

# The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization

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**OBJECTIVE:** Our purpose was to determine the risk of pregnancy after tubal sterilization for common methods of tubal occlusion.

**STUDY DESIGN:** A multicenter, prospective cohort study was conducted in U.S. medical centers. A total of 10,685 women who underwent tubal sterilization was followed up for 8 to 14 years. The risk of pregnancy was assessed by cumulative life-table probabilities and proportional hazards models.

**RESULTS:** A total of 143 sterilization failures was identified. Cumulative 10-year probabilities of pregnancy were highest after clip sterilization (36.5/1000 procedures) and lowest after unipolar coagulation (7.5/1000) and postpartum partial salpingectomy (7.5/1000). The cumulative risk of pregnancy was highest among women sterilized at a young age with bipolar coagulation (54.3/1000) and clip application (52.1/1000).

**CONCLUSIONS:** Although tubal sterilization is highly effective, the risk of sterilization failure is higher than generally reported. The risk persists for years after the procedure and varies by method of tubal occlusion and age. (AM J OBSTET GYNECOL 1996;174:1161-70.)

**Key words:** Tubal sterilization, pregnancy, sterilization failure

By 1988 tubal sterilization had become the most prevalent method of contraception among married and formerly married women in the United States,<sup>1</sup> and by 1990 more U.S. women had undergone tubal sterilization than were using oral contraceptives or any other single method of contraception.<sup>2</sup> Although millions of U.S. women have undergone tubal sterilization and the procedure is widely regarded as a highly effective method of contraception, data regarding effectiveness are largely limited to case series of individual surgeons or institutions. To date, we know of no large prospective studies of women undergoing tubal sterilization in the United States that have assessed the long-term effectiveness of the popular methods of tubal occlusion.

To assess further the effectiveness of various methods of tubal sterilization, we analyzed data from the U.S. Collaborative Review of Sterilization—a large, prospective, multicenter observational study conducted by the

Centers for Disease Control and Prevention (CDC) with support from the National Institute for Child Health and Human Development. This is the first report from the complete data set of the U.S. Collaborative Review of Sterilization.

## Material and methods

The U.S. Collaborative Review of Sterilization is a prospective study of women undergoing tubal sterilization at medical centers in Baltimore, Maryland; Buffalo, New York; Chapel Hill, North Carolina; Honolulu, Hawaii; Houston, Texas; Memphis, Tennessee; Sacramento, California; St. Louis, Missouri; and San Francisco, California. The study was approved by the institutional review board in each center. This report is based on the experiences of women who entered the study from 1978 through 1986.

All women eligible to be enrolled in the study were approached before sterilization. When a woman agreed to participate in the study, a trained nurse interviewer obtained detailed information on her history before the sterilization procedure. During and after the sterilization, characteristics of the surgical procedure, including intraoperative and postoperative complications, were recorded. Study participants were contacted by phone approximately 1 month after the procedure for a brief follow-up interview. Annual telephone follow-up for 5 years was planned; additional telephone follow-up was conducted for women enrolled early enough in the study to

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have had 8 to 14 years elapse since sterilization. If a woman could not be located at the scheduled yearly follow-up interview, information provided in the last completed follow-up interview was used in the analysis.

In the follow-up interview the study participant was asked, "Since your tubal sterilization, have you had a positive pregnancy test or been told by a physician that you were pregnant?" When a woman responded affirmatively, the interviewer then completed a separate form that provided additional information regarding the pregnancy. Whenever possible, medical records were obtained for review. The documentation of pregnancy status was based on the best available information regarding the pregnancy diagnosis and outcome.

Women were excluded from further follow-up if they had a pregnancy, a repeat sterilization, a tubal anastomosis, or a hysterectomy; if they died; or if they refused to be interviewed. For the purpose of life-table analyses a woman who had no pregnancies before any of these events was considered to be at risk for pregnancy until the date of the event, if the date was known. If the date of the event was not known, a woman was considered to be at risk for pregnancy until the midpoint of the interval between the dates of the interviews before and after the reported event.

We restricted this analysis to women who had the same method of occlusion on each fallopian tube and to women whose method of tubal occlusion was laparoscopic unipolar coagulation, laparoscopic bipolar coagulation, laparoscopic silicone rubber band application, laparoscopic spring clip application, or partial salpingectomy (including modified Pomeroy-type ligation, other types of partial salpingectomy, and total salpingectomy) performed by laparotomy. All laparoscopic procedures were performed among women not recently pregnant. Partial salpingectomies were performed post partum (after vaginal delivery or concurrent with cesarean section) or on an interval basis (among women not recently pregnant).

A pregnancy identified after sterilization was classified as either a true sterilization failure, a luteal phase pregnancy (pregnancy conceived before sterilization but identified after sterilization), a pregnancy resulting from tubal anastomosis or in vitro fertilization, or a pregnancy of unknown status (because of insufficient information). These classifications were based on all available information. Information requested included (1) date of last menstrual period, (2) date of pregnancy diagnosis and estimated gestational age at diagnosis, (3) date of pregnancy termination and estimated gestational age at pregnancy termination, (4) results of pregnancy tests, clinical examination, ultrasonographic examination, and (5) surgical reports and pathologic evaluation. A pregnancy was considered a luteal phase pregnancy if all available information was consistent with both a luteal phase pregnancy

and a true sterilization failure. Thus, when we had difficulty determining whether a true failure had occurred, we made a systematic effort to classify the pregnancy as a luteal phase pregnancy, which could potentially underestimate the likelihood of true sterilization failure.

On the basis of a review of all available information, the CDC principal investigator (H.B.P.) classified the pregnancy in consultation with the project director at the study center where the pregnancy was reported. A second CDC investigator (L.S.W.) also classified the pregnancy without knowledge of the first classification. Final classification was based on consensus.

Pregnancies classified as true failures were then further analyzed by using a standard life-table technique and the Cox proportional hazards model. All analyses were performed with the statistical package SAS<sup>®</sup>.<sup>3</sup>

## Results

Of the 10,863 women enrolled in the U.S. Collaborative Review of Sterilization who met the inclusion criteria for this analysis, 178 were excluded from analysis. One hundred thirty-six of these women were excluded because of loss to follow-up ( $n = 116$ ), refusal to be interviewed at 1-month follow-up ( $n = 17$ ), or refusal after prolonged loss to follow-up ( $n = 3$ ). Eight women were excluded because of hysterectomy ( $n = 4$ ), repeat tubal sterilization ( $n = 1$ ), or death at 1-month follow-up ( $n = 3$ ; none of these deaths were attributable to sterilization). Thirty-four women were excluded because of luteal phase pregnancies.

We examined selected demographic and medical characteristics of the remaining 10,685 women (Table I). The median age of these women at the time of sterilization was 30 years. Most of the women were white, non-Hispanic (52.7%) and most had been pregnant at least twice (88.6%). Silicone rubber band application was the most common sterilization technique (31.2% of participants) followed by bipolar coagulation (21.2%), postpartum partial salpingectomy (15.3%), clip application (14.9%), unipolar coagulation (13.4%), and interval partial salpingectomy (4.0%).

Our 10,685 study participants were followed up for varying periods; 89.2% were interviewed at approximately 1 year after sterilization. Of those eligible to be interviewed at 3, 5, and 8 to 14 years after sterilization, 81.0%, 73.0%, and 57.7%, respectively, were interviewed. At each follow-up interval women aged 18 to 27 years had a lower percentage of follow-up than older women; likewise, black, non-Hispanic women at all intervals had a lower percentage of follow-up than white, non-Hispanic women.

One hundred forty-three of the 10,685 women in this analysis had pregnancies classified as true sterilization failures. As noted, an additional 34 women not included in this analysis reported a pregnancy classified as a luteal

**Table I.** Percentage distribution of characteristics of women undergoing tubal sterilization by method

	<i>Bipolar coagulation</i> (n = 2267)	<i>Unipolar coagulation</i> (n = 1432)	<i>Silicone rubber band</i> (n = 3329)	<i>Spring clip</i> (n = 1595)	<i>Interval partial salpingectomy</i> (n = 425)	<i>Postpartum partial salpingectomy</i> (n = 1637)
Age at sterilization						
18-27 yr	30.6	19.6	30.0	43.8	28.2	43.3
28-33 yr	34.6	38.6	36.1	30.4	32.2	38.3
34-44 yr	34.8	41.8	33.9	25.8	39.5	18.4
Race-ethnicity*						
White, non-Hispanic	47.5	82.5	57.7	53.3	44.0	25.7
Black, non-Hispanic	50.1	13.3	29.0	44.4	25.9	38.2
Hispanic, American Indian, Alaskan Native, and Asian or Pacific Islander†	2.4	4.3	13.4	2.3	30.1	36.1
Marital status						
Ever married	78.8	91.6	81.5	75.9	86.1	84.5
Never married	21.2	8.4	18.5	24.1	13.9	15.5
Education						
<12 yr	20.8	12.4	21.9	26.1	19.3	24.8
12 yr	43.1	50.4	43.6	42.6	40.6	41.6
>12 yr	36.1	37.2	34.5	31.3	40.1	33.6
Gravidity						
<2	15.6	11.0	12.4	12.4	17.7	0.8
2	28.5	30.9	28.4	29.0	30.4	19.2
>2	55.9	58.1	59.3	58.6	52.0	80.0

\*For portions of the data collection period race and ethnicity were not separately reported.

†Sample sizes were insufficient for separate analyses of Hispanic, American Indian, Alaskan Native, and Asian or Pacific Islander women; therefore these categories were combined.

phase pregnancy. Another 16 pregnancies occurred after tubal anastomosis or in vitro fertilization, and five pregnancies were classified as having unknown status. The remainder of this report concerns only those 143 pregnancies classified as true sterilization failures. Of these 143 pregnancies, 21 (14.7%) ended in spontaneous abortion, 26 (18.2%) in induced abortion, 41 (28.7%) in delivery, and 47 (32.9%) in ectopic pregnancy. Six (4.2%) additional pregnancies were continuing at the time of interview; we had too little information to classify the status of 2 (1.4%) pregnancies. The classification of 95 (66.4%) pregnancies was based on a review of medical records by either the CDC investigators or the study center investigator or both. For the remaining 48 pregnancies classification was based on the study participant's history alone.

The classification of 9 of the pregnancies ending in spontaneous abortion was facilitated by medical records. However, records were unavailable for 12 other women; for these women classifications were based solely on self-reports. Separate life-table analyses of true sterilization failures were performed with and without the less well-documented spontaneous abortions included. Only those analyses with the less well-documented group included are reported in detail here.

When all sterilization methods are considered in the aggregate, the 10-year cumulative life-table probability of failure was 18.5 per 1000 procedures (95% confidence interval 15.1 to 21.8) when pregnancies ending in spontaneous abortion based on self-reports were included

(Table II) and 16.6 per 1000 procedures (95% confidence interval 13.5 to 19.7) when those pregnancies were excluded. The 10-year life-table method-specific probabilities of failure indicated a substantial difference in effectiveness among methods, with the most effective methods being postpartum partial salpingectomy and laparoscopic unipolar coagulation (7.5 pregnancies per 1000 procedures). Laparoscopic spring clip application had the highest probability of failure (36.5 pregnancies per 1000 procedures). The failure rates for postpartum partial salpingectomy and unipolar coagulation were reduced by excluding women whose pregnancies ended in spontaneous abortion on the basis of self-report only; after exclusion the 10-year probabilities of failure were 4.9 and 3.2 per 1000 procedures, respectively. The 10-year probabilities of failure for spring clip application, silicone rubber band application, bipolar coagulation, and interval partial salpingectomy were similar before and after exclusion.

The 10-year cumulative probability of failure is affected by age at tubal sterilization (Table III). We divided the cohort into three age groups nearly equal in size. The probability of failure for women sterilized at ages <28 years is greater than that for women sterilized at ages ≥34 years for all methods of sterilization except interval partial salpingectomy. For bipolar coagulation and silicone rubber band application these differences in risk are statistically significant. The relative differences in effectiveness between methods of sterilization diminish with increasing age at sterilization; by ages ≥34 years none of

**Table II.** Life-table cumulative probability of pregnancy among women undergoing tubal sterilization by method (cumulative probability per 1000 procedures and 95% confidence interval)

Method	No.*	Years since sterilization			
		1	2	3	4
Bipolar coagulation	2267	2.3 (0.3-4.2)	4.6 (1.8-7.5)	6.7 (3.2-10.2)	13.1 (7.9-18.2)
Unipolar coagulation	1432	0.7 (0.0-2.1)	2.3 (0.0-4.8)	2.3 (0.0-4.8)	2.3 (0.0-4.8)
Silicone rubber band application	3329	5.9 (3.3-8.5)	7.6 (4.5-10.6)	8.3 (5.1-11.4)	9.0 (5.7-12.4)
Spring clip application	1595	18.2 (11.5-24.9)	23.8 (16.1-31.5)	29.1 (20.5-37.7)	30.7 (21.9-39.6)
Interval partial salpingectomy	425	7.3 (0.0-15.5)	15.1 (3.1-27.1)	15.1 (3.1-27.1)	15.1 (3.1-27.1)
Postpartum partial salpingectomy	1637	0.6 (0.0-1.9)	3.9 (0.8-7.1)	4.6 (1.2-8.1)	5.4 (1.7-9.2)
All methods	10685	5.5 (4.1-6.9)	8.4 (6.6-10.1)	9.9 (8.0-11.8)	11.8 (9.7-14.0)

\*Number of women sterilized.

**Table III.** Life-table cumulative probability of pregnancy among women undergoing tubal sterilization by age (cumulative probability per 1000 procedures and 95% confidence interval)

Age at sterilization	No.*	Years since sterilization			
		1	2	3	4
18-27 yr					
Bipolar coagulation	693	3.0 (0.0-7.1)	10.8 (2.9-18.8)	10.8 (2.9-18.8)	21.3 (9.2-33.4)
Unipolar coagulation	280	3.7 (0.0-11.1)	3.7 (0.0-11.1)	3.7 (0.0-11.1)	3.7 (0.0-11.1)
Silicone rubber band application	994	9.5 (3.3-15.7)	10.7 (4.1-17.3)	13.2 (5.8-20.7)	14.7 (6.7-22.7)
Spring clip application	694	24.1 (12.5-35.8)	32.4 (18.8-46.1)	43.3 (27.2-59.3)	45.3 (28.8-61.8)
Interval partial salpingectomy	120	0.0 (0.0-0.0)	9.7 (0.0-28.6)	9.7 (0.0-28.6)	9.7 (0.0-28.6)
Postpartum partial salpingectomy	707	1.5 (0.0-4.3)	7.8 (1.0-14.6)	7.8 (1.0-14.6)	7.8 (1.0-14.6)
28-33 yr					
Bipolar coagulation	786	2.6 (0.0-6.2)	2.6 (0.0-6.2)	8.4 (1.7-15.1)	14.9 (5.7-24.0)
Unipolar coagulation	549	0.0 (0.0-0.0)	2.0 (0.0-5.8)	2.0 (0.0-5.8)	2.0 (0.0-5.8)
Silicone rubber band application	1199	4.3 (0.5-8.1)	7.9 (2.8-13.1)	7.9 (2.8-13.1)	9.0 (3.4-14.6)
Spring clip application	487	21.2 (8.2-34.3)	25.7 (11.4-40.1)	25.7 (11.4-40.1)	28.3 (13.1-43.5)
Interval partial salpingectomy	137	7.5 (0.0-22.0)	15.4 (0.0-36.6)	15.4 (0.0-36.6)	15.4 (0.0-36.6)
Postpartum partial salpingectomy	625	0.0 (0.0-0.0)	1.7 (0.0-5.0)	3.5 (0.0-8.3)	3.5 (0.0-8.3)
34-44 yr					
Bipolar coagulation	788	1.3 (0.0-3.8)	1.3 (0.0-3.8)	1.3 (0.0-3.8)	4.5 (0.0-9.6)
Unipolar coagulation	603	0.0 (0.0-0.0)	1.8 (0.0-5.3)	1.8 (0.0-5.3)	1.8 (0.0-5.3)
Silicone rubber band application	1136	4.5 (0.6-8.4)	4.5 (0.6-8.4)	4.5 (0.6-8.4)	4.5 (0.6-8.4)
Spring clip application	414	5.0 (0.0-11.9)	7.6 (0.0-16.2)	10.4 (0.2-20.5)	10.4 (0.2-20.5)
Interval partial salpingectomy	168	12.3 (0.0-29.2)	18.7 (0.0-39.6)	18.7 (0.0-39.6)	18.7 (0.0-39.6)
Postpartum partial salpingectomy	305	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	3.8 (0.0-11.4)

\*Number of women sterilized.

the differences between methods in the 10-year cumulative probability of failure are statistically significant.

We analyzed the following 10 factors to determine their impact on the relative risk of sterilization failure: sterilization method, age at sterilization, race-ethnicity, study site, education, marital status, gravidity, history of pelvic inflammatory disease, history of previous abdominal or pelvic surgery, and presence of adhesions recorded at sterilization. Only the first four factors were significant in a multivariate context (Table IV). After adjustment for age, race-ethnicity, and study site, three methods—interval partial salpingectomy, spring clip application, and bipolar coagulation—were significantly more likely than postpartum partial salpingectomy to result in sterilization failure. The increased risks of sterilization failure identified with silicone rubber band application and unipolar coagulation relative to postpartum partial salpingectomy

were not statistically significant. After adjustment for sterilization method, race-ethnicity, and study site, women sterilized at ages  $\geq 34$  years were at significantly less risk for sterilization failure than were women sterilized at ages 28 through 33 years. After adjustment for sterilization method, age, and study site, black, non-Hispanic women were at significantly greater risk for sterilization failure than were white, non-Hispanic women. After adjustment for sterilization method, age, and race-ethnicity, there were significant differences in the risk of sterilization failure between study sites. Some study sites had risks well above the average, and others had risks well below the average.

#### Comment

We found all methods of tubal sterilization to be highly effective in reducing the risk of pregnancy. However, the

*Years since sterilization*

5	6	7	8	9	10
16.5 (10.6-22.4)	18.3 (11.9-24.7)	20.7 (13.5-28.0)	22.0 (14.4-29.6)	23.3 (15.2-31.3)	24.8 (16.2-33.3)
2.3 (0.0-4.8)	2.3 (0.0-4.8)	2.3 (0.0-4.8)	2.3 (0.0-4.8)	4.0 (0.0-8.2)	7.5 (1.1-13.9)
10.0 (6.4-13.5)	10.0 (6.4-13.5)	13.0 (7.5-18.5)	16.1 (9.1-23.0)	16.1 (9.1-23.0)	17.7 (10.1-25.3)
31.7 (22.6-40.7)	31.7 (22.6-40.7)	31.7 (22.6-40.7)	31.7 (22.6-40.7)	34.0 (23.9-44.2)	36.5 (25.3-47.7)
15.1 (3.1-27.1)	15.1 (3.1-27.1)	15.1 (3.1-27.1)	15.1 (3.1-27.1)	20.1 (4.7-35.6)	20.1 (4.7-35.6)
6.3 (2.2-10.3)	6.3 (2.2-10.3)	6.3 (2.2-10.3)	6.3 (2.2-10.3)	7.5 (2.7-12.3)	7.5 (2.7-12.3)
13.1 (10.8-15.4)	13.5 (11.1-15.8)	14.6 (12.0-17.2)	15.5 (12.7-18.2)	16.9 (13.9-20.0)	18.5 (15.1-21.8)

*Years since sterilization*

5	6	7	8	9	10
26.4 (12.5-40.4)	30.0 (14.5-45.5)	39.2 (19.2-59.2)	43.9 (22.0-65.8)	48.7 (25.0-72.5)	54.3 (28.3-80.4)
3.7 (0.0-11.1)	3.7 (0.0-11.1)	3.7 (0.0-11.1)	3.7 (0.0-11.1)	3.7 (0.0-11.1)	3.7 (0.0-11.1)
18.2 (8.9-27.5)	18.2 (8.9-27.5)	25.5 (8.5-42.6)	25.5 (8.5-42.6)	25.5 (8.5-42.6)	33.2 (10.6-55.9)
45.3 (28.8-61.8)	45.3 (28.8-61.8)	45.3 (28.8-61.8)	45.3 (28.8-61.8)	45.3 (28.8-61.8)	52.1 (31.0-73.3)
9.7 (0.0-28.6)	9.7 (0.0-28.6)	9.7 (0.0-28.6)	9.7 (0.0-28.6)	9.7 (0.0-28.6)	9.7 (0.0-28.6)
7.8 (1.0-14.6)	7.8 (1.0-14.6)	7.8 (1.0-14.6)	7.8 (1.0-14.6)	11.4 (1.6-21.1)	11.4 (1.6-21.1)
18.7 (8.1-29.3)	21.3 (9.6-33.0)	21.3 (9.6-33.0)	21.3 (9.6-33.0)	21.3 (9.6-33.0)	21.3 (9.6-33.0)
2.0 (0.0-5.8)	2.0 (0.0-5.8)	2.0 (0.0-5.8)	2.0 (0.0-5.8)	6.5 (0.0-16.1)	15.6 (0.0-31.4)
9.0 (3.4-14.6)	9.0 (3.4-14.6)	13.0 (3.4-22.5)	21.1 (6.4-35.9)	21.1 (6.4-35.9)	21.1 (6.4-35.9)
31.3 (15.1-47.5)	31.3 (15.1-47.5)	31.3 (15.1-47.5)	31.3 (15.1-47.5)	31.3 (15.1-47.5)	31.3 (15.1-47.5)
15.4 (0.0-36.6)	15.4 (0.0-36.6)	15.4 (0.0-36.6)	15.4 (0.0-36.6)	33.5 (0.0-74.3)	33.5 (0.0-74.3)
5.6 (0.0-11.9)	5.6 (0.0-11.9)	5.6 (0.0-11.9)	5.6 (0.0-11.9)	5.6 (0.0-11.9)	5.6 (0.0-11.9)
6.3 (0.1-12.5)	6.3 (0.1-12.5)	6.3 (0.1-12.5)	6.3 (0.1-12.5)	6.3 (0.1-12.5)	6.3 (0.1-12.5)
1.8 (0.0-5.3)	1.8 (0.0-5.3)	1.8 (0.0-5.3)	1.8 (0.0-5.3)	1.8 (0.0-5.3)	1.8 (0.0-5.3)
4.5 (0.6-8.4)	4.5 (0.6-8.4)	4.5 (0.6-8.4)	4.5 (0.6-8.4)	4.5 (0.6-8.4)	4.5 (0.6-8.4)
10.4 (0.2-20.5)	10.4 (0.2-20.5)	10.4 (0.2-20.5)	10.4 (0.2-20.5)	18.2 (0.0-36.4)	18.2 (0.0-36.4)
18.7 (0.0-39.6)	18.7 (0.0-39.6)	18.7 (0.0-39.6)	18.7 (0.0-39.6)	18.7 (0.0-39.6)	18.7 (0.0-39.6)
3.8 (0.0-11.4)	3.8 (0.0-11.4)	3.8 (0.0-11.4)	3.8 (0.0-11.4)	3.8 (0.0-11.4)	3.8 (0.0-11.4)

failure rates of most methods were substantially higher than those from most previous reports.<sup>4-8</sup>

All methods of tubal occlusion require proper application to maximize effectiveness. The higher failure rates associated with sterilization by spring clip application and bipolar coagulation highlight the need for proper technique in the use of these methods. As described by Hulka and Reich,<sup>9</sup> the spring clip should be applied after the fallopian tube is placed on stretch. The clip should be placed on the proximal isthmus precisely at an angle of 90 degrees relative to the long axis of the fallopian tube. Before the jaws of the clip are closed, the clip should be advanced over the tube until the tube reaches the hinge of the clip. When closed, the clip should include a small portion of mesosalpinx. Soderstrom et al.<sup>10</sup> described specific strategies for reducing the risk of pregnancy after bipolar coagulation, including the use of generators placed in the cutting, bipolar mode at 25 W against a 100 Ω load, use of

an in-line current meter, and coagulation of at least three contiguous areas of the isthmus.

Most studies of sterilization failure have evaluated women for only 1 to 2 years after the procedure, yet pregnancies among our study participants occurred >1 to 2 years after sterilization. Thus the risk of sterilization failure must be considered in cumulative terms. The concept of cumulative risk is most important for women sterilized at a young age (who have a longer period at risk of pregnancy) and women sterilized with bipolar coagulation, unipolar coagulation, or silicone rubber band application (because these methods have a greater percentage of total failures occurring long after sterilization than do other methods).

The probabilities of failure between years 5 and 10 after sterilization in our study ranged from 1.2 per 1000 procedures for postpartum partial salpingectomy to 8.3 per 1000 procedures for bipolar coagulation. It is particu-

**Table IV.** Risk of sterilization failure by factors influencing risk\*

Factor	Relative risk	95% Confidence interval		Importance of factor	
		Lower limit	Upper limit	$\chi^2$ †	Significance
Method				17.26 (5)	$p = 0.004$
Postpartum partial salpingectomy	1.00	—	—		
Interval partial salpingectomy	3.87	1.42	10.58		
Spring clip application	3.70	1.53	8.98		
Bipolar coagulation	3.20	1.40	7.31		
Silicone rubber band application	2.34	0.90	6.08		
Unipolar coagulation	1.50	0.41	5.49		
Age at sterilization				16.36 (2)	$p < 0.001$
18-27 yr	1.25	0.87	1.82		
28-33 yr	1.00	—	—		
34-44 yr	0.46	0.27	0.79		
Race-ethnicity				17.00 (2)	$p < 0.001$
White, non-Hispanic	1.00	—	—		
Black, non-Hispanic	2.53	1.59	4.02		
Hispanic, American Indian, Alaskan Native, Asian or Pacific Islander	1.24	0.47	3.24		
Study site				33.40 (14)	$p = 0.003$
A	3.46	1.58	7.56		
B	3.05	0.68	13.65		
C	2.06	1.05	4.04		
D	2.04	0.68	6.12		
E	1.78	0.53	5.97		
F	1.61	0.41	6.24		
G	1.32	0.30	5.86		
H	1.00	—	—		
I	0.91	0.31	2.64		
J	0.89	0.28	2.89		
K	0.86	0.25	2.99		
L	0.80	0.22	2.91		
M	0.68	0.08	5.50		
N	0.68	0.09	5.25		
O	0.55	0.16	1.88		

\*Based on a Cox proportional hazards model.

† $\chi^2$  for a factor was obtained by deleting that factor from a full model with method, age at sterilization, race-ethnicity, and study site.

larly striking that among women 18 to 27 years old at bipolar coagulation 2.8% became pregnant between 5 and 10 years after the procedure. Thus the concept of cumulative risk may need to include the risk of pregnancy for >10 years after sterilization. As long as a woman is fertile, she may continue to be at risk for sterilization failure.

In our study the cumulative risk of pregnancy after tubal sterilization varied depending on age. In general, the younger a woman was at the time of sterilization, the more likely she was to have a sterilization failure. The older a woman was at the time of sterilization, the less likely the method of sterilization was to affect the cumulative probability of failure.

Because our study was conducted in medical centers where interval tubal sterilizations were routinely performed via laparoscopy, many women undergoing interval sterilization by laparotomy in our study probably had that approach because they were considered to be at increased risk for complications of laparoscopic sterilization. Although we studied too few women who underwent interval partial salpingectomy to measure reliably

the impact of risk factors for sterilization failure, we believe that the selected women undergoing interval partial salpingectomy in our study probably were inherently at greater risk for sterilization failure.

We anticipated problems of study bias in making decisions regarding inclusion and exclusion criteria, as well as classification of luteal phase pregnancies versus true sterilization failures. We made these decisions with the intent to minimize study bias and, when bias was likely, always to direct the bias in the same direction. Because preliminary analyses indicated that sterilization failures were far more likely than previously thought, we chose to eliminate any bias that would increase the estimated probability of failure.

To minimize selection bias in study enrollment we attempted to enroll all women meeting our study criteria in participating institutions. We have information regarding refusal to participate for the last 4354 women approached regarding study enrollment. That their refusal rate was only 5% indicates that selection bias was unlikely.

We attempted to follow up all women enrolled in the study for a minimum of 5 years (for women enrolled in

the early phase of the study we attempted an additional single follow-up at 8 to 14 years). Young women and black women were more likely than older or white women to have been lost to follow-up. Because young age and black race were associated with an increased risk of pregnancy after sterilization among those followed up in our study, our overall estimates of sterilization failure would be underestimated if the experience of those young women or those black women lost to follow-up was the same as that of those young women or black women who were followed up. To minimize bias resulting from loss to follow-up we excluded information regarding pregnancies that was obtained for women whom we were unable to locate or who refused interview. We would expect that women with pregnancies after tubal sterilization are likely to come to medical attention and be identified through a review of medical records. Therefore we restricted our analysis to pregnancies initially identified by telephone. For example, one institutional investigator identified pregnancies in women lost to follow-up by reviewing medical records. We excluded three pregnancies identified in this manner that would have been classified as true sterilization failures.

We made a distinction between luteal phase pregnancy and true sterilization failure on the basis of a priori decision rules that resulted in all borderline cases being classified as luteal phase pregnancies. Specifically, if a pregnancy was consistent with a luteal phase pregnancy on the basis of available information, it was classified as a luteal phase pregnancy even if it was also consistent with a true sterilization failure. We thereby made an effort to underestimate systematically the risk of true failures. In one case a woman reported a pregnancy consistent with a luteal phase pregnancy and a later pregnancy documented by medical records to be a true sterilization failure. This woman was classified as having only a luteal phase pregnancy because only the first reported pregnancy was used in our analysis.

Classification of spontaneous abortions was based on whether the woman's history alone was available or whether additional information was available (including at a minimum a record of a pregnancy test, physical examination, ultrasonography, or pathology report). Because failure rates were similar with and without inclusion of pregnancies classified as spontaneous abortions by history alone (only 14.7% of true sterilization failures were classified as spontaneous abortions), we doubt that over-reporting of spontaneous abortions biased our findings substantially. In addition, some women probably experienced spontaneous abortions that were not apparent to them and went unreported.

Surveys of U.S. women typically underreport induced abortion.<sup>11</sup> Data from the National Survey of Family Growth suggest that 47.5% of pregnancies after contraceptive failures result in induced abortion.<sup>12</sup> In our study

27.1% of sterilization failures resulted in induced abortion (after exclusion of ectopic pregnancies). To the extent that this discrepancy is explained by the underreporting of pregnancies that resulted in induced abortion, our estimates of the risks of sterilization failure would be underestimated.

Although the U.S. Collaborative Review of Sterilization enrolled study participants from across the country, the study population was not specifically selected to represent the general population, with regard to either characteristics of the women sterilized or the methods of tubal sterilization. Nonetheless, the ages of our study population are remarkably similar to those of women undergoing tubal sterilizations in U.S. hospitals, as determined by the National Hospital Discharge Survey (NHDS).<sup>13</sup> The average age at sterilization among both our study population and women sampled by NHDS in 1980 was 30 years. However, our sample included a higher percentage of black women and a lower percentage of white women than did the 1980 NHDS. Because our percentage distribution of the sterilization methods was not selected to represent that of the United States but rather was chosen on the basis of considerations regarding study power, the cumulative risk of sterilization failure in our cohort may not reflect that in the general population.

We attempted to identify factors other than choice of sterilization method that influenced the risk of sterilization failure. We found that race-ethnicity was a determinant of risk. Although black women were more likely than white women to experience sterilization failure after adjustment for other known factors, black race may have served as a marker for other unmeasured determinants of risk.

Because most participants in our study were enrolled in teaching institutions, the study findings can be generalized with comfort only to sterilizations in such settings. We are unable to estimate whether tubal sterilizations in our teaching institutions were more or less likely to have been successfully completed than sterilizations outside of teaching institutions. Stovall et al.,<sup>14, 15</sup> whose study population included participants in the U.S. Collaborative Review of Sterilization, reported on the use of the spring clip and the silicone rubber band in a residency training program. Twenty patients who became pregnant after sterilization and later underwent bilateral partial salpingectomy were evaluated. For all 20 women improper application of the occlusive devices was noted on gross and histologic evaluation. Our study included institutions in which experience with some methods was extensive and institutions in which experience was far less extensive. We identified substantial differences in the risk of sterilization failure by study site. How the factors noted affect generalizability to nonteaching settings remains unclear.

The failure rates reported here should not be consid-

ered in isolation but rather in conjunction with the safety and acceptability of the procedures evaluated. For example, although we have not yet evaluated the cumulative risks of ectopic pregnancy in our cohort, other evidence suggests that the risk of ectopic pregnancies is higher with coagulation methods than with other methods of tubal occlusion.<sup>16, 17</sup> Further, each sterilization technique is associated with known or suspected advantages and disadvantages. For example, postpartum partial salpingectomy was found to be one of the most effective techniques in our study, but an earlier report from this cohort revealed that women undergoing postpartum sterilization were 40% more likely than women undergoing interval sterilization to experience regret at having been sterilized.<sup>18</sup> Likewise, unipolar coagulation, another highly effective method in our study, is the technique most likely to result in serious injury or death. In a survey of deaths attributable to tubal sterilization in the United States, only 4 of 29 reported deaths from 1977 through 1981 were likely attributable to the use of a particular method of tubal occlusion, and 3 of these resulted from sepsis after apparent bowel injury with the use of unipolar coagulation devices.<sup>19</sup> Clip sterilization, the least effective technique in our study, is also the technique most likely to be successfully reversed by tubal anastomosis.<sup>20</sup>

In sum, tubal sterilization is a highly effective method of preventing pregnancy. However, pregnancy after sterilization occurs substantially more often than generally reported. Further, pregnancies continue to occur >1 to 2 years after sterilization. Thus establishing the concept of cumulative risk of pregnancy after sterilization is important, particularly for women sterilized at a young age.

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## Discussion

**DR. DAVID A. GRIMES**, San Francisco, California. This report, the first long-term follow-up from the Collaborative Review of Sterilization (CREST) of the Centers for Disease Control and Prevention, is a landmark contribution. The CREST study is unique because of its large size, 10-year follow-up, and elegant life-table analysis of sterilization failures.

This report challenges several widely held yet perhaps inaccurate beliefs about tubal sterilization. For example,



some authorities suggest that pregnancies occurring after tubal sterilization are "typically due to surgical or equipment failures" and that these pregnancies occur primarily in the first year after operation. Moreover, they claim that "after the first year, the risk of pregnancy becomes extremely small."<sup>1</sup> In contrast, the CREST data show that failures continue to occur well beyond the first year. By 5 years >1% of women in this study had a sterilization failure, and by 10 years the overall figure rose to 1.8%. Before this study most of what we knew about the efficacy of tubal sterilization in the United States came from small case-series reports from single institutions with limited follow-up.

However, these revelations about sterilization failures must not be interpreted in a vacuum. What are the alternatives for long-term contraception other than surgical sterilization? With the oral contraceptive the average first-year failure rate in national surveys is >2%. When corrected for underreporting of induced abortions in such surveys, the true figure may be as high as 8%.<sup>2</sup> Thus the cumulative probability of accidental pregnancy will be much higher than that with tubal sterilization. Information on long-term contraceptive efficacy of depot medroxyprogesterone acetate and subdermal levonorgestrel implants in the United States is limited.

In light of the CREST results the copper T 380A intrauterine contraceptive device becomes increasingly appealing for long-term contraception. Specifically, the efficacy of this device appears to rival the overall efficacy of tubal sterilization. The cumulative 8-year failure rate with the copper T 380A is 2.3%,<sup>3</sup> in contrast to 1.5% overall in the CREST study. For some sterilization methods such as spring clips the efficacy of the intrauterine contraceptive device appears to be superior. Moreover, use of the copper intrauterine contraceptive device is much simpler, safer, and, of course, immediately reversible. This copper intrauterine contraceptive device appears to be the most cost-effective method of contraception over 5 years of use.<sup>1</sup> In national surveys the proportion of women satisfied with their contraceptive method is higher for intrauterine contraceptive device users than for users of any other method, including sterilization.<sup>4</sup>

In any cohort study biases can influence results. In closing, I ask Dr. Peterson whether he could share with us his assessment of the potential impact of selection bias, information bias, and confounding on the CREST study results. Was there any differential loss to follow-up? In addition, can we safely extrapolate these results from teaching institutions to settings with more experienced surgeons?

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**DR. CHARLES B. HAMMOND**, Durham, North Carolina. The question is, was the bipolar technology a single burn or double burn or do you know what the pattern of sterilization was? Second, I would emphasize the data showing a >20% rate of these pregnancies being ectopic. Certainly patients need to be aware of that.

**DR. RONALD S. GIBBS**, Denver, Colorado. With your large sample size, I was wondering whether you were able to make a couple of stratifications, particularly in the postpartum patients.

Were you able to stratify those patients by whether they had vaginal delivery or cesarean section, there being some information that the failure rate is higher with tubal ligation at the time of cesarean section.

For the second stratification, were you able to stratify by Pomeroy versus other techniques?

And then one final question—How did you handle the requirement for tissue to confirm tubal ligation at the time of postpartum sterilization? Was that a requirement for entry?

**DR. ALLAN ROSENFELD**, New York, New York. I'm wondering whether through this study you were able to come up with any data on regret about sterilization related to age.

**DR. RONALD STRICKLER**, St. Louis, Missouri. Do you have any information on ovarian function and premature ovarian failure in this population?

**DR. DAVID P. SOPER**, Richmond, Virginia. As an investigator interested in the long-term follow-up of patients with sexually transmitted diseases, I am very impressed that you were able to follow up >10,000 women for 8 to 14 years with only an annual telephone call. Could you comment on how you were able to be so effective with your follow-up?

**DR. PETERSON** (Closing). Dr. Grimes, I appreciate your putting all this in perspective with the big picture and going right to the heart of the matter by asking key questions about study methods, particularly bias.

Bias is an issue for all epidemiologic studies, typically somewhat less for cohort studies like this than case-control studies but always an issue. We made an effort to anticipate bias in the design of the study and to minimize bias where bias was inevitable. We wanted to understand the likely direction of the bias so we could account for that in our analysis phase and in interpreting our data.

For example, with regard to selection bias we tried to enroll every woman undergoing sterilization who met the eligibility criteria in the participating institutions. We did that to minimize the likelihood of bias in selection of participants, and we were largely successful. In the last 4000 or so women enrolled, when we were carefully looking at the refusal rate, only 5% of women refused to participate. Because 95% of all women having sterilization who met the entry criteria were enrolled, we doubt there was substantial bias in selection of study participants.

We conducted a structured interview using a standardized data collection form that was administered by highly trained interviewers. We, as well as our project directors, worked very hard together to try to make sure that information was collected accurately, and I think it unlikely that we had substantial information bias.

Dr. Gibbs asked about the requirements for tissue. We had no requirements. The procedure was performed in the fashion that it was generally performed in that institution. So we got what we got, and that's one of the difficulties in interpretation, of course.

We couldn't, for example, randomize women to a method. So what we did was to collect detailed information about patient characteristics that could, in and of themselves, have influenced the likelihood of pregnancy after sterilization, such as age. We collected a large amount of data to try to make sure that we would be able to examine issues related to confounding. On multivariable analysis we found that age, race, and study site were confounders. So we did identify and control for those confounders in analysis.

I think the most serious issue with regard to bias in this study is the same as it is for many cohort studies, and that's the issue of loss to follow-up.

Dr. Soper asked about how we were able to be so effective in follow-up. I was pleased with the follow-up, but you always want more than you have in a long-term follow-up study. At 3 years we had 81% follow-up. At 5 years we had 73%, and at the 8- to 14-year long-term follow-up we had 58%. We had a variety of telephone numbers and maintained contact as closely as possible throughout the long-term follow-up period. We were able to achieve a high follow-up rate but not as high as we would have liked.

The key issue then with regard to bias is whether there were any differences in the likelihood of pregnancy between the women who were followed up and the women who could not be followed up.

One of the reasons we restricted our follow-up information to that gathered by telephone is that, whereas it was readily apparent that women who had become pregnant after sterilization would be more likely to interface with the system and be identified by our study investigators, we knew of no reason why women who had become pregnant would be more likely to be reachable by telephone than women who had not become pregnant.

We did exclude pregnancies that were identified by reviewing medical records or that otherwise came to the attention of the study project director at the site.

However, in looking at characteristics of women lost to follow-up and women whom we were able to follow up, we found that there were some differences that could have had an impact on the likelihood of failure, and they were tending to bias toward underestimating the risk. Specifically, we found that women who were lost to follow-up were more likely to be young and more likely to be black, and I mentioned that age and race did have an impact on failure rate. Women sterilized at a young age were more likely to have failures and women of black race were more likely to have failures. If the experience of the women whom we lost to follow-up was similar in terms of pregnancy risk to the experience of women whom we followed-up, then our bias would be toward an underestimate because the group that we lost would have had a higher failure experience than the group we found. So that's the likely direction of that bias to the extent that it occurred.

Dr. Grimes asked about generalizability, and I think that's a key question. I feel comfortable, given the high participation rate in our centers across the country, that we can reasonably generalize to the population of teaching centers from which we drew our sample. Whether we can generalize beyond that is unclear. We just don't know, for example, whether this experience is generalizable to community hospital settings.

Dr. Hammond asked a related question, and that was how were these procedures performed. Specifically, for example, was bipolar coagulation performed with one or two burns? We don't know yet, but we did capture that information and we're about to look at each of the methods in detail because what we saw for sterilization failure, in general, may or may not be true for each specific method in particular.

It's an important question because what we need to determine is whether the experience of our study population is the typical experience, the best scenario, or the worst scenario. There's good reason to believe, for example, that for bipolar coagulation it's not the best scenario. Soderstrom et al. found that if they used bipolar coagulation with the cutting mode as opposed to the coagulation mode—with 25 W at a 100  $\Omega$  load—endothelial tissue destruction was comparable to that for unipolar coagulation. So that one experiment would suggest that bipolar coagulation could be as effective as unipolar coagulation if it was done according to those specifications, but more work needs to be done to sort this out further.

Dr. Gibbs, on the question about stratification, we're attempting to do that now for each of the methods.

Dr. Rosenfield asked about regret. Surely this is one of the more important long-term issues that we can look at, particularly with divorce and remarriage. We do see regret after the procedure among some women.

We've not yet looked at the longest-term follow-up. We have analyzed and reported data on regret at 5 years, and we found that 6% of women had contacted a health care provider about the possibility of reversal. The actual rate of reversal was quite low, but with inquiries about reversal as a measure of regret, regret is not exceedingly rare. We found that age is the most important predictor of regret; a woman sterilized at a very young age, regardless of the number of children she has, is substantially more likely to regret than a woman sterilized at an older age.

Dr. Strickler asked about menstrual function. Ever since Williams et al.<sup>1</sup> in 1951 first proposed the possibility of a posttubal syndrome, there has been a great debate. We have looked at our data at 5 years after sterilization, and briefly, with women being compared to their own presterilization status, we see very little difference, if any, in the first couple of years and some slight differences at 5 years after sterilization that may be attributable to age.

In short, at this point we don't see convincing evidence that a posttubal syndrome exists.

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