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A Randomized Control Trial of Levobupivacaine, Bupivacaine *Versus* Placebo Extraperitoneal Infusion in Totally Extraperitoneal Laparoscopic Inguinal Hernioplasty

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Background. **Totally extraperitoneal (TEP) laparoscopic inguinal hernioplasty procedure is significantly less painful than open repair, but it is not completely painless. The aim of this study was to compare the effect of extraperitoneal infusion of 0.25% levobupivacaine, 0.25% bupivacaine, and placebo in patients undergoing TEP procedure in terms of pain reduction.**

Methods. **Twenty patients were included in each group for TEP procedure. Group A received 40 mL of 0.9% normal saline, group B received 40 mL of 0.25% bupivacaine, and group C received 40 mL of 0.25% levobupivacaine infused into the extraperitoneal space before closing. Postoperative pain was assessed at 4, 8, 12, 24, 36, and 48 h postoperatively. Analgesic requirement, complications, and overall satisfaction were also recorded.**

Results. **The demographic and surgical characteristics of the patients did not significantly differ among groups. There were no statistical differences among groups in postoperative pain scores, total IV-PCA morphine requirement, complications, and overall satisfaction.**

Conclusion. **Extraperitoneal infusion 40 mL of 0.25% bupivacaine or 0.25% levobupivacaine following TEP procedure did not show any benefit over placebo in terms of pain reduction.** © 2010 Elsevier Inc. All rights reserved.

Key Words: **laparoscopic; hernioplasty; levobupivacaine; bupivacaine; hernia; extraperitoneal; visual analogue pain scores; postoperative analgesia; pain; randomized control trial.**

INTRODUCTION

Totally extraperitoneal (TEP) laparoscopic inguinal hernioplasty has benefits of reduced postoperative pain, a short hospital stay, rapid recovery, and fast return to normal activity. Although TEP procedure is significantly less painful than open repair, it is not completely pain free. Pain following TEP is typically in the lower abdominal wall area and not localized to the small skin incisions [1,2,3]. Extraperitoneal infusion of large volume of 0.25% bupivacaine has been shown to be superior to placebo for postoperative analgesia [4]. However, using the same technique with 0.125% bupivacaine did not show any significant benefits over placebo [5].

Levobupivacaine is an s(–) enantiomer of the racemic bupivacaine with less cardiotoxicity and less neurotoxicity [6,7]. Randomized, double-blinded clinical studies stated that the anesthetic and analgesic effects of levobupivacaine are very similar to those of bupivacaine at the same dose [8,9]. However, sensory block tended to be longer with levobupivacaine [6]. This study aims to compare the effect of extraperitoneal infusion of 0.25% levobupivacaine, 0.25% bupivacaine, and placebo in patients undergoing TEP procedure in terms of pain reduction.

METHODS

Between February 2007 and January 2008, 60 ASA status I-III patients scheduled for elective TEP were enrolled into this double-blinded randomized control trial after informed consent was obtained. All protocols were approved by the ethics committee at Rajavithi Hospital. In this study, patients with a history of previous lower abdominal surgery, recurrent inguinal hernia, bilateral inguinal hernia, intolerance, or adverse reactions to the medications, known or

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expected difficult airway, acute or chronic pain, or recent analgesic drug use were excluded.

Eligible patients were allocated into three groups using block randomization: (1) TEP with 40 mL of 0.9% normal saline in extraperitoneal space; (2) TEP with 40 mL of bupivacaine 0.25% in extraperitoneal space; and (3) TEP with 40 mL of levobupivacaine 0.25% in extraperitoneal space. The TEP procedure was performed by one surgeon using the following technique. A small incision was made just below the umbilicus and abdominal wall was dissected until posterior rectus sheath was reached. The balloon dissection was placed and insufflated until the preperitoneal space was opened. Then the balloon was removed and changed to a Hasson trocar. The other two ports were located at 2 cm above the pubic symphysis (5 mm port) and in the middle between the first and second port (5 mm port). The rectus space was kept open with CO_2 gas at a pressure of 12 mmHg. The parietal peritoneum was dissected and retracted as cephalad as possible. Any accidental tear of the peritoneum was treated with clip, suture, or endoloop. The mesh was placed and transfixed with staples at the Cooper's ligament, transversalis fascia over the iliopubic tract, and transversus abdominis arch. Before closing peritoneal space, 0.9% normal saline or local anesthetic drug was infused into this space according to the randomized protocol and patients were placed in a 30° sitting position after infusion. The operation was carried out under general anesthesia using the same protocol as followed. No premedication was given. Standard monitoring was used and baseline blood pressure and pulse were recorded. General anesthesia was induced with propofol 2 mg/kg and fentanyl 1.5 μg/kg. Oropharyngeal intubation was facilitated by the administration of vecuronium 0.1 mg/kg and maintained with incremental IV dose of 1–2 mg. After intubation, anesthesia was maintained with oxygen, 70% N_2O, 1%–2% sevoflurane, and fentanyl 0.5–1 μg/kg to maintain blood pressure and pulse within 20% of patient's baseline values. Patients were ventilated with positive pressure ventilation to keep at $ETCO_2$ 30–35 mmHg. The anesthesiologist was blinded to patient's treatment assignment. At the end of the operation, residual neuromuscular blockade was antagonized with neostigmine 2.5 mg and atropine 1.2 mg. After endotracheal tube extubation, patients were transferred to the recovery room and were attended by anesthetic nurses who were also blinded to the patient's treatment assignment.

Demographic data, intraoperative fentanyl used, operative time, and anesthetic time were recorded. Patients were assessed at 4, 8, 12, 24, 36, and 48 h postoperatively. Both patients and assessor were blinded to randomization. Factors assessed included visual analogue pain scores (VAS); time to the first rescue analgesia; analgesic requirement; postoperative complications such as nausea, vomiting, pruritus, constipation, urinary retention, hematoma, and infection; and overall satisfaction. For measurement of VAS, all details of VAS were explained to patients after enrollment and were repeated with a test at admission. Patients were asked to mark a point on a 10 cm line marked "no pain" at one end and "most severe pain imaginable" at the other end. Patients' analgesic requirements were provided by intravenous morphine *via* patient controlled analgesia (IV-PCA) device. The IV-PCA device was programmed to deliver a 1-mg bolus dose (2 mL) of morphine with a 6-min lock-out period and a 10-mg per h limit dose. Patients were also asked to grade their overall degree of satisfaction with the procedure into one of three categories: fully satisfied, moderately satisfied, or dissatisfied. Routine postoperative care was done in each group. A dose of 1.2 gm clavulanate potassium and amoxicillin trihydrate was given 8-hourly as prophylactic antibiotic during the first 48 h postoperatively. Two tablets of paracetamol were given every 6 h around the clock for all patients.

Statistical Analysis

Continuous variables were reported as mean ± SD and analyzed using one way ANOVA, whereas categorical variables were reported as proportions and analyzed using χ^2 test. Pain score, time to the first rescue IV-PCA morphine analgesia, and the total IV-PCA morphine requirement in the first 48 h postoperatively were reported as medians and analyzed using the Kruskal-Wallis test. A P value less than 0.05 was considered statistically significant.

On the basis of a previous study [10], pain difference between the analgesic group and the control group was 1.5. A sample size of 15 patients per group was calculated to provide 90% power with 2-sided test using a significance level of 0.05.

RESULTS

There were no significant differences in demographic data among the three groups (Table 1). A comparison among the three groups of the visual analogue pain scores showed no significant difference (Table 2).

The median time to the first rescue IV-PCA morphine analgesia of the patients treated with levobupivacaine was lowest among the three groups (Table 3). However,

TABLE 1

Demographic Characteristics of Patients

Characteristics	Control ($n = 20$)	Bupivacaine ($n = 20$)	Levobupivacaine ($n = 20$)	P value
Age (y)	52.75 ± 13.87	51.05 ± 15.08	49.65 ± 17.39	0.819 (*)
Gender				0.343 (†)
Male	18 (90)	18 (90)	20 (100)	
Female	2 (10)	2 (10)	0 (100)	
ASA status				0.650 (†)
1	9 (45)	8 (40)	10 (50)	
2	10 (50)	12 (60)	10 (50)	
3	1 (5)	0 (0)	0 (0)	
Operative time (min)	58.75 ± 15.91	61.80 ± 18.20	69.35 ± 25.22	0.240 (*)
Anesthetic time (min)	89.50 ± 17.69	89.90 ± 19.94	98.50 ± 21.89	0.279 (*)
Fentanyl used (mcg)	106.43 ± 24.24	119.55 ± 32.92	115.23 ± 25.91	0.325 (*)
Number of staples used	4.50 ± 1.05	4.70 ± 0.92	4.85 ± 1.18	0.579 (*)
Site				0.517 (†)
Right	12 (60)	15 (75)	12 (60)	
Left	8 (40)	5 (25)	8 (40)	

Values are mean ± SD or n (%).
Statistics, * = One Way ANOVA, † = χ^2.

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