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Office Vaginoscopic Hysteroscopy in Infertile Women: Effects of Gynecologist Experience, Instrument Size, and Distention Medium on Patient Discomfort

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ABSTRACT **Study Objective:** To assess the roles of instrument diameter (5.0- or 3.5-mm external sheath), uterine distention medium (carbon dioxide [CO_2] or saline solution), and hysteroscopist experience in diagnostic hysteroscopy.
Design: Prospective, randomized, multicenter trial (Canadian Task Force classification I).
Setting: Two university medical centers in Italy.
Patients: One hundred eighty-four women attending an infertility clinic.
Interventions: Patients were randomly assigned to undergo conventional hysteroscopy (group 1, n = 92) or minihysteroscopy (group 2, n = 92) with CO_2 or saline solution as distention medium. The procedures were performed by hysteroscopists with varying degrees of experience. Patient discomfort was analyzed using the visual analog score. Procedure complications and patient satisfaction rate were also recorded.
Measurements and Main Results: Independent of hysteroscopist experience, less pain, fewer complications, and higher satisfaction rates were observed with minihysteroscopy. In addition, procedures in which saline solution was used resulted in less pain and fewer complications than those in which CO_2 was used, but only when performed by inexperienced hysteroscopists.
Conclusion: Instrument diameter and hysteroscopist experience, but not the distention medium, seem to be the primary variables that affect the perception of discomfort during office hysteroscopy. Journal of Minimally Invasive Gynecology (2010) 17, 344–350 © 2010 AAGL. All rights reserved.

Keywords: Diagnostic hysteroscopy; Infertile women; Pain; Surgical experience

Office hysteroscopy has distinct advantages, such as decreased anaesthetic-associated risks, enhanced time–cost-effectiveness, and increased patient acceptance, compared with inpatient hysteroscopy procedures performed with the patient under local or general anesthesia. However, diagnostic hysteroscopy is not widely performed in the office setting because of the associated discomfort and supposed high level of expertise needed to perform the procedure, especially in nulliparous women [1,2].

In recent years, various methods and technologic improvements have been used to reduce patient perception of pain. The vaginoscopic ''no touch'' approach to diagnostic hysteroscopy is better tolerated than the conventional technique in outpatient diagnostic hysteroscopy using both a rigid hysteroscope and a fibroscope [3–6]. The use of saline solution rather than carbon dioxide (CO_2) as a uterine distention medium [7] and the availability of high-resolution mini-endoscopes [8] have been proposed as major determinants in reducing the perception of pain. However, most studies enrolled patients with different physiologic features (nulliparous or pluriparous) and pathologic conditions (uterine myomas, abnormal uterine bleeding, and chronic

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pelvic pain) without considering the training level of the hysteroscopist as an independent variable for analysis. In addition, the instruments and techniques used were not standardized across trials.

The objective of the present prospective, randomized, multicenter study was to assess the specific roles of the following selected factors that influence the perception of pain: instrument diameter (5.0- or 3.5-mm external sheath), uterine distention medium (CO_2 or saline solution), and hysteroscopist experience in performing office vaginoscopic hysteroscopy. To highlight the specific effects of these factors, the technique was standardized, primary infertility was the only indication, and all additional surgical interventions (e.g., endometrial biopsy, office polypectomy, or myomectomy) were excluded.

Materials and Methods

A multicenter study was performed at 2 university medical centers in Italy from November 2006 to June 2008. The institutional ethical committee approved the study. The only indication for performing a diagnostic hysteroscopy was primary infertility. After providing written informed consent, 240 women were recruited from patients visiting our departments in Pisa and Cagliari. Women with acute infections, active bleeding, viable pregnancy, or previous hysteroscopy were excluded. Additional exclusion criteria included a history of cervical or pelvic surgery and a diagnosis of chronic pelvic pain or endometriosis. Subsequently, 184 patients were enrolled in the study.

To evaluate the effect of instrument diameter, patients were randomly assigned to undergo conventional hysteroscopy (INS1 group, n = 92) or minihysteroscopy (INS2 group, n = 92). Similarly, to evaluate the effect of the uterine distention medium, patients in the INS1 and INS2 groups were further randomized to 4 groups according to the distention medium used: MED1, MED2, MED3, and MED4 (Table 1). To evaluate the effect of hysteroscopist experience, the procedures were performed by gynecologists with various degrees of experience in office hysteroscopy: ''experienced'' hysteroscopists had each performed more than 500 office hysteroscopies before the beginning of the present study, and ''inexperienced'' hysteroscopists had each performed between 50 and 100 office hysteroscopies. Groups MED1, MED2, MED3, and MED4 were further randomized according to gynecologist experience to generate the following 8 groups of 23 patients each: EXP1 through EXP8 (Table 1) (Fig. 1). Randomization was based on a computer-generated randomization table.

Instruments and Techniques

The conventional hysteroscopy set (Karl Storz GmbH & Co KG, Tuttlingen, Germany) included a rigid optic (rod lens, 4.0 mm; 30-degree oblique vision) with a 5.0-mm single-flow sheath. The minihysteroscopy set (Karl Storz GmbH) included a rigid optic (rod lens, 2.9 mm; 30-degree for oblique vision) with a 3.5-mm single-flow. The patient, who was blinded to group assignment, was placed in a better gynecologic position. Illumination was provided using a 250-W xenon light source. Images were viewed on a high-resolution color monitor. An electronic Hamou-hysteroflator (Karl Storz GmbH) adjusted to a flow rate of up to 50 mL/min, and pressure not exceeding 100 mm Hg was used when the uterine cavity was distended with CO_2. Normal saline solution was instilled using a flexible 500-mL bag wrapped in a pressure cuff connected to a manometer and pumped up to 100 mm Hg.

The hysteroscope was gently inserted into the vagina without introducing the speculum. The vaginal labia were closed manually to limit exit of the CO_2 or saline solution and to permit vaginal inspection. The endoscope was then placed in the external ostium and advanced under visual control.

Anesthesia, dilation, and other intrauterine interventions were not allowed. In addition, to exclude any other cause of pain, patients undergoing endometrial biopsy or any additional surgical procedures (e.g., office polipectomy or myomectomy) were excluded from the pain evaluation scoring.

Outcome Measures

The primary outcome measure was pain, which was scored by the patient using a visual analog scale (VAS; 0 = no pain, 10 = worst pain). Patients were asked to quantify pain twice, once immediately after the procedure (VAS1) and once 15 minutes later (VAS2) in the absence of any staff involvement. Both outcomes provide the degree of pain perception due the hysteroscopic procedure and possible consequences of pain later. The secondary outcome measures

Table 1
Patient group characteristics

INS1 Mini-hysteroscope	MED1 Mini-hysteroscope and saline solution	EXP1: Mini-hysteroscope and saline solution used by experienced gynecologist EXP2: Mini-hysteroscope and saline solution used by inexperienced gynecologist
	MED2 Mini-hysteroscope and CO_2	EXP3: Mini-hysteroscope and CO_2 used by experienced gynecologist EXP4: Mini-hysteroscope and CO_2 used by inexperienced gynecologist
INS2 5-mm Hysteroscope	MED3 5-mm Hysteroscope and saline solution	EXP5: 5-mm Hysteroscope and saline solution used by experienced gynecologist EXP6: 5-mm Hysteroscope and saline solution used by inexperienced gynecologist
	MED4 5-mm Hysteroscope and CO_2	EXP7: 5-mm Hysteroscope and CO_2 used by experienced gynecologist EXP8: 5-mm Hysteroscope and CO_2 used by inexperienced gynecologist

EXP = gynecologist experience level; INS = instrument; MED = distention medium.