

THE RISK OF MENSTRUAL ABNORMALITIES AFTER TUBAL STERILIZATION

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ABSTRACT

Background The existence of a post-tubal-ligation syndrome of menstrual abnormalities has been debated for decades. We used data from the U.S. Collaborative Review of Sterilization to determine whether the likelihood of persistent menstrual abnormalities was greater among women who had undergone tubal sterilization than among women who had not.

Methods A total of 9514 women who underwent tubal sterilization and 573 women whose partners underwent vasectomy were followed in a multicenter, prospective cohort study for up to five years by means of annual telephone interviews. All women were asked the same questions about six characteristics of their menstrual cycles in the presterilization and follow-up interviews. Multiple logistic-regression analysis was used to assess the risk of persistent menstrual changes.

Results The women who had undergone sterilization were no more likely than those who had not undergone the procedure to report persistent changes in intermenstrual bleeding or the length of the menstrual cycle. They were more likely to have decreases in the number of days of bleeding (odds ratio, 2.4; 95 percent confidence interval, 1.1 to 5.2), the amount of bleeding (odds ratio, 1.5; 95 percent confidence interval, 1.1 to 2.0), and menstrual pain (odds ratio, 1.3; 95 percent confidence interval, 1.0 to 1.8) and to have an increase in cycle irregularity (odds ratio, 1.6; 95 percent confidence interval, 1.1 to 2.3). Among women who had had very heavy bleeding at base line, women who had undergone sterilization were more likely than women who had not undergone the procedure to report decreased bleeding (45 percent vs. 33 percent, $P=0.03$).

Conclusions Women who have undergone tubal sterilization are no more likely than other women to have menstrual abnormalities. (N Engl J Med 2000; 343:1681-7.)

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MORE women in the United States have undergone tubal sterilization than are using any other single method of contraception.¹ It is a highly effective^{2,3} and safe^{4,5} procedure, but questions remain as to whether it causes menstrual abnormalities. Indeed, since 1951, when Williams et al.⁶ hypothesized that sterilization might increase a woman's risk of abnormal bleeding, the existence of a post-tubal-ligation syndrome has

been debated. Although Williams et al. described abnormal bleeding as increased menstrual and intermenstrual bleeding, the post-tubal-ligation syndrome remains ill defined. Furthermore, although some gynecologists recommend hysterectomy for sterilization because of the allegedly frequent occurrence of this syndrome,⁷ the authors of a recent review of the evidence regarding such a syndrome observed that "the only consistency in the articles reviewed is their inconsistency."⁸

Resolving the debate about menstrual abnormalities after tubal sterilization is important for safeguarding women's health. We recently reported that women who undergo tubal sterilization are four to five times as likely as women whose partners undergo vasectomy to undergo hysterectomy later,⁹ and earlier we reported that 41 percent of women undergoing hysterectomy had undergone tubal sterilization.¹⁰

To determine whether women who undergo tubal sterilization have an increased risk of subsequent menstrual abnormalities, we examined data from the U.S. Collaborative Review of Sterilization, a large, multicenter, prospective study initiated in 1978 to evaluate the long-term safety and effectiveness of tubal sterilization. In a preliminary report,¹¹ we found that menstrual function after sterilization was more likely to be abnormal during the fifth year than during the second year, but the analysis had no comparison group and the changes could have resulted from aging. In this report from the completed study, we have been able to account for age and other factors by evaluating menstrual function before and after sterilization among women who underwent tubal sterilization and a comparison group of women whose partners underwent vasectomy.

METHODS

The methods of the U.S. Collaborative Review of Sterilization have been described elsewhere.^{2,9,11} Women planning to undergo tubal sterilization by a method selected jointly with their physicians were enrolled between 1978 and 1987 at medical centers in Baltimore; Buffalo, New York; Chapel Hill, North Carolina; Honolulu; Houston; Memphis, Tennessee; Sacramento, California; St. Louis; and San Francisco. Between 1985 and 1987, nonsterilized women

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whose partners were undergoing vasectomy were also enrolled in Buffalo, Chapel Hill, Houston, St. Louis, and San Francisco. Follow-up was completed in 1994 for the women who underwent sterilization and in 1993 for the women whose partners underwent vasectomy. Although the women undergoing tubal sterilization were followed for up to 14 years, the women whose partners underwent vasectomy were followed for a maximum of 5 years. Accordingly, only data through five years of follow-up were included in this analysis.

We enrolled women 18 to 44 years of age who were undergoing tubal sterilization by a method being studied at their institution or whose partners were undergoing vasectomy. We restricted the analyses of women undergoing tubal sterilization to those who had interval procedures (procedures performed in women who had not recently been pregnant) and who were undergoing a procedure in which both fallopian tubes were occluded by the same method. The study protocol was approved by the institutional review board at each center, and written informed consent was obtained from each woman. Before tubal sterilization or at approximately the time of vasectomy, a nurse-interviewer obtained a detailed menstrual history from each woman. The women were asked to describe their most recent "natural cycles" (i.e., cycles when they were not pregnant or breast-feeding and were not using hormonal contraception or an intrauterine device). For some women, the last such cycle had occurred years previously. In annual follow-up telephone interviews, the women were asked to describe their three most recent menstrual cycles by answering the same questions posed at the base-line interview, but they were not asked to compare their menstrual cycles before and after they underwent sterilization or their partner had a vasectomy. Annual follow-up interviews were discontinued if a woman became pregnant, was lost to follow-up, refused to be interviewed, or underwent tubal anastomosis, repeated tubal sterilization, or hysterectomy.

The women were asked about six features of their menstrual function: duration of bleeding (the usual number of days), cycle length (the number of days from the beginning of one menstrual period to the beginning of the next), presence or absence of bleeding or spotting between periods, cycle irregularity (on a four-point scale ranging from "always regular" to "almost always irregular"), amount of menstrual pain (on a four-point scale ranging from "none or almost none" to "severe pain"), and amount of bleeding (on a five-point scale ranging from "very light" to "very heavy"). Although the last three features are subjective, we compared the responses only with the same woman's responses before sterilization and not with those of other women. The outcome of interest was persistent change in any of these features of the menstrual cycle.

For intermenstrual bleeding, cycle irregularity, menstrual pain, and amount of bleeding, we considered persistent change as any change from base line in the same direction (increasing or decreasing) that was reported in at least three annual interviews during follow-up. Similarly, for the duration of bleeding (categorized as less than four, four to eight, and more than eight days), either an increase or a decrease that was reported in at least three follow-up interviews was considered a persistent change. For cycle length (categorized as <21 days, 21 to 35 days, or >35 days), persistent changes were those from <21 days or >35 days to 21 to 35 days or from 21 to 35 days to <21 days or >35 days in at least three follow-up years. Women with less than three follow-up years were assumed to have had no persistent change in any aspect of menstrual function.

For each feature, we compared the proportions of the women who had undergone sterilization and the women who had not who had persistent change, with stratification according to base-line menstrual function. We used logistic-regression analysis to compare the risk of persistent menstrual changes between the two groups while adjusting for age, base-line menstrual status, and self-reported race or ethnic group. Data from all women who completed at least one follow-up interview were included in the primary analysis. We then carried out similar analyses restricted to women with at least three years of follow-up data and to women with just two years of follow-up (with the definition of persistent menstrual change altered ac-

ordingly). In addition, we performed separate analyses to compare the proportions of women who had undergone sterilization and of women who had not who reported changes in the fifth year of follow-up. We also carried out separate analyses to determine whether there were any differences among the women whose most recent natural cycles occurred at base line.

RESULTS

Of the 9514 women undergoing sterilization, 8363 (88 percent), 7797 (82 percent), 7365 (77 percent), and 6589 (69 percent) were successfully contacted for interviews one, two, three, and five years after sterilization, respectively. The corresponding totals for the 573 women whose partners underwent vasectomy were 517 (90 percent), 486 (85 percent), 479 (84 percent), and 440 (77 percent). Because of funding constraints, data for the fourth year of follow-up were available for only 871 women who had undergone tubal sterilization and no women whose partners had undergone vasectomy. Only 147 women who had undergone tubal sterilization and 25 women whose partners had undergone vasectomy refused to provide information at a follow-up interview.

The median age of the women who underwent sterilization was 31 years (mean [\pm SD], 31 ± 6), and the median age of the women whose partners underwent vasectomy was 32 years (mean, 32 ± 5). About one third (34 percent) of the women undergoing tubal sterilization were black, as compared with just 2 percent of the women whose partners underwent vasectomy. Women who underwent tubal sterilization were more likely than women whose partners underwent vasectomy to have used oral contraceptives or intrauterine devices as their last contraceptive method (Table 1).

The proportion of women with persistent menstrual changes varied according to base-line menstrual status in both study groups (Table 2). In both groups, nearly all (97 percent to 99 percent) of the women had menstrual cycles lasting 21 to 35 days before sterilization, and fewer than 1 percent had persistent changes in cycle length (data not shown). Among women with heavy bleeding at base line, those who underwent sterilization were significantly less likely to have increased bleeding afterward than those whose partners had a vasectomy. Among those with very heavy bleeding at base line, women who underwent sterilization were significantly more likely to have decreased bleeding afterward than those whose partners had a vasectomy. Women who underwent sterilization were also more likely to report a decrease in the number of days of bleeding if they had four to eight days of bleeding per cycle before sterilization.

After adjustment for age, base-line menstrual characteristics, race or ethnic group, and an interaction between race or ethnic group and age, the women who underwent sterilization were found to be more likely than the women whose partners underwent vasectomy to have persistent decreases in the amount of bleed-

TABLE 1. BASE-LINE CHARACTERISTICS OF WOMEN WHO UNDERWENT TUBAL STERILIZATION AND WOMEN WHOSE PARTNERS UNDERWENT VASECTOMY.

CHARACTERISTIC	TUBAL STERILIZATION (N=9514)	VASECTOMY (N=573)
	no. (%)	
Age		
≤35 yr	7342 (77)	454 (79)
>35 yr	2172 (23)	119 (21)
Race or ethnic group*		
Non-Hispanic white	5523 (58)	513 (90)
Non-Hispanic black	3196 (34)	13 (2)
Hispanic, American Indian, Alaskan Native, or Asian or Pacific Islander	795 (8)	47 (8)
No. of pregnancies		
<2	1260 (13)	77 (13)
2	2730 (29)	189 (33)
>2	5524 (58)	307 (54)
Sterilization method		
Bipolar coagulation	2238 (24)	
Unipolar coagulation	1445 (15)	
Silicone rubber-band application	3432 (36)	
Spring-clip application	1625 (17)	
Thermocoagulation	317 (3)	
Interval partial salpingectomy	414 (4)	
Other†	43 (<1)	
Contraceptive method before sterilization		
Oral contraceptive	3050 (32)	122 (21)
Intrauterine device	864 (9)	30 (5)
Barrier method	2470 (26)	214 (37)
Other‡	673 (7)	125 (22)
None	2457 (26)	82 (14)

*Any woman whose race or ethnic group was unknown was assumed to be a non-Hispanic white. For portions of the data-collection period, information about race was not obtained for respondents who specified their ethnic group as "Hispanic." Because the samples were too small for separate analyses of Hispanic, American Indian, Alaskan Native, and Asian or Pacific Islander women, these categories were combined.

†This category included fimbriectomy and electrocoagulation of unknown type. All these women were excluded from analyses with stratification according to sterilization method.

‡This category included withdrawal and natural family planning or the rhythm method.

ing, days of bleeding, and menstrual pain (Table 3). Women who underwent sterilization were also more likely to have a persistent increase in cycle irregularity. When the analyses were restricted to women who had their most recent natural cycles immediately before sterilization, the persistent decreases in the amount of bleeding, days of bleeding, and menstrual pain for women who underwent sterilization were no longer statistically significant, but the persistent increase in cycle irregularity remained significant.

We performed an additional analysis of persistent menstrual changes that was restricted to women with at least three follow-up interviews; the results were similar to those in the primary analysis (data not shown). We also performed analyses restricted to women with just two years of follow-up, defining persistent changes as those that occurred in both follow-up years. There were no significant differences between

women who underwent sterilization and those who did not in the likelihood of menstrual changes (data not shown).

When we compared menstrual function in the fifth year after sterilization with function before sterilization, the effect of sterilization on menstrual changes varied according to age. The only statistically significant change that occurred both among women whose most recent natural cycles occurred at any time before sterilization and among those whose most recent natural cycles occurred immediately before sterilization was for women sterilized at the age of 35 years or more. These two groups of women were more likely than their counterparts who had not undergone sterilization to have increases in cycle irregularity (odds ratio, 2.0 [95 percent confidence interval, 1.1 to 3.4] and 2.4 [95 percent confidence interval, 1.1 to 5.1], respectively).

When the risk of menstrual changes was evaluated according to the method of tubal sterilization, no significant differences were seen between women undergoing sterilization by any of six methods and women who did not undergo sterilization, with respect to increases in the amount or duration of bleeding, intermenstrual bleeding, or menstrual pain. Women undergoing silicone rubber-band application, thermocoagulation, or interval partial salpingectomy were more likely than women who did not undergo sterilization to have an increase in cycle irregularity, whereas women undergoing unipolar or bipolar coagulation were more likely than women who did not undergo sterilization to have a decrease in cycle irregularity. The method of tubal sterilization that causes the most extensive tubal destruction (unipolar coagulation) was no more likely than the least destructive method (spring-clip application) to cause persistent worsening of menstrual function (Table 4).

Because the initial report of menstrual abnormalities after tubal sterilization described an increase in menstrual and intermenstrual bleeding,⁶ we examined the likelihood of a woman's having a syndrome consisting of a persistent increase in at least one of the following menstrual features and no persistent decrease in any of them: amount of bleeding, days of bleeding, or intermenstrual bleeding. Because women who underwent sterilization could also be at lower risk for these abnormalities than women who did not, we also examined the likelihood of their having a syndrome consisting of a persistent decrease in at least one of the three features and no persistent increase in any of them. There were no significant differences between the two groups of women in the likelihood of having either syndrome (Table 5).

DISCUSSION

The original concern about sterilization involved the risk of heavy bleeding and intermenstrual bleeding,⁶ but we found no evidence of either problem.

TABLE 2. PERSISTENT MENSTRUAL CHANGES AMONG WOMEN WHO UNDERWENT TUBAL STERILIZATION AND WOMEN WHOSE PARTNERS UNDERWENT VASECTOMY, ACCORDING TO MENSTRUAL FEATURES BEFORE TUBAL STERILIZATION OR VASECTOMY.*

MENSTRUAL CHARACTERISTIC	TUBAL STERILIZATION			VASECTOMY		
	NO. OF WOMEN AT BASE LINE†	PERCENT WITH PERSISTENT INCREASE	PERCENT WITH PERSISTENT DECREASE	NO. OF WOMEN AT BASE LINE†	PERCENT WITH PERSISTENT INCREASE	PERCENT WITH PERSISTENT DECREASE
Amount of bleeding	9274			566		
Very light	240	56	NA	10	60	NA
Light	1034	44	1	42	52	0
Average	4433	17	3	255	16	4
Heavy	2883	4‡	22	174	8‡	16
Very heavy	684	NA	45§	85	NA	33§
Pain with menses	9461			568		
None or almost none	4278	25	NA	245	28	NA
Pain not requiring medication	2384	14	19	132	16	16
Pain requiring medication	2104	4	27	130	3	23
Severe pain	695	NA	46	61	NA	39
Cycle irregularity	9442			571		
Always regular	5842	12	NA	356	9	NA
Usually regular	2350	3	29	139	1	25
Often irregular	559	1	54	30	0	53
Almost always irregular	691	NA	59	46	NA	52
Intermenstrual bleeding	9455			570		
No	8751	1	NA	551	1	NA
Yes	704	NA	56	19	NA	68
Days of bleeding	9275			563		
<4	1433	38	NA	54	39	NA
4–8	7734	<1	3¶	501	<1	1¶
>8	108	NA	60	8	NA	50

*As the study progressed, investigators added questions about menstrual cycles just before hysterectomy for women who underwent hysterectomy; no information regarding menstrual cycles in the year of hysterectomy was available for women who were enrolled early in the study. Data regarding menstrual characteristics immediately before hysterectomy were available for 243 (58 percent) of the 419 women who underwent hysterectomy within five years after tubal sterilization and for all of the 9 nonsterilized women who underwent hysterectomy. Analyses including these data as an additional year of follow-up had little effect on the results. NA denotes not applicable.

†Women with a missing or invalid code for a base-line menstrual characteristic were excluded.

‡There was a significant difference (P=0.01) between the vasectomy and the tubal-sterilization groups in the percentage of subjects with a persistent decrease.

§There was a significant difference (P=0.03) between the vasectomy and the tubal-sterilization groups in the percentage of subjects with a persistent increase.

¶There was a significant difference (P=0.01) between the vasectomy and the tubal-sterilization groups in the percentage of subjects with a persistent increase.

Furthermore, we found that women who underwent sterilization were likely to have decreases in the amount of bleeding, the number of days of bleeding, and the amount of menstrual pain and an increase in cycle irregularity. We know of no biologic explanation for these changes, most of which were beneficial, in women after tubal ligation. Perhaps most important, none of the findings were noted consistently in other studies. For example, of three other U.S. studies of cycle irregularity in women who underwent or did not undergo sterilization,¹²⁻¹⁴ only one found women who had undergone sterilization to have an increased risk of cycle irregularity.¹² The most likely explanation for the differences between the two groups of women in our study, including differences according to the method of sterilization, is chance, because of the multiple comparisons we made, or unmeasured differences between the study groups.

Sterilization has been hypothesized to cause menstrual abnormalities by adversely affecting ovarian function. However, laboratory studies comparing women before and after sterilization have found no consistent abnormalities in ovarian function.⁸ Tubal occlusion has been hypothesized to disrupt the ovarian blood supply. Although the tubal branch of the uterine artery, which is often occluded during sterilization, connects with the ovarian branch of the uterine artery, blood is also supplied to the ovary by the ovarian artery, which could not be affected by sterilization because it branches directly off the aorta and is remote from the occlusion site. Alternatively, tubal occlusion might cause an acute increase in pressure in the utero-ovarian arterial loop, damaging the ovary.¹⁵ However, nearly all studies that controlled for prior contraceptive use,⁸ including our preliminary study,^{11,16} found no menstrual changes two years af-

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TABLE 3. ODDS RATIOS FOR PERSISTENT MENSTRUAL CHANGES AMONG WOMEN WHO UNDERWENT TUBAL STERILIZATION AS COMPARED WITH WOMEN WHOSE PARTNERS UNDERWENT VASECTOMY, ACCORDING TO THE TIME OF THEIR MOST RECENT NATURAL MENSTRUAL CYCLE.*

MENSTRUAL FEATURE AND TIME OF LAST NATURAL CYCLE	TUBAL STERILIZATION	VASECTOMY	PERSISTENT	
			INCREASE	DECREASE
odds ratio (95% CI)†				
Amount of bleeding				
Any time before sterilization or vasectomy	9274	566	1.0 (0.8–1.3)	1.5 (1.1–2.0)
Immediately before sterilization or vasectomy	2371	256	0.7 (0.5–1.1)	1.0 (0.7–1.5)
Pain with menses				
Any time before sterilization or vasectomy	9461	568	0.9 (0.7–1.2)	1.3 (1.0–1.8)‡
Immediately before sterilization or vasectomy	2425	256	0.8 (0.6–1.2)	1.5 (1.0–2.4)§
Cycle irregularity				
Any time before sterilization or vasectomy	9442	571	1.6 (1.1–2.3)	1.3 (1.0–1.8)§
Immediately before sterilization or vasectomy	2412	258	2.8 (1.4–5.4)	1.3 (0.8–2.1)
Intermenstrual bleeding				
Any time before sterilization or vasectomy	9455	570	1.3 (0.6–3.0)	0.6 (0.2–1.7)
Immediately before sterilization or vasectomy	2415	258	1.4 (0.3–6.1)	1.1 (0.2–5.3)
Days of bleeding				
Any time before sterilization or vasectomy	9275	563	1.1 (0.7–2.0)	2.4 (1.1–5.2)
Immediately before sterilization or vasectomy	2384	253	0.9 (0.4–2.0)	2.4 (0.7–8.9)

*All menstrual cycles analyzed were natural cycles — i.e., cycles during which the women were not pregnant, breast-feeding, or using hormonal contraception or intrauterine devices. Natural cycles “any time before sterilization or vasectomy” may have occurred immediately before or many years before the woman underwent tubal sterilization or her partner underwent vasectomy. Natural cycles “immediately before sterilization or vasectomy” were those occurring in the three months before the procedure. Women with a missing or invalid code for a base-line menstrual feature were excluded.

†Odds ratios are for sterilized as compared with nonsterilized women and are based on a logistic-regression model with control for race or ethnic group, age at the time of sterilization or vasectomy, base-line menstrual features, and an interaction between race or ethnic group and age at the time of sterilization or vasectomy. CI denotes confidence interval.

‡The lower limit of the confidence interval was greater than 1.0 but was rounded to 1.0.

§The lower limit of the confidence interval was less than 1.0 but was rounded to 1.0.

TABLE 4. ODDS RATIOS FOR PERSISTENT MENSTRUAL CHANGES AMONG WOMEN WHO UNDERWENT TUBAL STERILIZATION, ACCORDING TO THE METHOD OF STERILIZATION.*

MENSTRUAL CHANGE	BIPOLAR COAGULATION (N=2238)	UNIPOLAR COAGULATION (N=1445)	SILICONE RUBBER-BAND APPLICATION (N=3432)	SPRING-CLIP APPLICATION (N=1625)	THERMO-COAGULATION (N=317)	INTERVAL PARTIAL SALPINGECTOMY (N=414)
	odds ratio (95 percent confidence interval)					
Amount of bleeding						
Increased	1.2 (0.9–1.6)	0.9 (0.7–1.2)	0.9 (0.7–1.2)	1.2 (0.9–1.6)	0.9 (0.6–1.4)	1.2 (0.8–1.8)
Decreased	1.7 (1.2–2.3)	1.3 (1.0–1.8)	1.6 (1.1–2.1)	1.1 (0.8–1.5)	2.0 (1.3–3.2)	1.4 (0.9–2.1)
Pain with menses						
Increased	1.0 (0.7–1.3)	0.9 (0.7–1.2)	0.7 (0.6–1.0)	1.1 (0.9–1.5)	1.3 (0.9–1.9)	0.8 (0.6–1.2)
Decreased	1.7 (1.3–2.3)	1.1 (0.8–1.5)	1.5 (1.1–2.0)	0.8 (0.6–1.1)	2.0 (1.3–3.1)	1.3 (0.9–2.0)
Cycle irregularity						
Increased	0.7 (0.5–1.1)	1.2 (0.8–1.7)	2.3 (1.6–3.3)	1.1 (0.7–1.6)	7.2 (4.6–11.4)	2.0 (1.2–3.3)
Decreased	2.3 (1.7–3.3)	1.5 (1.1–2.1)	1.1 (0.8–1.4)	0.9 (0.6–1.3)	0.8 (0.5–1.3)	1.4 (0.9–2.1)
Intermenstrual bleeding						
Increased	1.7 (0.7–4.1)	1.1 (0.4–2.9)	0.7 (0.3–1.7)	2.1 (0.9–5.1)	1.9 (0.6–6.0)	1.4 (0.4–4.8)
Decreased	0.7 (0.3–2.1)	0.9 (0.3–2.7)	0.4 (0.2–1.2)	0.4 (0.1–1.2)	1.2 (0.3–4.4)	0.5 (0.2–1.6)
Days of bleeding						
Increased	1.7 (1.0–3.0)	1.1 (0.6–2.0)	1.0 (0.6–1.8)	0.9 (0.5–1.6)	1.8 (0.8–3.9)	0.8 (0.4–1.8)
Decreased	1.7 (0.8–4.0)	1.6 (0.7–3.8)	2.9 (1.3–6.3)	3.7 (1.6–8.3)	1.8 (0.6–5.7)	4.4 (1.8–10.9)

*Odds ratios are for women who underwent sterilization by the methods listed as compared with women whose partners underwent vasectomy and was based on logistic-regression analysis with control for age at the time of sterilization, base-line menstrual characteristics, race or ethnic group, and an interaction between race or ethnic group and age at the time of sterilization or vasectomy. For each analysis of menstrual change according to the method of sterilization, the number of women may vary because of missing or invalid codes for a base-line menstrual feature. Forty-three women who underwent sterilization by other methods have been excluded from this analysis.

TABLE 5. ODDS RATIOS FOR A PERSISTENT INCREASE OR DECREASE IN MENSTRUAL FLOW OR INTERMENSTRUAL BLEEDING AMONG WOMEN WHO UNDERWENT TUBAL STERILIZATION AS COMPARED WITH WOMEN WHOSE PARTNERS UNDERWENT VASECTOMY, ACCORDING TO THE TIME OF THE MOST RECENT NATURAL MENSTRUAL CYCLE.*

TIME OF LAST NATURAL CYCLE	TUBAL STERILIZATION	VASECTOMY	PERSISTENT INCREASE PERSISTENT DECREASE	
			odds ratio (95% CI)†	
Any time before sterilization or vasectomy	9477	572	1.2 (1.0–1.6)‡	1.1 (0.9–1.4)
Immediately before sterilization or vasectomy	2429	259	0.9 (0.6–1.3)	0.8 (0.6–1.2)§

*A persistent increase was defined as a persistent increase in at least one of the following characteristics and no persistent decrease in any of them: amount of bleeding, days of bleeding, or intermenstrual bleeding. A persistent decrease was defined as a persistent decrease in at least one of the following characteristics and no persistent increase in any of them: amount of bleeding, days of bleeding, or intermenstrual bleeding. All menstrual cycles analyzed were natural cycles — i.e., cycles during which the women were not pregnant, breast-feeding, or using hormonal contraception or intrauterine devices. Natural cycles classified as occurring “any time before sterilization or vasectomy” may have occurred immediately before or many years before the woman underwent tubal sterilization or her partner underwent vasectomy. Natural cycles occurring “immediately before sterilization or vasectomy” were those occurring in the three months before the procedure. Women with a missing or invalid code for a base-line menstrual feature were excluded.

†Odds ratios are for women who underwent sterilization as compared with women whose partners underwent vasectomy and are based on a logistic-regression model with control for age at the time of sterilization, base-line menstrual features, and race or ethnic group. CI denotes confidence interval.

‡The lower limit of the confidence interval was less than 1.0 but was rounded to 1.0.

§Age at the time of sterilization or the partner’s vasectomy was an effect modifier. The odds ratios (and corresponding 95 percent confidence intervals) for different age groups were as follows: 0.7 (0.4 to 1.0) for women 35 years of age or younger and 1.3 (0.6 to 2.7) for women older than 35 years.

ter sterilization, and we found no changes constituting a syndrome at five years. It is unlikely that acute damage to the ovary would neither alter hormonal status nor lead to symptoms within several years.

We anticipated that some women who underwent sterilization might have menstrual changes during some years and the opposite changes in other years. Accordingly, we required that changes be persistent if they were to be considered evidence of a clinical syndrome. Although we had follow-up data on women who underwent sterilization for up to 14 years after the procedure, follow-up data for the women whose partners underwent vasectomy were limited to 5 years, and thus we are unable to rule out the possibility that other changes occurred more than 5 years after sterilization. As noted above, however, such a delayed syndrome lacks biologic plausibility.

Follow-up rates for the first year were high, but they dropped substantially by the fifth year. Because follow-up was conducted by telephone and because few women declined to be interviewed when contacted, the women lost to follow-up were largely those who could not be reached by telephone. We are unaware of any systematic error that might be introduced by missing data for these women. Among the women whom we were unable to contact at five years, women who had undergone sterilization were no more likely than wom-

en who had not undergone this procedure to have either persistent increases or persistent decreases in the amount of bleeding before the fifth year of follow-up (as defined by changes occurring in more than one year).

Because there has been no consensus regarding the definition of a post-tubal-ligation syndrome, the existence or nonexistence of the syndrome has been difficult to study. Our data argue against any syndrome of menstrual problems after sterilization. The debate about a post-tubal-ligation syndrome has persisted not only because the syndrome has been ill defined, but also because many women are observed to have menstrual abnormalities after sterilization. We believe that this observation is attributable primarily to the fact that tubal sterilization and menstrual abnormalities are common and are therefore likely to occur coincidentally. Another likely explanation is that many women (one third of the women in our study) stop taking oral contraceptives at the time of sterilization and may have menstrual abnormalities as a result. The indications for hysterectomy in women with a previous tubal sterilization should be the same as in women without tubal sterilization.⁷

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APPENDIX

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