

THE SAFETY AND EFFICACY OF TUBAL STERILIZATION: AN INTERNATIONAL OVERVIEW*

H.B. PETERSON, I. LUBELL, F. DeSTEFANO and H.W. ORY

Family Planning Evaluation Division, Centers for Disease Control, Atlanta, Georgia, and The Association for Voluntary Sterilization, Inc., New York, NY, USA

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Abstract

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This article presents a synthesis of some of the major published studies on the efficacy and safety of tubal sterilization. The conclusions of this overview are that tubal sterilization is a safe operation, long-term sequelae of tubal sterilization have not been well documented, and the risk of pregnancy following tubal sterilization is less than 1 in 100. Continued study is needed to determine how to make a safe and effective procedure even safer and more effective.

Key words: Tubal sterilization; Pregnancy; Mortality; Morbidity; Menstruation

Introduction

Over the past decade, tubal sterilization has emerged as one of the world's most frequently used methods of fertility control. It is esti-

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mated that up to 1980 over 60 million women had been surgically sterilized [31], making an understanding of the risks and benefits of tubal sterilization a matter of global concern.

To date, the risks and benefits of the various tubal sterilization techniques have not been well detailed. Because the major increase in the world-wide popularity of tubal sterilization did not occur until the early 1970's [25] and because some of the surgical techniques in frequent use today did not become generally available until as late as the mid-1970's, there has been little time to study the safety and efficacy of the different tubal sterilization techniques. In addition, most reports regarding female sterilization are from single centers and describe single procedures. In these studies complications were not uniformly defined and different methodologies were used, making comparisons difficult. Yet, a number of important national and international studies have been completed which provide useful information on the subject. In this report we review these studies and assess the current knowledge of the safety and efficacy of tubal sterilization.

Safety

The short and long-term risks

The current consensus, derived from international morbidity and mortality studies, is that tubal sterilization is a safe operation.

Fewer data are available regarding potential long-term risks. The short-term risks and the current status of investigations into the potential long-term risks of female sterilization are discussed below.

Short-term risks

Morbidity. Several large national studies, including ones conducted in the United Kingdom by the Royal College of Obstetricians and Gynaecologists (RCOG) [7] and in the United States by the American Association of Gynecological Laparoscopists (AAGL) [20] and the Centers for Disease Control (CDC) [12], have determined that major complication rates for tubal sterilization are low, on the order of 1–6/100 procedures. The RCOG and the AAGL studies illustrate that morbidity rates vary both with the surgical technique employed and with the experience of the surgeon. Although these studies are not strictly comparable because of differences in methodology, the general picture is consistent; major morbidity for most techniques occurs infrequently.

The Collaborative Review of Sterilization (CREST) conducted by the CDC is a prospective study begun in 1978 and which involves nine medical centers in five American cities [12]. A preliminary analysis has begun on data from the first 2 years of the study. Major complications were divided into several categories and then method-specific and category-specific complication rates were determined. As shown in Table I, major complication rates for laparoscopy are 2/100 and for laparotomy are nearly 6/100. These rates are for women having interval procedures only; pregnancy-associated procedures have been excluded. There were a number of factors, including diabetes, obesity, and use of general anesthesia which predisposed women to increased risk from either type of procedure. Even controlling for these risk factors, sterilizations performed via laparotomy were still associated with an approximately three-fold greater risk for major complications than sterilizations performed via laparoscopy.

Table 1. Comparison of serious complication rates^a of interval tubal sterilization by surgical approach. Collaborative Review of Sterilization (CREST), Centers for Disease Control, United States, Sept. 1978 to Jan. 1981.

Complication	Surgical approach	
	Laparoscopy (n = 3711)	Laparotomy (n = 416)
Unintended major surgery	1.2	1.0
Febrile morbidity	0.3	3.6
Transfusion	0	0
Rehospitalization	0.6	1.4
Death	0	0
>1 Complication	2.0	5.8
Unadjusted relative risk (95% confidence interval)	1 (Referent)	2.9 (1.9, 4.5)

^aPer 100 procedures.

Further analysis is required to determine whether the risk of serious complications of laparotomy tubal sterilization varies according to abdominal incision length, but it is already apparent from the CREST study that the choice of surgical approach for sterilization may appreciably affect the risk of complications.

Short-term risk

Mortality. Several recent studies have demonstrated that death attributable to tubal sterilization is rare but does occur. Two national studies of laparoscopic sterilization, one reported by the RCOG [7] in the United Kingdom and the other by the AAGL [20] in the United States, estimate case-fatality rates for laparoscopic sterilization of ten deaths and two deaths per 100,000 procedures, respectively. An international study conducted by the International Project/Association for Voluntary Sterilization (IPAVS) reviewed 256,000 sterilizations which were performed with various techniques. The overall case-fatality rate in that series was six deaths per 100,000 procedures [4]. A similar rate of four deaths per 100,000 sterilizations

was estimated by the CDC [17] after a review of deaths occurring among 500,000 tubal sterilizations in the United States. Like the IPAVS study, the CDC report reviewed a variety of sterilization techniques.

CDC conducted a study in cooperation with the government of Bangladesh and identified 71 deaths there associated with 109,000 tubal sterilizations during a 15-month period (unpublished data), resulting in a case-fatality rate of 19 deaths per 100,000 procedures. Although this rate is higher than the aforementioned estimates, it is consistent with reports of deaths from tubal sterilizations performed in temporary camps set up specifically to perform sterilizations in rural areas of India [5]. It is important that the risk of death associated with various methods of fertility control be assessed in perspective with the risk of childbearing. In Bangladesh, the maternal mortality rate is 570 deaths per 100,000 live births [8], a much greater risk than that associated with sterilization. If we consider deaths as an outcome of tubal sterilization, the 19 deaths observed could be compared to the 68 maternal deaths that might be expected had those sterilizations not been performed.

Several studies have been conducted which address not only the risk of death but also the causes of death associated with tubal sterilization. In the United States, the CDC has identified 27 deaths attributable to tubal sterilization that occurred since 1977 (unpublished data). The single leading cause of these deaths was cardiorespiratory arrest during general anesthesia. In the Bangladesh study, the leading cause of death was over-sedation associated with use of local anesthesia. In the IPAVS series [4], the leading cause of death was complications associated with anesthesia. In a review of 100,000 laparoscopies in France [16], the leading cause of death was, again, complications associated with anesthesia. Thus, to date the greatest risk of death from tubal sterilization is associated with the anesthesia for the operation.

In trying to identify preventable risk

factors for sterilization deaths in the United States, the CDC has determined that only three of 27 deaths identified were the direct result of complications of a particular method of sterilization. These three deaths followed bowel burns associated with the use of unipolar coagulation devices. Over 100 bowel burns have been reported with the use of these devices since 1975. The unipolar system appears to have greater risk than the alternative methods of laparoscopic tubal occlusion without demonstrably greater benefit. Therefore, the CDC has recently asked that the use of these devices for sterilization in the United States be reconsidered [6,18].

Potential long-term risks

The question whether tubal sterilization predisposes a woman to menstrual disturbances was raised as early as 1951 [24]. Since that time a variety of reports [1,2,14,22] have suggested that observed differences in menstrual function after sterilization can be attributed to factors other than the sterilization procedure, i.e. menstrual problems prior to sterilization, oral contraceptive use before sterilization, previous pelvic inflammatory disease, or age alone, the woman being older following sterilization than she was before sterilization. In the published epidemiologic studies to date, there is no convincing evidence that a posttubal syndrome exists.

Information regarding hormonal status after tubal sterilization is scanty and contradictory. In separate studies, Radwanska [21] and Donnez [13] reported that women after sterilization had lower midluteal serum progesterone levels than normal controls. Corson [11] has reported that the hormonal status of women following sterilization is not appreciably different from that of women who have had a hysterectomy or from that of normal controls. There is no published comparison of presterilization and poststerilization hormone function. Until this research is done, the question of hormonal status after sterilization will be unanswered.

Efficacy

Sterilization failure

There are two important and obvious concerns regarding the efficacy of tubal sterilization: intrauterine and ectopic pregnancies. Intrauterine pregnancies are unplanned and usually unwanted after sterilization. Ectopic pregnancies can be fatal. Existing published studies of pregnancy after sterilization are difficult to interpret and compare [9,10,15,19,23]. Method failure and surgeon failure as well as true failures and luteal phase pregnancies are not always distinguished. Incomplete follow-up of patients and variations in length of follow-up also make interpretation and comparison difficult.

One of the key difficulties in comparison of existing studies of pregnancy after sterilization is the variation in how pregnancy rates are reported. The importance of using a standard method for determining pregnancy rates can be seen in Table II which summarizes results from a study in Singapore of 10,174 tubal sterilizations performed in 1970 through 1975 [9]. The study demonstrated that while most pregnancies after sterilization occur during the first year after sterilization, a substantial number also occur during the second year after sterilization. Pregnancy rarely occurs after that time. Marked differences between pregnancy rates can be calculated using a crude rate, a Pearl rate, and a cumulative failure rate by life-table analysis.

Table II. Pregnancy after tubal sterilization. Singapore, 1970~1975^a

Number of ligations	Number of failures	Crude failure rate ^b	Pearl rate ^c	Cumulative failure rates ^d		
				12 months	24 months	36 months
10,174	49	0.48	0.30	0.47	0.81	0.85

^a Adapted from Cheng *et al.* [9].

^b Per 100 procedures.

^c Per 100 woman-years.

^d Per 100 women followed.

The crude rate is simply the ratio of the number of failures to the number of sterilizations; there is no attempt to take into consideration the length of follow-up after sterilization.

The Pearl rate is the ratio of the number of failures per 100 woman-years at risk of failure. Using a woman-year denominator, however, requires that the risk be constant over time. This is not the case for the risk of pregnancy following tubal sterilization.

The cumulative failure rate is defined in terms of observation time or time period during which a pregnancy could possibly be identified. The importance of accounting for variation in observation time after sterilization is readily apparent in Table II. At 12 months, the cumulative failure rate (0.47) is almost identical to the crude rate (0.48), and is substantially greater than the Pearl rate (0.30). At 24 months, the cumulative rate nearly doubles, increasing from 0.47 to 0.81. The rate at 36 months (0.85), however, is not appreciably different from the rate at 24 months. Thus, calculation of cumulative failure rates by life-table techniques takes into account changing levels of risk of pregnancy with time and is the preferred method for reporting failure rates following tubal sterilization.

There is some evidence that pregnancy rates may vary not only because of the various ways in which they are determined and expressed, but also because certain techniques may be more likely than others to result in failure. For example, in the Singapore study 8000 of the 10,000 sterilizations reviewed were performed via laparotomy during the postpartum, postabortion, and interval periods. The failure rate for those procedures, based on the 36-month life-table rate, was 0.34. The reason for the discrepancy between that rate and the overall rate of 0.85 in Table II is that nearly 2000 of the 10,000 procedures were performed using the culdoscopic technique, which had a failure rate nearly five times greater than that associated with laparotomies [9]. There were too few laparoscopic steril-

izations in the Singapore series to address their relative efficacy. A membership survey conducted by the AAGL indicates that the crude pregnancy rate after laparoscopic sterilization is two to six pregnancies per 1000 procedures, depending on the laparoscopic technique employed [19]. This is very similar to the Crude rate of 1.9 pregnancies per 1000 procedures for the laparotomy approach in the Singapore study.

The risk of failure following sterilization may depend not only on the surgical approach to the fallopian tube (laparotomy, laparoscopy, colpotomy, or culdoscopy) but also on the method of tubal occlusion (e.g. ligation, coagulation, or mechanical occlusion). At this time, however, there is insufficient information to determine which methods of tubal occlusion are the most effective.

A relatively infrequent but potentially fatal complication of sterilization failure is ectopic pregnancy. In the Singapore study, 16% of pregnancies following sterilization were ectopic gestations [9]. In the AAGL membership survey of laparoscopic sterilization, 25% of sterilization failures resulted in ectopic pregnancies [19]. Although a substantial percentage of pregnancies after sterilization are ectopic gestations, there is no evidence that a woman's absolute risk of ectopic pregnancy is increased by having a sterilization performed. It is likely, in fact, that because she is so much less likely to get pregnant at all (compared with a woman who does not use contraception) that her absolute risk is actually decreased. If a woman does become pregnant after sterilization, however, the possibility of an ectopic gestation is of immediate concern. Early diagnosis and treatment of this complication can save her life.

To summarize: methodologic problems make interpretation of studies of sterilization failure difficult, but it can be concluded that less than 1 in 100 sterilized women will get pregnant. For those women who do become pregnant, however, ectopic pregnancy is an important concern occurring in 16-25% of such pregnancies. Comparisons of failure rates

associated with different methods of tubal sterilization as determined by large, multicenter studies should help clarify the risks of pregnancy after sterilization.

Conclusion

In summary, tubal sterilization has emerged as one of the world's most frequent methods of fertility control. Studies conducted to date indicate that female sterilization is, in general, safe and effective. The short-term risks of morbidity appear low, and no long-term risks have been documented. Death after sterilization is rare but does occur. There is information to suggest that some sterilization-attributable deaths can be prevented. Sterilization failure rarely occurs, but when it does, ectopic pregnancy is an important concern.

The above conclusions can be drawn because much effort has been expended in a short time to document the safety and efficacy of female sterilization. Continued study is needed to determine how to make a safe and effective procedure even safer and more effective.

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Address for reprints:

Frank DeStefano, M.D.
U.S. Dept of Health and Human Services
Public Health Service
Center for Disease Control
Atlanta, GA 30333
USA