

Prospective multicentre randomized controlled trial to evaluate factors influencing the success rate of office diagnostic hysteroscopy

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BACKGROUND: Diagnostic hysteroscopy is not widely performed in the office setting, one of the reasons being the discomfort produced by the procedure. This randomized controlled trial was performed to evaluate the effects of instrument diameter, patient parity and surgeon experience on the pain suffered and success rate of the procedure. **METHODS:** Patients were randomly assigned to undergo office diagnostic hysteroscopy either with 5.0 mm conventional instruments ($n = 240$) or with 3.5 mm mini-instruments ($n = 240$). Procedures were stratified according to patient parity and surgeon's previous experience. The pain experienced during the procedure (0–10), the quality of visualization of the uterine cavity (0–3) and the complications were recorded. The examination was considered successful when the pain score was <4 , visualization score was >1 and no complication occurred. **RESULTS:** Less pain, better visualization and higher success rates were observed with mini-hysteroscopy ($P < 0.0001$, $P < 0.0001$ and $P < 0.0001$, respectively), in patients with vaginal deliveries ($P < 0.0001$, $P < 0.0001$ and $P < 0.0001$, respectively) and in procedures performed by experienced surgeons ($P = 0.02$, $P = \text{NS}$ and $P = \text{NS}$, respectively). The effects of patient parity and surgeon experience were no longer important when mini-hysteroscopy was used. **CONCLUSIONS:** Our data demonstrate the advantages of mini-hysteroscopy and the importance of patient parity and surgeon experience, suggesting that mini-hysteroscopy should always be used, especially for inexperienced surgeons and when difficult access to the uterine cavity is anticipated. They indicate that mini-hysteroscopy can be offered as a first line office diagnostic procedure.

Key words: diagnostic/mini-hysteroscopy/office/pain/visualization

Introduction

Although diagnostic and operative laparoscopy are well established in gynaecology, diagnostic and operative hysteroscopy are not used equally worldwide. Operative hysteroscopy has been accepted progressively as the best option for the treatment of intra-uterine pathologies such as polyps, submucous myomas, septum and adhesions. Diagnostic hysteroscopy is, however, not widely used in the office setting because of the discomfort produced by the procedure. Indeed, conventional hysteroscopy is performed under general anaesthesia with a 4 mm optic with 5 mm external sheath, speculum and tenaculum to grasp and fix the uterus and it sometimes requires cervical dilatation. Since it seems invasive, traumatic and painful and since both physicians and patients expect diagnostic procedures to be simple, short, pain-free and ambulatory, it is not surprising that it has low

acceptability, at least as a first line diagnostic tool in the office setting.

The most important challenge for the office approach is to reduce patient discomfort to a minimum. This should not be underestimated since many patients still prefer the in-patient approach believing that it will be pain free (Kremer *et al.*, 2000). Several alternatives have been proposed for pain reduction during office diagnostic hysteroscopy, but the results are still inconclusive (Davies *et al.*, 1997; Nagele *et al.*, 1997; Wieser *et al.*, 1998; Wong *et al.*, 2000; Yang and Vollenhoven, 2002; De Angelis *et al.*, 2003a). Over the last years, major technical improvements, such as the use of saline as distension medium (Nagele *et al.*, 1996), the availability of high-resolution mini-endoscopes (Campo *et al.*, 1999) and the atraumatic insertion of the instruments (Bettocchi and Selvaggi, 1997), have led to the development

of the mini-hysteroscopy. This technique avoids most traumatic uterine manoeuvres leading to a less painful and better tolerated examination (Cicinelli *et al.*, 2003a,b; De Angelis *et al.*, 2003b) and has increased the feasibility and acceptability of the office diagnostic hysteroscopy. Therefore, it is now recommended as a first line diagnostic tool for the evaluation of abnormal uterine bleeding (AUB) (Cooper and Brady, 1999; Loverro *et al.*, 1999) and infertility (Brown *et al.*, 2000; Nawroth *et al.*, 2003) and also for operative purposes (Bettocchi *et al.*, 2004).

The advantages of the mini-hysteroscopy have been reported in many studies (Kremer *et al.*, 2000; Cicinelli *et al.*, 2003a,b; De Angelis *et al.*, 2003b). Since those studies were performed by experienced surgeons and enrolled mostly patients with AUB and with previous vaginal deliveries, it remains unclear whether the same conclusions can be validated for gynaecologists at different levels of training and for patients with other indications and without previous vaginal deliveries. Therefore, this multicentre randomized controlled trial (RCT) was performed to compare the performance of office conventional hysteroscopy versus mini-hysteroscopy and to evaluate the effects of patient parity and surgeon's experience.

Materials and methods

Patients and experimental design

The study was performed at Leuven Institute for Fertility and Embryology (Leuven, Antwerp and Lier, Belgium), Kliniek Sint-Jan (Brussels, Belgium) and Onze Lieve Vrouw Ziekenhuis (Aalst, Belgium) from January 1998 to December 2000 and was approved by the institutional ethical committee. Women with any indications for diagnostic hysteroscopy, such as infertility, AUB, tamoxifen

follow-up or abnormal findings at ultrasound, hysterosalpingography, magnetic resonance imaging (MRI) or biopsy were included. Women with acute infections, active bleeding or viable pregnancy were excluded. In cases of previous vaginal delivery, a history of cervical surgery was an additional exclusion criterion. After giving written informed consent, 480 patients were evaluated.

To evaluate the effect of the instrument diameter, patients were randomly assigned with a computer-generated sequence and sealed envelopes to undergo conventional hysteroscopy (group 1, *n* = 240) or mini-hysteroscopy (group 2, *n* = 240). To evaluate the effect of patient parity, women with (groups 1.1 and 2.1) and without (groups 1.2 and 2.2) vaginal deliveries were differentiated. To evaluate the effect of surgeon's experience, the procedures were performed by six gynaecologists with experience in hysteroscopy under general anaesthesia but with different levels of experience in office hysteroscopy, i.e. three 'experienced' surgeons who had performed >1000 office hysteroscopies each before this study (groups 1.1.1, 1.2.1, 2.1.1 and 2.2.1) and three 'inexperienced' surgeons who had not performed any office hysteroscopy before this study (groups 1.1.2, 1.2.2, 2.1.2 and 2.2.2). This experimental design determined a total of eight groups (*n* = 60 in each group) and allowed us to evaluate the effect of three factors, i.e. instrument diameter, patient parity and surgeon's experience (Figure 1).

Instruments and technique

The conventional hysteroscopy set (ACMI, Santa Barbara, CA) included a rigid optic (rod lens, 4.0 mm, 30° foroblique vision) with a 5.0 mm single-flow sheath. The mini-hysteroscopy set (ACMI) included two instruments from which the surgeon could choose according to his/her clinical judgement: a rigid optic (rod lens, 2.7 mm, 30° foroblique vision) with a 3.5 mm single-flow sheath and a semi-rigid single-flow fibrescope (2.4 mm, 12° foroblique vision). To ascertain a correct diagnosis, instrument changing was allowed in cases of technical difficulties. Both sets of instruments were put on the table and, just before starting the examination, a nurse opened

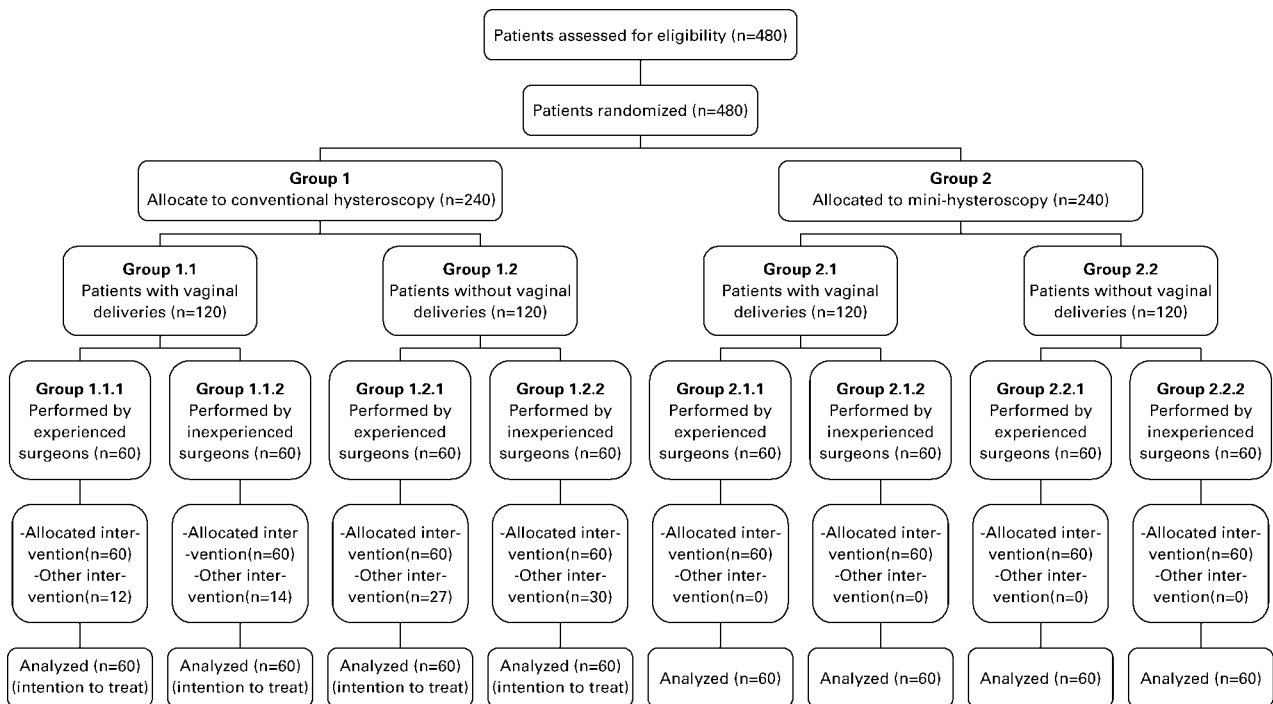


Figure 1. Trial profile.

the envelope assigning the conventional or mini-hysteroscopy group. The patient, who was kept blinded to group assignment, was placed in the gynaecological position. A Collin's speculum was introduced and the vagina was disinfected with chlorhexidine. The endoscope, connected to a three-chip video-camera and xenon light source at 250 W (ACMI), was placed in the external ostium and advanced under visual control after speculum removal. Saline (room temperature, 80–120 mmHg) was used as a distension medium. Anaesthesia, dilatation and other intra-uterine interventions were not allowed, whereas the use of volsellum was only allowed when surgeons considered it necessary for the introduction of the hysteroscope.

Outcome measures

The primary outcome measure was pain, which was scored by the patient with a 10cm visual analogue scale (VAS, 0 = no pain, 10 = intolerable pain) at the end of the procedure and in the absence of any of the staff involved. The secondary outcome measures included quality of visualization of the uterine cavity, complication rate and success rate, which were scored by the surgeon. Quality of visualization of the uterine cavity was scored with a grading system (0 = no, 1 = insufficient, 2 = sufficient, 3 = excellent). Visualization was scored as 0 when the assigned instrument had to be changed, but the patient remained in the assigned group for statistical analysis (intention to treat). Vasovagal reaction, uterine perforation, cervical lacerations and bleeding were recorded as complications. The examination was arbitrarily considered successful only when the pain score was <4, the quality of visualization of the uterine cavity was >1 and no complication occurred, since it was accepted that under these conditions, office hysteroscopy can be offered as a routine first line diagnostic procedure.

All hysteroscopic findings were recorded in a standardized pre-design form. A complete visualization of the cervical canal, uterine cavity and tubal ostia and absence of any anatomical alterations were required to categorize the examination as normal. It was considered abnormal when any major or minor abnormalities, regardless of their clinical significance, were detected. If for any reason, i.e. patient tolerance, technical or anatomical problems, no or insufficient visualization was obtained, it was stated that the examination failed to achieve a diagnosis.

Statistical analyses

Sample size was calculated based on estimates for pain scores. An SD of 2.5 cm in the 10 cm VASmm was found in pilot studies, which is consistent with recent reports (Shankar *et al.*, 2004). To detect a difference of at least 2.5 cm (80% power, 5% significance, two-tailed test) evaluating three factors simultaneously, i.e. instrument diameter, patient parity and surgeon's experience, a sample size of at least 25 patients in each group would be needed. Statistical analyses were performed with the SAS System (SAS Institute, Cary, NC) and the Graph Pad Prism 4 (GraphPad Prism Software Inc., San Diego, CA). Multifactorial analyses were performed with proc GLM (continuous and ordinal variables) and proc logistic (nominal and dichotomous variables). Unifactorial analyses were performed with Mann–Whitney and Kruskal–Wallis with Dunn tests (continuous and ordinal variables), and Fisher's exact test (comparison of frequencies). Two-tailed *P*-values <0.05 were considered significant. Data are presented as means ± SE unless otherwise indicated.

Results

All patients included in the study and randomly allocated to conventional hysteroscopy (group 1: *n* = 240) or to mini-hysteroscopy (group 2: *n* = 240) received the assigned intervention and were analysed (Figure 1). The conventional 5.0 mm hysteroscope had to be changed to a mini-hysteroscope in 83 cases, i.e. 12 in group 1.1.1, 14 in group 1.1.2, 27 in group 1.2.1 and 30 in group 1.2.2, but patients remained in the assigned group for statistical analysis (intention to treat). Although the mini-hysteroscopy system included 3.5 and 2.4 mm scopes, the latter was used only in five cases in group 2 and in 13 cases in group 1.

The ages (median, range) of patients in groups 1 (34, 20–78 years) and 2 (35, 19–70 years) were similar. The number of post-menopausal patients in groups 1 (*n* = 29) and 2 (*n* = 27) were similar. This comparability was also observed for procedures performed by 'experienced' and 'inexperienced' surgeons but, as expected, patients with vaginal deliveries were older and more likely to be post-menopausal than patients without vaginal deliveries (*P* < 0.0001 and *P* = 0.0001; Table I).

The indications for hysteroscopy were infertility in 219 cases (46%), AUB in 230 cases (48%) and others in 31 cases (6%),

Table I. Age, indications, findings and complications rates in patients who underwent office diagnostic hysteroscopy

	Conventional hysteroscopy				Mini-hysteroscopy			
	With vaginal deliveries		Without vaginal deliveries		With vaginal deliveries		Without vaginal deliveries	
	Experienced	Inexperienced	Experienced	Inexperienced	Experienced	Inexperienced	Experienced	Inexperienced
Age (years): median (range)	38 (23–65)	43 (26–68)	31 (22–78)	31 (20–52)	38 (28–70)	39 (27–61)	31 (19–65)	31 (23–67)
Post-menopausal	11 (18%)	13 (22%)	3 (5%)	2 (3%)	8 (13%)	10 (17%)	5 (8%)	4 (6%)
Indications								
Infertility	29 (48%)	3 (5%)	48 (80%)	32 (54%)	22 (37%)	7 (12%)	50 (83%)	28 (47%)
AUB	31 (52%)	49 (82%)	7 (12%)	23 (38%)	38 (63%)	47 (78%)	7 (12%)	28 (47%)
Others	0 (0%)	8 (13%)	5 (8%)	5 (8%)	0 (0%)	6 (10%)	3 (5%)	4 (6%)
Findings								
Normal	35 (59%)	25 (42%)	36 (60%)	32 (54%)	36 (60%)	26 (44%)	40 (67%)	33 (55%)
Abnormal	23 (38%)	31 (52%)	22 (37%)	20 (23%)	24 (40%)	32 (53%)	19 (32%)	26 (44%)
No diagnosis	2 (3%)	4 (6%)	2 (3%)	8 (13%)	0 (0%)	2 (3%)	1 (1%)	1 (1%)
Complications	0 (0%)	1 (2%)	2 (3%)	5 (8%)	0 (0%)	1 (1%)	1 (1%)	2 (3%)

Procedures were performed randomly either with conventional hysteroscopy (group 1) or with mini-hysteroscopy (group 2) in patients with vaginal deliveries (groups 1.1 and 2.1) or without vaginal deliveries (groups 1.2 and 2.2) for 'experienced' surgeons (groups 1.1.1, 1.2.1, 2.1.1 and 2.2.1) or 'inexperienced' surgeons (groups 1.1.2, 1.2.2, 2.1.2 and 2.2.2).

i.e. tamoxifen follow-up ($n = 2$), abnormal findings at ultrasound ($n = 23$), hysterosalpingography ($n = 3$), MRI ($n = 2$) or biopsy ($n = 1$). They were distributed similarly in groups 1 and 2, being infertility in 112 (47%) and 107 (45%) cases, AUB in 110 (46%) and 120 (50%) cases, and others in 18 (7%) and 13 (5%) cases, respectively. In patients with vaginal deliveries and in procedures performed by 'inexperienced' surgeons, the most common indication was AUB, whereas in patients without vaginal deliveries and in procedures performed by 'experienced' surgeons, it was infertility ($P < 0.0001$ and $P < 0.0001$; Table I).

The findings were normal in 263 cases (55%) and abnormal in 197 cases (41%), whereas no diagnosis could be obtained in 20 cases (4%). These findings were distributed similarly in groups 1 and 2, being normal in 128 (53%) and 135 (56%) cases and abnormal in 96 (40%) and 101 (42%) cases, whereas no diagnosis could be obtained in 16 (7%) and four (2%) cases, respectively. An equivalent distribution of findings was also observed according to patient parity, whereas the frequency of abnormal findings in the procedures performed by 'inexperienced' surgeons was relatively higher ($P = 0.002$; Table I).

Mini-hysteroscopy compared with conventional hysteroscopy was associated with less pain (1.8 ± 0.1 versus 3.4 ± 0.2 , $P < 0.0001$), better visualization (2.8 ± 0.03 versus 1.7 ± 0.1 , $P < 0.0001$) and higher success rates (208 out of 240, 87% versus 105 out of 240, 44%, $P < 0.0001$). The complications rates were, however, similar and very low overall (four out of 240, 1.3% versus eight out of 240, 3.3%, $P = NS$). All complications were vasovagal reactions, whereas uterine perforation, cervical lacerations or bleeding were not reported.

In a multifactorial analysis, all outcome variables were highly influenced by instrument diameter and patient parity, and slightly influenced by surgeon's experience. Pain scores were lower with mini-hysteroscopy ($P < 0.0001$), in patients with vaginal deliveries ($P < 0.0001$) and when the procedures were performed by 'experienced' surgeons ($P = 0.02$, Figure 2). Visualization scores were higher with mini-hysteroscopy ($P < 0.0001$) and in patients with vaginal deliveries ($P < 0.0001$), but not affected by surgeon experience ($P = NS$, Figure 3). The complication rate was not affected

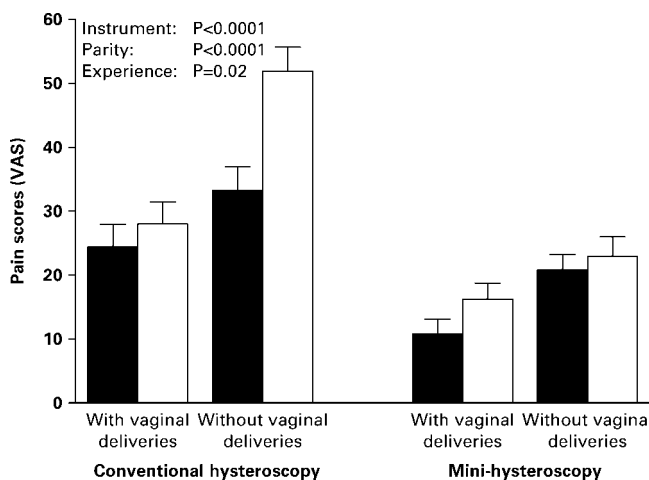


Figure 2. Pain experienced during office diagnostic hysteroscopy performed either with conventional instruments or with mini-instruments in patients with or without vaginal deliveries for 'experienced' ({}sqf) or 'inexperienced' ({}squ) surgeons. Pain was scored using a 10 cm visual analogue scale (0 = no, 10 = intolerable). Means \pm SE, together with significances of a three-way analysis (proc GLM), are indicated.

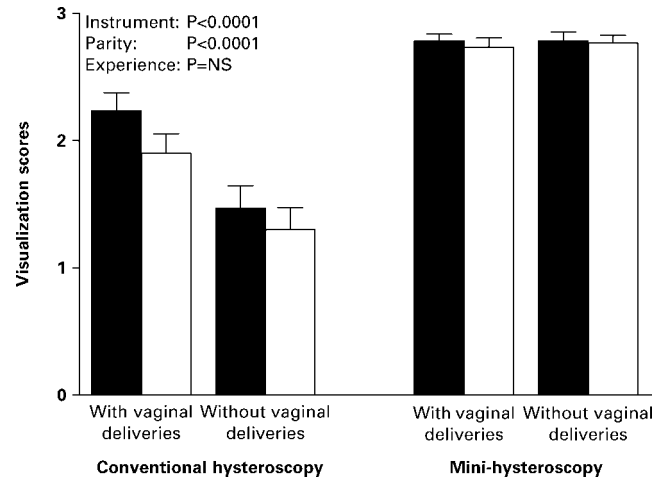


Figure 3. Quality of visualization of the uterine cavity during office diagnostic hysteroscopy performed either with conventional instruments or with mini-instruments in patients with or without vaginal deliveries for 'experienced' ({}sqf) or 'inexperienced' ({}squ) surgeons. Visualization was scored using a grading system (0 = no, 1 = insufficient, 2 = sufficient, 3 = excellent). Means \pm SE, together with significances of a three-way analysis (proc GLM), are indicated.

by instrument diameter ($P = NS$) and surgeon's experience ($P = NS$), but it was lower in patients with vaginal deliveries ($P = 0.02$, Table I). Success rates were higher with mini-hysteroscopy ($P < 0.0001$) and in patients with vaginal deliveries ($P < 0.0001$), but not affected by the surgeon's experience ($P = NS$, Figure 4).

This multifactorial analysis was consistent with the inter-group comparisons, which revealed the worse performance in group 1.2.2 (conventional hysteroscopy, without vaginal deliveries, 'inexperienced' surgeon) and the best in group 2.1.1 (mini-hysteroscopy, with vaginal deliveries, 'experienced' surgeon). The beneficial

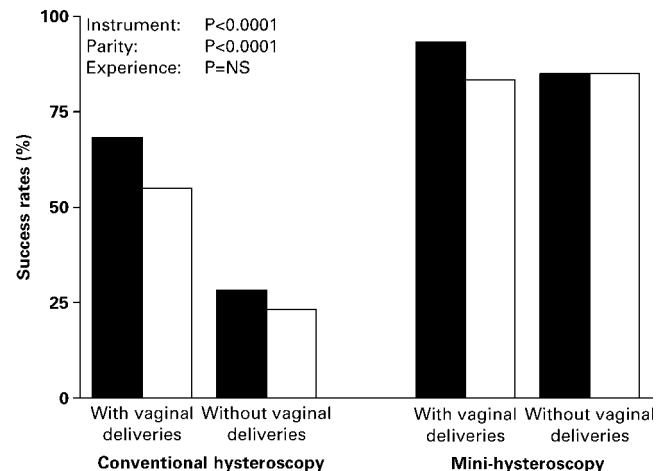


Figure 4. Success rates obtained with office diagnostic hysteroscopy performed either with conventional instruments or with mini-instruments in patients with or without vaginal deliveries for 'experienced' ({}sqf) or 'inexperienced' ({}squ) surgeons. Procedures were considered successful when pain scores were < 4 , visualization scores > 1 and when no complication occurred. Frequencies, together with significances of a three-way analysis (proc logistic), are indicated.

effect of previous vaginal deliveries and of surgeon's experience was, however, no longer observed when mini-hysteroscopy was used.

The multifactorial analysis also demonstrated that the indication, which was a non-controlled factor, slightly influenced the overall results. In patients with AUB, more pain was seen ($P = 0.002$), less visualization ($P < 0.05$), lower success rates ($P = 0.02$) and more abnormalities ($P < 0.05$) than in patients with infertility.

Discussion

To the best of our knowledge, this is the first RCT comparing conventional instruments versus mini-instruments for office diagnostic hysteroscopy that includes an evaluation of the effects of patient parity and surgeon's experience. In contrast to a recently reported RCT (Cicinelli *et al.*, 2003b) performed by experienced surgeons and enrolling only patients with AUB and mostly with vaginal deliveries, our study includes procedures performed by surgeons without experience in office procedures and patients without vaginal deliveries and other indications, such as infertility. It should therefore be more sensitive for detecting differences and has the advantage that the results can be more generalized. To highlight the specific effect of the instrument, the technique was standardized using a distension medium associated with good visualization and minimal pain (Nagele *et al.*, 1996; Shankar *et al.*, 2004) and avoiding anaesthesia and additional uterine interventions, which could shift pain scores to lower or higher values, respectively.

This study demonstrates that mini-hysteroscopy induces less pain and provides better visualization than conventional hysteroscopy, probably due to the less traumatic passage through the cervical canal and the internal ostium. The differences in visualization scores were only related to the quality of visualization of the uterine cavity, rather than to the quality of image itself, since it is obvious that the 4.0 mm optic provides a better image than the 2.7 mm optic. Since the smallest fiberoptic 2.4 mm hysteroscope was required very seldom, our data indicate that the rod lenses 3.5 mm total diameter hysteroscope, combining the advantages of good optical quality and small diameter, is suitable for most cases. Although no differences in complication rates could be detected, probably due to the overall very low values, the success rates were higher with mini-hysteroscopy.

Our data also demonstrated the relative importance of patient parity and surgeon's experience. A better performance was observed in patients with vaginal deliveries and in procedures performed by 'experienced' surgeons when conventional hysteroscopy was performed. This was not surprising since in those patients and in those surgeons, an easier access to the uterine cavity and less traumatic manoeuvres, respectively, can be expected. Interestingly, both patient parity and surgeon's experience were no longer important when mini-hysteroscopy was performed, indicating that a small diameter endoscope can counteract the difficulties determined by the anatomy and by the operator, which broadens the indications for diagnostic hysteroscopy for any patient and for any gynaecologist.

In conclusion, our data demonstrate the importance of instrument diameter, patient parity and surgeon's experience for office diagnostic hysteroscopy. They highlight the clinical relevance of correct instrument selection, especially for inexperienced surgeons and in patients in whom difficult access to the uterine cavity is anticipated. Therefore, this study confirms and extends the advantages of mini-hysteroscopy, indicating its potential as a first line office diagnostic procedure since it is associated with minimal patient discomfort, excellent visualization and very low complication and failure rates.

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