Evaluation of pain in outpatient diagnostic hysteroscopy with gas

Avaliação da dor na histeroscopia diagnóstica ambulatorial com gás

Daniela Barreto Fraguglia Quental Diniz¹, Daniella de Batista Depes², Ana Maria Gomes dos Santos³, Simone Denise David⁴, Salete Yatabe⁵, Reginaldo Guedes Coelho Lopes⁶

ABSTRACT

Objective: To evaluate the intensity of pain reported by patients undergoing outpatient diagnostic hysteroscopy. Methods: Exam performed with a 5-mm lens hysteroscope, vaginal speculum, tenaculum and uterine distention with carbon dioxide gas. Before and after the examination, patients were interviewed to define, in a verbal scale from 0 to 10, pain values that they expected to feel and that they experienced after the end, and also if they would repeat it if indicated. Data were analyzed using Statistical Package for the Social Sciences 15.0, statistic significance was defined as p < 0.05 with a study power of 95%. **Results:** Fifty-eight patients were included with mean age of 50.9 years, with 32.8% at postmenopause and 6.9% nulliparous. Among those with previous deliveries, mean parity was 2.21 and at least one vaginal delivery had occurred in 63.8%. Only 24.1% of patients knew how the exam would be done. 62.1% needed an endometrial sample and the result was considered satisfactory in 89.7%. The means of expected and experienced pain were similar (6.0 versus 6.1), and 91.4% of women would repeat the hysteroscopy if necessary. The only factor associated with less pain after the exam was previous vaginal delivery, with a decrease of pain score from 7.1 to 5.5 (p = 0.03). Mean pain was significantly lower in those who agreed to repeat the exam (5.8 *versus* 9.4; p = 0.003). **Conclusions**: Outpatient diagnostic hysteroscopy with gas can be associated with moderate but tolerable discomfort and satisfactory results.

Keywords: Pain measurement; Pain measurement/diagnosis; Hysteroscopy/methods; Ambulatorial care; Outcome and process assessment (Health Care)

RESUMO

Objetivo: Avaliar a intensidade da dor referida pelas pacientes submetidas à histeroscopia diagnóstica ambulatorial. Métodos: Exame realizado com ótica de 5 mm, espéculo, pinçamento do colo com Pozzi e distensão da cavidade uterina com dióxido de carbono. Antes e depois do exame, as pacientes foram entrevistadas para definir, em uma escala verbal de 0 a 10, valores para espectativa de dor e dor experimentada após seu término, e também se elas o repetiriam se houvesse indicação. Os dados foram analisados no Statistical Package for the Social Sciences 15.0, com significância estatística definida como p < 0.05 e poder do teste de 95%. **Resultados**: Foram incluídas 58 pacientes, com idade média de 50,9 anos, sendo 32,8% na pós-menopausa e 6.9% nulíparas. Dentre as pacientes com partos anteriores, a paridade média foi 2,21 e pelo menos um parto normal ocorreu em 63,8%. Apenas 24,1% das pacientes sabiam como o exame seria feito, 62.1% necessitaram de biópsia endometrial e o resultado foi considerado satisfatório em 89,7% dos casos. As médias de dor esperada e referida pelas pacientes foram semelhantes (6,0 versus 6,1), e 91,4% das mulheres repetiriam a histeroscopia guando necessário. O único fator associado à redução da dor após o exame foi o antecedente de parto normal, com queda de 7,1 para 5,5 (p = 0,03). A média de dor foi significativamente menor nas pacientes que aceitariam repetir o exame (5,8 *versus* 9,4; p = 0,003). **Conclusões:** A histeroscopia diagnóstica ambulatorial com gás pode estar associada a desconforto moderado, porém tolerável, com resultados satisfatórios.

Descritores: Medição da dor; Medição da dor/diagnóstico; Histeroscopia/métodos; Assistência ambulatorial; Avaliação de processos e resultados (Cuidados de Saúde)

Study carried out at Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" — HSPE-FMO, São Paulo (SP), Brasil.

Corresponding author: Daniela Barreto Fraguglia Quental Diniz — Rua Dr. Eduardo Amaro, 152, conj. 44 — Paraíso — CEP 04104-080 — São Paulo (SP), Brazil — Tel.: 11 5572-2572 — e-mail: dradanieladiniz@hotmail.com

Received on: May 16, 2009 - Accepted: Dec 11, 2009

¹ Master's degree; Assistant physician of the Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" — HSPE-FMO, São Paulo (SP), Brazil.

² Master's degree; Head of the Endoscopic Gynecology Sector of Gynecology and Obstetrics Service of Hospital do Servidor Público Estadual de São Paulo "Francisco Morato de Oliveira" – HSPE-FMO, São

³ Post-graduate student from the Instituto de Assistência Médica ao Servidor Público Estadual; Assistant physician of the Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" – HSPE-FMO, São Paulo (SP), Brazil.

⁴ Post-graduate student from the Instituto de Assistência Médica ao Servidor Público Estadual; Assistant physician of the Department of Gynecology and Obstetrics Service of Hospital do Servidor Público Estadual "Francisco Morato de Oliveria" – HSPE-FMO, São Paulo (SP), Brazil.

⁵ Post-graduate student of the Escola Paulista de Medicina of Universidade Federal de São Paulo – UNIFESP, São Paulo (SP), Brasil; Assistant physician of Department of Gynecology and Obstetrics of Hospital do Servidor Público Estadual "Francisco Morato de Oliveria" – HSPE-FMO. São Paulo (SP). Brazil.

⁶ PhD; Director of the Gynecology and Obstetrics Service at Hospital do Servidor Público Estadual "Francisco Morato de Oliveria" - HSPE-FMO, São Paulo (SP), Brazil.

INTRODUCTION

Video-hysteroscopy has become, in the last years, a great work-up method in Gynecology, and it is considered the gold standard approach to intrauterine pathologies. The technological development associated with an improvement in medical training and ability made hysteroscopy a simple, secure and highly accurate method to access the cervical canal, uterine cavity and tubal ostium, performed in an outpatient setting with minimum discomfort to women⁽¹⁾.

The main indications for this procedure are abnormal uterine bleeding, infertility, repeated abortions, diagnosis and follow-up of endometrial hyperplasia, diagnosis and staging of endometrial cancer, identification of foreign bodies, investigation of intrauterine pathologies suspected in other exams, pre and postoperative control of hysteroscopic surgeries and tubal catheterization sterilization. The technique does not have absolute contraindications but, in general, it is not indicated in acute inflammatory pelvic disease, mucopurulent cervicitis, after recent uterine perforation and if pregnancy is suspected or confirmed, when risks and benefits should be considered⁽²⁻³⁾. Hysteroscopy has 98% sensibility in the investigation of the uterine cavity compared with only 65% of curettage, and offers the advantages of outpatient care, no need of general anesthesia, thus reducing time and costs for the physician, the patient and the health care system⁽⁴⁾. Despite the great acceptance by the physicians, it is very important to know how well the patients tolerate the procedure since the main limitation is the fact of being an invasive exam that may cause pain and discomfort.

Considering every single component involved in the cause of pain, it begins with the vaginal reflex when the speculum is introduced, followed by cervical cleaning and the traction with the tenaculum. A great number of nerve endings are found close to the isthmus justifying why this is the most tender spot. Cervical ripening is another important cause of pain and it depends on the diameter of the optical lens, increasing as it becomes larger. Nerve endings are also present in the myometrium and may cause pain when the cavity is distended with CO₂. The biopsy performed to get an endometrial sample, depending on the technique, sometimes can be even as painful or more painful than the exam itself^(1,4-5).

During and immediately after hysteroscopy, patients may report hypogastric pain similar as that during their period, especially those submitted to elevated intracavitary pressures or fast uterine distention. Tubal ostium opening may occur when the distention pressure exceeds 75 to 100 mmHg and the $\rm CO_2$ enters the peritoneal cavity, and it is occasionally reported as

a shoulder pain caused by the diaphragm and phrenic nerve irritation⁽⁴⁻⁵⁾.

OBJECTIVE

The purpose of this study was to evaluate the acceptance of patients to outpatient diagnostic hysteroscopy, measured by a verbal pain scale, and compliance to undergo the same exam again, if necessary.

METHODS

A prospective observational cohort study conducted at Hospital do Servidor Público Estadual "Francisco Morato de Oliveira" (HSPE-FMO), a public teaching hospital in São Paulo, Brazil, from April 1st, 2005 to July 21th, 2006 included women referred to the Department of Endoscopic Gynecology, with an indication to undergo hysteroscopy (suspected endometrial pathologies), who met the inclusion criteria: age over 18 years, without contraindications to the exam and that agreed to join the study by signing an informed consent form.

All exams were performed by one of the two experienced physicians, without analgesia or anesthesia, in an appropriate outpatient office. The procedure was performed with the standard approach, beginning with the patient in lithotomy position with exposure of the cervix with speculum and traction of the anterior lip with a tenaculum. A Storz Hamou II rod lens rigid hysteroscope (4 mm optics, 30°, within a 5 mm sheath) was inserted under direct vision into the uterine cavity. Carbon dioxide was the distention media with pressure controlled by a hysteroflator maintaining 50 to 75 mmHg with 50 ml/min flow rate. The image was transmitted in real time to a monitor, allowing physicians, nurses and patient to watch the exam. An endometrial sample was obtained only when necessary (hysteroscopic findings of some disease), and it was oriented and performed with a 3- to 5-mm Novak curette at the end.

Before the beginning of the procedure, all patients answered a questionnaire about the exam, if they knew why it was indicated, how it would be done, and how much pain they supposed it might cause. Immediately after the procedure, the patients were asked again about pain they experienced during the exam and if they would agree to repeat the exam if necessary. The pain score was quantified using a verbal pain scale graduated from 0 (no pain) to 10 (the worst pain ever), when a score of 0 to 4 indicated a minimal pain, 5 to 7 moderate pain and 8 to 10 indicated severe pain.

A sample calculation was done considering an standard deviation of 2.7 points⁽⁶⁾, to detect the minimum variation in the verbal pain scale (1.0) with statistical significance defined as p = 0.05 and study

power of 95%. It resulted in 43 patients so we had 58 patients randomly assigned by convenience.

The variables studied included age, number of pregnancies, parity, postmenopause status, presence of a previous vaginal delivery, presence of previous uterine surgery (including cesarean section, curettage, conization and hysteroscopic surgeries), need of endometrial sampling, satisfaction with the exam and the pain score. All data were analyzed with software Statistical Package for the Social Sciences (SPSS) 15.0. Quantitative variables were first evaluated for their homogeneity and distribution; median, mean and standard deviation were defined. The absolute and relative frequencies of qualitative variables were assessed. Student's *t*-test was used to compare the means in independent samples.

The Research Ethics Committee of the HSPE-FMO approved this study.

RESULTS

The study included 58 patients with characteristics listed in table 1. The mean age was 53 years, 33.3% were at postmenopausal status, none of them using hormonal replacement therapy. Two patients (3.4%) were nulliparous and were excluded from the parity mean calculation. The mean number of pregnancies was 2.81 (ranging from 1 to 13) and the mean number of deliveries was 2.37 (ranging from 1 to 5). As to the type of delivery, 58.9% had at least one cesarean section and 66.1% at least one vaginal delivery. Previous uterine

Table 1. Characteristics of patients and outpatient hysteroscopy (n = 58), HSPE, São Paulo 2005-2006

Characteristics	Mean (standard deviation, range)	
Age (years)	50.93 (12.6; 21-86)	
Gestational history Pregnancy*	2.81 (1.75; 1-13)	
Parity*	2.37 (1.07; 1-5)	
Duration of menopause (years)†	16 (11.41; 1-41)	

 $^{^{\}ast}$ Excluding nulliparous (n = 56); † including only postmenopausal status (n = 19)

Characteristics	n (%)
Nulliparous	2 (3.3)
Genital status Postmenopausal Premenopausal	19 (32.8) 38 (67.2)
Previous vaginal delivery (one or more)*	37 (63.8)
Previous C-section (one or more)*	33 (58.9)
Previous uterine surgery	35 (60.3)
Previous hysteroscopy	10 (17.2)
Knows how the exam is done	14 (24.1)
Need of biopsy	36 (62.1)
Technical difficulty	10 (17.2)
Satisfactory exam	52 (89.7)
Patient acceptance to repeat the exam	53 (91.4)

n = 58

surgeries were present in 60.3% and endometrial biopsies were performed in 32 patients (62.1%).

Only 16 (24.1%) women knew how the exam would be done but 54 (93.1%) thought it would be important to help define the diagnosis. The exam was considered satisfactory in 52 (89.7%) patients, and 53 (91.4%) women said that they would repeat the exam if necessary.

The pain score was similar before and after the exam, with mean pain expected of 6.05 (SD = 2.39) and mean reported pain of 6.1 (SD = 2.34), p = 0.91 (non significant). Patients were stratified according to possible pain determinant factors (table 2). When stratified by postmenopausal status, the mean pain scores were 6.47 before and 5.81 after the exam with a difference that was not statistically significant. There was also no difference in patients with a history of uterine surgery. The need for biopsy changed the mean pain score from 5.3 to 6.38 (p = 0.06), with a trend to increase but still not significant.

Table 2. Mean pain scale after hysteroscopy stratified by characteristics of patients and of the exam. HSPE, Sao Paulo, 2005-2006

Characteristics	Mean pain scale (verbal analogue scale 0-10)		
	Yes	No	p value*
Agreement to repeat the exam	5.79	9.40	0.003
Previous vaginal delivery(s)	5.54	7.10	0.03
Postmenopausa	6.47	5.81	0.08
Previous hysteroscopy	7.30	5.85	0.12
Knows how the exam is done	5.42	6.31	0.28
Need of biopsy	6.39	5.64	0.30
Previous uterine surgery	5.60	6.15	0.66

^{*} Student's t test (two-tailed), significance considered p < 0.05

The patients who agreed to undergo the same exam again if necessary experienced a lower pain score, with a mean of 5.79, compared with those that would not repeat it (mean of 9.4, p = 0.03).

The only independent factor involved in the pain score decrease with statistical significance was the presence of a previous vaginal delivery (p = 0.03), with a decrease of the mean score reported after the exam from 7.1 (in the group of nulliparous or only cesarean sections) to 5.54 in the group that had at least one vaginal delivery.

DISCUSSION

Outpatient diagnostic hysteroscopy and endometrial sampling replaced the uterine curettage as the gold standard investigation method for abnormal uterine bleeding and endometrial conditions, providing a precise evaluation of the intrauterine cavity, besides

^{*}Excluding nulliparous, n = 56

other obvious advantages of no need to use anesthesia or hospitalization⁽⁶⁾.

According to different authors, pain is the main limiting factor to the outpatient procedure and one of the causes of impaired accuracy of the exam, sometimes leading to unsatisfactory results^(1,4-5).

In our study, the mean score of pain reported after the exam was considered moderate according to our grade of pain, that is, minimal pain (0 to 4), moderate (4.1 to 7) and severe (7.1 to 10)⁽⁷⁾. This score was higher than others published by some authors, probably because in all patients we used a 5-mm diameter optics and tenaculum as a standard research protocol⁽⁸⁾. Cicinelli showed that a small hysteroscope diameter is of great value to reduce pain and vagal reflex⁽⁹⁾. Morgan et al., in a trial performed after the hysteroscopic exam, reported that 45% of women classified pain as moderate or severe and, despite that, most preferred to repeat the exam in an outpatient setting because of faster return to daily activities and to avoid general anesthesia⁽¹⁰⁻¹¹⁾.

Several studies unsuccessfully tried to find an efficient method of analgesia without admission to hospital. A great part of the discomfort attributed to the exam is caused by uterine contraction, so it was supposed that prostaglandin synthesis inhibitors could decrease pain, but when the mephenamic acid was used one hour before the exam, the discomfort was similar to the placebo group during the procedure, only being significant after the said procedure⁽¹²⁾. Similar results were found when intravenous tramadol and sublingual buprenorphine were used⁽¹³⁻¹⁴⁾.

Some authors, studying local intrauterine anesthesia with lidocaine diluted in saline alone or combined with cervical anesthesia affirmed that this procedure may be even more painful that the exam itself ^(4,15). Paracervical anesthesia does not reduce pain and may also cause bleeding, despite the risk of intravascular injection leading to bradycardia and hypotension ^(4,12).

Readman and Maher⁽⁴⁾, in a literature review of 10,232 patients submitted to outpatient hysteroscopy, affirm that there was no increase in the success rate of the exam with any of the analgesia protocols, and the acceptance rate ranged from 83 to 93% in the trial population.

In our study, the exam was considered unsatisfactory when the uterine cavity was not reached or its vision was not good enough to lead to a conclusion; this occurred in six exams and the causes were bleeding in four patients, technical problems with bad luminosity and one false path. Our success rate was similar to the findings in the literature that range from 69 to 100%, and the main causes of failure described in articles and reviews are pain, cervical stricture and poor visibility⁽⁴⁾.

Although some authors consider the postmenopausal status as a predictive factor for pain increase, we found similar results in this group compared to those during menacme⁽⁵⁾.

A relevant data was that the mean pain score after the exam was statistically lower in those patients with at least one previous vaginal delivery, and even though it would be obvious, it is not verified by other trials⁽⁴⁾.

Based on the hypothesis that a soft and wider cervical canal could help avoid pain, some authors used misoprostol prior to the exam but the results showed no benefits⁽¹⁵⁾.

Endometrial sampling is considered a moment of great discomfort, sometimes even worse than the hysteroscopy itself ⁽¹⁶⁾. The women in this study showed an increase in the pain score, still not statistically significant, but since the biopsy was performed only in 62.1% of the group, and this study was not designed to evaluate biopsy as the main factor, probably the sample group was not high enough to measure the effect of that outcome⁽⁴⁾.

It is supposed that a greater acceptance could be reached offering to the patients a detailed explanation of the method, reducing anxiety and expectation^(6,12), but this study showed that the patients who had been previously informed by their doctors about the procedure did not experience any relief in their discomfort. Those submitted to hysteroscopy once before, who knew all steps of the exam, even referred worse pain than those undergoing their first exam.

Five patients would not repeat the exam again, and all of them experienced severe pain with a mean score of 9.4. Excluding those patients from the study, the mean score of pain in the group drops to 5.7.

It is very likely that if we used small diameter optics and performed the exam without the need of cervical traction with the tenaculum, patients would feel less pain. Recent articles showed that the use of saline for distension instead of carbon dioxide gas reduces pain, and that vaginoscopy approach, developed by Bettocchi et al., with no need of speculum or tenaculum, seems to be well tolerated by patients^(1,4,6,17-21).

CONCLUSIONS

Outpatient diagnostic hysteroscopy with gas can be associated with moderate but tolerable discomfort (mean pain score of 6 in a 0 to 10 pain scale, with 91.4% acceptance to repeat the exam), with satisfying results.

REFERENCES

 Garbin O, Kutnahorsky R, Göllner JL, Vayssiere C. Vaginoscopic versus conventional approaches to outpatient diagnostic hysteroscopy: a two-centre randomized prospective study. Hum Reprod. 2006;21(11):2996-3000.

- Crispi CP, Damian Jr JC, Damian BB, Panisset KSP, Raymundo TS, Rainho AFR. Indicações. In: Crispi PC, editor. Tratado de videoendoscopia e cirurgia minimamente invasiva em ginecologia. 2ª ed. São Paulo: Revinter; 2006. p. 758-69
- Lippi UG, Lopes RGC, Baracat FF, editores. Ginecologia: manual de normas e condutas. S\u00e3o Paulo: EPUB; 2003.
- 4. Readman E, Maher PJ. Pain relief and outpatient hysteroscopy: a literature review. J Am Assoc Gynecol Laparosc. 2004;11(3):315-9.
- Cicinelli E, Didonna T, Ambrosi G, Schönauer LM, Fiore G, Matteo MG. Topical anesthesia for diagnostic hysteroscopy and endometrial biopsy in postmenopausal women: a randomised placebo-controlled double-blind study. Br J Obstet Gynaecol. 1997;104(3):316-9.
- Lau WC, Ho RY, Tsang MK, Yuen PM. Patients acceptance of outpatient hysteroscopy. Gynecol Obstet Invest. 1999;47(3):191-3.
- Litta P, Bonora M, Pozzan C, Merlin F, Sacco G, Fracas M, et al. Carbon dioxide versus normal saline for outpatient hysteroscopy. Hum Reprod. 2003;18(11):2446-9.
- De laco P, Marabini A, Stefanetti M, Del Vecchio C, Bovicelli L. Acceptability and pain of outpatient hysteroscopy. J Am Assoc Gynecol Laparosc. 2000;7(1):71-5.
- Cicinelli E. Diagnostic minihysteroscopy with vaginoscopic approach: rationale and advantages. J Minim Invasive Gynecol. 2005;12(5):396-400.
- Morgan M, Dodds W, Wolfe C, Raju S. Women views and experiences of outpatient hysteroscopy: implications for a patient-centered service. Nurs Health Sci. 2004;6(4):315-20.
- Tong S, Zachariah R, Chua BG, Vollenhoven B. Hysteroscopy under general anesthesia, a near painless procedure. Aust N Z J Obstet Gynaecol. 2003;43(5):344-5.
- Nagele F, Lockwood G, Magos AL. Randomised placebo controlled trial of mefenamic acid for premedication at outpatient hysteroscopy: a pilot study. Br J Obstet Gynaecol. 1997;104(7):842-4.

- Floris S, Piras B, Orrù M, Silvetti E, Tusconi A, Melis F, et al. Efficacy of intravenous tramadol treatment for reducing pain during office diagnostic hysteroscopy. Fertil Steril. 2007;87(1):147-51.
- Lin YH, Hwang JL, Huang LW, Chen HJ. Use of sublingual buprenorphine for pain relief in office hysteroscopy. J Minim Invasive Gynecol. 2005;12(4): 347-50.
- Da Costa AR, Pinto-Neto AM, Amorim M, Paiva LH, Scavuzzi A, Schettini J. Use of misoprostol prior to hysteroscopy in postmenopausal women: a randomized, placebo-controlled clinical trial. J Minim Invasive Gynecol. 2008;15(1):67-73.
- Al-Sunaidi M, Tulandi T. A randomized trial comparing local intracervical and combined local and paracervical anesthesia in outpatient hysteroscopy. J Minim Invasive Gynecol. 2007;14(2):153-5.
- Cicinelli E, Rossi AC, Marinaccio M, Matteo M, Saliani N, Tinelli R. Predictive factors for pain experienced at office fluid minihysteroscopy. J Minim Invasive Gynecol. 2007;14(4):485-8.
- De Carvalho Schettini JA, Ramos de Amorim MM, Ribeiro Costa AA, Albuquerque Neto LC. Pain evaluation in outpatients undergoing diagnostic anesthesia-free hysteroscopy in a teaching hospital: a cohort study. J Minim Invasive Gynecol. 2007;14(6):729-35.
- Campo R, Molinas CR, Rombauts L, Mestdagh G, Lauwers M, Braekmans P, et al. Prospective multicentre randomized controlled trial to evaluate factors influencing the success rate of office diagnostic hysteroscopy. Hum Reprod. 2005;20(1):258-63.
- Gupta JK, Clark TJ, More S, Pattison H. Patient anxiety and experiences associated with an outpatient "one-stop" "see and treat" hysteroscopy clinic. Surg Endosc. 2004;18(7):1099-104.
- 21. Bettocchi S, Di Spiezio Sardo A, Ceci O, Nappi L, Guida M, Greco E, et al. A new hysteroscopic technique for the preparation of partially intramural myomas in office setting (OPPluM technique): A pilot study. J Minim Invasive Gynecol. 2009;16(6):748-54.