

A Clinical and Medico-Legal Review of Tubal Ligation in Canada

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INTRODUCTION

Female sterilization is one of the most common gynaecological procedures performed in Canada. In a 12-month period in 2009–2010 there were 24 023 tubal ligations performed in Canada (Dr Doug Bell, CMPA, personal communication, May 2012). Tubal ligation was the third most common gynaecological procedure to provoke litigation, involving 15% of cases and 12% of costs associated with gynaecology cases.

Litigation most commonly arises from the inherent failure rate associated with the procedure itself, poor surgical performance, or inadequate preoperative counselling or consent. In the 10-year period from 1999 to 2008, 54 civil actions for failed tubal ligation were initiated in Canada. The frequency of reported cases declined during this period, with 34 reports in the first five years and 20 in the second five years. During the same 10-year period there was a downward trend in cases of general medical negligence and gynaecological negligence (Dr Doug Bell, CMPA, personal communication, May 2009).

CLINICAL ISSUES

Specific Risks of Laparoscopy

Complications of laparoscopic surgery include injury to adjacent structures, hematomas, port site infections, CO₂ retention pain, and anaesthetic risks. Overall complication rates are from 0.4% to 1.0 %^{1,2} For elective procedures, the list of all potential complications should be discussed with the patient.

Key Words: Tubal ligation, laparoscopy, complications

Competing Interests: None declared.

Received on December 18, 2011

Accepted on March 14, 2012

Over 50% of laparoscopic complications occur during abdominal entry, and 25% are not recognized until the postoperative period.³ Delayed diagnosis of intraoperative complications, especially bowel injuries, can have serious consequences for the patient and is a frequent cause of litigation.³ Serious complications involving visceral or major vascular injury occur at a frequency of one in 1000 cases.³ In Canada between 1990 and 1998, 15 of 40 bowel injuries and one of 13 major vessel injuries alleged by plaintiffs in laparoscopic cases occurred in association with tubal ligation (Dr Doug Bell, CMPA, personal communication, May 2009). Vascular injuries are reported at a frequency of 0.1 to 6.4 per 1000 laparoscopic procedures. Bleeding is often retroperitoneal and may go unnoticed intraoperatively.³

According to the United States Collaborative Review of Sterilization, the odds ratio of complications from general or regional anaesthesia is approximately three times that from local anaesthesia.⁴

The risk of having to perform laparotomy after a severe complication of laparoscopic sterilization was reported as 1.9 per 1000 cases in a large prospective study.³ Laparoscopic tubal ligation should be performed only in a centre where immediate laparotomy is available. Overall complication rates for laparoscopic sterilization, excluding failure, are approximately 1%.³ In the United States, mortality is quoted at one to four deaths per 100 000 procedures, most of these resulting from complications of general anaesthesia.³

The laparoscopic approach is generally considered contraindicated in patients with severe cardiopulmonary disease, in patients with morbid obesity, and in patients

with a history of multiple abdominal procedures with potential for significant adhesion formation.

The hysteroscopic insertion of micro inserts for tubal occlusion may be safely performed in a physician's office under local anaesthesia. As of December 2011, one case of litigation related to hysteroscopic sterilization had been reported in Canada (Dr Doug Bell, CMPA, personal communication, May 2012).

Regret After Sterilization

Patient ambivalence towards sterilization is an absolute contraindication to the procedure. Sterilization should be considered permanent and irreversible, and it should be clear that patients understand this before they make the decision to proceed. Regret has been reported by 2% to 26% of women who have undergone sterilization procedures.⁵ In the CREST study the regret rate was 7%.⁴ A further study of 1101 women undergoing Filshie clip sterilization reported regret in 4% when women were followed for five to 15 years.⁵

The CREST study also reported a sterilization reversal rate of 0.2%.⁴ In a large Quebec trial the sterilization reversal rate was 1.8%. Regret was three times more common in women under 30 years of age. Young women in this series who had been sterilized between 15 and 29 years of age had a sterilization reversal rate of 4.2%.⁶ This emphasizes the need for discussion of reversible methods of contraception in younger women.

Discussion of Tubal Ligation Failure

The CREST study, the first study addressing long-term follow-up of women after sterilization, reported a 10-year cumulative probability of pregnancy of 18.5/1000 in a longitudinal trial involving 10 863 patients who had surgery between 1978 and 1986.⁴ Failure rates varied by technique and were greatest for Hulka clip procedures (36.5/1000) and lowest after unipolar coagulation and postpartum partial salpingectomy, each having a failure rate of 7.5/1000 procedures. Women who had undergone application of Filshie clips were not included in this study.

Women sterilized at a young age by bipolar coagulation or Hulka clip application had a cumulative risk of pregnancy of 54.3/1000 and 52.1/1000 respectively. These rates are higher than pregnancy rates associated with reversible methods of contraception. Counselling regarding rates of tubal ligation failure has been influenced by the results of

the CREST study. A study of bipolar coagulation for tubal sterilization by Peterson et al. showed a reduced failure rate when three or more sites per fallopian tube were coagulated.⁷ This study reported only five years of follow-up, whereas the CREST study showed high failure rates five to 10 years after bipolar tubal coagulation.⁴ Coagulation of three or more sites would effectively destroy most of the tube and make tubal reanastomosis very difficult.

In a retrospective study involving 311 960 patients in Quebec, Trussel et al. reported failure rates after tubal sterilization of 8/1000. Although the sterilization methods were not specifically reported, most procedures were performed using Filshie clips.⁶

In a retrospective multicentre trial Kovacs and Krins reported the largest series of Filshie clip sterilizations, involving approximately 30 000 cases between 1994 and 1998. They reported 73 documented failures, giving a failure rate of 2.4/1000.⁸

Failure rates are increased from 2.7/1000 for interval procedures to 9/1000 for postpartum procedures when Filshie clips are used.^{9,10}

Factors Affecting Tubal Ligation Failure

In all studies, age less than 30 years is a risk factor for failure because of greater fecundability and subsequent years of exposure to pregnancy. Distorted anatomy affecting access to tubes has been a factor in many cases resulting in litigation, especially when the patient was not informed of the situation. Postoperative hysterosalpingography should be performed if is not certain that both tubes are occluded. Neither occlusion of the wrong structure nor incomplete occlusion of the tube is defensible, as these surgical errors fall below the standard of care.

Incompletely closed Filshie clips were a factor in a large number of litigation cases brought in Australia in 2000. These cases arose because of failure of the applicator to close down the clips properly.^{11,12} In one geographic area, 10% of women who had Filshie clip sterilization subsequently became pregnant (40 times the reported failure rate). It was not known prior to these cases that the clip applicator required calibration, and this has since led the manufacturer to produce disposable applicators.

In a study of 131 sterilization failures, Varma and Gupta analyzed whether time to failure was predictive of negligence.¹³ The cause of failure was established by direct pelvic visualization or histology of the fallopian tubes or a combination of both. Filshie clips were used in 47% of the cases analyzed. Most failures (72.5%) occurred in the first 12 months after application.

ABBREVIATIONS

CMPA Canadian Medical Protective Association

CREST Collaborative Review of Sterilization

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