

Vaginoscopic versus traditional office hysteroscopy: a randomized controlled study

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BACKGROUND: A randomized, controlled study was performed to compare vaginoscopic versus traditional (speculum with or without tenaculum) hysteroscopy in terms of pain score and procedure time. **METHODS:** Three hundred patients were randomized in two groups: Group A, diagnostic hysteroscopy with vaginoscopic approach (150 patients) and Group B, diagnostic hysteroscopy with traditional approach (150 patients). All procedures were performed using a semi-rigid 3.5-mm minihysteroscope with a 0° grade optic. Patients of each group were divided into three subgroups according to their reproductive status: fertile nulliparous (FN), fertile multiparous (FM) and post-menopausal (MEN) women. Women were asked to rate their degree of pain during four phases of the procedure: introduction of hysteroscope (Group A) or speculum (Group B) into the vagina (Phase I) and progression through cervical canal up to internal uterine orifice (IUO) (Phase II), inspection of uterine cavity (Phase III) and performing of endometrial biopsy (Phase IV). A total pain score was calculated for each group. For each patient, the duration of hysteroscopy was recorded from the introduction to the extraction of the scope (Group A) or of the speculum (Group B). **RESULTS:** Although the median total pain scores were 2 in each group, the 95% confidence interval for vaginoscopic hysteroscopy (1.86–2.01) was significantly ($P < 0.05$) lower than that for traditional hysteroscopy (2.10–2.26). Comparison between the corresponding phases of the procedure showed the only significant difference during Phase I of the procedure [Group A: 1 (95% CI 1.0–1.18) versus Group B: 2 (95% CI 2.3–2.8); $P < 0.05$]. No significant differences in terms of duration of the procedure were observed between the two approaches. **CONCLUSIONS:** When surgeons using vaginoscopic hysteroscopy with a semi-rigid minihysteroscope were compared with those using traditional approach and the same instrumentation, the operating times and the patients' pain scores were similar.

Key words: pain score/procedure time/traditional hysteroscopy/vaginoscopic hysteroscopy introduction

Introduction

Hysteroscopy can be regarded as the *gold standard* for the evaluation of the uterine cavity and subsequent detection of intrauterine pathology.

It is a safe and simple procedure and, if it can be carried out successfully in an outpatient setting without anaesthesia, it would be an attractive practice.

Notwithstanding, the international literature suggests that outpatient hysteroscopy without any form of analgesia or anaesthesia is a well-tolerated procedure with a high success rate (Finikiotis, 1990; Nagele *et al.*, 1996; Lau *et al.*, 1999; De Iaco *et al.*, 2000; Kremer *et al.*, 2000; Cameron *et al.*, 2001; Yang and Vollenhoven, 2002)—in general, it continues to be considered an invasive and painful technique by most gynaecologists and patients.

Indeed, pain experienced during the procedure continues to represent the most common reason for failure, and this can

occur even if local anaesthesia is used (Marana *et al.*, 2001; Yang and Vollenhoven, 2002; De Angelis *et al.*, 2003; Sharma *et al.*, 2005).

Thus, pain continues to represent the main limiting factor to a large-scale use of office hysteroscopy (Campo *et al.*, 2005).

To minimize patient's discomfort and maximize the chance of success of the procedure and its widespread use, a new technique based on the employment of small-diameter rigid and flexible hysteroscopes and an atraumatic insertion technique (vaginoscopic approach) has been developed. This technique has permitted complete elimination of any kind of premedication, analgesia or anaesthesia, making the procedure faster and complication-free (Bettocchi and Selvaggi, 1997; Campo *et al.*, 1999; Cicinelli *et al.*, 2003; Cicinelli, 2005).

Until now in all published studies, the vaginoscopic approach has been performed with different-sized standard rigid hysteroscopes (Bettocchi and Selvaggi, 1997; Paschopoulos *et al.*,

1997; Campo *et al.*, 1999; Cicinelli *et al.*, 2003; Pellicano *et al.*, 2003; Sharma *et al.*, 2005).

In the recent years, a semi-rigid 3.5-mm fibre-optic minihysteroscope (Versascope, Gynecare, Ethicon) has been developed. No studies comparing this semi-rigid hysteroscope with a standard rigid one of same size of pain score have been reported. However, our clinical experience and the technical features of semi-rigid hysteroscopes suggest that hysteroscopic procedures performed with this instrument might offer a better compliance.

However, the flat tip of the scope and the standard 0° angle of vision may interfere with cervical penetration and cavity exploration (Cicinelli, 2005).

The aim of this prospective, randomized, controlled study was to compare surgeons and hysteroscopic methods (vaginoscopic and traditional approach), using this new semi-rigid hysteroscope, to assess whether vaginoscopic approach is associated with a lower pain score without any increase in procedure time.

Materials and methods

The protocol of the study was approved by our Institutional Review Board, and the study was conducted according to the guidelines of the Declaration of Helsinki (1975). Patients' flow chart is shown in Figure 1.

From February 2003 to November 2004, all patients who were referred to the Unit of Hysteroscopy of the Department of Obstetrics were asked to participate in a study on two different approaches of diagnostic hysteroscopy. Three hundred and eighty-five patients were

considered eligible for the study. Three hundred and twenty-two patients accepted to participate, with 22 of these refusing the randomization process, thus leaving a population of 300 patients who were included in this randomized trial (Figure 1).

Before entering the study, the purpose of the study was clearly explained to women attending our Unit of Hysteroscopy, and a printed explanatory consent form was signed and obtained by all subjects enrolled.

Indications for hysteroscopy included abnormal uterine bleeding, increased endometrial thickness at ultrasound, suspect of endometrial polyp, myoma or carcinoma, endocervical polyp and repeated spontaneous abortion or unexplained infertility. The contraindications were the presence of active infection of the genital tract, cervical cancer, heavy bleeding, severe cardiovascular disease and suspected pregnancy.

The primary outcome measure was the median pain score. On the basis of the existing literature (Sharma *et al.*, 2005) and our preliminary results, a sample of 100 patients in each group would provide 90% power to detect a difference of 25% in the median pain score during all phases of the procedure with significance level of 5%, assuming a baseline value of 2 and given that the expected SD in the pain scores would be 0.67 pain score units.

All patients were prospectively randomized and divided into two groups consisting of 150 patients each. Randomization was achieved with sealed envelopes containing computer-generated random numbers in blocks of 6.

Randomization and recruitment to the study were carried out independently of the clinician who later performed the hysteroscopy.

Patients in Group A were subjected to vaginoscopic hysteroscopy, whereas patients in Group B underwent traditional hysteroscopy, for scope introduction into the external uterine orifice (EUO).

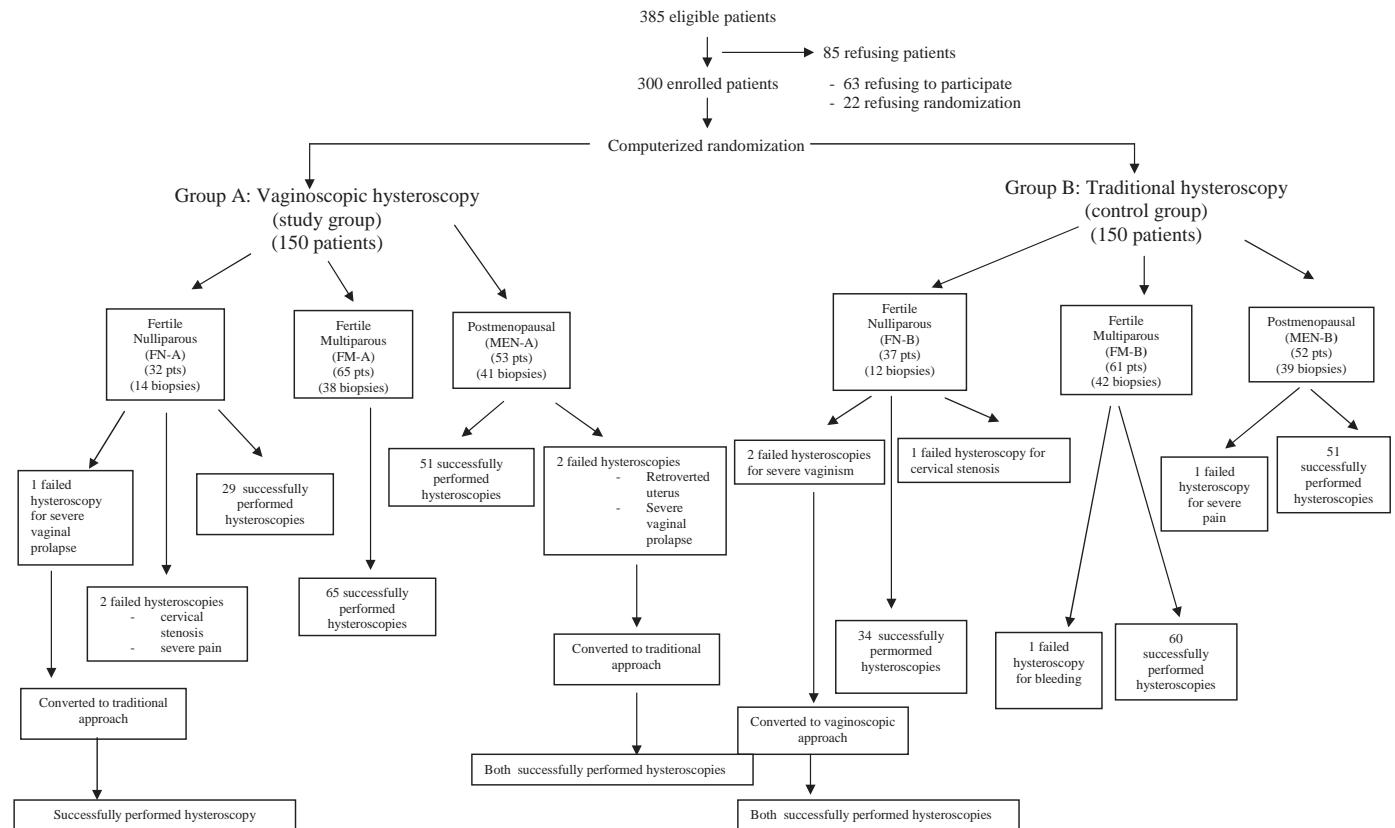


Figure 1. Patients' enrolment and randomized assignment.

Vaginoscopic technique

The technique avoids the need to introduce a speculum and a tenaculum; the vagina, being a cavity, can be distended by introducing the distension medium through the hysteroscope placed into the lower vagina; the anatomy can then be followed by gentle movements of the instrument towards the cervix and cervical canal.

Traditional technique

A speculum is inserted in the vagina to visualize the cervix, and a tenaculum (if required) is applied to the anterior lip of uterine cervix to create counter-traction and to facilitate the insertion of the optic.

Patients of each group were divided into three subgroups based on their reproductive status: fertile nulliparous (FN), fertile multiparous (FM) or post-menopausal (MEN). Patients from Group B were considered as control group.

Women were considered 'fertile' if they were in the period of their life lasting from the menarche to the menopause.

Hysteroscopy was performed using a 3.5-mm minihysteroscope (Versascope, Gynecare, Ethicon, Sommerville, NJ, USA) with a 0° grade optic. Illumination was provided by a 250-W Xenon light source. The images were viewed on a high-resolution colour monitor using one-chip camera, and unusual lesions were recorded by video. Normal saline was used for uterine distension and was instilled from a flexible 500-ml bag wrapped in a pressure cuff connected to a manometer and pumped up to 80–120 mmHg.

No pharmacological preparations or local anaesthetics were administered before the examination. Women in whom vaginoscopic approach failed underwent traditional hysteroscopy; women in whom traditional approach failed underwent vaginoscopic approach; and women in whom both approaches failed were planned for hysteroscopy under general anaesthesia.

The endometrial surface was inspected systematically, and the tubal ostia were identified. The hysteroscope was then pulled back towards the internal uterine orifice (IUO) to obtain a panoramic view of the whole cavity.

If indicated, endometrial biopsy tissue was taken with the biopsy forceps under direct visualization. When indicated, two or three biopsies for each patient were performed. The endocervical canal was inspected during withdrawal of the hysteroscope.

All vaginoscopic hysteroscopies were performed by the most experienced operators (A.D.S.S., M.P. and S.B.) for vaginoscopic technique. Similarly, traditional hysteroscopies were performed by operators with most experience on using this technique (G.A., M.G. and R.P.).

Operative time was recorded from the introduction to the extraction of the scope (Group A) or of the speculum (Group B).

Women were asked to rate their degree of pain during four phases of the procedure: introduction of hysteroscope (Group A) or speculum (Group B) in vagina (Phase I), progression through cervical canal up to IUO (Phase II), inspection of uterine cavity (Phase III) and performing of endometrial biopsy (Phase IV). A second operator (G.B.), next to the patient, quizzed the patient during the procedure.

During the different phases of hysteroscopy, patients were asked to record their degree of pain with a visual analogue scale (VAS). Specifically, pain sensation was scored on a scale of 1 to 5, indicating 1 = no pain, 2 = slight pain, 3 = tolerable pain, 4 = severe pain and 5 = intolerable pain (Guida *et al.*, 2003).

A total pain score was calculated considering all the individual pain score values in all phases of the procedure for each group.

Statistical analysis was performed using the SPSS 9.0 (SPSS, Chicago, IL, USA).

The Shapiro–Wilk's test was performed to evaluate data distribution of all variables. Age, weight, parity, uterine size and procedure

time showed a normal distribution, and differences between groups were evaluated by two-tailed Student's *t*-test for independent data. Differences in pain score between the groups were calculated by Mann–Whitney *U*-test. Statistical significance was set at $P < 0.05$.

Results

No significant differences in age, weight, uterine size and parity between patients of Groups A and B (Table I) were observed. Patients' allocation and randomization are shown in Figure 1.

No major adverse events were recorded during hysteroscopy performed.

Hysteroscopy failed in five patients, and an additional five patients had to undergo an alternate hysteroscopy to the one they were assigned. These 10 patients were excluded from the statistical analysis. For further details, please refer to Figure 1.

Directed biopsies were performed in 14 FN-A patients, 38 FM-A patients, 41 MEN-A patients, 12 FN-B, 42 FM-B and 39 MEN-B patients.

Data on pain score in Groups A and B are shown in Figure 2.

Primary analysis showed that although the median total pain scores were two in both Groups A and B, the 95% confidence interval for vaginoscopic hysteroscopy (1.86–2.01) was significantly ($P < 0.05$) lower than that for traditional hysteroscopy (2.10–2.26).

The secondary analysis of corresponding phases showed a significantly higher pain score during Phase I in Group B in comparison with Group A [2 (2.3–2.8 95% CI) versus 1 (95% CI 1.0–1.18), $P < 0.05$], whereas no significant differences were detected during the Phases II, III and IV (median pain score 2 in all phases of both groups) (Figure 2).

In subgroup analysis, we observed a trend to have lower pain score values during Phase I in FN [1 (0.9–1.2 95% CI) versus 2 (1.7–2.9 95% CI)] and MEN women [1 (1.1–1.4 95% CI) versus 3 (2.1–2.6 95% CI)] undergoing vaginoscopic hysteroscopy.

The time required for the procedures is summarized in Table II. Regardless of the hysteroscopic approach, the duration of the procedure was significantly longer ($P < 0.001$) in patients who underwent endometrial biopsy. However, no statistically significant differences in procedure time were detected between Groups A and B, irrespective of whether endometrial biopsies were performed or not.

In subgroup analysis, we observed a trend of reduction in time procedure in FN and MEN women undergoing vaginoscopic approach, and in FM women undergoing traditional approach.

Table I. Patient's characteristics

Characteristic	Group A (vaginology)	Group B (traditional)	Significance
Age (years)	43 ± 14.6	40 ± 15.6	Not significant
Weight (kg)	69.7 ± 14.8	72.2 ± 13.7	Not significant
Uterine size (hysterometry) (cm)	7.6 ± 2.1	7.9 ± 3.4	Not significant
Parity	1.5 ± 0.7	1.3 ± 0.8	Not significant

All values are mean ± SD.

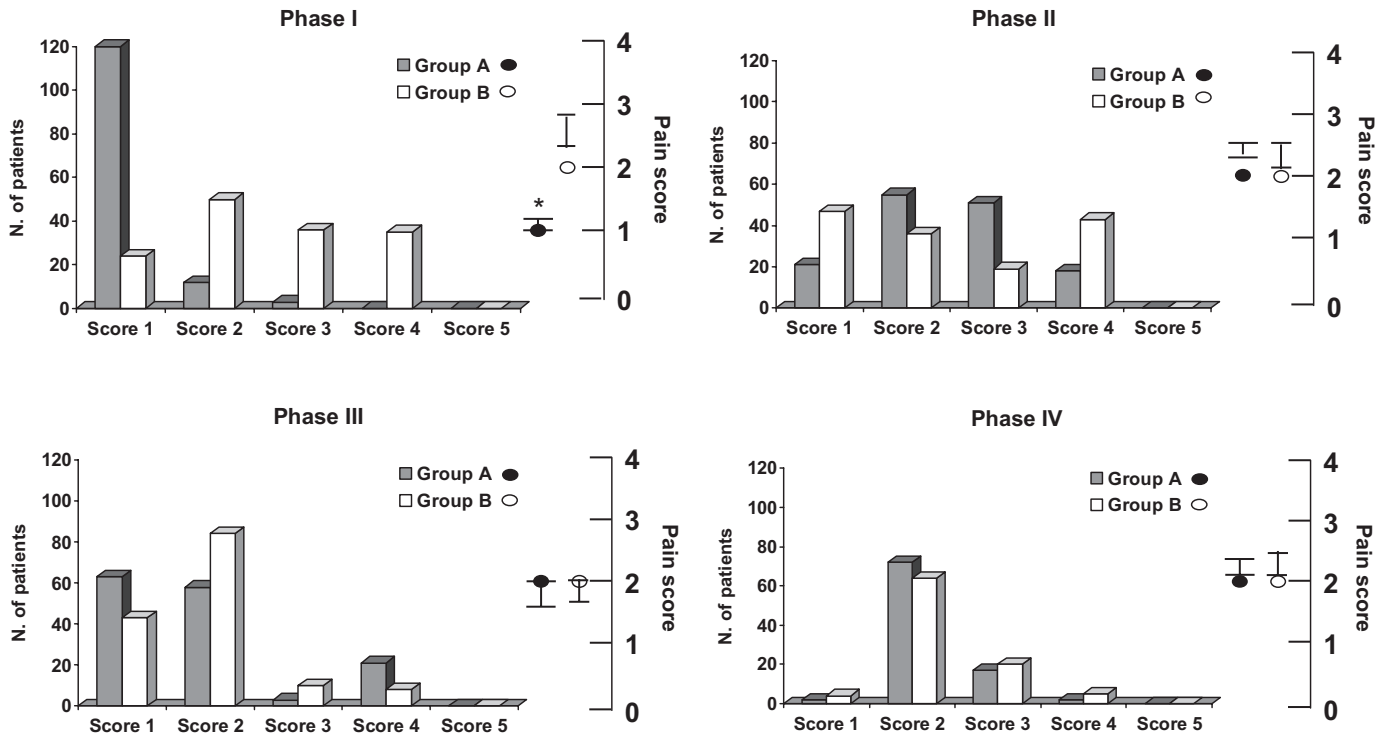


Figure 2. Pain score distribution in Groups A and B. The number of patients for each phase (left side) and median pain score with 95% confidence interval (right side) are shown in each graphic. Group A, vaginoscopic group and Group B, traditional group. Phase I: introduction of hysteroscope (Group A) or speculum (Group B) in vagina; Phase II, progression through cervical canal up to internal uterine orifice; Phase III, inspection of uterine cavity and Phase IV, performing of endometrial biopsy. Pain sensation was scored on a rank scale from 1 to 5, indicating 1 = no pain, 2 = slight pain, 3 = tolerable pain, 4 = severe pain and 5 = intolerable pain. **P* < 0.05 versus Group B.

Table II. Duration of procedure

Groups	Number of patients	Procedure time ± SD (s)
A	145	273.29 ± 68.87
B	145	269.11 ± 62.48
A without biopsy	54	215.08 ± 57.82
B without biopsy	55	214.56 ± 46.14
A with biopsy	91	308.97 ± 49.86
B with biopsy	90	302.55 ± 45.31
A + B with biopsy	181	305.75 ± 47.62*
A + B without biopsy	109	214.83 ± 52.08
FN-A with biopsy	13	291.70 ± 33.20
FM-A with biopsy	38	322.10 ± 54.11
MEN-A with biopsy	40	302.40 ± 48.02
FN-B with biopsy	11	317.68 ± 45.80
FM-B with biopsy	41	281.08 ± 38.80
MEN-B with biopsy	38	322.21 ± 41.28
FN-A without biopsy	16	199.20 ± 42.0
FM-A without biopsy	27	233.25 ± 58.02
MEN-A without biopsy	11	199.85 ± 69.20
FN-B without biopsy	23	221.68 ± 45.20
FM-B without biopsy	19	193.04 ± 46.21
MEN-B without biopsy	13	231.25 ± 38.24

Group A, vaginoscopic approach; Group B, traditional approach; FN, fertile nulliparous women; FM, fertile multiparous women; MEN, post-menopausal women.

**P* < 0.001 versus A + B without biopsy.

Discussion

Nowadays office hysteroscopy represents the gold standard technique for intrauterine diagnostic evaluation. The main limitation to

its widespread use is higher pain and lower patients' compliance in comparison with other less invasive diagnostic tools (i.e. ultrasonography).

In recent years, the reduction of hysteroscope calibre, the rare need for anaesthetics or analgesia and the introduction of vaginoscopic technique have significantly improved patients' compliance to hysteroscopy. Furthermore, according to several authors (Campo *et al.*, 1999; Cicinelli *et al.*, 2003; Pellicano *et al.*, 2003), vaginoscopic approach for hysteroscopy avoids the need for any premedication and renders the procedure faster with a very low rate of complications.

The aim of this study was to compare surgeons and hysteroscopic methods (vagoscopic and traditional approach) using a semi-rigid mini-hysteroscope to verify whether vaginoscopic approach is associated with better compliance without expansion of the procedure time.

A serious limitation to this study was that the two hysteroscopic techniques were performed by different operators. This was because vaginoscopic approach is a relatively recent technique; therefore, it was not possible to select an operator with identical skills in the two techniques at our institute. Three operators with the highest skill were selected for carrying out the vaginoscopic technique. The skill level was based on the number of hysteroscopies performed, years of placement at the hysteroscopic unit and the frequency of visits to foreign centres in which vaginoscopy was routinely performed. Similarly, three operators deemed to have the highest skill in the traditional technique were also selected. This

ensured that the bias related to inter-operator differences was at its lowest level possible.

Data obtained showed that even if the median total pain scores were similar in both groups, the 95% confidence interval for the vaginoscopic group was significantly lower than that for the traditional group.

However, this difference, although statistically significant, was not clinically important. Indeed, as the mid-points of the 95% confidence interval ranges are 1.94 for vaginoscopic hysteroscopy and 2.18 for traditional hysteroscopy, that 0.24 difference between the two groups accounts for just over 4% of the range in the pain score from 1 to 5 and therefore cannot be clinically important.

In subgroup analysis, we observed a trend to have lower pain score values during Phase I in FN and MEN women undergoing vaginoscopic hysteroscopy, a finding that may be worth testing in a subsequent larger randomized controlled trial.

These data could be particularly relevant considering that patients undergoing hysteroscopy are often very anxious; so lowering the pain sensation in Phase I of this procedure could contribute to a better performance mainly in those patients (nulliparous and old women.) who might otherwise require local or general anaesthesia (Bettocchi and Selvaggi, 1997).

No significant differences of duration of procedure were detected between the two hysteroscopic approaches.

In subgroup analysis, we observed a trend of reduction in time procedure in FN and MEN women undergoing vaginoscopic approach and in FM women undergoing traditional approach. These data might be tested in a subsequent larger randomized controlled trial.

These data are in disagreement with those of other authors (Sharma *et al.*, 2005), who have recently demonstrated that vaginoscopic hysteroscopy with either a 2.9-mm or a 4-mm 30° scope is significantly quicker to perform than the traditional technique independent of the reproductive status of patients.

However, our data can be explained by the fact that the use of a 0° hysteroscope that lacks foreblique viewing makes it more difficult and subsequently longer for the operator to detect and to get through the OUE, especially in cases of very anteverted or retroverted uteri.

In conclusion, our data demonstrate that when surgeons using vaginoscopic hysteroscopy with a semi-rigid minihysteroscope were compared with those using traditional approach and same instrumentation, the operating times and the patients' pain scores were similar. Further studies comparing rigid and semi-rigid hysteroscopes with vaginoscopic approach are needed to better evaluate the real impact of vaginoscopic approach on patients' compliance.

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References

- Bettocchi S and Selvaggi L (1997) A vaginoscopic approach to reduce the pain of office hysteroscopy. *J Am Assoc Gynecol Laparosc* 4(2),255–258.
- Cameron ST, Walker J, Chambers S and Critchley H (2001) Comparison of transvaginal ultrasound, saline infusion sonography and hysteroscopy to investigate post-menopausal bleeding and unscheduled bleeding on HRT. *Aust N Z J Obstet Gynaecol* 30,291–294.
- Campo R, Van Belle Y, Rombauts L, Brosens I and Gordts S (1999) Office mini-hysteroscopy. *Hum Reprod Update* 5,73–81.
- Campo R, Molinas CR, Rombauts L, Mestdagh G, Lauwers M, Braekmans P, Brosens I, Van Belle Y and Gordts S (2005) Prospective multicentre randomized controlled trial to evaluate factors influencing the success rate of office diagnostic hysteroscopy. *Hum Reprod* 20,258–263.
- Cicinelli E (2005) Diagnostic minihysteroscopy with vaginoscopic approach: rationale and advantages. *J Minim Invasive Gynecol* 12,396–400.
- Cicinelli E, Parisi C, Galantino P, Pinto V, Barba B and Schonauer S (2003) Reliability, feasibility, and safety of minihysteroscopy with a vaginoscopic approach: experience with 6,000 cases. *Fertil Steril* 80,199–202.
- De Angelis C, Perrone G, Santoro G, Nofroni I and Zichella L (2003) Suppression of pelvic pain during hysteroscopy with a transcutaneous electrical nerve stimulation device. *Fertil Steril* 79(6),1422–1427.
- De Iaco P, Marabini A and Stefanetti M (2000) Acceptability and pain of outpatient hysteroscopy. *J Am Assoc Gynecol Laparosc* 7,71–75.
- Finikiotis G (1990) Outpatient hysteroscopy: pain assessment by visual analogue scale. *Aust N Z J Obstet Gynaecol* 30,89–90.
- Guida M, Pellicano M, Zullo F, Acunzo G, Lavitola G, Palomba S and Nappi C (2003) Outpatient operative hysteroscopy with bipolar electrode: a prospective multicentre randomized study between local anaesthesia and conscious sedation. *Hum Reprod* 18,840–843.
- Kremer C, Duffy S and Moroney M (2000) Patient satisfaction with outpatient hysteroscopy versus day case hysteroscopy: randomized controlled trial. *BMJ* 320,279–282.
- Lau WC, Ho RY, Tsang MK, and Yuen PM (1999) Patient's acceptance of outpatient hysteroscopy. *Gynecol Obstet Invest* 47,191–193.
- Marana R, Marana E and Catalano GF (2001) Current practical application of office endoscopy. *Curr Opin Obstet Gynecol* 13,383–387.
- Nagele F, O'Connor H, Davies A, Badawy A, Mohamed H and Magos A (1996) 2500 outpatient diagnostic hysteroscopies. *Obstet Gynecol* 88,87–92.
- Paschopoulos M, Paraskevaidis E, Stefanidis K, Kofinas G and Lolis D (1997) Vaginoscopic approach to outpatient hysteroscopy. *J Am Assoc Gynecol Laparosc* 4,465–467.
- Pellicano M, Guida M, Zullo F, Lavitola G, Cirillo D and Nappi C (2003) Carbon dioxide versus normal saline as a uterine distension medium for diagnostic vaginoscopic hysteroscopy in infertile patients: a prospective, randomized, multicenter study. *Fertil Steril* 79,418–421.
- Sharma M, Taylor A, Di Spiezio Sardo A, Buck L, Mastrogamvrakis G, Kosmas I, Tsirkas P and Magos A (2005) Outpatient hysteroscopy: traditional versus the 'no-touch' technique. *BJOG* 112,963–967.
- Yang J and Vollenhoven B (2002) Pain control in outpatient hysteroscopy. *Obstet Gynecol Surv* 57(10),693–702.

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