because they declined to be interviewed after prolonged loss to follow-up, 4 because they underwent hysterectomy before the one-month follow-up interview, 1 because she had a second tubal-sterilization procedure before the one-month follow-up, and 3 because they died before that time.

Of the remaining 10,685 women who were thus eligible for long-term follow-up, 89.2 percent were interviewed at 1 year, 81.0 percent at 3 years, 73.0 percent at 5 years, and 57.7 percent at 8 to 14 years. We found that, once contacted, women were likely to continue to cooperate with the study; only 217 (2.0 percent) declined to provide information at one of the annual follow-up interviews.

The median age of the women at the time of sterilization was 30 years (range, 18 to 44; mean [±SD], 31±6). Most women were white and had been pregnant at least twice (Table 1). In all, 143 women (1.3 percent) reported pregnancies that were classified as true failures of sterilization. For 66.4 percent of these pregnancies, the classification was based on a review of medical reports by the investigators. The remainder were classified on the basis of the woman’s history alone. Of these 143 pregnancies, 47 (32.9 per-

TABLE 1. CHARACTERISTICS OF WOMEN UNDERGOING TUBAL STERILIZATION, ACCORDING TO METHOD.\*

CHARACTERISTIC	BIPOLAR	UNIPOLAR	SILICONE	SPRING-CLIP	INTERVAL	POSTPARTUM	ALL
	COAGULATION (N=2267)	COAGULATION (N=1432)	RUBBER-BAND APPLICATION (N=3329)	APPLICATION (N=1595)	PARTIAL SALPINGECTOMY (N=425)	PARTIAL SALPINGECTOMY (N=1637)	METHODS (N=10,685)
	percent						
Age at sterilization							
<30 years	42.6	31.7	42.5	54.8	35.3	57.0	44.8
≥30 years	57.4	68.3	57.5	45.2	64.7	43.0	55.2
Race or ethnic group†							
Non-Hispanic white	47.5	82.5	57.7	53.3	44.0	25.7	52.7
Non-Hispanic black	50.1	13.3	29.0	44.4	25.9	38.2	34.9
Hispanic, American Indian, Alaskan Native, or Asian or Pacific Islander‡	2.4	4.3	13.4	2.3	30.1	36.1	12.3
Gravidity							
<2	15.6	11.0	12.4	12.4	17.7	0.8	11.3
2	28.5	30.9	28.4	29.0	30.4	19.2	27.5
>2	55.9	58.1	59.3	58.6	52.0	80.0	61.2
History of pelvic inflammatory disease§							
Yes	13.2	20.8	14.0	17.7	15.1	11.7	14.4
No	86.8	79.2	86.0	82.3	84.9	88.3	85.6

\*Because of rounding, percentages do not always total 100.

†For portions of the data-collection period, information about race was not obtained for respondents who specified that their ethnic group was “Hispanic.” All Hispanic respondents are grouped together here.

‡Because sample sizes were insufficient for separate analyses of Hispanics, American Indians, Alaskan Natives, and Asians or Pacific Islanders, these categories were combined. One woman whose race or ethnic group was unknown was assumed to be a non-Hispanic white.

§A total of 2737 women were not asked about their history of pelvic inflammatory disease. The percentages shown include only women who were asked for this information.

**TABLE 2.** CUMULATIVE PROBABILITY OF ECTOPIC PREGNANCY AMONG WOMEN WHO HAD UNDERGONE TUBAL STERILIZATION, ACCORDING TO TIME SINCE STERILIZATION.\*

METHOD	No. OF WOMEN	No. OF ECTOPIC PREGNANCIES†	YEARS SINCE STERILIZATION		
			1	5	10
no./1000 procedures (95% CI)					
Bipolar coagulation	2,267	24	0.5 (0.0–1.3)	10.1 (5.4–14.7)	17.1 (9.8–24.4)
Unipolar coagulation	1,432	1	0.0	0.0	1.8 (0.0–5.2)
Silicone rubber-band application	3,329	10	0.6 (0.0–1.5)	2.5 (0.6–4.4)	7.3 (1.6–12.9)
Spring-clip application	1,595	7	1.3 (0.0–3.1)	3.6 (0.4–6.7)	8.5 (1.0–16.0)
Interval partial salpingectomy	425	3	4.9 (0.0–11.6)	7.5 (0.0–15.9)	7.5 (0.0–15.9)
Postpartum partial salpingectomy‡	1,637	2	0.0	1.5 (0.0–3.6)	1.5 (0.0–3.6)
All methods	10,685	47	0.7 (0.2–1.2)	4.0 (2.6–5.3)	7.3 (5.0–9.6)

\*The probabilities were derived with life-table methods. CI denotes confidence interval.

†The number of ectopic pregnancies is that identified during 10 years of follow-up.

‡This category includes women undergoing sterilization after vaginal delivery (n=1166) or at the same time as a cesarean section (n=471).

cent) were ectopic; all but 1 of these (an ovarian pregnancy after bipolar coagulation) were tubal pregnancies. Classification of 76.6 percent of the ectopic pregnancies was based on a review of medical records. The remaining 23.4 percent were classified on the basis of history alone.

The 10-year cumulative probability of ectopic pregnancy for all methods of tubal sterilization combined was 7.3 per 1000 procedures. The probability of ectopic pregnancy varied substantially according to the method of tubal sterilization (Table 2); bipolar coagulation had the highest probability of failure (17.1 ectopic pregnancies per 1000 procedures) and postpartum salpingectomy the lowest (1.5 per 1000). The 10-year cumulative probability of ectopic pregnancy also varied according to the women's age at the time of sterilization (Table 3). For all methods except postpartum partial salpingectomy, the probability of ectopic pregnancy was greater for women sterilized before the age of 30 than for older women; the difference was statistically significant, however, only for bipolar coagulation. Women sterilized by bipolar coagulation before the age of 30 had a 10-year cumulative probability of ectopic pregnancy of 31.9 per 1000 procedures — 27 times as high as the rate for postpartum partial salpingectomy (1.2 per 1000,  $P < 0.001$ ). For women who were 30 or older at the time of sterilization, there were no significant differences in the probability of ectopic pregnancy among the methods of tubal occlusion (excluding unipolar coagulation, for which no ectopic pregnancies were reported).

We determined the proportion of ectopic pregnancies among all pregnancies after sterilization for each method of tubal occlusion. The highest proportion

(0.65) was among women who underwent bipolar coagulation, followed by the women who underwent interval partial salpingectomy (0.43), those with silicone rubber-band application (0.29), those with postpartum partial salpingectomy (0.20), those with unipolar coagulation (0.17), and those with clip application (0.15). The proportion of ectopic pregnancies for all methods combined was three times as high in the 4th through 10th years after sterilization (0.61) as in the first 3 years (0.20); ( $P < 0.001$ ). For all methods combined, the cumulative probability of ectopic pregnancy in the 4th through 10th years after sterilization (5.3 per 1000 procedures) was significantly higher than the cumulative probability in the first 3 years (2.0 per 1000;  $P = 0.006$ ); the annual rate of ectopic pregnancy in the 4th through 10th years after sterilization (0.8 per 1000 woman-years) was no lower than the rate in the first 3 years (0.7 per 1000 woman-years). The cumulative probability of ectopic pregnancy in the 4th through 10th years after bipolar coagulation (13.8 per 1000 procedures) was four times as high as that in the first 3 years (3.3 per 1000;  $P = 0.005$ ).

Among the 10 potential risk factors for ectopic pregnancy after tubal sterilization (Table 4), the method of tubal sterilization, age at the time of sterilization, race or ethnic group, and history of pelvic inflammatory disease before sterilization (as reported by the women themselves) were statistically significant. There were no significant interactions between any two variables. After adjustment for age, race or ethnic group, and history of pelvic inflammatory disease, both bipolar coagulation (relative risk, 10.0; 95 percent confidence interval, 2.2 to 45.1) and interval partial salpingectomy (relative risk, 7.4; 95

RISK OF ECTOPIC PREGNANCY AFTER TUBAL STERILIZATION

**TABLE 3.** CUMULATIVE PROBABILITY OF ECTOPIC PREGNANCY 10 YEARS AFTER TUBAL STERILIZATION, ACCORDING TO AGE AT THE TIME OF STERILIZATION.

METHOD	<30 yr			≥30 yr		
	NO. OF WOMEN	NO. OF ECTOPIC PREGNANCIES*	NO./1000 PROCEDURES (95% CI)†	NO. OF WOMEN	NO. OF ECTOPIC PREGNANCIES*	NO./1000 PROCEDURES (95% CI)†
Bipolar coagulation	966	17	31.9 (15.2–48.7)	1301	7	7.6 (1.9–13.2)
Unipolar coagulation	454	1	5.9 (0.0–17.5)	978	0	0.0
Silicone rubber-band application	1414	4	7.8 (0.0–17.8)	1915	6	6.9 (0.2–13.7)
Spring-clip application	874	5	11.1 (0.0–23.4)	721	2	5.8 (0.0–14.9)
Interval partial salpingectomy	150	2	14.6 (0.0–34.7)	275	1	3.7 (0.0–11.1)
Postpartum partial salpingectomy	933	1	1.2 (0.0–3.5)	704	1	1.8 (0.0–5.2)

\*The number of ectopic pregnancies shown is that identified during 10 years of follow-up.

†CI denotes confidence interval.

**TABLE 4.** RISK OF ECTOPIC PREGNANCY, ACCORDING TO SELECTED FACTORS INFLUENCING RISK.

FACTOR	NO. OF WOMEN	RELATIVE RISK OF ECTOPIC PREGNANCY (95% CI)*	P VALUE†
Method			<0.001
Postpartum partial salpingectomy‡	1637	1.0	
Bipolar coagulation	2267	10.0 (2.2–45.1)	
Interval partial salpingectomy	425	7.4 (1.2–44.7)	
Spring-clip application	1595	4.6 (0.9–23.2)	
Silicone rubber-band application	3329	4.2 (0.9–19.9)	
Unipolar coagulation	1432	1.2 (0.1–14.5)	
Age at sterilization			0.03
≥30 yr‡	5894	1.0	
<30 yr	4791	1.9 (1.0–3.5)	
Race or ethnic group§			<0.001
Non-Hispanic white‡	5636	1.0	
Non-Hispanic black	3732	4.0 (1.9–8.3)	
Hispanic, American Indian, Alaskan Native, or Asian or Pacific Islander	1317	2.2 (0.6–8.6)	
History of pelvic inflammatory disease			0.04
No‡	6800	1.0	
Yes	1148	2.7 (1.3–5.5)	
Unknown	2737	1.4 (0.7–2.9)	

\*Relative risks are based on Cox proportional-hazards analysis. CI denotes confidence interval.

†The P values pertain to the significance of the factors in the model. Study site, education, marital status, gravidity, history of previous abdominal or pelvic surgery, and presence or absence of adhesions at the time of sterilization were not significant factors.

‡Women with this characteristic served as the reference group.

§One woman whose race or ethnic group was unknown was assumed to be a non-Hispanic white.

percent confidence interval, 1.2 to 44.7) were significantly more likely than postpartum partial salpingectomy to result in ectopic pregnancy.

**DISCUSSION**

We found that the 10-year cumulative probability of ectopic pregnancy after tubal sterilization varied according to the method of sterilization and age at the time of the procedure. Among women who un-

derwent sterilization before the age of 30 years, the greatly increased probability of ectopic pregnancy after bipolar coagulation (27 times as high as the probability with postpartum partial salpingectomy) is notable, because this is the most popular sterilization technique for women who have not just delivered a child.<sup>10</sup>

Our finding that women who underwent interval partial salpingectomy had a significantly greater risk

of ectopic pregnancy than those who underwent postpartum partial salpingectomy is probably due to chance or bias. The relatively few women who underwent interval partial salpingectomy were generally those for whom laparoscopy was considered to pose unacceptable risks, often because of risk factors that were themselves likely to reduce the effectiveness of the sterilization procedure.

We previously reported that a woman's age at the time of tubal sterilization affected the likelihood of failure of the procedure,<sup>8</sup> which, in turn, affects the likelihood of ectopic pregnancy. In the current study, we found that women who were under 30 at the time of sterilization were nearly twice as likely as older women to have a subsequent ectopic pregnancy. We suspect that the primary effect of age on the risk of ectopic pregnancy is its effect on fecundity.<sup>11</sup>

We anticipated problems of bias in analyzing data, and as discussed in a previous report,<sup>8</sup> we tried to eliminate any bias that would increase the estimated probability of a failure of sterilization. For example, among women who were lost to follow-up, we expected that those who became pregnant would be more likely to seek medical care than those who did not become pregnant. An attempt to reduce loss to follow-up by a review of medical records would tend to identify more women who became pregnant. To minimize this bias, we included only pregnancies initially identified by telephone.

There were no major differences in the frequency of loss to follow-up among the groups of women who underwent different sterilization procedures. However, more young women and non-Hispanic black women were lost to follow-up than were older women or non-Hispanic white women. Young women and non-Hispanic black women in our study were at increased risk for ectopic pregnancy after sterilization; we may therefore have underestimated the risks of ectopic pregnancy in our entire cohort if the young women and non-Hispanic black women who were lost to follow-up had the same risk of ectopic pregnancy as those who were followed.

Although our study is based on the experience of thousands of women who underwent sterilization in medical centers across the United States, our findings may not be generalizable to the U.S. population as a whole. The women were not randomly selected from among all the women undergoing sterilization in the United States; most were enrolled at teaching centers, and their risk of pregnancy after sterilization may differ from that of women sterilized in other settings.

Procedural technique is probably a critical determinant of the risk of sterilization failure.<sup>12,13</sup> For example, one experiment suggests that systems designed for bipolar coagulation can be highly effective, producing a degree of coagulation similar to that produced by unipolar systems, if specific techniques are

used.<sup>13</sup> Similarly, preliminary analyses from our study suggest that the probability of pregnancy after bipolar coagulation is low when the fallopian tube is coagulated sufficiently. If the use of proper techniques for tubal sterilization became more widespread after enrollment in this study was completed, our results may overestimate current risks.

The risks of ectopic pregnancy for the six methods of tubal sterilization we evaluated should be considered not in isolation but, rather, in the context of the overall risks and benefits of the methods. For example, although bipolar coagulation was found to have the highest 10-year cumulative probability of ectopic pregnancy, it is generally considered to be a safer procedure than unipolar coagulation. Unipolar coagulation, in which both jaws of the grasping forceps serve as an active electrode, with current flowing through the patient to a ground plate underneath her buttocks (as compared with bipolar coagulation, in which one jaw of the grasping forceps is an active electrode and the other is the return electrode), is the technique most likely to result in serious injury or death.<sup>14</sup> Both silicone rubber-band application (in which a band is placed over a loop of fallopian tube) and spring-clip application (in which a small plastic clip is placed over the tube) were associated with higher rates of ectopic pregnancy than unipolar coagulation, but they are more likely than unipolar coagulation to be successfully reversed by tubal anastomosis.<sup>15</sup> Postpartum partial salpingectomy was associated with the lowest probability of ectopic pregnancy, but women undergoing this procedure were found in an earlier report on this cohort to be 40 percent more likely than women having procedures at a time separate from pregnancy to regret having been sterilized.<sup>16</sup>

Ectopic pregnancy after tubal sterilization is not rare, particularly among women sterilized before the age of 30, and all women undergoing this procedure should be informed that ectopic pregnancy may occur long after sterilization. In addition, those who provide care to women of childbearing age should not assume that a history of tubal sterilization rules out the possibility of an ectopic pregnancy in a woman who has symptoms or signs of pregnancy, especially of ectopic pregnancy.

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## APPENDIX

The Design, Coordination, and Analysis Center for the U.S. Collaborative Review of Sterilization Working Group was the Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta. Participants other than the authors were N.G. Courey, State University of New York at Buffalo; P.D. Darney, University of California, San Francisco; E.R. Friedrich, Washington University School of Medicine, St. Louis; R.W. Hale and R.T. Nakayama, Kapiolani Medical Center, Honolulu; J.F. Hulka, University of North Carolina School of Medicine, Chapel Hill; A.N. Poindex-

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