Hysteroscopy: a technique for all? Analysis of 5,000 outpatient hysteroscopies

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Objective: 1) To investigate the relationship between operator experience and the success of outpatient hysteroscopy; and 2) to determine if the introduction of normal saline and the use of narrow-caliber hysteroscopes and vaginoscopic approach are associated with a lower failure rate.

Design: Retrospective study.

Setting: Teaching-hospital based outpatient hysteroscopy clinic.

Patient(s): Five thousand consecutive women undergoing outpatient hysteroscopy between October 1988 and June 2003.

Intervention(s): The hysteroscopies were carried out both by experienced operators and by trainees. Procedures were performed using 4-mm and 2.9-mm telescopes with 5-mm and 3.5-mm diagnostic sheaths, respectively. Between October 1988 and 1996, the uterine cavity was distended with CO₂ (CO₂ period), whereas normal saline was preferred after 1997 (1997–2003: saline period). Traditional technique of hysteroscope insertion and vaginoscopic approach were used depending on operator preference and experience and patient characteristics.

Main Outcome Measure(s): Success, failure, and complication rates.

Result(s): The hysteroscopies were successfully performed in nearly 95% of cases by 362 operators (mean 13.8 hysteroscopies per operator) with different levels of expertise. Failure and complication rates were 5.2% and 5.4%, respectively, without any significant difference between CO_2 and saline periods. Vasovagal attacks and shoulder pain were significantly higher during the CO_2 period. The success of outpatient hysteroscopy was negatively affected by postmenopausal status, nulliparity, need for cervical dilatation or local anaesthesia, traditional technique of hysteroscope insertion, and use of a 5-mm hysteroscope.

Conclusion(s): A high level of expertise is not a prerequisite to performing hysteroscopy on an outpatient basis. Recent advances in technique and instrumentation facilitate this approach and might encourage greater adoption by the wider gynecology community. (Fertil Steril® 2008;89:438–43. ©2008 by American Society for Reproductive Medicine.)

Key Words: Complication, experience, failure, outpatient hysteroscopy, success, vaginoscopy

Hysteroscopy can be regarded as the gold standard for the evaluation of the uterine cavity in cases of abnormal uterine bleeding, infertility, recurrent pregnancy loss, and suspected intrauterine out-growth (1, 2). It has replaced conventional cervical dilatation and curettage under general anesthesia, which has been shown to be diagnostically relatively inaccurate (3–6), for the investigation of abnormal uterine bleeding.

Hysteroscopy can be performed in the office setting (outpatient hysteroscopy) or as a day-case procedure, under general

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anesthesia (inpatient hysteroscopy). Outpatient hysteroscopy has been shown to be as accurate as inpatient hysteroscopy. But compared with a traditional inpatient procedure, it has the advantage of reduced anesthetic risks, enhanced timecost effectiveness, and patient preference (3, 7-8).

We believe the success of outpatient diagnostic hysteroscopy is based on three fundamental criteria: instrument quality, characteristics of the distension medium, and the ability and experience of the operators (9).

Recent technical advances, such as the introduction of small-diameter rigid and flexible hysteroscopes, have made it possible to perform hysteroscopy in the outpatient setting (10–13). Moreover the introduction of an atraumatic insertion technique ("no touch" technique or vaginoscopic



approach) has further minimized the patient's pain and discomfort (11, 14–19).

Carbon dioxide (CO₂) and normal saline are the most commonly used distension medium for diagnostic hysteroscopy. Although CO₂ gas is generally well tolerated, uterine distension with normal saline has been shown to be more comfortable for the patient, to be more cost-effective, and to provide superior hysteroscopic views in cases of intrauterine bleeding (4, 13, 17, 20–22).

However, despite the high sensitivity and specificity, technical improvements, high patient acceptability, the low failure and complication rates, it has been estimated that only 15% of gynecologists in the United States routinely perform office hysteroscopy (23) and that only 36% of the members of the American Association of Gynecological Laparoscopists do so (24). Reasons given for this include a perceived paucity of patients who would benefit from the procedure, a duplication of procedures for patients who need surgery in the operating room, the expense of the capital equipment, poor reimbursements, and the perception that a high level of expertise is needed to perform the procedure (23). The scientific literature contributes to propagate the latter, because most studies on feasibility and safety of outpatient hysteroscopy state in the text that "all of the examinations were performed by one or a few experienced operators."

We report the outcome and findings in 5,000 consecutive patients who underwent the examination in a teaching hospital-based outpatient hysteroscopy clinic. By definition, therefore, the hysteroscopies were carried out both by experienced operators and by trainees. Our analysis focused on: 1) the relationship between operator experience and the success of the procedure; and 2) determining if the introduction of normal saline and the use of narrow-caliber hysteroscopes and the no touch technique are associated with a lower failure rate.

MATERIALS AND METHODS

We conducted a retrospective review of 5,000 patients who underwent outpatient hysteroscopy between October 1988 and June 2003. The hysteroscopies were done at the John Radcliffe Hospital, Oxford (October 1988 to May 1990), and The Royal Free Hospital, London (June 1990 to June 2003). The study was approved by our Institutional Review Board, and all patients had given their informed consent for the hysteroscopy.

The most common indication for the procedure was abnormal uterine bleeding (84.7% of cases), and other reasons were subfertility (7.2%), check hysteroscopy after hysteroscopic surgery (3.5%), and lost intrauterine contraceptive device (1%) (Table 1). The women were defined as premenopausal, perimenopausal, and postmenopausal according to the following criteria: premenopausal—all women <45 years old with regular and/or irregular menstrual cycles; perimenopausal—women >45 years old with regular and/or irregular

TABLE 1

Patient characteristics.

| Number of cases | 5,000 | |
|---|--------------|--|
| Age, yrs (range) | 44.2 (17–87) | |
| Parity, mean | 1.59 | |
| Nulliparous (%) | 1,448 (29.8) | |
| Menopausal status (%) | | |
| Premenopausal | 3,426 (68.5) | |
| Perimenopausal | 679 (13.6) | |
| Postmenopausal | 895 (17.8) | |
| Current use of gynecologic | 1376 (27.5) | |
| medication (%) | | |
| Hormonal | 931 (18.6) | |
| Nonhormonal | 402 (8.0) | |
| Both | 43 (0.9) | |
| None | 3597 (72.3) | |
| Previous uterine surgery (%) | 859 (17.1) | |
| Cesarean section | 304 (6.1) | |
| Myomectomy | 170 (3.4) | |
| Endometrial ablation | 159 (3.2) | |
| Cervical surgery | 101 (2.0) | |
| Others | 125 (2.5) | |
| Primary indication for hysteroscopy (%) | | |
| Abnormal uterine bleeding ^a | 4216 (84.7) | |
| Subfertility ^b | 360 (7.2) | |
| Control after | 174 (3.5) | |
| hysteroscopic surgery | () | |
| Lost IUCD | 48 (1.0) | |
| <i>Note:</i> IUCD = intrauterine contraceptive device. | | |
| ^a Includes menorrhagia, intermenstrual bleeding, post- | | |

 ^a Includes menorrhagia, intermenstrual bleeding, postcoital bleeding, and postmenopausal bleeding.
^b Includes infertility and recurrent miscarriage.

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menstrual cycles; and postmenopausal—women at least 1 year after the last menses or those who were taking estrogen replacement therapy.

Between October 1988 and April 1998 hysteroscopy was performed using a standard 4-mm telescope with a 30° fore-oblique lens and a 5-mm diagnostic sheath. After April 1998, hysteroscopy was performed using both the 4-mm telescope and the newer 2.9-mm optic with a 30° fore-oblique lens and a 3.5-mm diagnostic sheath (all instruments manufactured by Storz, Tuttlingen, Germany). Illumination was provided by a high-intensity cold light source via a fiber-optic lead. All the procedures were monitored using a video camera and a monitor.

Between October 1988 and 1996, the uterine cavity was generally distended with CO_2 (CO_2 period) via an electronic Hamou hysteroflator (Storz) adjusted to a flow rate of 45 mL/min and a pressure not exceeding 100 mm Hg. Following the results of our study in 1996 (13), we changed the distension medium to normal saline (1997–2003: saline period) infused at a pressure of 100 to150 mm Hg by a pressure bag.

Patients were placed in the lithotomy position and an antiseptic solution was used to wash the vaginal cavity and the cervix. A bimanual examination was then performed to assess the size and position of the uterus. Diagnostic hysteroscopy was then performed using two different techniques:

- Traditional technique: A Sims speculum was inserted into the vagina to visualize the cervix, and a vulsellum was then applied to the anterior lip of uterine cervix to create counter-traction to facilitate the insertion of the hysteroscope.
- No-touch technique: This was introduced in our clinic in 1999 and avoids the use of a speculum and a tenaculum. The hysteroscope is first introduced into the introitus of the vagina. The vagina is then distended with the saline distension medium. This facilitates visualization of the anatomy. The hysteroscope is then directed towards the cervix, the cervical canal, and then into the uterine cavity (14, 15, 19).

From 1988 to 1999, all hysteroscopies were performed with the traditional technique. After 1999, hysteroscopies were performed with either technique depending on operator preference and experience and patient characteristics. Whichever technique was used, the hysteroscope was guided through the endocervical canal and and into the uterine cavity under direct vision. The cavity was then systematically examined, starting at the fundus and tubal ostia and finishing in the endocervical canal, which was examined in more detail during withdrawal of the hysteroscope. Cervical dilatation up to Hegar 4–6 and/or intracervical local anesthesia were carried out only when required. If this became necessary with the no touch technique, the hysteroscopy was continued using the traditional approach.

Endometrial biopsies were performed based on symptoms or abnormal hysteroscopic findings. Most biopsies were done using a small metal curette (1988 to 1996) or with a Pipelle de Cornier (1996 onwards; Laboratoire CCD, Paris, France). If a target biopsy was required, it was done using either 5-Fr biopsy forceps with an operative hysteroscope or a small metal curette. Minor surgical procedures were performed via 7-mm and 5-mm operative sheaths for 4-mm and 2.9-mm hysteroscopes, respectively, using flexible scissors or grasping forceps (all of the equipment manufactured by Storz). Minor surgical procedures involving the cervix (e.g., removal of IUD, cervical polypectomy) were performed with conventional instruments.

All hysteroscopies were defined as attempted or not attempted; the latter included cases where there was a contraindication or the patient chose to cancel the procedure. Hysteroscopies which were attempted were classified as successful (complete or incomplete) or failed according to the following criteria: complete—the entire uterine cavity including both tubal ostia were visualized; incomplete—the entire uterine cavity could not be examined (e.g., part of cavity was obscured by blood clots, fibroids, or other focal lesions, technical problems with the instruments, lack of distension); and failed—examination of the uterine cavity was not possible (e.g., because of pain, vasovagal attack, cervical stenosis, extreme anxiety, heavy bleeding). Failed hysteroscopies were referred for investigation under general anaesthesia or for other investigations.

The hysteroscopic view, defined as the quality of the panoramic overview inside the uterine cavity, was defined as good or poor according to the following criteria: good–the view was of a high quality, allowing for a rapid assessment of the shape of the uterine cavity, the endometrium, and any focal lesions; poor–the view of the uterine cavity was of low quality, allowing for only slow identification of structural abnormalities.

Data collection was performed by four people (A.D.S., G.M., V.P., and P.T.) using a dedicated Access database (Microsoft, Redmond, WA). Data analysis was done using Access, Excel (Microsoft), and SPSS 9.0 (SPSS, Chicago, IL). Statistical significance was assessed using χ^2 and Fisher exact tests. All tests were two sided, and *P*<.05 was considered to be statistically significant.

RESULTS

The baseline characteristics of the 5,000 women are summarized in Table 1. Most women were multiparous and premenopausal and complained of abnormal uterine bleeding. The outcomes are shown in Table 2. In 98.2% of cases a hysteroscopy was attempted and in 89.7% completed. The hysteroscopic view was judged as good in 92.7% of successful hysteroscopies. The main reasons for canceling the hysteroscopy were high blood pressure before the procedure (18 cases), patient choice (16 cases), and severe anxiety (15 cases).

The hysteroscopies were performed by 362 different operators, the average number of hysteroscopies per operator was 13.8. A small percentage of operators (7.7%) performed >20 hysteroscopies (Table 3). The majority of hysteroscopies (72%) were performed by operators with lower experience (<50 hysteroscopies/operator).

The main reasons for failed hysteroscopies are shown in Figure 1.

Two thousand seven hundred fifty-four hysteroscopies were attempted in the CO_2 period (group A) and 2,156 in the saline period (group B).

| TABLE 2 Technical outcome of 5,000 outpatient hysteroscopies. | | | |
|--|--|--------------------------|--|
| | Attempted | Not attempted | |
| Total Complete Incomplete Failed | 4,910 (98.2%) 4,487 (89.7%) 163 (3.3%) 260 (5.2%) | 90 (1.8%) — — — | |
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| TABLE 3 | |
|--|-----------------------------------|
| Operator experience. | |
| Number of hysteroscopies performed | Operators (%) |
| <20 20–50 >50 | 334 (92.2) 20 (5.5) 8 (2.2) |
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One hundred thirty-five failed hysteroscopies (135/2,754: 4.9%) occurred in group A, and the other 125 (125/2,156: 5.7%) occurred in group B. No significant difference in failure rate was detected between the two groups ($\chi^2 = 1.94$; P=n.s.).

Failure of hysteroscopy was mainly influenced by postmenopausal status (7.6% vs. 4.8%; $\chi^2 = 11.0$; P < .001), nulliparity (6.2% vs. 4.8%; $\chi^2 = 4.4$; P < .05), need for cervical dilatation (6.6% vs. 3.5%; $\chi^2 = 24.9$; P < .001) or local anesthesia (7.4% vs. 3.0%; $\chi^2 = 49.4$; P < .001), traditional technique of hysteroscope insertion (5.5% vs. 0.9%; $\chi^2 = 33.8$; P < .001), and use of a 4-mm optic (4.9% vs. 2.7%; $\chi^2 =$ 7.3; P < .01).

The most frequent complications during hysteroscopy procedure are shown in Figure 2.

The overall rate of complications was 5.4% (266/4,910). One hundred fifty-one complications (151/2,754: 5.48%) occurred in group A and 115 (115/2,156: 5.3%) in group B. No significant difference in complication rates was detected between the two groups ($\chi^2 = 0.05$; *P*=n.s.). Complications led to failed hysteroscopy in 54.8% of cases (146/266). Vasovagal attacks ($\chi^2 = 13.49$; *P*<.001) and shoulder pain ($\chi^2 = 9.57$; *P*<.01) were significantly higher in group A.



The occurrence of a complication during hysteroscopy was mainly influenced by nulliparity ($\chi^2 = 4.14$; P < .05), need for cervical dilatation ($\chi^2 = 27.64$, P < .05) or local anaesthesia ($\chi^2 = 42.51$; P < .05), traditional technique of hysteroscope insertion ($\chi^2 = 21.47$; P < .05), and use of a 4-mm optic ($\chi^2 = 4.33$; P < .05).

The 4-mm and 2.9-mm scopes were used in 84.7% and 15.3% of cases, respectively.

The traditional (group C) and the vaginoscopic technique (group D) for insertion of the hysteroscope were used in 81.9% and 18.1% of cases, respectively.

A lower percentage of failed hysteroscopies was detected in group D with either the 4-mm or the 2.9-mm scope, in comparison with group C (2.9 mm: 4.4% vs. 1%; $\chi^2 = 9.0$; P < .01; 4 mm: 5.1% vs. 0.5%; $\chi^2 = 16.5$; P < .001).

Five hundred forty-eight minor procedures were performed during hysteroscopy. The operative sheath with hysteroscopic flexible instruments (grasping, scissors, biopsy forceps) was used in 182 (33.2%) cases, for target biopsies (n = 56), polypectomies (n = 83), removal of intrauterine devices (n = 30), adhesiolysis (n = 5), and other minor procedures (n = 8).

Vaginal instrumentation (tenaculum, Kocher, biopsy forceps) after hysteroscopic examination of uterine cavity was used in 366 cases (76.8%) for biopsies (n = 4), polypectomies (n = 316), removal of intrauterine device (n = 39), adhesiolysis (n = 6), and other minor procedures (n = 1).

DISCUSSION

To the best of our knowledge, this is the first report in international literature of a large series of outpatient hysteroscopies in which the procedures were performed by a large number of operators with different levels of expertise.

In 1996, Nagele et al. (2) analyzed the outcome of the first 2,500 hysteroscopies performed in our department, with the main aim of demonstrating the feasibility and acceptability of outpatient diagnostic hysteroscopy.

Our descriptive analysis of 5,000 hysteroscopies (including the 2,500 reported by Nagele et al.) fills a gap in the existing literature. Previously in the published studies, hysteroscopies were performed by one or a few experienced operators. The present data demonstrate that a high level of expertise is not a prerequisite to performing hysteroscopy on an outpatient basis.

In the present series, 362 operators with different levels of expertise successfully performed hysteroscopies in nearly 95% of cases. This success rate is in accordance with other large series performed by one or a few experienced operators (11, 14, 20, 25).

A limitation of the present study is the difficulty in evaluating the level of expertise of the operator. However, because most of the operators had performed fewer than 20



hysteroscopies during a 15-year period, it could be hypothesized that they were likely to be doctors in training.

Our clinical experience suggests that if the first ten hysteroscopies performed by a trainee are closely supervised by an experienced operator it is possible to avoid any serious complication without lowering the success rate.

Recently, Campo et al. (25) investigated the relative importance of a surgeon's experience in a prospective multicenter randomized controlled trial. They discovered that experienced surgeons had better outcomes only when 5.0-mm conventional instruments were used. This was not the case when hysteroscopies were performed with minihysteroscopes (3.5 mm).

The present data also confirm this. The failure rate was significantly higher when using the 5-mm hysteroscope, suggesting that a narrow hysteroscope can overcome anatomic challenges and operator limitations.

The second objective of our analysis was to determine if the introduction of normal saline, smaller hysteroscopes, and the vaginoscopic approach have lowered the failure rate.

In 1996, Nagele et al. (13) compared patient acceptability and the clinical feasibility of the two most-used distension media (CO₂ and normal saline) in 157 patients undergoing outpatient hysteroscopy. Their results showed that procedure times were significantly longer for CO₂ (because of the occurrence of bubbles during the procedure) and that abdominal and shoulder tip pain was significantly higher. After the results of that study, all of the outpatient hysteroscopies in our department have been performed using normal saline as the distension medium.

After 1996, other studies have confirmed that normal saline is more acceptable to patients (17, 22), is quicker to perform (22), and offers advantages in terms of good visualization of uterine cavity in the presence of blood clots, mucus, and debris and increasing confidence in diagnosis (21).

Our descriptive analysis did not show a significantly higher number of complications and failed hysteroscopies between the CO_2 and saline periods, suggesting that factors other than distension medium could exert a primary role in determining the success or failure of outpatient hysteroscopy.

However, two severe complications—vasovagal attack and shoulder pain—were significantly higher in the CO_2 period. Taking into account that these complications globally represent 22% of all of the complications reported in the present analysis, we believe that the use of normal saline has largely contributed to making the procedure safer and more acceptable to patients.

These results are in keeping with Agostini et al (26) who have recently evaluated the risk of vasovagal syndrome in 2079 women undergoing outpatient hysteroscopy. They showed that it is significantly higher with the use of CO₂, regardless of the indication for hysteroscopy, parity, and menopausal status of the patient.

Recent technical and instrumental improvements have significantly increased the feasibility and acceptability of hysteroscopy. The use of new thin telescopes (minitelescopes) 1-2 mm lower in caliber compared with conventional 4-mm ones improves the acceptability of the examination (11, 27); indeed, a 1- to 2-mm reduction in the telescope diameter and consequently in the total hysteroscope size (minihysteroscopes) reduces the section area of the instrument by about 50%–75%. This could well explain why minihysteroscopes are less painful than conventional ones (11, 28). Furthermore, in recent years, new techniques for the introduction of the hysteroscope into the external uterine orifice have been developed to reduce the patient's pain and discomfort.

The vaginoscopic approach is a nontraumatic technique, in which the hysteroscope is introduced into the vagina without a speculum and tenaculum (14, 15). The vagina is distended by the distension medium (normal saline) at the same pressure (60–80 mm Hg) used for the subsequent distension of uterine cavity (17). This approach has permitted complete elimination of any kind of premedication, analgesia, or anesthesia, making the procedure faster and complication free (11, 14). A recent review (16) has shown that diagnostic minihysteroscopy with vaginoscopic approach is accurate without significant discomfort or risk.

In a prospective randomized controlled study performed in our unit, Sharma et al. (29) demonstrated that vaginoscopic hysteroscopy is significantly faster to perform than the traditional technique. Although there was no difference in pain scores between the two techniques, local anesthetic requirements were least in those who underwent vaginoscopic hysteroscopy with a narrow-bore hysteroscope.

Data from our retrospective analysis confirmed that the use of minihysteroscopes and vaginoscopic approach is associated with significantly lower failure rates.

CONCLUSIONS

Outpatient hysteroscopy represents a simple and safe approach for intrauterine evaluation. The present large series shows that a high level of expertise is not a prerequisite. In addition, recent advances in technique and instrumentation facilitate this approach and, we believe, should encourage its higher adoption by the wider gynecology community.

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