Office hysteroscopy and compliance: mini-hysteroscopy versus traditional hysteroscopy in a randomized trial

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BACKGROUND: Diagnostic hysteroscopy has not yet been generally accepted as a well-tolerated office procedure. The aim of our study was to verify compliance, side-effects and haemodynamic variations when a mini-hysteroscope is used. METHODS: A prospective randomized trial on office hysteroscopy was performed by comparing the use of a traditional 5 mm hysteroscope (group A) and of a 3.3 mm mini-hysteroscope (group B). Two patient groups (A and B), each comprising 100 cases, were formed on the basis of a randomized computer-generated list. RESULTS: A marked reduction in the mean (± SD) pelvic pain score during office hysteroscopy was seen in group B (2.3 ± 2.1) as compared with group A (4.6 ± 2.2) (P < 0.0001, Mann–Whitney test). This result was also confirmed when using an alternative approach: four classes of pelvic pain at the visual analogue score (VAS). A significant reduction was observed in the incidence of moderate and severe pelvic pain in group B at the end of the examination (P = 0.001) and 5–10 min later (P < 0.05). CONCLUSIONS: The use of mini-hysteroscopes (3.3 mm with diagnostic sheath) lowers considerably the level of pelvic pain the patients feel: it is halved in comparison with traditional calibre hystoscopes (2.3 ± 2.1, on a 0–10 VAS). Furthermore the outpatient hysteroscopy failure rate is less than half (2%) with the mini-hysteroscope compared with the traditional 5 mm hysteroscope (5%). As for side-effects and haemodynamic parameters, no differences were observed except for an increase (P < 0.05) in bradycardia in group B. The advantage of this technique is self-evident, if the patients’ compliance is taken into account: in many cases the introduction or withdrawal of the vaginal speculum was reported as the greatest discomfort.

Key words: compliance/mini-hysteroscopy/office hysteroscopy/pelvic pain/side-effects

Introduction

The technological advances made in recent years—for example the introduction of small-diameter hystoscopes—have brought about remarkable progresses in the field of office hysteroscopy, even though large-diameter instruments are still widely used (De Iaco et al., 2000; Giorda et al., 2000). However, the main limiting factor to a large-scale use of office hysteroscopy is the level of pain or discomfort a patient feels during or soon after the procedure, which is often caused by the instrument diameter (Bettocchi, 1996). The level of pelvic pain experienced by the patients during office hysteroscopy has been studied by several authors: Munro et al. (1994) asserted that in spite of local anaesthesia many patients still experienced pain and discomfort; Nagele et al. (1997) reported that an increasing number of diagnostic hysteroscopies were being performed in an outpatient setting, but pain was the most common cause for failure to complete the investigation (Nagele et al., 1997; Paschopoulos et al., 1997). In a study on the acceptability and pain of office hysteroscopy, De Iaco (2000) observed that this procedure is painful even when it is performed by an experienced surgeon using a non-traumatic technique.

For these reasons, numerous studies have been carried out in the last decade on the use of local anaesthesia such as paracervical (Finikiotis et al., 1992; Vercellini et al., 1994; Cininelli et al., 1998), intracervical (Broadbent et al., 1992) or transcervical (Zapi et al., 1995; Cininelli et al., 1996; Cininelli et al., 1997; Lau et al., 2000) anaesthesia; lignocaine spray (Davies et al., 1997; Zullo et al., 1999; Soriano et al., 2000); eutectic mixture of local anaesthetics (EMLA) cream (Stigliano et al., 1997) before office hysteroscopy; however, its efficacy as a pain-relieving method has not been definitely proven (Wieser et al., 1998).

The main purpose of our Gynecological Endoscopy Unit has always been to diminish the level of pelvic pain or discomfort felt by the patient during office hysteroscopy in order to make this procedure acceptable and well tolerated; our aim was to make it ‘pain-free’ and therefore widespread as against its presently limited application in Italy.
An Italian multicentre study (Tantini et al., 2000) evaluated the use of diagnostic and operative hysteroscopy as well as the number of hysteroscopies performed in Italian Gynecological Units every year. A total of 394 Operative Units in public hospitals (50.5% of the departments in our country) and 50 Operative Units in private clinics (27.4%) were surveyed. The results demonstrated that diagnostic and operative hysteroscopies had never been performed in 21.1 and 40.8% of the samples respectively. Within the last study year only 5.7% of the Units had carried out >500 examinations, whereas <300 and <100 procedures per year had been performed by 82.4 and 48% of the Units respectively.

In our previous study, we had investigated the use of an electrical nerve stimulation device as a pain-relieving method during hysteroscopy. The data were extremely positive with reference to the reduction of the level of pelvic pain during office hysteroscopy and greater acceptability of the procedure by the patients (De Angelis et al., 2003).

The aim of the present study was to compare two endoscopes of different calibres—a traditional 5 mm Hamou I hysteroscope and a smaller 3.3 mm hysteroscope—in order to evaluate the level of pelvic pain, the incidence of side-effects, haemodynamic parameters (heart rate, systolic and diastolic pressure) and the image quality.

**Materials and methods**
This prospective randomized study, performed between from January 2 to June 30, 2000, included 215 patients who had been referred to our Center for Minimally Invasive Therapy, Department of Obstetrics and
Gynaecology, with different indications for treatment with office hysteroscopy, Departmental Institutional Approval and the patient’s informed consent to the study were obtained.

A randomized computer-generated list was used to allocate the subjects into two groups, A and B, of 105 and 102 patients respectively (Figure 1). In group A, diagnostic hysteroscopy was performed by means of a 4 mm traditional optic Hamou I Storz (Tuttlingen, Germany) with a 5 mm thick outer diagnostic sheath; the patients in group B were treated by means of a 2.7 mini-hysteroscope (Circon, USA) with a 3.3 mm diagnostic sheath.

Eight patients out of 215 were excluded from the study before randomization for the following reasons: history of cardiovascular disease in five cases (ischaemic myocardial disease, atrio-ventricular conduction disease) and refusal to undergo office hysteroscopy after they had read the informed consent form in the remaining three cases.

With the patient lying in a lithotomic position, a bimanual pelvic examination was perfomed; the cervix was then visualized through a small-size vaginal speculum. At this point the hystroscope was introduced into the uterine cavity without dilating the cervix or using a tenaculum. No pharmacological preparations or local anaesthesia were administered before the examination.

In both groups, hysteroscopy was performed using a 270 W metal halide light source and a 3-CCD Microdigital IIIe enhanced camera (Circon). Once the instrument entered into the uterine cavity, CO2 was introduced into the uterine cavity without dilating the cervix or using a small-size vaginal speculum. At this point the hystroscope was introduced into the uterine cavity without dilating the cervix or using a tenaculum. No pharmacological preparations or local anaesthesia were administered before the examination.

In both groups, hysteroscopy was performed using a 270 W metal halide light source and a 3-CCD Microdigital IIIe enhanced camera (Circon). Once the instrument entered into the uterine cavity, CO2 was delivered by means of an automatic, constant-flow and variable-pressure hystro¯ator (Storz, Germany) with a mean ï¬ow rate of 25–30 ml/min and a 100 mmHg intrauterine pressure limit. The hysteroscopic procedure was not brought to an end in five cases in the Hamou hystroscope group and in two cases treated with the mini-endoscope (Figure 1).

The indications for hysteroscopy were the same for both groups: abnormal uterine bleeding (AUB) in pre- and post-menopausal age, AUB following HRT; ultrasound indications (endometrial thickening pattern, endometrial polyps) (37%); infertility (6.5%); abnormal cytology (1.5% = three cases with cytological finding of macrophages and histiocytes with a pathologist’s indication for an endometrial examination); monitoring of the endometrium (tamoxifen therapy, HRT, previous hyperplasia) (10.5%); cervical polyps (3.5%); post-surgery assessment (12%); and others (4%).

The evaluation of the level of pain the patient had felt during office hysteroscopy on a 10 cm VAS gave some very significant results [group A, mean 4.6 ± 2.2; group B, mean 2.3 ± 2.1; (P < 0.0001) Mann–Whitney test] (Figure 1, Figure 2). The level of pelvic pain, the main limiting factor to the large-scale use of hysteroscopy, was halved by the use of mini-endoscopes as compared with traditional hystoscopes.

When the level of pain was rated according to the four classes of the VAS (severe 8–10, moderate 4–7, mild 1–3, no pain), the incidence of moderate–severe pain was found to be lower in group B than in group A (P = 0.001, χ²-test); group A: no pain 4%, mild pain 25%, moderate pain 57%, severe pain 14%; group B: no pain 30%, mild pain 47%, moderate pain 21%, severe pain 2% (Figure 3).

Furthermore, the pelvic pain the patients had experienced was evaluated also 5 min after the examination: this time a more significant reduction was achieved in group B compared with group A (group A: no pain–mild pain 85%,
moderate–severe pain 15%; group B: no pain–mild pain 97%, moderate–severe pain 3%; \( P < 0.05 \), \( \chi^2 \)-test).

As to the incidence of nausea, shoulder pain and dizziness, no statistically significant differences were observed between the groups.

No cases of bradycardia (bpm <60) were seen in group A whereas five cases occurred in group B where the frequency rate decreased temporarily to 56 bpm (Table II). Four of these patients recovered spontaneously without the use of any medication, but the remaining case required the administration of 0.5 mg atropine i.v.

The evaluation of the heart rate at the beginning and at the end of the procedure showed a reduction in both groups (group A: 80.9 ± 10.5 versus 74.94 ± 8.47 bpm; group B: 79.71 ± 10.8 versus 72.94 ± 9.4 bpm; \( P = 0.96 \), Mann–Whitney test), but it was not statistically significant.

Systolic and diastolic pressure increased in both groups (systolic pressure: group A, 131.6 versus 134.6 mmHg; group B, 126.9 versus 135.1 mmHg; \( P = 0.125 \), Mann–Whitney test; diastolic pressure: group A, 82 versus 83.7 mmHg; group B, 80 versus 85.5 mmHg, \( P = 0.84 \), Mann–Whitney test) probably as a result of pelvic pain or emotional stress, but these data were not statistically significant.

The small calibre hysteroscope required a higher mean CO\textsubscript{2} flow than the traditional hysteroscope (group A, 35.05 ± 2.8; group B, 37.18 ± 4.24 ml/min; \( P = 0.0016 \), Mann–Whitney test). The duration of the procedure was just as long in both groups (group A, 133.6 ± 59.9 s; group B, 130.93 ± 72.64 s; \( P = \text{NS} \), Mann–Whitney test).

**Discussion**

The use of mini-hysteroscopes (3.3 mm) has brought about a small revolution in hysteroscopy by lowering the level of pelvic pain the patients feel. In our study it has been halved compared with traditional calibre hysteroscopes, hence the invasiveness of the examination is also reduced.

Even the failure rate of outpatient hysteroscopy is less than half (2%) with the mini-hysteroscope compared with the traditional 5 mm hysteroscope (5%). This means that in at least three cases out of 100 patients, we do not need the operating theatre to perform diagnostic hysteroscopy under general anaesthesia.

The image quality provided by the mini-endoscope with a lens system (2.7 mm) is almost as high as that of the traditional hysteroscopic optics (4 mm) in terms of luminosity, outline definition and width of the visual field.

However, the use of mini-optics did not allow a good observation of the uterine cavity in 5% of the cases. Actually the diameter of the instrument was too small for the specific anatomic conditions of the uterus: a wide open cervical canal, a notably thickened endometrium, and the presence of blood inside the uterine cavity. In these cases, a greater optical lens (5 mm) had to be used to satisfactorily bring the examination to an end.

The advantage of using mini-optics is self-evident if we consider the patient’s compliance: in most examinations only a slight pain or simply a feeling of discomfort during or at the end of the examination (mean pelvic pain 2.3 ± 2.1 in the 0–10 VAS) is reported, which is comparable to the level of pain felt during transvaginal ultrasound. Sometimes the worst discomfort is linked only to the introduction or withdrawal of the speculum.

It can be inferred from the above that the great diagnostic advantages of the endoscopic technique and the extremely high acceptance and tolerability by the patients may widen the use of the procedure, as is certainly desirable for the hysteroscopic technique. However, the use of mini-optics entails a suitable pre-training with traditional hysteroscopic optics, which is certainly more indicated to acquire the necessary operative skills and the correct spatial orientation.
Another limitation to the use of mini-optics is its high costs: even though the initial costs do not differ very much, mini-endoscopes are more delicate and wear out more easily than large-calibre instruments, thus requiring more frequent substitutions.

Last, but not least, the higher incidence of bradycardia in the mini-optic group observed in our study must be considered. Such a result was very surprising: actually the smaller calibre and consequently the reduced trauma at the level of the internal uterine os should have led to a lower stimulation of Frankenhaeuser’s ganglion at the beginning of the vagal stimulus point, and therefore to a lower depression in the cardiac frequency.

Other mechanisms are evidently at work. As found in this study and in a previous investigation (Yang and Vollenhoven, 2002), there is no direct correlation between the level of pain reduction and a lower incidence of bradycardia: a progressive reduction in the level of pelvic pain felt during the endoscopic examination does not correspond to a lower negative stimulus on the cardiac frequency.

We have put forward various assumptions to explain this behaviour. First, the use of a 4 mm Novak cannula in ~40% of the cases might have given rise to the vaso-vagal activation. However, in the remaining 60% of the cases, only hysteroscopy with mini-optics had been performed. This means that there is a different cause for bradycardia.

Second, based on the CO₂ flow data, we noted that there was a significant difference against the use of mini-optics versus traditional optics (a higher flow for the former). It is then possible that higher CO₂ pressure and flow velocity might be required to maintain the CO₂ flow constant. Hence it can be assumed that the uterine cavity distends more rapidly and abruptly, with a higher stimulation on the sensitive nerve fibres on the uterine wall. This would somehow produce a vaso-vagal activation.

Finally, as a last assumption, a chemical stimulatory effect of CO₂ on the nervous ends (see phrenic reflection in laparoscopy for comparison) rather than a mechanical distortion of the uterine walls can be considered. In this case, a different outcome should be reached with the use of a liquid as a means to distend the uterine cavity.

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References


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