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Pre-emptive analgesia by nerve stimulator guided pudendal nerve block for posterior colpoperineorrhaphy

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ABSTRACT

Objective: To assess the effect of pre-emptive analgesia by bilateral nerve stimulator-guided pudendal nerve block (PNB) on pain intensity and consumption of analgesics following posterior colpoperineorrhaphy.

Study design: Prospective randomized observer-blinded study. The study included 130 patients who were scheduled to undergo posterior colpoperineorrhaphy under general anesthesia (GA). They were invited to enroll in the study during the period from October 2009 to August 2011 at TAIBA Hospital in Kuwait. Patients were randomly allocated to two groups of 65 patients each: GA alone or GA combined with pre-emptive nerve stimulator-guided PNB with 10 mL of 0.25% bupivacaine in each side. The primary outcome measures were VAS pain scores and postoperative analgesic consumption.

Results: Postoperative average VAS pain scores, IM pethidine consumption and IV paracetamol consumption during the first 24 h; were highly significantly lower in the PNB group compared to the GA alone group. This technique was also associated with a significantly higher overall patient satisfaction compared to GA alone, without obvious side effects.

Conclusion: Pre-emptive analgesia by bilateral nerve stimulator-guided PNB is a simple and useful technique that when combined with GA was found to substantially reduce postoperative pain and consumption of analgesics during the first 24 h postoperatively, and shorten the time to return to normal activities compared to GA alone for patients undergoing posterior colpoperineorrhaphy. The use of PNB was also associated with a high overall patient satisfaction. Thus, the results of the present study may recommend the use of nerve stimulator-guided PNB in posterior colpoperineorrhaphy patients.

1. Introduction

The concept of pre-emptive analgesia to reduce postoperative pain was founded on a series of successful animal experimental studies that demonstrated central nervous system plasticity and sensitization after nociception [1]. Pre-emptive analgesia is defined as an antinociceptive treatment that prevents the establishment of altered central processing of afferent input, which amplifies postoperative pain [2]. By decreasing the altered central sensory processing, pre-emptive analgesia is thought to consequently decrease the incidence of hyperalgesia and allodynia after surgery [3].

Traditionally, colporrhaphy is a surgical procedure to correct genital prolapse. An abnormal or subjectively wide vagina may be associated with sexual dysfunction, and recently some gynecologists have performed colporrhaphy on patients with a sensation of a wide vagina in whom loss of the ability to experience orgasms was the main symptom [4].

Pudendal nerve block (PNB) provides analgesia of the perineum [5]. A peripheral nerve stimulator, which is an excellent teaching method for regional anesthesia, helps the anesthesiologist in this type of blockade due to location monitored by perineal muscle contraction [6].

The purpose of this prospective randomized observer-blinded study was to assess the effect of pre-emptive analgesia by bilateral nerve stimulator-guided pudendal nerve block on pain intensity and consumption of analgesics following posterior colpoperineorrhaphy (posterior repair and perineoplasty).

2. Materials and methods

This is a prospective randomized observer-blinded study conducted at TAIBA Hospital in Kuwait during the period from October 2009 to August 2011. One hundred thirty women who were scheduled to undergo posterior colpoperineorrhaphy under

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general anesthesia were invited to enroll in the study. The CONSORT 2010 statement was followed in reporting this study.

Inclusion criteria included American Society of Anesthesiologists (ASA) physical status I–II and age between 25 and 45 years. Exclusion criteria included intolerance to local anesthetic agents or narcotics, coagulation disorders, ASA physical status of more than II, history of a major psychiatric disorder, chronic pain syndrome, history of substance abuse, and current opioid use. The study was approved by the hospital's Ethics Committee. Patients were provided with complete information about the techniques of analgesia and anesthesia.

All included participants were asked to participate in the study by the study personnel soon after admission to the ward and a written consent was obtained from each woman. Patients were randomly allocated to two groups of 65 patients each: general anesthesia alone (group I) or general anesthesia combined with pre-emptive analgesia by bilateral nerve stimulator-guided pudendal nerve block (group II) with 10 mL of 0.25% bupivacaine (Marcaine, Abbott Hospital Products, Abbott Park, IL, USA) in each side.

Randomization was performed through a computer-generated, random-number list. The random number list was generated by means of the QuickCalcs (GraphPad Software Inc., La Jolla, CA, USA). The group assignment numbers were sealed in an envelope and kept by the study supervisor. After the written consent was signed, the opaque envelope was unsealed to determine which analgesic technique would be performed.

All subjects received antibiotic prophylaxis with ceftriaxone 1 g intravenously within an hour before surgery. All patients were premedicated by midazolam 0.2 mg/kg I.V. in the holding area. Then general anesthesia was induced by IV fentanyl 1–1.5 μg/kg, propofol 1–2 mg/kg and rocuronium 0.6 mg/kg to facilitate tracheal intubation, then rocuronium 0.15 mg/kg as maintenance. Anesthesia was maintained with nitrous oxide 50% and isoflurane 0.5–1.0 MAC in oxygen. The lungs were mechanically ventilated, and the end-tidal carbon dioxide concentration was maintained at 30–40 mmHg.

After induction of general anesthesia and draping, and before starting surgery, pudendal nerve blocks were performed by the same anesthesiologist, with women in the lithotomy position, according to the transperineal approach described by Bolandard [5]. The puncture site was located at the intersection of a line running from the superior aspect of the anus to the medial edge of the ischial tuberosity. After skin disinfection, a 100 mm nerve stimulator needle (MultiStim, PAJUNK®, Germany) connected to a nerve stimulator (MultiStim VARIO Nerve Stimulator, PAJUNK® MEDIZINTECHNOLOGIE GmbH, Germany) was introduced. The needle direction was perpendicular to the skin in all planes. Stimulation was begun using 2 mA current for 0.1 ms at 1 Hz. Motor responses indicating successful stimulation of the pudendal nerve included anal sphincter contraction, vulva constrictor muscle contraction, and movement of the clitoris [5]. When the best motor response at the lowest intensity (0.5–0.6 mA) was obtained, the study solution was injected in 5 mL increments with negative aspiration before each increment [7]. Each patient in the PNB group received a 10 mL pudendal nerve block injection (0.25% bupivacaine) in each side.

All surgeries were performed transvaginally under general anesthesia. Before the end of surgery, all patients received IM pethidine (l mg/kg) for postoperative analgesia (as starting analgesia). After surgery, all patients were monitored in the recovery room for 30 min to 1 h, after which time the patient was shifted to the postoperative ward.

Postoperative pain intensity was then assessed by using a visual analog pain scale (VAS) [8] at 1, 3, 5, 7, 18, and 24 h after surgery [9]. The patient-derived VAS scores of pain with the 100 mm gauge (based on a 0–100 linear VAS: 0 = no pain, 100 = worst pain imaginable) were recorded during the first 24 h postoperatively. Patients with a VAS score $>$ 50 mm during the stay in hospital were given IM pethidine (l mg/kg) as supplemental analgesia, whereas patients with VAS score of 30–50 mm were given IV paracetamol (Perfalgan® IV infusion, Bristol-Myers-Squibb, Italy) (with a maximum dose of 1 g every 6 h), starting in the postoperative ward and for 24 h postoperatively. Patients with a VAS score $<$ 30 mm received no supplemental analgesics.

The average scoring of pain was calculated for each woman at the end of the 24 h study period. In addition, overall patient satisfaction with analgesia was assessed by a second anesthesiologist on postoperative day 1 using a 4-point verbal scale ranging from very satisfied to very dissatisfied (1: very dissatisfied, 2: dissatisfied, 3: satisfied, 4: very satisfied) [10].

Demographic data, duration of surgery, adverse effects of the pudendal nerve block, recovery room stay, medical and surgical complications, postoperative nausea and vomiting (PONV), urinary retention, pethidine consumption in milligrams, VAS scores of pain intensity before any analgesia, average VAS pain scores and the need for supplemental analgesics during the 24 h study period, patient satisfaction and duration of hospital stay were recorded. Patients had appointments at the outpatient clinic 4 days, 8 days and 2 weeks after discharge from hospital and the time to resume normal activities was recorded.

The primary outcome measures of the study were average postoperative VAS pain scores and postoperative analgesic consumption. Secondary measures included adverse effects of the pudendal block, medical and surgical complications, length of hospital stay and time to resume normal activities.

Sample size calculation was performed before patients' recruitment. Based on a previous report; to detect a clinically significant reduction in VAS pain scores from 40 mm to 20 mm, it was necessary to recruit 64 women per group (5% level of significance with 80% power and anticipated effect size of 0.5). The sample size calculation was made using *A priori Sample Size Calculator for a Student's t-Test*. Therefore, we decided to include 65 women per group.

Demographic, clinical, surgical and anesthetic outcomes and VAS scores of each group were compared using *t*-test, Chi-square test, Fisher exact test and repeated measures analysis of variance (ANOVA), where appropriate. P values >0.05 were considered statistically non-significant, P values <0.05 were considered statistically significant and P values <0.01 were considered statistically highly significant for all comparisons. The Windows version of SPSS 11.0.1 (SPSS Inc., Chicago, IL) was used for data management and statistical analysis.

3. Results

One hundred forty-two patients were enrolled in the study, of whom 12 dropped out before randomization (five cancelled their surgery, four decided to undergo spinal anesthesia, and three gave no specific reason for not participating in the study) (Fig. 1). Of the 130 patients who had been randomized for the study, no patients (from either group) dropped out after randomization. All patients received the allocated intervention. All included patients were followed up and all entered into the final data analysis.

The two groups were similar with regard to age, parity, weight, height, body mass index, clinical characteristics, and operative time. However, PNB patients had a highly significant shorter duration of recovery room stay ($P < 0.01$) compared to GA alone patients (Table 1). Successful pudendal nerve stimulation was achieved in all patients in the PNB group and the mean minimal intensity of stimulation was 0.6 mA.