

# Office Single Puncture Laparoscopy Sterilization with Local Anesthesia

George H. Miller, MD

## ABSTRACT

**Background and Objectives:** Recently there has been a renewed interest in office based laparoscopy sterilization utilizing local anesthesia with conscious intravenous sedation. The safety of performing the procedure outside of a hospital environment has been questioned. The author attempts to determine the incidence of major complications with a review of the literature and a retrospective chart review of his personal cases.

**Methods:** During the period from 1971 to 1995, the author performed 1,753 laparoscopic procedures, utilizing local anesthesia in 1,562 cases and general anesthesia in the remainder. The focus of this chart study is the 1,190 laparoscopy sterilization cases performed in an office exam room setting, utilizing local anesthesia and conscious intravenous analgesia. Conventional 10 mm single puncture laparoscopy equipment was used. Major complications were defined as requiring laparotomy, blood transfusion, cardiopulmonary resuscitation, or emergency transfer to the hospital.

**Results:** The author's series contained one major complication, which was easily handled in the office environment. A review of the literature, including the author's series, revealed a major complication incidence of 5 out of 20,568 cases reviewed. None of these five complications would have required immediate laparotomy or blood transfusion to prevent a fatality.

**Conclusion:** The author proposes that there is no documented evidence that office laparoscopy places the patient at increased risk for a life-threatening complication and should be considered by experienced gynecologic laparoscopists who are interested in cost containment.

**Key Words:** Laparoscopy sterilization; Local anesthesia; Safety; Office; Experienced gynecologic laparoscopist

## INTRODUCTION

Tubal sterilization done via laparoscopy is the most common contraceptive method utilized in females in the U.S. today when measured in woman reproductive years. Local anesthesia was utilized widely shortly after the procedure was introduced in the U.S. in the late 1960s.<sup>1</sup> Currently, the procedure is not commonly performed in an office setting using conventional laparoscopy equipment. Possible reasons for this hesitancy may be fear of life-threatening complications of anesthesia and of the procedure itself. The recent introduction of the mini laparoscope and rationing of the health care dollar will no doubt result in an increase in the number of office laparoscopic procedures done with local anesthesia.

In the 1970s death rates from laparoscopy done under general anesthesia far exceeded that of local anesthesia regardless of the surgical setting. Pulse oximetry and other monitoring equipment have narrowed this difference in more recent years. This report is made to determine the risk of performing the procedure outside of the hospital environment.

The author has been in solo practice of obstetrics and gynecology for 27 years and has performed 1,753 laparoscopic procedures during this period of time. Local anesthesia was utilized in 1,562 cases and general anesthesia was used in the remainder. Prior to attempting the procedure in the office located across the street from the hospital, the author performed 10 procedures under local anesthesia in the hospital with anesthesiologist standby and 363 cases under local anesthesia in the hospital without anesthesiologist standby. The focus of this study is the 1,190 cases of laparoscopy sterilization done in the physician's office under local anesthesia since 1976.

## MATERIALS AND METHODS

Throughout the entire study period 10 mm operating laparoscopes were utilized with N<sub>2</sub>O as the insufflating agent. A Wolff scope under direct vision along with a Semm combination insufflator, light source and coagulation unit were utilized with the first 700 patients. This equipment was located on a moveable cart equipped with N<sub>2</sub>O and O<sub>2</sub>

Martin Street Professional Bldg., 325 Martin Street, Suite #1, Twin Falls, ID 83301, U.S.A.

EMAIL: 72345.271@compuserve.com

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cylinders. Operating instruments were placed on a separate Lakeside cart. Various unipolar coagulating forceps were utilized with the first 200 patients in the study group and Kleppinger bipolar forceps with the remainder. A Valtchev uterine cannula was used, having the ability to rotate the uterus 90° to the axis of the handle. This feature was especially helpful in the massively obese patient.

An Olympus scope with an Elmo color video camera system and an eight-inch JVC Monitor were added in 1989 and utilized in the remaining 492 patients in the study group. At that time a Valley Lab Force II electrocoagulating unit, Olympus xenon light source and piped gasses to the two operating/exam rooms were added.

The operating/exam rooms measure 8 x 10 feet and initially were equipped with conventional Hamilton exam tables to be replaced later with Ritter Mark IV electric exam tables with knee crutches. Both types of tables offer an advantage over conventional operating room tables allowing the pelvis to be tilted without use of Trendelenberg position. Each exam room was utilized as both operating and recovery room.

#### **Analgesia & Anesthesia:**

An intravenous line with 500 ml Ringers lactate was used on all patients. During the early years of the study 10 mg of diazepam was given to the patient to take orally one hour prior to surgery followed by an average dose of 20 mg alphaprodine (Nisentyl) and 0.5 mg scopolamine given intravenously immediately prior to the procedure. Because of the marked respiratory depression reported with alphaprodine the intravenous analgesic was changed to fentanyl 1 mg in 1983. The scopolamine was eliminated in 1989. The oral preoperative sedation was changed to flurazepam hydrochloride 45 mg orally the night before surgery and repeated one hour prior to surgery. The periumbilical area was infiltrated with 5-10 ml of 1% lidocaine with epinephrine for trocar insertion. A paracervical block was utilized in the first 100 patients but abandoned as unnecessary. The first 100 patients had a 22-gauge spinal needle inserted into the suprapubic area to anesthetize the cornual insertion of the fallopian tubes with lidocaine. This technique was later replaced with the topical application of 10 ml of 4% lidocaine sprayed on all tubal surfaces and surrounding visceral peritoneum. The first 200 patients were monitored with a pulse monitor and the remainder with a pulse oximeter. Approximately 30% received supplemental O<sub>2</sub> by mask. Resuscitation equipment included an Ambu resuscitation bag, laryngoscope with endotracheal tubes and a vial of succinyl choline to be used for intubation in case of laryngeal spasm. Naloxone 1.5 mg was added to the remaining 500 ml of Ringers following the procedure to reverse the effects of the narcotic prior to ambulation.

Atropine 0.2-0.4 mg intravenous was used for bradycardia. Using the current regimen patients remain awake during the procedure and are able to communicate with the staff.

Patients with history of previous pelvic infection, pelvic surgery and obesity were not excluded from consideration for office surgery. It was not necessary to exclude any patient on the basis of poor risk.

#### **Current Procedure:**

Patients undergo a complete general medical history, physical exam and view a video describing the procedure, risks and benefits prior to scheduling the procedure. The patient is instructed to eat a light breakfast, avoiding caffeine, the morning of the procedure, which is performed after noon, and asked to void immediately prior to being taken to the exam room. An intravenous line is started and the patient is placed in knee crutches. The vagina is prepped with Septisol and the abdomen with Betadine solution. The abdomen is insufflated with 2.5-5 liters of N<sub>2</sub>O through a Veress needle. The amount of gas insufflated is dependent on the patient's size and resulting intraabdominal pressures. Intraabdominal pressures are monitored so as not to exceed 30 mm Hg. While the abdomen is being insufflated, a Valtchev uterine cannula is inserted into the cervix for control of the uterus during the procedure. A reusable, sharp 10 mm trocar and cannula is inserted through a small, crescent-shaped stab wound at the inferior border of the umbilicus. A 10 mm operating laparoscope with xenon light source and video camera are used to view the pelvic organs and to aid in explaining anatomy and pathology to the patient. A cannula inserted through the scope's operating port is used to spray 10 ml of 4% lidocaine on tubal and surrounding peritoneal surfaces. The fallopian tubes are coagulated with bipolar electrocautery until full blanching occurs in the mid portion of the tube. Additional coagulation is carried out immediately on either side of the original blanched area coagulating a total of one cm of tube. The gas is vented and the skin incision approximated with three interrupted 4-0 nylon sutures. The patient is given the option of removing the skin sutures with a disposable suture removal kit or returning to the office a week later. Patients are in the office a total of 1 1/2-2 hours and are discharged to the care of a responsible adult. A registered nurse is present with the sedated patient at all times. During the procedure the nurse manages the laparoscopic and video equipment, and manipulates the uterine cannula under the physician's direction. The operator is the only one "scrubbed" during the procedure. Operating time is approximately fifteen minutes. Four to six procedures can be performed in an afternoon utilizing two exam rooms.

## RESULTS

1. One patient was found to have an unexpected tubal gestation and was transferred to the hospital for treatment. 2. A respiratory arrest secondary to alphaprodine was successfully treated with Ambu bag resuscitation and intravenous naloxone. This patient had not been monitored with a pulse oximeter, which is now the standard practice. Alphaprodine is no longer used because of the potential of marked respiratory depression. Severe respiratory depression has not occurred with the dosage of fentanyl utilized in this series. 3. Two patients had dense pelvic adhesions, requiring completion of the procedure at the hospital at a later date. 4. During a six-month period in 1985, four staphylococcal periumbilical wound infections were encountered. All personnel were cultured and one R.N. was found to be a carrier. This situation was rectified and no subsequent wound infections have occurred. 5. Several obese patients required reinsertion of the trocar at a 85° angle when failure of intraabdominal insertion occurred with the standard 45° angle. The procedure was then modified to utilize an 85° angle on massively obese patients. 6. Failure at creating a pneumoperitoneum in two massively obese patients required reinsertion of the Verres needle into the posterior cul-de-sac. 7. Five intrauterine and four ectopic pregnancies were subsequently encountered in patients who had a laparoscopy sterilization during the study period, making an incidence of 7.6 unintended preg-

nancies per 1000 sterilizations. This is well within the rate of 19 per 1,000 for bipolar sterilizations recently reported in the U.S. Collaborative Review of Sterilization study.<sup>2</sup>

## Economics and Reimbursement:

Unless the facility has certification as an approved surgery unit, insurance companies will usually reimburse only for supplies used. A charge of \$320 is made for supplies, which essentially covers all costs. The physician's fee is covered by most plans with the usual rate of reimbursement as if done in the hospital. A few insurance plans will not reimburse unless done in an approved surgical care unit. These patients are operated on at the hospital under local anesthesia at an average hospital billing of \$1,500. A larger fee would be allowed if the office had an approved operating room rating. However the increase charges would defeat the goal of providing female sterilization at the lowest possible cost. There has been no increase in premium in professional liability insurance with full disclosure to the carrier.

## DISCUSSION

A review of the available literature<sup>1-17</sup> was carried out in order to assess the safety of utilizing local anesthesia for laparoscopy. **Table 1** summarizes this review. Many of the smaller studies were done to determine the safety of local

\* O.R.: H=Hospital outpatient surgery; S=Free standing surgical care center; O= Office

\*\* Insufflating Agent: R=room air

\*\*\* Author's series

**Table 1.**

Summary of cases reported in literature utilizing local anesthesia.

Author	Dates	#Case	O.R.*	Compli.	Major Insuffl. Agent**	Comments
Wheless <sup>1</sup>	'71	50	H	0	CO <sub>2</sub>	Johns Hopkins Hospital
Chaturachinda <sup>6</sup>	'71	200	H	0	R	Remote Village Hospital, Thailand
Fishburne <sup>7</sup>	'72	149	H	0	N <sub>2</sub> O	U. of N. Carolina
Penfield <sup>8</sup>	'72-'76	1200	S	0	N <sub>2</sub> O	Syracuse, N.Y. 2 freestanding clinics
Brown <sup>9</sup>	'74	15	H	0	N <sub>2</sub> O	U. of N. Carolina
Pelland <sup>10</sup>	?-'75	100	H	0	N <sub>2</sub> O	Medical College of Wisconsin
Fishburne <sup>11</sup>	'75-'76	110	O	0	N <sub>2</sub> O	Clinic in North Carolina Baptist Hosp.
Destefano <sup>5</sup>	'78-'81	553	H	0		Multicenter prospective study, 5 hospitals
Koetsawang <sup>12</sup>	'79-'82	300	H	0		Bangkok, Thailand
Pattinson <sup>4</sup>	'80-'82	8509	H	2		Africa: 1 anaphylaxis to local; 1 bladder inj
Spielman <sup>13</sup>	'82	21	H	0		U. of N. Carolina
Poindexter <sup>14</sup>	'80-'88	2827	H	0	N <sub>2</sub> O	Baylor College of Medicine
Falfoul <sup>15</sup>	'88-'89	55	H	0		Tunis. All immediately post partum
Milki <sup>16</sup>	'88-'91	52	H	0	R	Stanford U., GIFT & ZIFT procedures
Snabes <sup>17</sup>	?-'91	5	H	0	N <sub>2</sub> O	Baylor Col. of Med. cyanotic heart disease
Gupta <sup>3</sup>	'85-'88	4500	H	2	R	India: 1 cardiac & 1 resp. arrest. 0 deaths
Merger <sup>18</sup>	?-'95	732	H	0		New Caledonia. All immed. post partum
Miller <sup>***</sup>	'76-'95	1190	O	1	N <sub>2</sub> O	Twin Falls, ID. 1 resp. arrest 0 deaths
<b>TOTALS</b>		20568		<b>5</b>		<b>No Deaths, No immediate lifesaving laparotomy or blood transfusions necessary.</b>

anesthesia in a defined risk group or to report an innovative technique. Studies were excluded if there was no mention of major complication rates. For the purpose of this review, the author was interested in the incidence of life-threatening complications which could not be handled in an office environment. Major complications were defined as those requiring laparotomy, blood transfusion, cardiopulmonary resuscitation, or emergency transfer to the hospital.

There were no deaths reported in 20,568 cases and only five patients had major complications. Gupta,<sup>3</sup> in his series of 4,500 cases in India, reported one cardiac and one respiratory arrest, both successfully resuscitated. There was no mention of pulse oximetry in this study; presumably, these complications occurred secondary to hypoxia with the use of intravenous analgesia. Pattinson's<sup>4</sup> series of 8,509 cases in Africa reported one case of trocar injury to the bladder and a case of anaphylaxis from local anesthetic. Each of these complications could have been handled adequately in the office setting. The bladder injury could be transferred to the hospital for repair. The respiratory and cardiac arrest could have probably been prevented with pulse oximetry monitoring and appropriate oxygen therapy. The office should, however, be equipped to handle these emergencies. Anaphylaxis secondary to local anesthetic, especially lidocaine, is rare and does not prevent widespread usage in physician's offices. Most local anesthetic reactions can be adequately treated in a physician's office.

The absence in these reports of the numerous "nightmare" scenarios which have been reported in cases done under general anesthesia is interesting. One can only postulate the reasons. With local anesthesia, the patient is awake enough to give instant feedback should the Veress needle be inserted extra-peritoneally or excess gas insufflated to the point of dyspnea. The operator may have attained a higher skill level prior to attempting the use of local anesthesia and may be more cautious with a patient who is awake. It is also likely that, at least in the U.S., most cases done by trainees are done under general anesthesia. Trocar and insufflating injuries to large vessels are certainly possible regardless of the anesthetic. However, a direct puncture of the aorta may have a fatal outcome even in the hospital operating room.

Destefano<sup>5</sup> reported a multicenter prospective study to assess the safety of the various methods of female sterilization. In the series of 3,500 laparoscopy tubal sterilizations, the incidence of major complications in cases done under local anesthesia was one-fifth the rate in cases done under general anesthesia. Major complications in this study were defined as: unintended major surgery resulting from the laparoscopy; blood transfusion; febrile morbidity; life

threatening event; re-hospitalization or death. No blood transfusions or deaths were reported in either group and no unintended major surgery was reported in the local anesthesia group. Thus, if these procedures performed under local anesthesia were done in an ambulatory setting, none would have required emergency transfer to the hospital. Operator skill was not accounted for.

## SUMMARY AND CONCLUSION

The author's series contained one major complication in 1,190 cases, which was easily handled in the office environment. A review of the literature revealed a major complication incidence of 5 out of 20,568 cases reviewed. None of these five complications would have required immediate laparotomy or blood transfusion to prevent a fatality. Although the average physician's office does not afford the security of the backup systems in place at a well-equipped hospital or surgical care center, there appears to be no documented evidence that office laparoscopy places the patient at increased risk for a life-threatening complication which could not be handled in the office.

The subject of laparoscopy outside of the hospital is both current and controversial. When one considers potential risks of this procedure, one must also consider the obstetrical risks which may occur by not offering sterilizations at the lowest possible cost. This study's population included a high percentage of patients referred by the local health department which has a fixed budget for sterilizations. The reduced cost per procedure enabled the health department to provide sterilizations to almost twice the number of patients who are in a relatively high risk obstetrical group.

Economic considerations should never be placed above patient safety. Experienced gynecologic laparoscopists should be able to safely perform the procedure in a well-equipped non-hospital environment using local or general anesthesia.

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