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J. of Ambulatory Surgery 12 (2006) 181–185

Ambulatory Surgery

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Use of paracervical analgesia for outpatient hysteroscopic surgery: A randomized, double-blind, placebo-controlled study

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Received 16 August 2005; accepted 28 November 2005
Available online 23 January 2006

Abstract

Twenty-five women receiving sedation for outpatient hysteroscopic polypectomy were injected with 0.25% bupivacaine 10 mL (paracervical group) and another 25 received the same volume of saline (control group) at the cervical fornix. Both groups were given target-controlled propofol sedation during the procedure. More propofol (mg/min) was needed for adequate anesthesia in the control group compared to the paracervical group (6.5 versus 4.6). In addition, the postoperative pain scores were lower in the paracervical group than in the control group. Hemodynamic changes and postoperative side effects were similar in the two groups. This prospective, randomized, double-blind, placebo-controlled study confirmed the effective use of paracervical blocks. This approach has the effect of reducing the amount of intraoperative propofol and decreasing postoperative pain in outpatient hysteroscopic surgery.

Keywords: Outpatient hysteroscopy; Paracervical block; Postoperative pain; Propofol

1. Introduction

Outpatient hysteroscopy has replaced traditional dilatation and curettage under general anesthesia for diseases involving the uterine cavity. This effective alternative has been shown to have an improved sensitivity for diagnosis of 98% compared to 65% for dilatation and curettage [1,2]. This has the advantage of allowing direct visualization of the uterine cavity, thus more easily distinguishing between polyps and myomas, as well as allowing for the removal of small polyps hysteroscopically [3].

In a recent review of hysteroscopy, success rates are reported from 69 to 100% and acceptability rates, assessed by questionnaires, ranged from 83 to 99% [4]. The most common reason for failure is pain. When analgesia protocols are reviewed, no one is better than another for the control of pain. Paracervical anesthesia can reduce pain and vasovagal reactions at hysteroscopy [5]. However, recent reports have failed to find substantial or conclusive evidence for the use of the paracervical block as the sole anesthetic in outpatient hysteroscopy [6–10]. The technical approach including grasping the cervix with a tenaculum and injection of local anesthetics can be more painful than the hysteroscopy itself [11].

The purpose of this prospective, randomized, double-blind, placebo-controlled trial was to assess the postoperative analgesic efficacy of preoperative paracervical block using 0.25% bupivacaine for outpatient hysteroscoic polypectomy. We also evaluated the sparing effect of propofol after paracervical analgesia.

2. Materials and methods

This study was approved by the Hospital Ethics Committee for clinical research. Fifty women scheduled for

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doi:10.1016/j.ambsur.2005.11.004

outpatient hysteroscopic surgery, to remove small cervical polyps, were enrolled after written consent was obtained. Participants were randomized into two groups using a computer generated block number put inside a sealed envelope. The randomization and medication were prepared by a nurse who was not involved in the procedure. The surgeon, anesthesiologist and the patient were all blinded to the identity of the medication used. No premedication was given.

After baseline recording of electrocardiogram, heart rate, noninvasive blood pressure and peripheral oxygen saturation, a standardized sedation regimen was initiated in the lithotomy position. The target-controlled infusion (TCI) system runs on a microcomputer connected to an infusion pump (Becton-Dickinson infusion system, Le Grande Chemin, France). An infusion of propofol with a preset target concentration of 4.0 μg/mL was started until the patient had reached and maintained adequate sedation (sedation level 5 on a 1–5 sedation scale: eyes closed, not aroused on mild physical stimulation). A bivalve speculum was then inserted to expose the cervix under antiseptic conditions. The anterior lip of the cervix was grasped with a single-tooth tenaculum. A paracervical block was performed using a 25-gauge spinal needle. The paracervical group ($n = 25$) received 10 mL of 0.25% bupivacaine and the placebo group ($n = 25$) received the same volume of normal saline. After negative aspiration, a solution was injected at 4 and 8 o'clock around the cervical fornix. Hysteroscopy was started 5 min after the injection. No prior cervical dilatation was performed. A rigid 25.5 French hysteroscope with a 30° fore-oblique view (Hystero-Resectoscope, Richard Wolf GMBH, Knittlingen, Germany) was inserted into the uterine cavity under direct vision. Uterine distension was maintained by a steady stream of glycin solution (Urion, Choongwae Pharma Corp., Whasung, Korea) at 100 mmHg using a hystero-insufflator (2220 Hystero-Pump, Richard Wolf GMBH, Knittlingen, Germany).

Easy operability without patient's movement was the main end point of the sedation. This was defined as a deep sedation in which the patients achieved unconsciousness but kept purposeful responsiveness with intolerable pain. If this clinical end point was not reached with the target concentration of 4 μg/mL, the target concentration was increased in steps of 0.5 μg/mL until the procedure could be performed. Once sedation was properly maintained, the target concentration was decreased in steps of 0.1 μg/mL every 1 min. When an inadequate sedation sign was observed (making a grimace, movement or abrupt increase of heart rate) the target concentration was increased in the same way. During the entire procedure, 5 L/min of oxygen was administered via face mask. Positive pressure ventilation was available as required in the event of hypoxemia ($SpO_2 < 90\%$). No opioids were administered.

Blood pressure and heart rate were measured and recorded at 2 min intervals during the procedure. Total dose of propofol, target-concentration, calculated-concentration and effective site-concentration of propofol on the TCI system, were recorded at the end of surgery. Each woman was asked to report the pain experienced using the visual analogue pain score (VAS from 0 to 10) before the sedation, 1 h after the procedure, at discharge and 24 h after procedure by direct in person or telephone interview. For postoperative pain in the recovery room, 30 mg intramuscular ketorolac tromethamine was given if needed. All patients were instructed to take 400 mg of ibuprofen orally every 6 h for 24 h after discharge whether or not they were experiencing pain.

The patients were assessed regularly to establish their readiness for discharge with 15 min interval: stable vital signs, controllable pain, level of nausea, ability to walk without dizziness and ability to retain oral fluids. An independent observer, blinded to the study protocol, collected the data in the recovery room.

A power analysis was performed to determine the sufficient sample size required to establish a significant difference in the hemodynamic variables and in the postoperative pain scores. Data used was collected from a preliminary study, using an α-value of 0.05, and power of 0.9. All results are expressed as the mean ± S.D. or by percentage. Student t-test and Mann–Whitney U-test where appropriate were used for the study variables. Repeated measured ANOVA was performed to compare changes of intraoperative hemodynamics. Chi-square and Fisher's exact test were applied to the variables of postoperative assessments. A P-value < 0.05 was considered statistically significant. Statistical calculations were performed using SPSS 10.0.

3. Results

Both groups were similar in terms of age, weight, height and parity (Table 1). The mean duration of hysteroscopy was longer in the control group than in the paracervical group (Table 2). In addition, significantly more propofol was used for sedation in the control group compared to the paracervical group. During the procedure, total fluid administered

Table 1
Patient characteristics of the two groups

	Control group ($n = 25$)	Paracervical group ($n = 25$)
Age (years)	41.4 ± 9.3	39.5 ± 8.2
Weight (kg)	58.5 ± 7.1	55.7 ± 6.3
Height (cm)	161.3 ± 9.7	159.8 ± 8.8
Parity		
Nulliparous	2 (8)	3 (12)
Multiparous	23 (92)	22 (88)
Menopausal status		
Premenopausal	18 (72)	16 (64)
Postmenopausal	7 (28)	9 (36)

Values are given as mean ± S.D. or number of patients (proportion). There are no significant differences between the two groups.

Table 2
Intraoperative data and discharge time of the two groups

	Control group ($n=25$)	Paracervical group ($n=25$)
Duration of surgery (min)	22.1 ± 11.5	16.3 ± 8.6*
Dose of propofol (mg/min)	6.5 ± 1.0	4.6 ± 1.4*
Fluid administered (mL)	235.4 ± 66.7	242.1 ± 46.7
Urion used (mL)		
Input	3718 ± 2885	2184 ± 2299
Output	3206 ± 2505	2607 ± 1929
Discharge time (min)	104.8 ± 33.9	89.9 ± 38.9

Values are given as mean ± S.D.
* $P<0.05$ compared to the control group.

intravenously as well as total urion used were similar in the both groups. Discharge time from the end of procedure in the paracervical group was shorter when compared to the control group, but these differences were not statistically significant.

At the end of the procedure, the target concentration (target conc.), calculated concentration (calculated conc.) and effective site concentration (effective conc.) of propofol on the TCI system are presented in Table 3. The concentrations of propofol administered for the maintenance of sedation were significantly lower in the paracervical group when compared to the control group.

The blood pressure and heart rate measures during sedation and the procedure showed no significant differences between the two groups, although there was a trend to lower values when these parameters were compared to the baseline measures (Fig. 1).

The postoperative pain scores, at one hour after the procedure and at discharge were significantly lower in the paracervical group compared to the control group (Fig. 2). At discharge, pain scores in the paracervical group were almost zero these measures were significantly lower than in the control group. More patients received intramuscular ketorolac, as an analgesic rescue, for postoperative pain in the control group when compared to the treatment group.

There were no major complications and no patient required hospital admission after the hysteroscopy. There was no case of local anesthetic intravasation (persistent bradycardia and severe hypotension, tremor, convulsion, etc.) observed. The incidence of shoulder tip pain, nausea, dizziness and headache were similar in the both groups (Table 4).

Table 3
The concentrations of propofol on the TCI system for sedation at the end of hysteroscopy

	Control group ($n=25$)	Paracervical group ($n=25$)
Target conc. (μg/dL)	5.16 ± 1.4	3.36 ± 1.0*
Calculated conc. (μg/dL)	5.17 ± 1.4	3.39 ± 0.9*
Effective conc. (μg/dL)	5.04 ± 1.4	3.75 ± 1.1*

Values are given as mean ± S.D. Conc.: concentration.
* $P<0.05$ compared to the control group.

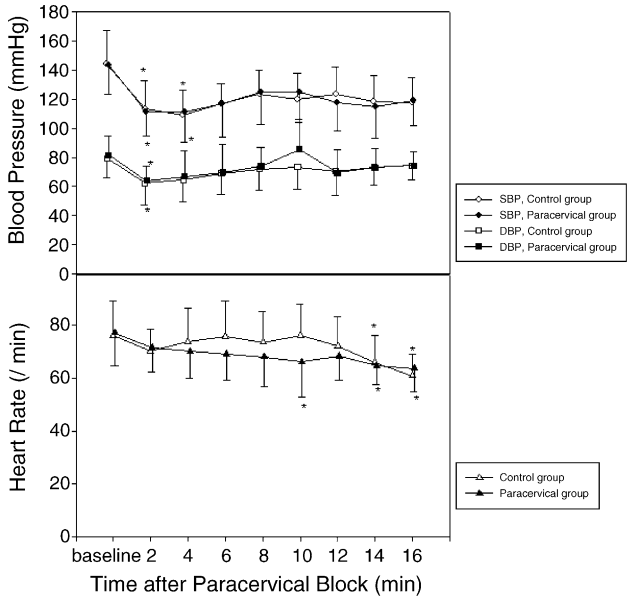

Fig. 1. Blood pressures and heart rates during the procedure. The changes of systolic and diastolic blood pressures were similar in the two groups. Heart rates of every epoch showed no significant differences between the groups. *$P<0.05$ compared to the baseline values.

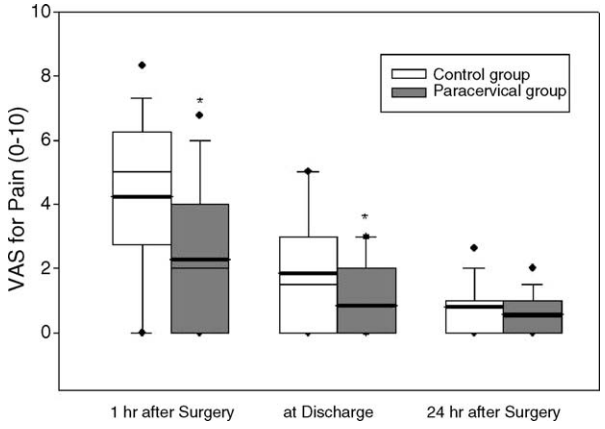

Fig. 2. Postoperative pain scores. VAS in 1 h after procedure and at discharge were significantly lower in the paracervical group than in the control group. However, VAS at 24 h after procedure was similar in the two groups. Box plots are showed 5th/95th percentile with entire ranges (dots), means (bold solid lines), and median (simple solid lines). *$P<0.05$ compared to the control group.

Table 4
Postoperative complications in the two groups

	Control group ($n=25$)	Paracervical group ($n=25$)
Ketorolac rescue	4 (16%)	0 (0%)*
Shoulder tip pain	2 (8%)	1 (4%)
Nausea	5 (20%)	6 (24%)
Dizziness	4 (16%)	3 (12%)
Headache	1 (4%)	1 (4%)
Urinary difficulty	0 (0%)	1 (4%)

Values are given as the number of patients (proportion).
* $P<0.05$ compared to the control group.

Intraoperative bradycardia and hypotension occurred more frequently in the paracervical group (2.8%) compared to the control group (0%), but these findings were not statistically significant. All of the participants recovered spontaneously after a few minutes. The number of patients needed a positive pressure ventilation for hypoxemia was 2 (8%) in the control group and 1 (4%) in the paracervical group ($P > 0.05$). In one patients of them reached 82% SpO_2 (lowest value), recovered immediately after positive ventilation with oxygen. One patient in the paracervical group complained of difficulty of urination after the procedure but recovered uneventfully after two and half hours.

4. Discussion

Peripheral nerve blocks can be used as part of a multimodal analgesic technique to provide safe intraoperative and effective postoperative pain management with minimal side effects. Many studies have shown that patients who receive peripheral nerve blocks experience reduced postoperative pain and analgesia requirements and report improved satisfaction with their pain management [12,13]. In the outpatient setting, peripheral nerve blocks have facilitated early ambulation and discharge by decreasing side effects of sedative drugs, such as drowsiness, nausea and vomiting [14,15]. However, the propofol concentrations reached in the control group are indicative of general anesthesia; if sedation is the goal, providing separate analgesia such as with paravervical blocks is critical.

The results of the present study suggests benefits from paracervical blocks using 0.25% bupivacaine combined with propofol sedation for patients at higher risk for experiencing pain, especially those with cervical stenosis, polyps or adhesions. In addition, patients with a high level of anxiety were considered at higher risk for pain. However, there are limitations. The use of peripheral nerve blocks requires skilled and knowledgeable clinicians. Clinicians with specific technical expertise are required for the administration of the nerve block and other, equally skilled clinicians are required to monitor patients intraoperatively and postoperatively. Furthermore, additional time is required for induction and onset of the effects of the block. This time requirement could be met easily by administering the block before surgery in a designated preoperative holding area where appropriate monitoring is available. However, the expected onset time of the paracervical block using lidocaine has been known less than 5 min [5,9,10], the impact of this onset period on the sedation may be minimal in the clinical use.

We responded to the patient's movement and heart rate changes by changing the target-concentration of propofol. In this study, we assessed adequacy of anesthesia by the absence of patient movement. In a report by Jacoby et al. [16] movement is reported to be a sensitive sign for assessing adequacy of anesthesia, since the EEG only monitors hypnosis. This assumes that adequate anesthesia involves both prevention of movement in response to a pain stimulus (analgesia) and hypnosis. The heart rate and electrocardiogram can be also used to monitor anesthetic adequacy. For example, an increase in the degree of respiratory sinus arrhythmia accompanies decreases in the depth of propofol anesthesia [17]. Although these signs are most extensively used to monitor anesthesia, they are modified by disease, drugs and surgical technique. In addition, the degree of interpatient variability is high. Furthermore, these clinical signs are not always helpful in detecting awareness under anesthesia. Measuring and monitoring of the depth of sedation using a processed-EEG technique such as bispectral analysis could have been helpful.

In conclusion, we confirmed that preoperative use of paracervical blocks with 0.25% bupivacaine has a propofol sparing effect during outpatient hyteroscopic surgery. This protocol has the benefit of improving postoperative pain management until the patient discharge.

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