

# Patient Safety in Hysteroscopic Procedure

Wachyu Hadisaputra, Cindikia Ayu Sholekha Hani, Nidya Annisa Putri

Department of Obstetrics and Gynecology, Universitas Indonesia/College of Indonesia Obstetricians and Gynecologists, Jakarta, Indonesia

## Abstract

This article aims to explain about outpatient hysteroscopy, where this procedure is currently being carried out. However, this procedure is also widely chosen by patients, because of its convenience, fast procedure, minimal complications, and of course more economical than day-case hysteroscopy. Before taking the procedure, it is important to explain to the patient about the disease, therapy, and the procedure to be carried out. Consent needs to be obtained voluntarily. We searched related publications using “patient safety” and “office hysteroscopy” and “informed consent” and “medical procedure” and “patient safety” and “injury” and “operative hysteroscopy” as keywords. This search had considered articles that had been published between 2002 and 2021. The conclusion from this library is that patient’s convenient and safety is the top priority of outpatient hysteroscopy. Outpatient hysteroscopy showed higher satisfaction results than day-case hysteroscopy. Because it is more comfortable, faster, patients can immediately return to their activities and of course more efficient.

**Keywords:** Informed consent, injury, medical procedure, office hysteroscopy, operative hysteroscopy, patient safety

## INTRODUCTION

Patient safety is a health-care discipline that emerged with the evolving complexity in health-care systems and the resulting rise of patient harm in health-care facilities. It aims to prevent and reduce risks, errors, and harm that occur to patients during the provision of health care. To ensure successful implementation of patient safety strategies, transparent policies, leadership capacity, data to drive safety improvements, skilled health-care professionals, and effective involvement of patients in their care are all needed.<sup>[1]</sup>

Every year, millions of patients suffer injuries or die because of unsafe and poor-quality health care.<sup>[2]</sup> Another problem is that resource pooling systems to make health care readily accessible to all are nonexistent in most resource-poor countries. The result is that the majority of the population relies on out-of-pocket payments to access health care.<sup>[3]</sup> The

frequency of gynecological complications increases day by day due to the increasing cesarean rates.<sup>[4]</sup>

Office hysteroscopy is a diagnostic and operative procedure technique with many advantages compared with operating room-based hysteroscopy: it does not require hospital admission, preoperative tests, and general or regional anesthesia. It has decreased postsurgical recovery period, global cost of the procedure, and rate of complications such as cervical tears, uterine perforation, and those due to distention medium.<sup>[5]</sup> Patients preferred office-based hysteroscopy, and office-based procedures are associated with higher patient satisfaction and faster recovery.<sup>[6]</sup>

Outpatient hysteroscopy should be performed in an appropriately sized and fully equipped treatment room. This may be a dedicated hysteroscopy suite or a multipurpose facility. Outpatient hysteroscopy can be associated with substantial anxiety;<sup>[7]</sup> however, the treatment room should be private and patient-friendly, with a separate, ideally adjoining,

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**Address for correspondence:** Prof. Wachyu Hadisaputra,  
Kintamani Street No 39, South Jakarta, Postal Code 12950, Indonesia.  
E-mail: wachyuhadi@yahoo.com

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changing area with a toilet. Adequate resuscitation facilities should be available, as should a comfortable recovery area with refreshment-making facilities.<sup>[8]</sup>

It is to note that patients with an ASA score >2 and large pathologies, where surgery will exceed 30 min, and the requirement of large diameter instruments are contraindications for ambulatory (in-office) surgery. In cases of myomas, ambulatory surgery is limited by the size, position, and hardness of the myoma. Recently, a new ambulatory surgical technique to prepare large (>1, 5 cm) submucous myomas with partially intramural development (G1 and G2) in an outpatient setting with miniaturized office hysteroscopes was put to practice. Currently, in an ambulatory setting, we limit treatment myomas Type 1–3 to a maximum size of 2 cm.<sup>[9]</sup>

## METHODS

We conducted a comprehensive search to identify relevant studies. The electronic search was conducted from September to November 2021. Time restriction was applied to the year of publication from 2002 to 2021, and we used literatures only from the English language. All titles and abstracts were examined that met our search terms and full publications were reviewed, when necessary. Search with the terms: (patient safety) and (office hysteroscopy) and (informed consent) and (medical procedure) and (patient safety) and (injury) and (operative hysteroscopy). However, we summarized 16 full-text studies in the table.

## DISCUSSION

### Hysteroscopy

Hysteroscopy is an endoscopic surgical procedure that has become an essential tool to evaluate intrauterine pathology. It offers direct visualization of the entire uterine cavity and provides the possibility of performing a biopsy of suspected lesions missed by dilatation and curettage (D and C) [Figures 1 and 2]. Today, many hysteroscopic procedures can be performed in the office or outpatient setting. This is due to the feasibility

of operative hysteroscopy using saline as a distending medium, the vaginoscopic approach of hysteroscopy, and the availability of mini-hysteroscopic endoscopes.<sup>[10]</sup>

Compared with hysterosalpingography and vaginal probe ultrasound, hysteroscopy has been shown to have superior sensitivity and specificity in evaluating the uterine cavity. Fedele showed the sensitivity of hysteroscopy to be 100% and the specificity to be 95%. This is a good adjunct to hysteroscopy in that it will help detect intramural and subserosal uterine lesions.<sup>[11]</sup>

Advances in technology have led to the miniaturization of high-definition hysteroscopes without compromising optical performance, thereby making hysteroscopy a simple, safe, and well-tolerated office procedure.<sup>[10]</sup> Recent research published showed that 17.6% of women rate their pain during hysteroscopy as >7/10, and only 7.8% report no pain at all.<sup>[12]</sup>

Other potential benefits of office hysteroscopy include patient and physician convenience, avoidance of general anesthesia, less patient anxiety related to familiarity with the office setting, cost-effectiveness, and more efficient use of the operating room for more complex hysteroscopic cases.<sup>[6]</sup>

An outpatient hysteroscopy service offers a safe, convenient, and cost-effective means of diagnosing and treating abnormal uterine bleeding as well as aiding the management of other benign



**Figure 1:** Classical Hysteroscopy, before the era of Video Endoscopy (WH - 1983)



**Figure 2:** The modern Operative Hysteroscopy / Resectoscopy (WH - 2020)

**Table: Main Outcomes<sup>14</sup>**

Variable	Outpatient group (n=49)	Day case group (n=48)	Difference (95%)	P
No (%) of patients satisfied	41 (84)	37 (77)	4.0 (-9 to 22)	0.42
No (%) of patients who needed analgesia at the end of Hysteroscopy	6 (12)	7 (14)	1.0 (-10 to 17)	0.74
Pain score at 30 minutes (scale 0-10)	0.4 (0-1,2)	0.3 (0-2.2)		0.34
Minutes to recovery of full mobility (interquartile range)	0 (0-5)	105 (80-120)		<0.001
No (%) of patients needing pain relief D0*	15 (30)	16 (33)	-1.0 (-13 to 24)	0.77
No (%) of patients needing pain relief D1†	11 (22)	11 (23)	0 (-14 to 19)	0.93
Median No (range) of days of analgesia	0 (0-2)	0 (0-4)		0.27
Full recovery on day (interquartile range)	2 (1-2.7)	3 (2-4)		<0.05
Days away from work (interquartile range)	1 (0-1.6)	3 (2-4)		<0.0001
Minutes away from home (interquartile range)	120 (110-170)	480 (450-525)		<0.0001

\*Patients who need some form of oral or injectable analgesia on day of procedure (immediately after procedure or at home). †Patients who need some form of oral or injectable analgesia on day after procedure

gynecological conditions (e.g., fertility control, subfertility, and miscarriage and abnormal glandular cervical cytology).<sup>[13]</sup>

All patients who had undergone outpatient hysteroscopy indicating full recovery at 30 min. The day-case group scored <12, mainly because of postoperative nausea or vomiting. Patients in the day-case group took significantly longer to recover full mobility and full fitness than those in the outpatient group. The outpatient group was fully mobile immediately after the procedure. Women in the outpatient group spend significantly less time away from home and less time off work than those in the case group.<sup>[14]</sup>

The same study demonstrated high and equivalent levels of women’s satisfaction with outpatient hysteroscopy in conscious women compared with day-case procedures under general anesthesia. There were also economic benefits for women, the health service, and society at large. Compared with day-case methods under general anesthesia, women undergoing outpatient hysteroscopy required significantly less time off work than the day-case group (0.8 days vs. 3.3 days,  $P < 0.001$ ) and experienced reduced loss of income and travel costs. Costs per woman to the National Health Service were estimated to be substantially less for outpatient procedures.<sup>[15]</sup>

### Best timing to do hysteroscopy

In premenopausal women with regular menstrual cycles, the optimal timing for diagnostic hysteroscopy is during the follicular phase of the menstrual cycle after menstruation. Pregnancy should be reasonably excluded before performing hysteroscopy. Hysteroscopy during the secretory phase of the cycle may make diagnosis more difficult because a thickened endometrium may mimic polyps. Some women with unpredictable menses can be scheduled at any time for operative hysteroscopy. Still, ideally, patients who are actively bleeding may not undergo the procedure because adequate visualization could be impaired.<sup>[6]</sup>

### Office setup

To perform an office, hysteroscopy usually takes 10–15 min from when the patient is in the examination room until the room is turned over for the next patient. In short, four office hysteroscopies can be performed in the office simultaneously that it takes to do one hysteroscopy in the operating room. The patient receives no intravenous sedation or general anesthesia and can return to her normal activities immediately.<sup>[11]</sup>

In general, there will be a complement of up to three support staff consisting of at least one registered general nurse and health-care assistants. When possible, one of the staff members should act as the woman’s advocate during the procedure to provide reassurance, explanation, and support.<sup>[8]</sup>

### Informed consent

Adequate, clear, and simple written patient information should be provided with the appointment letter. The information will vary according to local circumstances and the type of service offered. It is a good clinical practice to obtain formal consent for outpatient hysteroscopy before the procedure.<sup>[8]</sup> Informed consent, a fundamental tenet of surgical practice, is an opportunity to simultaneously build the patient–physician relationship and improve patient education and understanding of their illness.<sup>[16]</sup>

Before any examination or treatment, clinicians should discuss with the patient the potential harm, benefits, and alternatives of the proposed care.<sup>[17]</sup> Conversations regarding informed consent necessarily rely on the rapport between the consenting patient and the surgeon.<sup>[16]</sup>

Obtaining patient consent is a necessary and critical process enshrined in medical practice that is characterized within a model of three domains: (provision of) information, comprehension (of information by the patient), and voluntariness (of patient’s decision without coercion). It highlights the elements of consent that are important to both

doctors and patients and demonstrates the gaps between the outcomes that have traditionally been measured in consent research and perhaps should be measured going forward.<sup>[17]</sup>

### Analgesia

No studies were identified addressing the issue of timing of analgesia before outpatient hysteroscopy. The onset of action of these drugs means that to be effective, they need to be given in advance of the woman's appointment. Optimal timing depends upon the agent used (half-life, rate of absorption, etc.) and the route of administration. Still, in general, simple, nonopioid analgesics given orally, such as 1000-mg paracetamol or 400-mg ibuprofen, should be taken around 1 h before the scheduled appointment time. Thus, it is more practical to advise women to take simple analgesics before their appointment rather than administer them in the hospital. Routine patient information leaflets posted to the woman with details of their appointment can advise them to consider taking simple analgesics before they attend their appointment, with the proviso they have taken them before without ill effects. This approach is likely to be of more benefit in those units offering simultaneous hysteroscopic diagnosis and treatment (i.e., the "see and treat" clinic), where the levels of discomfort experienced are likely to be increased.<sup>[8]</sup>

### Distension medium

For routine outpatient hysteroscopy, the choice of distension medium between carbon dioxide and normal saline should be left to the operator's discretion as neither is superior in reducing pain. However, uterine distension with normal saline appears to reduce the incidence of vasovagal episodes. Uterine distension with normal saline allows improved image quality and provides outpatient diagnostic hysteroscopy to be completed more quickly than carbon dioxide.<sup>[8]</sup>

The ideal distending medium should allow clear visualization of the uterine cavity, be isotonic, nontoxic, hypoallergenic, nonhemolytic, be rapidly cleared by the body, readily available, and inexpensive. With the advent of bipolar electrosurgery, a conductive electrolyte containing medium is advantageous. Normal saline satisfies all these criteria and for this reason, appears to be fluid distension medium of choice for mechanical hysteroscopy surgery and bipolar electrosurgery.<sup>[18]</sup>

### Cervical dilation

In the conscious woman, dilatation of the cervix causes pain and discomfort and generally requires local anesthesia. Instillation of local anesthetic into the cervical canal does not reduce pain during diagnostic outpatient hysteroscopy but may reduce the incidence of vasovagal reactions. Topical application of local anesthetic to the ectocervix should be considered where the application of a cervical tenaculum is necessary.<sup>[8]</sup>

Application of local anesthetic into or around the cervix reduces the pain experienced during outpatient diagnostic hysteroscopy. However, it is unclear how clinically significant this reduction in pain is. Consideration should be given to the routine administration of intracervical or paracervical local anesthetic, particularly in postmenopausal women. Routine administration of intracervical or paracervical local anesthetic is not indicated to reduce the incidence of vasovagal reactions.<sup>[8]</sup>

Prostaglandin or misoprostol administration before diagnostic hysteroscopy is performed under general anesthesia is associated with a reduction in cervical resistance and the need for cervical dilatation in premenopausal women compared with placebo. However, no such benefit was noted in postmenopausal women.<sup>[16]</sup> The use of preoperative misoprostol reduced rates of false passage formation but did not reduce rates of uterine perforation during operative hysteroscopy.<sup>[6]</sup>

### Complications

Pain is still the main cause of office hysteroscopy failure. Factors related to pain experience during hysteroscopy are still not well-known. An adequate knowledge of anatomy is essential to understand the physiology of pain in hysteroscopy. Anxiety, although it is difficult to assess, also has a role in pain perception.<sup>[5]</sup>

Upon recognition of vasovagal signs (hypotension and bradycardia) or symptoms (nausea, vomiting, diaphoresis, pallor, or loss of consciousness), the procedure should be stopped, and patient assessment and supportive care should be undertaken (vital signs including pulse and blood pressure and "ABCs" – airway, breathing, and circulation). Most vasovagal reactions resolve with supportive measures such as raising the patient's legs or placement in the Trendelenburg position. If symptoms or bradycardia persist, atropine may be administered as a single dosage of 0.5 mg intravenously every 3–5 min, not to exceed a total of 3 mg.<sup>[6]</sup>

Excessive absorption of distending fluid can result in severe complications, including pulmonary edema, neurologic complication, and death. The use of electrolyte-free, hypotonic distending media is associated with a greater risk of hypotonic hyponatremia and cerebral edema. Complications from fluid overload may be minimized with careful perioperative planning, use of a fluid management system, and evaluation of the intracavitary lesions removed. Preventive measures include limiting excess fluid absorption, promptly recognizing and treating fluid overload, and selecting a distending medium that minimizes risk.<sup>[6]</sup>

Uterine trauma (lacerations to the cervix or uterine perforation) is recognized with blind and endoscopic instrumentation of the

uterus, with an estimated perforation incidence of 0.002%–1.7%.<sup>[12]</sup> The incidence of uterine trauma is low for diagnostic outpatient hysteroscopy performed with small-diameter endoscopes (outer sheath diameter under 5.5 mm) under direct vision.<sup>[13]</sup> Factors associated with uterine trauma include the need for blind dilatation, cervical stenosis (e.g., atrophy, cervical surgery, previous cesarean section, and nulliparity), a tortuous cervical canal (e.g., in association with fibroids), and a deviated uterine cavity (e.g., acute flexion, pelvic adhesions, and fibroids).<sup>[13]</sup>

## CONCLUSION

Patient safety is the absence of preventable harm to patient during the process of health care and reduction of unnecessary harm associated with health care to an acceptable minimum. Patient preferred office-based hysteroscopy and office-based procedures because it offers a safe, convenient, shorter time procedures, and cost-effective compared with day-care procedure. It is associated with higher patient satisfaction and faster recovery.

Informed consent is an opportunity to build the patient–physician relationship and improve patient education. Before any examination or treatment, clinicians should discuss with the patient the potential harm, benefits, and alternatives of the procedures. To achieve patients safety, we need to involve patient consent, good equipment setup, and nurse chaperone. Complications of the procedure can be reduced by a skilled surgeon and well-expertise. Always be vigilant for the risk of complications.

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