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Training of residents in laparoscopic tubal sterilization: Long-term failure rates

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Abstract

Objectives—Laparoscopic tubal sterilization with bipolar coagulation is a common and effective method of contraception, and a procedure much used to teach laparoscopic surgical skills to Obstetrics and Gynaecology residents (trainees); but it has an inherent risk of failure. This study investigated the long-term failure rate of this procedure when performed by Obstetrics and Gynaecology residents on women treated in their teaching clinics.

Methods—From 1991 to 1994, Obstetrics and Gynaecology residents carried out 386 laparoscopic tubal sterilizations with bipolar coagulation at Yale-New Haven Hospital. Six to nine years after the procedure, the women concerned were contacted by telephone and data were collected about sterilization failure.

Results—Two failures of laparoscopic tubal sterilization with bipolar coagulation were identified: an ectopic pregnancy and a spontaneous abortion. For this time period, the long-term sterilization failure rate was 1.9% (0–4.4%).

Conclusions—The long-term sterilization failure rate for laparoscopic tubal sterilization with bipolar coagulation performed by residents is comparable to the results of prior studies. These findings can be used to properly counsel women at a teaching clinic about the risks of sterilization failure with this procedure, and attest to the adequacy of residents' training and supervision.

Keywords

Sterilization; Tubal sterilization; Sterilization failure; Bipolar coagulation; Ectopic pregnancy; Laparoscopic training

INTRODUCTION

Tubal sterilization accounts for 28% of contraceptive methods used by women of reproductive age in the United States, and up to 40% of contraceptive methods used throughout the world^{1,2}. More than 700,000 tubal sterilization procedures are performed annually in the United States: about half in the postpartum period, and the other half as interval procedures^{3,5}. Common methods of interval laparoscopic tubal sterilization include unipolar coagulation, bipolar coagulation, partial salpingectomy, and mechanical occlusion techniques using spring clips or silastic rings. In the United States, laparoscopic tubal

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sterilization is most commonly performed using bipolar coagulation¹. If properly done, bipolar coagulation is highly effective and has low long-term failure rates^{6–8}. It is considered a safe, effective, and cost-efficient outpatient procedure^{2,9}.

Tubal sterilization, whether carried out postpartum or as an interval laparoscopic procedure, has a known risk of failure¹⁰. Early studies of sterilization failure were short-term in nature; subjects were followed for 12 to 24 months after the procedure, and failure rates of 0.2–0.5% were identified². These failure rates, however, were difficult to generalize since the conclusions were often based on the outcomes of one surgeon or one hospital². The *U.S. Collaborative Review of Sterilization* (CREST) in 1996 was the first long-term investigation of the failure risk of sterilization¹¹. This multicentre prospective cohort study identified 10,685 women who had undergone sterilization between 1978 and 1986; the patients were assessed 8 to 14 years post-sterilization. Sterilization failure appeared to be significantly more frequent than previously reported; moreover, most failures had occurred more than one to two years after sterilization^{2,11}. Data from this study were used to assess sterilization failure by procedure method and risk factors associated with sterilization failure.

Beside the CREST study, few contemporary studies have investigated the long-term failure risk of laparoscopic tubal sterilization¹². Furthermore, no studies have evaluated the long-term failure rate of laparoscopic tubal sterilizations with bipolar coagulation performed by Obstetrics and Gynaecology residents (trainees). It is important to identify the long-term sterilization failure rates among women at a teaching clinic to enable evidence-based counselling about the risk of sterilization failure in this setting. Since laparoscopy is an essential component of surgical training in Obstetrics and Gynaecology, sterilization failure data allow assessment of the adequacy of resident education, supervision and training with this procedure.

METHODS

This retrospective cohort study used operating room records to identify all women who underwent laparoscopic tubal sterilization at Yale-New Haven Hospital through the *Women's Center*, the Obstetrics and Gynaecology residents' clinic, from 3 October 1991 to 29 December 1994. Earlier records from the operating room and the Women's Center were not available. This time period enabled a study of long-term sterilization outcomes. Three hundred eighty-six subjects met these inclusion criteria. Residents performed all surgical procedures under direct faculty supervision. For all sterilizations, bipolar coagulation was utilized and at least three contiguous areas of the isthmic region of each Fallopian tube were desiccated until the current flow meter on the bipolar generator (Richard Wolf Medical Instruments Corporation, Vernon Hills, Illinois) read zero. This study was approved by the Yale University School of Medicine Human Investigation Committee.

Data were collected in December 2000, six to nine years after the sterilization procedures had taken place. The telephone numbers listed in the operating room records were used to initiate contact with all 386 subjects. When the telephone number was in service, multiple attempts were made to contact each woman until a person answered the telephone or six attempts were unsuccessful. After the study was explained to the woman and verbal consent was obtained, data were collected by telephone interview. The subject's identity was verified, and it was confirmed that the sterilization procedure had been performed at Yale-New Haven Hospital through the Women's Center. Thereafter, it was asked whether a pregnancy had occurred since sterilization and how this pregnancy was managed. Finally, information with regard to the patient's interval gynaecologic history was gathered. Medical records, if available, were used to verify all claims of sterilization failure.

This study was powered to detect a <1.75 -fold difference from the results of the CREST study using $\alpha = 0.05$ and $1-\beta$ of 90%. Standard error and 95% confidence interval calculations were performed.

RESULTS

Three hundred eighty-six subjects were identified six to nine years after laparoscopic tubal sterilization with bipolar coagulation. Of these subjects, 107 (27.7%) were successfully contacted. Approximately 800 subject-years of follow-up were achieved. Two sterilization failures were identified. For this time period, the long-term sterilization failure rate was 1.9% (0–4.4%). The study achieved 90% power to detect a 1.68-fold difference from the results of the CREST study.

The age of the women at the time of sterilization ranged from 21 to 43 years, with a mean age and median age of 30 years. At the time of sterilization, 36 subjects (34%) were 21 to 27 years old, 42 subjects (39%) were 28 to 33 years old, and 29 subjects (27%) were 34 to 43 years old.

The first woman with sterilization failure had a history of three normal spontaneous vaginal deliveries and one elective termination. She denied a history of sexually transmitted infections (STIs). Sterilization was performed at age 23; the failure occurred five years later, when an ampullary tubal pregnancy was diagnosed and successfully treated with laparoscopic right salpingectomy. The subject's history was confirmed by a review of her medical records.

The second woman with sterilization failure reported a spontaneous abortion two years after her laparoscopic sterilization. Her obstetric and gynaecologic history included three term deliveries, one elective termination, two spontaneous abortions, and one episode of STI (chlamydia). A review of medical records revealed a caesarean delivery with tubal sterilization by the Pomeroy method in 1983 at the age of 26; histologic examination had confirmed that two segments of Fallopian tube had been removed. A spontaneous abortion occurred in 1992 at age 35. Subsequently she underwent laparoscopic tubal sterilization with bipolar coagulation. She reported another spontaneous abortion in 1994, and underwent hysterectomy that same year. The second spontaneous abortion was unconfirmed and based solely on the woman's recollection, thus the overall sterilization failure rate may be *lower* than previously stated.

Of the 105 subjects without sterilization failure, five underwent a hysterectomy during the follow-up period. Hysterectomy was carried out three years after sterilization in one woman, and between six and nine years after sterilization in the other four women. The indications for these procedures were not determined.

DISCUSSION

Six to nine years after laparoscopic tubal sterilization with bipolar coagulation, the failure rate among this urban teaching clinic population was 1.9% (0–4.4%). This rate was comparable to the sterilization failure rate with bipolar coagulation demonstrated in the CREST study¹¹. Our study was adequately powered to detect a clinically meaningful difference.

The CREST study investigated the long-term failure risk of sterilizations performed between 1978 and 1986, 5 to 16 years prior to the procedures included in this study¹¹. The overall 10-year cumulative probability of pregnancy was 18.5 per 1000 procedures, and 24.8 per 1000 laparoscopic bipolar coagulation procedures. The cumulative probability of

sterilization failure with bipolar coagulation was 18.3 per 1000 procedures at six years after the procedure (1.83% [1.2–2.5%]), and 23.3 per 1000 procedures at nine years (2.33% [1.5–3.1%])¹¹. The highest 10-year cumulative risk of pregnancy occurred among women sterilized before the age of 28 with bipolar coagulation: it amounted to 54.3 per 1000 procedures. Other studies have similarly demonstrated associations between increased risk of sterilization failure and younger age at sterilization, duration of time since sterilization, and method of sterilization^{10,13,14}.

Several other studies have evaluated laparoscopic tubal sterilization procedures in residency training programmes with regard to length of time for each procedure, complication rates, and estimated blood loss. Most of these studies pertained to laparoscopic sterilization methods other than bipolar coagulation, and the subjects were followed for a maximum of 24 months^{15–18}. One retrospective study investigated sterilization failure rates for laparoscopic tubal sterilization performed by residents¹⁹. That study was limited to two years of follow-up, and the Pomeroy method was predominantly used ($n = 99$). Of the 62 subjects selected for sterilization with bipolar coagulation, two failures occurred. The two-year sterilization failure rate was 1.9% overall, and 3.2% with bipolar coagulation. These sterilization failure rates did not significantly differ from rates reported previously, but the duration of follow-up was relatively short.

Current laparoscopic technology with video monitors, DVD capabilities, and refined instruments enables effective resident education in the operating room. Intraoperative teaching of laparoscopic surgery is a core requirement of residency training in Obstetrics and Gynaecology. Trainees need to practise laparoscopic skills and our patients deserve a high standard of surgical care; these goals are not mutually exclusive. Thus the rate of sterilization failure can be considered a measure of resident education, training, and supervision at a teaching hospital. In this study, we identified a long-term rate of laparoscopic tubal sterilization failure similar to that shown in prior studies.

Our study is unique because all procedures were performed in the same fashion, all involved resident surgeons, and long-term follow-up was achieved. This study was limited by the ability to contact subjects by telephone, each subject's recall of pertinent events, and the loss of subjects to follow-up over time. In an urban teaching clinic population, follow-up many years after a procedure is difficult and a response rate approaching 30% is not unusual. Similarly, in the CREST study, young women and black women were more likely to be lost to follow-up¹¹. Despite these limitations, we achieved approximately 800 subject-years of follow-up.

The two subjects with sterilization failure were at higher risk for failure: both were young at the time of first sterilization, and one had a history of sterilization failure and chlamydia. Likewise, risk factors for sterilization failure in the CREST study included sterilization at younger ages (<28 years old), and a history of pelvic inflammatory disease¹¹. When sterilization is performed on women at a young age, the concept of 'cumulative risk of sterilization failure' is important; these women are at greatest risk for sterilization failure due to the many reproductive-age years ahead of them¹¹.

In conclusion, the long-term sterilization failure rate for laparoscopic bipolar coagulation performed by trainees was comparable to the long-term risk of sterilization failure identified by the CREST study. Therefore, these findings can be used to properly counsel women in a resident's clinic about the risk of sterilization failure. Furthermore, when proper technique is taught and utilized, laparoscopic bipolar coagulation is an effective means of sterilization in spite of the variable surgical experience of the operators. This procedure is often a teaching tool for laparoscopic skills, and reasonable outcomes are achieved.

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