

Complications of Interval Laparoscopic Tubal Sterilization

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In 1978, the Centers for Disease Control initiated a multicenter prospective study to assess the safety of the various female sterilizing operations and the ways in which they could be made safer. During the first 31 months, 3500 women who underwent interval laparoscopic tubal sterilization by electrocoagulation or Silastic banding without other concurrent operations were enrolled in the study. When a standard definition of complications was used, the overall rate of an intraoperative or postoperative complication was 1.7 per 100 women. Several patient factors increased the risk of complications twofold or more: diabetes mellitus, previous abdominal or pelvic surgery, lung disease, a history of pelvic inflammatory disease, and obesity. There was a fivefold difference in complication rates between procedures performed under general anesthesia and those done under local anesthesia. (*Obstet Gynecol* 61:153, 1983)

Tubal sterilization is one of the most frequently performed elective intraabdominal surgical procedures of reproductive-age women in the United States. From 1976 through 1978, an average of 650,000 women per year underwent tubal sterilization operations in U.S. hospitals.¹ With so many American women undergoing tubal sterilization, any morbidity associated with the procedure could have a major public health impact. As these are usually elective procedures performed on healthy young women tubal sterilization surgery should be made as safe as possible. To date, the incidence of complications from tubal sterilization, factors related to the development of complications, and the morbidity associated with these complications have not been well established. Most of the studies conducted in the United States represent the past experience of a single surgeon or medical center and have used different definitions of complications.²⁻⁷

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In 1978, the Centers for Disease Control initiated a multicenter prospective study to assess the safety of the various sterilizing operations and the ways in which they could be made safer. A planned interim analysis was done for the first 31 months of data collection, focusing on intraoperative and postoperative complications that occurred among women who underwent interval laparoscopic tubal sterilizations by electrocoagulation or Silastic banding. The authors developed a definition of standard complication categories, measured the morbidity associated with these complications, and analyzed the factors that altered the risk of complications. The rate of complications was less than 2 per 100 women; the safest procedures were those done under local anesthesia.

Materials and Methods

The Collaborative Review of Sterilization began in September 1978. From then through March 1981, 9 hospitals in 5 U.S. cities had participated in the study. All 9 hospitals were affiliated with university medical centers. At each hospital, trained nurse-interviewers identified all women 15 to 44 years of age who were scheduled to undergo tubal sterilization and attempted to contact these women to request their participation in the study. During the study period, 4618 women underwent interval laparoscopic tubal sterilizations at the participating hospitals; 4250 (92%) were enrolled in the study. All women who agreed to participate signed a consent form.

Of the study participants who underwent interval laparoscopic procedures, 3500 (82%) underwent tubal sterilization by electrocoagulation or Silastic banding without other concurrent surgery. Women who underwent concurrent diagnostic dilatation and curettage or simple biopsy were not excluded.

The same standard questionnaire was used at each hospital. Women were interviewed preoperatively to obtain information on demographic characteristics as well as pregnancy, contraceptive, and medical history. In many instances, the nurse-interviewer attended the operation to determine the details of surgery, but in some cases these surgical details were obtained from the patient's chart after surgery. Information on the postoperative hospital course was abstracted from the hospital charts. The nurse-interviewers attempted to contact all the women by telephone after surgery to obtain details on their posthospitalization recovery. Follow-up information was obtained from 98% of the study participants. Of the women who provided follow-up interviews, 95% were contacted between 2 and 15 weeks after surgery; the median follow-up interval was 34 days.

Standard Complication Categories

Six standard categories of intraoperative and postoperative complications were defined:

1. Unintended major surgery: any laparotomy, repair of a perforate viscus, or repair of a major blood vessel that was performed intraoperatively or postoperatively during the same hospitalization, that was not planned and was necessary because of a problem related to the tubal sterilization
2. Transfusion: any intraoperative or postoperative blood transfusion
3. Febrile morbidity: oral temperature 38.0°C or higher on at least 2 postoperative days, excluding the first 24 hours after surgery
4. Life-threatening event: any intraoperative or postoperative cardiac or respiratory arrest, myocardial infarction, pulmonary embolus, anaphylactic shock, or disseminated intravascular coagulation
5. Rehospitalization: readmission to a hospital between the time of discharge and the follow-up interview because of a complaint or problem that the woman perceived to be related to the tubal sterilization
- ii Death: death or complication leading to death occurring within 42 days of surgery

These categories of complications were chosen because they represent life-threatening events or can reasonably be expected to result in increased morbidity. They also make comparison between institutions and surgical procedures possible because they are objective, clearly defined outcomes that are not subject to much variability in interpretation and they are not related to a particular sterilization method.

The standard categories of complications are similar

to the main complication categories associated with therapeutic abortion procedures, as determined by the Joint Program for the Study of Abortion.⁶ The authors have also used the same 6 standard categories to study complications of hysterectomy. Unless specifically stated otherwise "complication" refers to an intraoperative or postoperative complication as defined by the standard categories.

The anesthetic method used was classified as local if local, spinal caudal, or epidural anesthesia was used without a general anesthetic agent, and as general if a general anesthetic agent was used during the entire procedure.

Analysis

Analysis was restricted to the 3500 women who underwent interval laparoscopic tubal sterilization by electrocoagulation or Silastic banding without other concurrent surgery. Analyses according to method of tubal occlusion were by the intended method at the initiation of surgery. Women with asthma, bronchitis, or emphysema were combined into one "lung disease" group. The percentage of ideal body weight was determined by Hamwi's formula.⁷

For statistical analysis, relative risks with 95% confidence limits were computed using Miettinen's test-based method.⁸ To control for potentially confounding effects of several variables simultaneously, a logistic regression analysis was used.⁷ In the results, if the 95% confidence interval does not include 1.0, the result is significant at P value $< .05$.

Results

The majority of study participants were white and between 25 and 34 years of age; more than 80% had at least a high school education (Table 1). In the "black and other" racial category, 97% were black. Eight women were less than 20 years of age; 148 women (4%) were nulliparous. Nearly 7% were reported to have undergone the tubal sterilization for a medically indicated reason.

Overall, 1.7% of the women had at least 1 complication in one of the standard categories (Table 2). The most frequent complication was unintended major surgery; in all cases this was unintended laparotomy. Of these 37 laparotomies, 4 were performed to control bleeding, 3 because of some other complication, 1 because of equipment malfunction, and 29 because of technical difficulties in completing the sterilization by laparoscopy. Of the 29 women who underwent a laparotomy because of technical difficulties, 66% (19) had pelvic or abdominal adhesions, compared with

Table 1. Demographic, Medical, and Surgical Characteristics of Women Having Interval Laparoscopic Tubal Sterilizations, September 1977-March 1981

Characteristic	Percent distribution (N = 3500)
Race	
White	67.9
Black and other	32.1
Age (yr)	
15-24	12.9
25-34	57.0
35-44	30.1
Education	
<12 years	18.1
High school graduate	46.3
>12 years	35.6
Marital status	
Ever married	86.6
Never married	13.4
Gravidity	
0	4.2
1-2	40.1
3-4	41.0
≥5	14.7
Previous induced abortions	
0	81.5
≥2	13.6
Reason for sterilization	
Permanent contraception	93.2
Medically indicated	6.8
Intended method	
Electrocoagulation	67.6
Silastic bands	32.4
Anesthesia	
General	84.2
Local	15.8

18% of women who did not undergo a laparotomy. If the 30 women who underwent a laparotomy because of equipment malfunction or technical difficulties were excluded, the unintended surgery rate would be 0.2 per 100 and the overall complication rate would be 0.8 per 100 procedures.

Sixteen women were rehospitalized for the following reasons: pelvic infection (3), heavy vaginal bleeding (3), pregnancy (3), abdominal or pelvic pain (2), completion of the tubal sterilization (2), peritonitis secondary to a bowel burn (1), bronchitis (1), and depression (1).

Febrile morbidity occurred infrequently. Of the 7 women who developed fever on 2 or more days, 1 had septicemia, 2 had urinary tract infections, and 4 had no specific source of infection identified. None of the women required an intraoperative or postoperative blood transfusion. There were no life-threatening events and no deaths.

To determine to what extent the standard complica-

tion categories detected potentially serious complications, the standard categories were compared with a more extensive listing of complications. In addition to the standard complication categories, the expanded list of complications included mechanical injury to abdominal viscera, major vessel injury, anesthetic complications, pelvic hematoma, lower extremity or pelvic thrombosis, and life-threatening infections. The standard categories detected 58 of 62 (94%) women who had a potentially serious complication. Of the 4 women not included in the standard complication categories, 2 had bowel burns (both had an uneventful recovery and did not require additional surgery or rehospitalization) and 2 had lower extremity thromboses. Had these 4 women been included in the standard complication categories, the overall complication rate would have been 1.8 rather than 1.7 per 100.

The median postoperative hospital stay increased from 0 nights for women with no complications to 2 nights for women who had at least 1 complication. The occurrence of a complication also increased the median total convalescence (number of days of postoperative hospitalization plus the number of days before resuming normal activities after discharge from the hospital) from 4 days to 14 days in women without a complication. Thirty-six percent of women who developed a complication had a total convalescence longer than 21 days, compared with only 2% of women who had no complications.

Several factors that could be identified preoperatively were associated with a twofold or greater relative risk of complications (Table 3). Using logistic regression, the relative risks shown in Table 3 were adjusted by simultaneously controlling for intended method of tubal occlusion in addition to each of the other listed risk factors except diabetes mellitus. There were too few women (47) with a history of diabetes mellitus to control for this variable satisfactorily in the logistic regression analysis. When adjusted, the relative risk of general anesthesia relative to local anesthesia de-

Table 2. Complications

Complication	No.	Rate/100 procedures
Unintended major surgery	37	1.1
Rehospitalization	16	0.5
Febrile morbidity	7	0.2
Transfusion	0	0
Life-threatening event	0	0
Death	0	0
One or more complications	58	1.7

Includes 3500 procedure done by electrocoagulation or Silastic bands, identified by the Collaborative Review of Sterilization.

Table 3. Complication Rates by Presence or Absence of Selected Preoperatively Identifiable Factors

Factor	Complication rate (per 100)				Relative risk* of 1 or more complications (95 % conf. int.)
	Unintended major surgery	Rehospital- iza tion	Febrile morbidity	One or more complications	
Diabetes mellitus					
No	1.0	0.4	0.2	1.6	1 (referent)
Yes	4.3	4.3	0	8.5	5.4 (2.2, 13.3)
Anesthesia					
Local	0	0.4	0	0.4	1 (referent)
General	1.3	0.5	0.2	1.9	5.2 (1.5, 18.3)
Previous abdominal or pelvic surgery					
No	0.6	0.4	0.2	1.1	1 (referent)
Yes	2.3	0.8	0.3	3.1	2.7 (1.7, 4.5)
Lung disease†					
No	1.0	0.3	0.2	1.4	1 (referent)
Yes	1.9	1.6	0.5	3.8	2.7 (1.5, 4.8)
History of PID					
No	1.0	0.5	0.1	1.5	1 (referent)
Yes	1.7	0.4	1.7	3.4	2.2 (1.1, 4.6)
Percent ideal body weight†					
<120	0.7	0.4	0.1	1.2	1 (referent)
≥120	1.7	0.7	0.3	2.5	2.1 (1.3, 3.4)

Includes 3500 procedures done by electrocoagulation or Silastic bands, identified by the Collaborative Review of Sterilization.

PID = pelvic inflammatory disease.

* Unadjusted, calculated by dividing the rate when the factor is present by the rate when the factor is not present (referent category).

† History of asthma, bronchitis, or emphysema.

‡ Hamwi's formula.⁴

creased to 4.2 (95% confidence interval, 1.0 to 18.4), whereas the adjusted relative risks for the other risk factors in Table 3 varied by less than 10% from the unadjusted level.

The choice of tubal occlusion method was not strongly associated with the occurrence of complications, although electrocoagulation did have a 1.6 times higher risk (95% confidence interval, 0.8 to 3.2) than did Silastic banding. Among the electrocoagulation procedures, those done with unipolar instruments carried risks of complications similar to those done with bipolar instruments.

For several of the factors listed in Table 3, differences in overall complication rates by presence or absence of the particular factor were largely caused by different rates of unintended major surgery. This latter complication was usually attributable to the presence of abdominal or pelvic adhesions. When presence of adhesions was controlled for along with the preoperatively identifiable risk factors, the adjusted relative risk of one or more complications for general anesthesia versus local anesthesia increased to 6.5 (95% confidence interval, 1.6 to 27.0). In contrast, the relative risk for a history of previous abdominal or pelvic surgery decreased to 1.9 (95% confidence interval, 1.1 to 3.1), and the relative risk for history of pelvic inflammatory disease decreased to 1.3 (95% confidence interval, 0.6

to 2.8). The relative risks for the other factors in Table 3 were not appreciably changed.

Race, age, gravidity, number of previous induced abortions, smoking history, reported reason for tubal sterilization (medically indicated versus permanent contraception), history of cardiovascular disease, history of ovarian cysts, history of fibroids, use of an intrauterine contraceptive device during the month before surgery, use of oral contraceptives during the month before surgery, and concurrent diagnostic dilatation and curettage did not significantly alter the risk of complications. Women with more than a high school education had a slightly higher risk of complications than did women with a high school education or less, but this finding was of borderline statistical significance.

Discussion

The results suggest that interval laparoscopic tubal sterilization is, in general, a safe procedure with a rate of an intraoperative or postoperative complication of less than 2 per 100 women. However, there were 2 possible shortcomings of the study. First, use of the standard definitions of complications could have underestimated the complication rate. Second, because all the participating hospitals were affiliated with uni-

versity teaching centers, the results may not be representative of what could be expected among all laparoscopists performing tubal sterilizations.

To perform epidemiologic analyses 6 standard complication categories were defined. One justification for use of these standard definitions was that complications in the standard categories could be objectively demonstrated to be associated with increased morbidity (as measured by increased hospitalization and total convalescence). Furthermore, when the definitions of complications were compared with an extensive listing of complications, they detected more than 90% of women who had what could be considered a potentially serious complication.

Febrile morbidity was probably underascertained. Approximately 50% of the women enrolled in the study were discharged from the hospital on the day of surgery. As these women did not routinely monitor their temperature at home, the authors did not know whether they developed febrile morbidity. However, it was expected that women discharged from the hospital on the day of surgery who developed febrile morbidity at home would have been at greater risk of requiring rehospitalization than women who did not develop febrile morbidity. Thus, determining whether women were rehospitalized probably to some extent compensated for incomplete ascertainment of febrile morbidity in calculating the overall complication rate.

Although all the hospitals in the study were affiliated with university teaching centers, the complication rates were similar to those of 2 national studies of laparoscopic sterilization. The only other large prospective study of laparoscopic tubal sterilization in a developed country was conducted in the United Kingdom by the Royal College of Obstetricians and Gynaecologists during 1976 and 1977.¹⁰ The only category of complications comparable to the categories in the present study was procedures requiring a laparotomy. In the Royal College study, the laparotomy rate was 1.2 per 100 laparoscopic tubal sterilization procedures. This is almost identical to the rate of 1.1 per 100 procedures found in the present study. The only national information available in the U.S. on complications of laparoscopic tubal sterilization comes from membership surveys conducted by the American Association of Gynecologic Laparoscopists. The rate of laparotomies done because of some complication (eg, bowel burns, hemorrhage, trocar injury) was 2.7 per 1000 procedures in the 1976 survey¹¹ and 1.8 per 1000 in the 1979 survey.¹² In the Collaborative Review of Sterilization, the comparable rate of laparotomies done because of some complication was 2.0 per 1000 procedures (7 per 3500 procedures).

The lowest complication rates were associated with

procedures done under local anesthesia. The difference in risk between general anesthesia and local anesthesia was greater than fivefold and unlikely to have been due to chance. Most of the difference in risk by type of anesthesia was related to unintended laparotomies. The reason for this is not clear: it may be that local anesthesia acted as an indicator of some other variable; perhaps women less likely to have complications were selected to have local anesthesia. However, when differences in other risk factors that could be identified preoperatively were controlled for, the relative risk for procedures done under general anesthesia remained 4 times higher than those done under local anesthesia.

Operator skill could not be controlled for. The lower complication risk of procedures performed under local anesthesia may have been attributable to these procedures being done by surgeons with greater skill or experience in performing laparoscopic tubal sterilizations.

Studies of mortality associated with laparoscopic tubal sterilization have found cardiorespiratory complications during general anesthesia to be the leading causes of death.¹³⁻¹⁵ Thus, the type of anesthesia is apparently a major determinant of both morbidity and mortality from laparoscopic tubal sterilization.

That women with diabetes mellitus or lung disease would be at increased risk of complications was not unexpected. Much of the increased risk for women with a history of previous abdominal or pelvic surgery or pelvic inflammatory disease is related to the greater likelihood of these women having pelvic or abdominal adhesions. That obesity increases the risk of complications from surgery in general and laparoscopy specifically is well recognized.¹⁵

In the present study, the occurrence of a complication increased the postoperative hospital stay by about 2 nights and the total convalescence by approximately 10 days. From 1976 through 1978, almost 200,000 interval laparoscopic tubal sterilizations were performed in U.S. hospitals per year.⁷ Applying the complication rate of our study to these data indicates that approximately 4000 women per year would have 1 or more complications ($0.02 \times 200,000$) as a result of undergoing interval laparoscopic tubal sterilization procedures. This would result in approximately 8000 nights of increased hospitalization and 40,000 days of increased convalescence per year.

The study indicates that interval laparoscopic tubal sterilization is in general a safe procedure. However, because such a large number of women undergo tubal sterilization, making these operations even safer could result in substantially reduced morbidity and health care costs on a national level. The safest procedures

identified in this study were those performed under local anesthesia.

Con tribu tors

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