Operative Hysteroscopy in an Office-Based Surgical Setting: Review of Patient Safety and Satisfaction in 414 Cases

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ABSTRACT

Study Objective: To determine the safety and satisfaction among patients undergoing operative hysteroscopy in an office-based setting.

Design: Retrospective analysis (Canadian Task Force classification II-2).

Setting: Physician’s private office.

Patients: Women undergoing operative hysteroscopy in an office setting.

Interventions: Three hundred eighty-seven women underwent a total of 414 operative hysteroscopic procedures, with use of parenterally administered moderate sedation, a 9-mm operative resectoscope, and sonographic guidance. All patients were American Society of Anesthesiologists class I-III.

Measurements and Main Results: A total of 305 primary operative hysteroscopic procedures were performed including endomyometrial resection, myomectomy, polypectomy, removal of a uterine septum, and adhesiolysis. One hundred nineteen (26.3%) repeat operative procedures were performed in women in whom previous endometrial ablation and resection had failed. The average procedure required a mean (SD) of 37.6 (13.5) minutes to complete, and produced 14.1 (10.2) g of tissue. Ninety-nine percent of all procedures were completed. Only 1 patient required a hospital transfer for evaluation of a uterine perforation necessitating diagnostic laparoscopy. There were 8 (1.9%) postoperative infections, and no complications attributable to use of conscious sedation. Two hundred fifty-five women (65.6%) responded to our telephone survey. Two hundred fifty-two (98.8%) respondents were either “very satisfied” or “satisfied.” Two hundred forty-nine women (97.6%) preferred the office to a hospital setting, whereas 6 (2.4%) would have preferred a hospital setting. All but 5 respondents would recommend this procedure to a friend.

Conclusion: Major operative hysteroscopic surgery can be performed in an office-based setting with a high degree of safety and patient satisfaction. Journal of Minimally Invasive Gynecology (2013) 20, 56–63 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Endomyometrial resection; Hysteroscopic; Moderate sedation; Myomectomy; Office-based surgery; Sonographic guidance

DISCUSS

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Operative hysteroscopy encompasses an important set of skills in the gynecologic armamentarium for the treatment of infertility, pregnancy loss, and abnormal uterine bleeding.

The introduction of small-diameter operative hysteroscopy has enabled a few skilled and motivated surgeons to perform operative hysteroscopy in an office-based surgical (OBS) setting. The advantages of operative hysteroscopy include the possibility to diagnose and treat lesions in a single session and the convenience and efficiency for both the physician and patient. An additional benefit of office-based operative hysteroscopy has been suggested by Lindhe et al [1], who more than a decade ago, noted the cost savings per case of at least 50% when compared with the hospital equivalent. In western New York State, we estimate the cost to the insurance companies for an average office-based hysteroscopy procedure to be $350.

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hysteroscopy in an OBS setting to be in the same range observed by Lindheim and colleagues.


In 2000, Lindheim et al [1] reported a series of 33 infertile women who underwent various hysteroscopic procedures including polypectomy, myomectomy, and adhesiolysis, in which small-diameter hystoscopes (≤4 mm) were used along with either mechanical scissors or a Gynecare Versapoint bipolar electrode (Ethicon, Inc., Somerville, NJ). All procedures were performed in an OBS setting, using a wide variety of analgesic and anesthetic regimens. That same year, Sesti et al [3] reported excellent results in a series of 42 women who underwent hysteroscopic polypectomy in an OBS setting using the Gynecare Versapoint bipolar system and local anesthesia.

In 2004, Bettocchi et al [4] reported on 4863 operative hysteroscopic procedures performed using a 5.0-mm diameter operative hystroscope and 5F instruments. The procedures included the removal of cervical and endometrial polyps along with adhesiolysis and repair of “anatomic impediments.” Bettocchi et al [4] used a vaginoscopic technique “without analgesics or anesthesia,” and noted that patients reported little discomfort, although those undergoing removal of endometrial polyps were more likely to experience “moderate” discomfort.

To date all of the reported operative hysteroscopies in an OBS setting have been performed using small diameter (≤5 mm) instruments and, with few exceptions, without parenterally administered analgesia or sedation. This is the first report of office-based hysteroscopic surgery using a full-size 26F (9 mm) operative resectoscope. The use of larger instruments, parenterally administered agents to achieve moderate sedation [5,6], and ultrasound guidance enabled us to safely perform complex and highly invasive procedures with a high degree of safety and patient satisfaction.

Materials and Methods

Three hundred eighty-seven women underwent a total of 448 operative hysteroscopic procedures in the private office of a physician (M.W.), with use of a standard 9-mm continuous-flow gynecologic resectoscope. Procedures included endometrial resection [7] myomectomy, polypectomy, and repeat surgery after failure of both resectoscopic and nonresectoscopic endometrial ablation. Endometrial resection (Fig. 1) is the systematic and geometric approach for removing the entire endometrium in long continuous strips of tissue to a depth of 4 to 5 mm below the endometrial basalis in all portions of the uterus; the depth is decreased to 2 to 3 mm in the cornual region. This is followed by the deep coagulation of the exposed myometrium using a ball-end electrode.

All patients underwent extensive screening including a complete history and physical examination, transvaginal ultrasound, and selected laboratory studies. Formal counseling included discussion of alternate treatment regimens and the potential for immediate and delayed complications associated with hysteroscopic surgery. Most patients did not undergo diagnostic hysteroscopy before the operative procedure.

All procedures were performed in a dedicated operating room located within an accredited OBS setting as required under New York State Public Health Law §230-d [8]. Patients above American Society of Anesthesiologists class III were excluded from undergoing a procedure in an OBS setting. Numerous patients required formal medical clearance before the procedure, and in women aged >50 years, an electrocardiogram was obtained within 30 days before the surgery.

The operating room team consisted of 5 individuals including the surgeon (M.W.), a first assistant, a trained sono­grapher (A.D.), a fluid management specialist, and a registered nurse (C.B.) dedicated solely to monitoring the patient and administering intravenous analgesics and sedatives. All operating room personnel were trained and credentialed in advanced cardiac life support, crew resource management [9], and the use of moderate conscious sedation, as well as procedure-specific training.

In nearly all instances, patients were seen the day before surgery for preoperative counseling, peroperative instructions, and insertion of a 3-mm laminaria japonica. In patients who requested tubal sterilization, Essure (Conceptus, Inc., Mountain View, CA) sterilization procedures were performed at the time of laminaria insertion, although several patients underwent Essure (Conceptus, Inc., Mountain View, CA) sterilization procedures before hysteroscopic surgery. Patients were informed that hysterosalpingography would not be feasible as required by the manufacturer’s instructions for use. Patients were asked not to eat solid food for a minimum of 4 hours before surgery, but were allowed clear liquids until 2 hours before the scheduled operating room time.

On the day of surgery, an intravenous catheter and heparin lock was placed in all patients, and 2 g ampicillin was administered intravenously several minutes before surgery.
Patients allergic to penicillin received either 500 mg metronidazole or 300 mg clindamycin intravenously. Most patients also received 0.6 mg atropine intravenously just before surgery. Patients with a history of narcotic-related nausea often received premedication with 12.5 to 25 mg promethazine intravenously.

Before each procedure, the patient’s maximum allowable fluid absorption (MAFA_{limit}) [10] was calculated. In accordance with AAGL [11] guidelines, no patient was allowed to absorb more than 1500 mL glycine 1.5% or 2500 mL normal saline solution. Whenever the MAFA_{limit} was calculated to be less than allowable according to AAGL guidelines, the lesser of the 2 limits was imposed. Whenever the MAFA_{limit} exceeded the AAGL guidelines, the lesser of the 2 restrictions was employed.

Most procedures were performed using a monopolar 26F (9 mm) continuous-flow resectoscope (Karl Storz Endoscopy America, Inc., Culver City, CA, and Circon-ACMI, division of Circon Corp., Stamford, CT); occasionally, in the presence of marked cervical stenosis or a small postmenopausal uterus, a 22F (7 mm) resectoscope was used either as the sole instrument or in combination with the larger resectoscope. Glycine 1.5% was administered via either the Dolphin (Circon ACMI) or Hamou Endomat (Karl Storz Endoscopy America) fluid management system. A small number of procedures were performed using a 26F bipolar resectoscope (Karl Storz Endoscopy America). All procedures were performed under sonographic guidance using a 3.5-MHz abdominal transducer placed just above the symphysis pubis by one of us (A.D.).

Nearly all patients received an initial dose of 2.5 to 5.0 mg midazolam and 50 to 100 μg fentanyl, intravenously. Additional doses were given only after a minimum elapsed interval of 3 minutes, and included no more than 2.5 mg midazolam or 50 μg fentanyl. Supplemental medication could include a sedative, an opiate, or a combination of both. In the latter part of the study period, during a nationwide shortage of parenterally administered opiates and benzodiazepines, nalbuphine hydrochloride and ketamine were used in conjunction with orally administered midazolam.

Procedures commenced with removal of the laminaria japonica. Dilation was performed using a Hegar dilator under sonographic guidance. A total of 20 mL saline solution containing 2.5 U vasopressin was injected intracervically at the 3-o’clock and 9-o’clock positions using a 21-gauge × 1½-inch needle. After insertion of a continuous-flow resectoscope, operative procedures were generally initiated with pump pressure varying from 140 to 175 mm Hg and adjusted to balance satisfactory visualization with fluid intravasation. The surgeon was apprised of fluid deficits in 50- to 100-mL increments. A standard endomyometrial resection technique [7] with only slight modification [12] was used, combined with resection of endometrial polyps and removal of submucous and intramural leiomyomas as they were found. All procedures were digitally recorded using a MediCapture USB200 device (MediCapture, Inc., Philadelphia, PA).

Patients recovered in the operating room, and were monitored according to a standardized post-anesthesia recovery protocol described by Aldrete and Kroulik [13]. Discharge criteria included a post-anesthesia recovery score (Fig. 2) of ≥9, the ability to walk out of the office (i.e., without a wheelchair), and vaginal bleeding <1 g/min. The next day, patients were contacted by one of us (A.D. or C.B.) via telephone.

A simple patient satisfaction survey form was devised (Fig. 3), and attempts were made to contact all patients who had undergone office-based hysteroscopic surgery from March 29, 2007, to March 27, 2012. The questionnaire was administered as a telephone survey by one of us (A.D. or C.B.).

**Results**

A total of 414 office-based hysteroscopic procedures were performed in 387 patients. The mean (SD; 95% CI) age of the patients was 44.2 (6.9; 43.5–44.9) years. Three hundred five women (73.7%) underwent primary procedures, and the remaining 109 (26.3%) underwent repeat operative procedures after failure of nonresectoscopic endometrial ablation, myomectomy, or previous endomyometrial resection in procedures performed outside of the present study. A summary of the procedures and their indications are given in Tables 1 and 2, respectively.

Of the 305 women undergoing a primary hysteroscopic procedure, 64 (21.0%) were asked to undergo previous diagnostic hysteroscopy to determine whether they were suitable candidates for surgery. The remaining 79% underwent a single-stage diagnostic and operative procedure. None of the patients requiring repeat surgery were asked to undergo diagnostic hysteroscopy. Three hundred sixty-four women (87.9%) underwent placement of a 3- or 4-mm laminaria japonica on the day before surgery.

In 2007, a total of 6 procedures were attempted and completed in our office, representing 10.0% of the total performed that year. In 2008, 18 procedures, representing 27.3% of that year’s total, were achieved in the OBS setting. From January 1, 2009, to March 27, 2012, a total of 390 procedures were performed at our facility, representing 98.0% of the total performed during those years. Of the 8 procedures completed in the hospital during that period, 1 was performed in an otherwise healthy woman who requested a hospital-based setting, and the remaining 7 in patients with medical contraindications to office-based surgery.

Four hundred eleven of 414 procedures (99.3%) were completed. Three hundred ninety-two (94.7%) were accomplished using a combination of parenterally administered midazolam and fentanyl. Ninety-eight women (23.7%) with a history of nausea and vomiting due to previously administered anesthetics were premedicated using promethazine in doses varying from 12.5 to 25 mg. Of the women receiving the midazolam-fentanyl combination, the mean (SD; 95% CI) dose required to accomplish the procedure was 10.57 (3.5; 10.23–10.91) mg midazolam and 200.1 (88.5; 191.6–208.6) μg fentanyl. The duration of the...
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Discharge procedures (SD; 95% CI) were performed repeat hysteroscopy and endometrial curettage. Nineteen procedures (4.6%) were accomplished using a combination of glycine and saline solution, and the remaining 3 (0.7%) were performed using saline solution alone. The fluid deficit of the patients receiving glycine was 461 (420.4-501.6) mL. The 22 women who received normal saline solution absorbed 758 (448; 570.8-945.2) mL. There were no instances of excess fluid absorption.

The mean (SD; 95% CI) specimen weight was 14.1 (10.2; 13.1-15.1) g for the entire series. The relationship between specimen weight and type of procedure is given in Table 3. The histologic diagnoses for all 414 procedures are given in Table 4. There were 4 instances of complex hyperplasia, none of which had been detected at endometrial curettage or biopsy within the previous 6 months.

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EMR = endometrial resection.
There were 11 complications (2.7%). Eight women (1.9%) developed infections within the first 36 hours; most became febrile within 30 minutes after the procedure, and were given parenteral antibiotic therapy. None of the infectious complications required hospitalization. One uterine perforation (0.2%) occurred with an active electrode, requiring a hospital transfer and diagnostic laparoscopy; no visceral injury was sustained, and the patient was discharged after 48 hours of observation. Two uterine ruptures occurred, which precluded completion of the procedure. Nine additional uterine ruptures transpired, which neither altered the postoperative course nor precluded completion of the procedure. In all 9 cases, the uterine defect was first noted because of a rapid increase in the patient’s fluid deficit. These defects were generally estimated to be <5 mm. Uterine rupture was differentiated from perforation by careful and immediate review of the digital video recording to determine whether a device had passed through the uterine serosa. In all instances, the rupture occurred at the fundus, just medial to the midline; no ruptures occurred at the cornua. Ten women (2.4%) in whom bleeding exceeded 1 g/min required uterine tamponade using a Foley catheter. The catheter was kept in place for 45 minutes to 2 hours before discharge from the office.

No complications were attributable to use of any parenterally administered analgesics or sedatives. Although transient mild hypoxemia (oxygen saturation concentration in hemoglobin, 80%–90%) did occur, such incidents responded quickly to supplemental oxygen in combination with verbal and tactile stimulation. In no instances was the use of naloxone or flumazenil required. There were no instances of vaginal reactions.

A total of 255 women responded to our telephone survey. Patients who underwent more than a single procedure during the study were asked to respond separately for each procedure. Of the 11 women who experienced complications, 9 completed the survey, representing 3.5% of the total respondents. Two hundred ten (92.4%) were “very satisfied” (95% confidence interval [CI], 91.94% to 92.96%), and 31 (16.5%) were “satisfied” (95% CI, 91.94% to 92.96%) with the procedure. Three women (1.2%) were “somewhat dissatisfied” (95% CI, −0.14% to 2.54%), 1 because she thought she had been inadequately sedated, and 2 because of prolonged nausea and vomiting after the procedure. Two hundred forty-nine respondents (97.6%) expressed preference for an office-based procedure (95% CI, 97.5% to 97.7%), and only 6 women (2.4%) (95% CI, 0.52% to 4.28%) would have preferred a hospital setting. Of the 6 women, 1 believed she had been inadequately sedated, and 3 others (all registered nurses) simply explained that they would have been more comfortable in a hospital setting but cited no specific deficiencies. Two hundred forty-nine respondents (98.0%) (95% CI, 97.8% to 98.2%) stated they would recommend the procedure to a friend. Of the 5 who would not recommend the procedure to a friend, 3 women noted above explained that they would have felt more comfortable in a hospital setting, and 2 women stated that they had hoped for a better surgical outcome.

Discussion

Until the 1990s, the role of office-based hysteroscopy was limited to its use as a diagnostic tool. The introduction of small-diameter continuous-flow hystoscopes with dedicated working channels designed to accommodate operating instruments made it possible for several ground-breaking surgeons [1–4] to treat some uterine and cervical diseases in the office setting without cervical dilation, thereby avoiding the use of general anesthesia.

In 1999, Kung et al [14] reported the treatment results in 10 women with symptomatic submucous leiomyomas, endometrial polyps, uterine septae, and intrauterine synechiae.
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Hysteroscopy was the introduction of instruments to visualize and treat cervical diseases, but requires a paradigm shift in thinking about patient comfort and safety. The exclusive reliance on small-diameter instruments in office-based hysteroscopy is a limiting factor. To provide safety and comfort to patients, it is necessary to develop methods that can accommodate instruments larger than 6 mm in diameter. This can be achieved by using larger hysteroscopes or by developing new methods of instrument delivery. The use of larger instruments can improve the efficacy of hysteroscopic therapy and allow for the treatment of a wider range of cervical conditions. The complications that can occur with large diameter instruments are similar to those associated with small diameter instruments, but may require different management strategies. The development of new techniques and instruments is essential to improve the safety and effectiveness of hysteroscopic treatment.
a muscular layer < 1 cm in thickness as distention occurs. Patients who experience uterine rupture do not seem to note increased pain during or immediately after the procedure.

The present study does not include long-term outcomes; however, it is worth noting that in women who underwent endometrial resection without myomectomy, the average specimen weight of 11.9 g compares favorably with our (M.W. and A.D.) previous series that was performed with the patients under general anesthesia [33].

The limitations of the present study include its retrospective nature and that telephone surveys are prone to some element of selection bias inasmuch as dissatisfied patients are less likely to respond. Surveys performed at varying intervals after the original procedure are likely to be less accurate than surveys conducted within a standardized interval such as 24 to 72 hours after completion. Another limiting factor of the present study is that women who experience favorable menstrual outcomes are more apt to report greater rates of satisfaction with office-based surgery. Additional studies will be necessary to determine whether the rates of repeat operation in women undergoing office-based hysteroscopic surgery are comparable with those that we have reported in a hospital or ambulatory surgical center setting [33].

Gynecologists considering incorporation of operative hysteroscopy into an OBS setting must carefully consider the costs of initiating such a program. Expenses will vary with local regulatory and state medical board requirements, equipment that is already available to the practitioner, and whether used or new instruments are purchased. Many offices may already own much of the necessary paraphernalia such as an office-appropriate operating room table, an electrosurgical generator, a video camera with monitor, an ultrasound machine, and an emergency cart. Fluid management systems and resectoscopes can often be purchased from companies specializing in used medical equipment at a fraction of the cost of their newer models. The importance of redundant equipment, in particular a second resectoscope, cannot be overstated. In the final analysis, one must consider the expected patient volume and start-up costs before investing substantial time and resources.

Finally, one must consider that the benefits to the physician are maximized when OBS blends well into the daily patient flow of one’s practice. We find it most useful to schedule operative hysteroscopic procedures as the first case in either the morning or afternoon session. Although we have accommodated as many as 6 operative hysteroscopic procedures in a week, we believe that 1 or 2 procedures per week is sufficient for the physician to derive the benefits of OBS while enabling the operating room crew to develop and maintain the necessary skills required for patient safety.

Conclusions

The advantages of office-based hysteroscopic surgery are 4-fold. First, it often enables the gynecologist to combine the diagnostic and treatment phases of patient management, obviating the need for multiple interventions and anesthetics. Second, this approach produces substantial cost savings to the insuror and the patient. Third, many women prefer the familiar environment of the office setting. Fourth, the physician benefits from the ease of scheduling, more efficient use of time, and improved reimbursement, compared with hospital- or ambulatory surgical center-based procedures.

There are 2 advantages of a large-diameter resectoscope: its efficiency and adaptability to a variety of concomitant procedures. It is particularly efficient in removing large quantities of tissue that is likely to need smaller instruments. Bettocchi et al [15], who have considerable experience in removal of leiomyomas and polyps in an OBS setting, note that the “use of the 5F Versapoint electrodes to treat these larger myomas (greater than 2 cm) is time consuming and yields lower quality final results.” In addition, the larger-diameter resectoscope is adaptable to all types of hysteroscopic procedures including endomyometrial resection, polypectomy, myomectomy, and repeat operative hysteroscopy; in many cases, 2 or more of these procedures are required in the same patient. The use of a single instrument obviates the need for multiple specialized instruments such as a nonresectoscopic endometrial ablation device combined with a resectoscope or tissue morcellation apparatus for management of menorrhagia in a woman with a moderately sized submucous leiomyoma.

The limitations on hysteroscopic surgery in an OBS setting are 3-fold: operator skill and experience, the existence of intrauterine disease beyond what can be managed with a small-diameter hystroscope, and the capacity to provide patient comfort. Patient comfort is critical in performing advanced office-based procedures.

We have demonstrated that a large-diameter resectoscope can be safely used in a properly equipped and accredited office by a physician working with a dedicated and motivated operating room team. However, patient satisfaction requires careful consideration of her need for analgesia and sedation. The influx of numerous technological innovations in the past two decades has increased the range of what is possible in an office setting. The continued advancement of office-based surgery, however, will depend not only on new technology but on development of safe, effective, and proven protocols for administration of adequate sedatives and analgesics in the OBS setting. Residency and fellowship programs are encouraged to provide the necessary and extensive training indispensable for managing the challenges of providing appropriate analgesia and sedation in the office setting.

Physicians must consult their state medical boards to meet any formal accreditation requirements. Failure to comply with regulatory requirements may be grounds for license revocation. It is worth noting that as of this writing, only 9 states required accreditation once various thresholds have been crossed; 25 states have no requirements for office-based surgery or office-based anesthesia [34,35]. In the absence of state regulations for OBS, compliance with both state and national standards is important. The guidelines for participation in an OBS, however, will vary from state to state. In most states, both OBS and office-based anesthesia are considered to be under the jurisdiction of the primary specialty, the practice of OB-GYN.}

References
management, ob- and anesthetics. Costs savings to in order to achieve a more efficient procedure, many things to keep in mind when deciding how to proceed. The resectoscope has been shown to be an efficient device for removing large polyps and small smaller uterine polyps in an office setting (34,35). Although the device has not been formally accredited by the Accreditation Council for Graduate Medical Education (ACGME), it is time to consider rethinking the use of this device. In addition, studies have shown that the device can be safely used without anesthesia in many cases (36). However, it is important to note that the device may not be appropriate for all patients, and that the decision to use it should be made on a case-by-case basis.

References