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Outpatient operative hysteroscopy with bipolar electrode: a prospective multicentre randomized study between local anaesthesia and conscious sedation

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BACKGROUND: The study was designed to compare local anaesthesia and conscious sedation for outpatient bipolar operative hysteroscopy in terms of pain control and patients' satisfaction. METHODS: A prospective multicentre randomized study was carried out in university hospitals and in a private endoscopy unit. A total of 166 women with surgically treatable lesions associated with infertility or abnormal uterine bleeding was considered eligible for the study. Patients were randomized, using a computer-generated randomization list, into two groups. Group A (82 patients) underwent operative hysteroscopy with local anaesthesia. Group B (84 patients) received conscious sedation. Operative hysteroscopy was performed with a bipolar electrosurgical device to cut, vaporize and coagulate. Main outcome measures were pain control during the procedure, the post-operative pain score at 15 and 60 min, and at 24 h after the procedure, and patients' satisfaction rate. RESULTS: All procedures were completed within 35 min, the amount of saline used varied from 400–1200 ml. There were no significant differences between local anaesthesia and conscious sedation in terms of pain control during the procedure and in postoperative pain at different intervals. Satisfaction rate was similar in the two groups. CONCLUSIONS: Both local anaesthesia and conscious sedation can be used for operative hysteroscopy using a bipolar electrosurgical system without significant differences in terms of pain control and patients' satisfaction.

Key words: bipolar hysteroscopic electrosurgery/conscious sedation/local anaesthesia/pain control/satisfaction rate

Introduction

Operative hysteroscopy has been used for various indications, such as endometrial polyps, adenomyosis, uterine septa, adhesions and uterine leiomyomata, in women with abnormal uterine bleeding, infertility, or recurrent pregnancy loss (Vilos, 1999).

Currently, the most common devices used to perform these operations are hysteroscopic scissors, unipolar electrosurgery and neodymium-yttrium-aluminium garnet (Nd:YAG) laser fibres (Kung *et al*., 1999). However, these methods have some disadvantages. Although laser fibres can be placed through a 5-French operative port of the hysteroscope and allow surgery within small intrauterine cavities using normal saline distension medium, they are very expensive. In addition, unipolar electrosurgery cannot be used with a normal saline solution as distension medium since the current is dissipated into the extremely low-impedance surroundings. Thus, the use and the excessive absorption of hypotonic solution may induce some complications such as hyponatraemia and hyponatraemic encephalopathy, transient blood oxygen desaturation, hypercapnia, coagulopathy, and postoperative hyperammonaemia deriving from oxidative deamination of the aminoacid glycine (Arieff and Ayers, 1993; Kirwan *et al*., 1993; Goldenberg *et al*., 1994; Rosemberg *et al*., 1995).

A small cervix and a small uterine cavity frequently interfere with the use of instrumentation of >5 mm in diameter. Moreover, the cervix and uterine cavity may be small in infertile patients as a result of nulliparity, intrauterine adhesions, septa, polyps, or fibroids (Vilos, 1999).

In recent years a new bipolar device has been developed. It can be used with normal saline solution as a distension medium and requires minimal cervical dilatation. Bipolar electrosurgery has been used with general anaesthesia (Fernandez *et al*., 2000; Golan *et al*., 2001) or with the association of local anaesthesia plus conscious sedation (Kung *et al*., 1999; Vilos, 1999; Lindheim *et al*., 2000).

The aim of this prospective randomized study was to compare local anaesthesia or conscious sedation in terms of pain control and patients' satisfaction during bipolar hysteroscopic electrosurgery.

Materials and methods

From March 2000–January 2001, 166 patients (mean age ± SD, 33 ± 4 years), with surgically treatable lesions associated with infertility or abnormal uterine bleeding, were referred to two university hospitals and to a private endoscopy unit.

Exclusion criteria were: (i) menopausal women (FSH >40 mIU/ml, 17β-estradiol <20 pg/ml); (ii) and/or pregnant (positive β-hCG test) women and (iii) those with a history of anaesthetic or surgical complications. These patients were randomized into two groups using a computer-generated randomization list in blocks of two. In group A (82 patients) hysteroscopy was performed using local anaesthesia. Group B (84 patients) received conscious sedation.

This study was approved by the Institutional Review Board of the University of Naples. Each patient signed an informed consent form after receiving an extensive explanation of the surgical procedure and on the two types of anaesthesia. All women accepted the randomization.

Before surgery each patient underwent a complete clinical history and physical examination to exclude the presence of metabolic or cardio-respiratory disorders.

In all patients the diagnosis of intrauterine pathology was performed in the hysteroscopic unit using an office 5.5 mm instrument. Before hysteroscopy, all patients underwent vaginal examination to ascertain the position and size of the uterus, and a speculum was inserted into the vagina to expose the esocervix.

Paracervical anaesthesia (group A) was performed with 10 ml of 1% mepivacaine hydrochloride solution injected with a 22-gauge spinal needle on four sites (at 3, 5, 7 and 9 o'clock positions) at the junction of the cervix and vagina (Vercellini *et al*., 1994). Conscious sedation (group B) was performed immediately before surgery with the i.v. administration of 0.5 mg of atropine and 0.25 mg of fentanyl, followed by an i.v. slow injection of 2.0 mg of midazolam (Ipnovel, Roche, Milan, Italy) (Pellicano *et al*., 1998, 2001. No patient required endotracheal intubation. All patients maintained control of their airways, and additional analgesia was provided only on request.

All women underwent operative hysteroscopy using the Versapoint, a new hysteroscopic bipolar electrosurgical device (Kung *et al*., 1999; Vilos, 1999; Fernandez *et al*., 2000; Lindheim *et al*., 2000; Golan *et al*., 2001). The electrode was introduced into the 5-F working channel of a 5.5 mm hysteroscope (Wolf, Tuttlingen, Germany). A 60 W power setting was used for tissue coagulation and 130 W for tissue cutting were used.

Uterine septa and adhesions were divided utilizing a ball or twizzle electrode respectively. Submucous myomata and endometrial polyps were vaporized and resected. All polyps were removed by incising the stalk with the twizzle electrode. Myomas were coagulated at the base and linearly incised into small pieces, using either the twizzle or spring electrode and removed with a grasper.

All tissues were removed and sent for histopathologic evaluation.

During and after operative procedure, patients were asked to record their degree of pain by means of a visual analogue scale (VAS). Specifically, pain control was scored on a rank scale ranging from 1–5, indicating: 1 = no pain; 2 = slight pain; 3 = tolerable pain; 4 = severe pain; 5 = intolerable pain (Pellicano *et al*., 2002). Post-operative pain score was evaluated immediately after surgery, 15 min, 60 min, 24 h and 3 days after the procedure.

Postoperatively, analgesics were administered when requested by the patient. The analgesics consisted of ketoprofene 100 mg i.m. or ketorolac 30 mg i.m.

Satisfaction rate was assessed before the patients' discharge. Each woman had to answer to the following question: ''What is your level of satisfaction regarding the surgical procedure performed?'' Women had to choose between three different assessments of satisfaction: high satisfaction, moderate satisfaction and no satisfaction (Pellicano *et al*., 2002). Patient were discharged once they had no discomfort.

We determined that 80 patients per group would have >80% power of detecting a difference of 0.75 SD in the pain score. The statistical analysis was performed with the use of a commercial software program (Statistica for Windows, Statsoft, Inc., Tulsa, USA). Differences in age and parity were compared with the use of the two-tailed Student's *t*-test for unpaired data. Differences in operative time and amount of saline solution used and the mean discharge time between the two groups were compared using the Wilcoxon sum rank test. A repeated-measures analysis of variance (ANOVA) was performed to detect differences in postoperative pain scores between the two groups. Satisfaction rate was compared with the χ^2-test. $P < 0.05$ was considered as statistically significant.

Results

The two groups were comparable for age, parity, and indications for hysteroscopy (Table I).

Indication for surgical hysteroscopy were submucous myomata (n = 47), uterine septum (n = 12), intrauterine adhesions (n = 55) and endometrial polyps (n = 52) (Table I). Polyps ranged in size from 5 mm to 1 cm, and were both pedunculated and sessile; the vast majority of myomas were 1–2.5 cm. In two cases myomas were 3–3.5 cm.

Operative data are shown in Table II. The amount of saline used varied from 400–1200 ml. All procedures finished within 35 min. No differences were noted between the two groups in terms of operative and discharge times (Table II). No significant complications occurred during surgery. The main complication was related to vagal reaction and associated symptoms (e.g. pallor, nausea and vomiting) (Table II).

Pain control during and after surgery is reported in Table III. There were no significant differences in the pain experienced during the procedure between the two groups. Postoperative pain score did not differ between the two groups, at 15 or 60 min, 24 h or 3 days. Specifically, during the procedure pain scores were 1.8 ± 0.8 and 1.6 ± 0.7 in groups A and B

Table I. Clinical characteristics and indications of 166 patients undergoing operative hysteroscopy

Group	A: local anaesthesia	B: conscious sedation
No. of patients	82	84
Age (years)[a]	33.5 ± 4.1	32.6 ± 3.9
Parity[a]	0.7 ± 0.2	0.8 ± 0.4
Submucosal myoma <2 cm (n)	13	11
Submucosal myoma >2 cm (n)	10	13
Endometrial polyps (n)	28	24
Septum (n)	7	5
Sinechiae or intrauterine adhesions (n)	24	31

[a] Values are mean ± SD.

Table II. Operative data and complications data of 166 patients undergoing operative hysteroscopy

Group	A: local anaesthesia	B: conscious sedation
Operative time (min)[a]	22.3 ± 7.5	20.8 ± 5.1
Volume of normal saline used (ml)[a]	930 ± 270	850 ± 190
Discharge time (min)[a]	95 ± 25	105 ± 20
Uterine perforation (*n*)	–	–
Fluid overload (*n*)	–	–
Haemorrhage (*n*)	–	–
Pallor/hypotension (*n*)	4	5
Nausea and vomiting (*n*)	3	4

[a] Values are mean ± SD.

Table III. Pain control and satisfaction rate of 166 patients undergoing operative hysteroscopy

Group	A: local anaesthesia	B: conscious sedation
Pain during the procedure[a]	1.8 ± 0.8	1.6 ± 0.7
Postoperative pain at 15 min[a]	1.6 ± 0.9	1.5 ± 1.0
Postoperative pain at 1 h[a]	1.5 ± 1.1	1.2 ± 0.6
Postoperative pain at 24 h[a]	0.5 ± 0.3	0.7 ± 0.4
Postoperative pain at 3 days[a]	0.2 ± 0.1	0.2 ± 0.1
Requirement for postoperative analgesics (patients = *n*)	5	4
Satisfaction rate (%)		
Very satisfied	64.6	66.7
Moderately satisfied	27.8	29.7
Not satisfied	7.6	3.6

[a]VAS score, mean ± SD.

respectively. After the procedure, the pain scores were 1.6 ± 0.9 versus 1.5 ± 1.0 (group A versus group B respectively) after 15 min, 1.5 ± 1.1 versus 1.2 ± 0.6 (group A versus group B respectively) after 60 min, 0.5 ± 0.3 versus 0.7 ± 0.4 (group A versus group B respectively) after 24 h and 0.2 ± 0.1 versus 0.2 ± 0.1 (group A versus group B respectively) after 3 days.

Only nine patients (5 and 4 patients in groups A and B respectively) required postoperative analgesics (Table III).

Satisfaction rates are also reported in Table III. No significant difference in the satisfaction rate was observed between women treated with local anaesthesia and conscious sedation. In detail, 64.6% of women in group A and 66.7% of women in group B considered themselves to be very satisfied after operative hysteroscopy; 27.8% of women of group A and 29.7% of group B were moderately satisfied with the procedure and only 7.6% of group A and 3.6% of group B were not satisfied after the procedure (Table III).

Discussion

Our study suggests that there is no difference between local anaesthesia and conscious sedation in terms of pain control and patients' satisfaction when performing an operative hysteroscopy with a bipolar electrosurgical system.

In our experience the versapoint system has been shown to be safe and versatile, especially in an outpatient setting. Since the versapoint electrode is small and the hysteroscope has a maximum diameter of 5.5 mm, there is still enough room in the uterine cavity for manipulation, in contrast to the larger resectoscopes; furthermore, high pressure is not needed in order to create more space to perform the intervention.

Advantages of a low pressure environment include less absorption of NaCl 0.9%; (in case of excessive absorption of saline solution, pulmonary and brain oedema with risk of death may still occur) (Kung *et al*., 1999; Vilos, 1999); less dilation of the cavity, with the objective that patients should experience less pain [pain during hysteroscopy occurs with cervical os dilatation and uterine cavity distension; the introduction of small diameter hysteroscopes has eliminated the need for general anaesthesia, allowing the performance of in-office (Lindheim *et al*., 2000) or outpatient hysteroscopy (Kung *et al*., 1999)].

Although some authors suggest the administration of conscious sedation with or without a paracervical block (Kung *et al*., 1999; Vilos, 1999), others have reported the need for general anaesthesia (Fernandez *et al*., 2000; Golan *et al*., 2001). In this study we have compared the efficacy of just local anaesthesia or conscious sedation in terms of satisfaction, intra and postoperative pain.

A low incidence of vagal reactions in both groups was observed. Paracervical infiltration was effective as conscious sedation, to reduce discomfort and possibly prevent vagal reactions. Furthermore this technique can be performed in an outpatient setting with good compliance for patients and a reduced discharge time, without the need for general anaesthesia.

We believe that, using this approach, a high percentage of patients with endometrial polyps and selected patients with submucous fibroids, uterine synechiae and uterine septa could be effectively managed as outpatients.

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