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■ Original Article

Local Infiltration of Bupivacaine versus Placebo for Post-Operative Pain Relief Following Elective Lichtenstein Hernioplasty: A Randomized Controlled Trial

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ABSTRACT

Introduction: Postoperative pain relief is of paramount importance in any surgery.

Objective: To compare the effect of local infiltration of bupivacaine versus placebo for post-operative pain relief following inguinal hernioplasty.

Materials and Methods: Ours was a prospective randomized controlled trial conducted on 120 patients undergoing elective Lichtenstein hernioplasty. Patients were divided into two groups of 60 each. One group received local infiltration with 10 mL bupivacaine 0.25% below the external oblique aponeurosis and 15 mL bupivacaine 0.25% subcutaneously after completion of the surgical procedure. The other group received an equal amount of normal saline infiltrated in the similar manner. Visual Analogue Scale measured the pain.

Results: The baseline parameters were similar in both the groups. Postoperative pain was significantly decreased in patients receiving bupivacaine ($p < 0.05$). Mean time to first request for rescue analgesic was increased from 245 ± 19.42 minutes to 472 ± 19.42 minutes ($p < 0.05$). The consumption of supplementary analgesics during the 24-hour study period reduced from a mean of 2.8 ± 0.12 to 1.7 ± 0.09 doses in bupivacaine group ($p < 0.05$).

Conclusion: Local infiltration of bupivacaine is an effective modality for post-operative pain relief in inguinal hernioplasty.

Keywords: bupivacaine, analgesia, post-operative, hernia, lichtenstein

INTRODUCTION

Pain is defined by International Association for the Study of Pain as “an unpleasant sensory and emotional experience

associated with actual or potential tissue damage” [1]. Any surgical procedure causes postoperative pain that should be alleviated as soon and as effective as possible to reduce

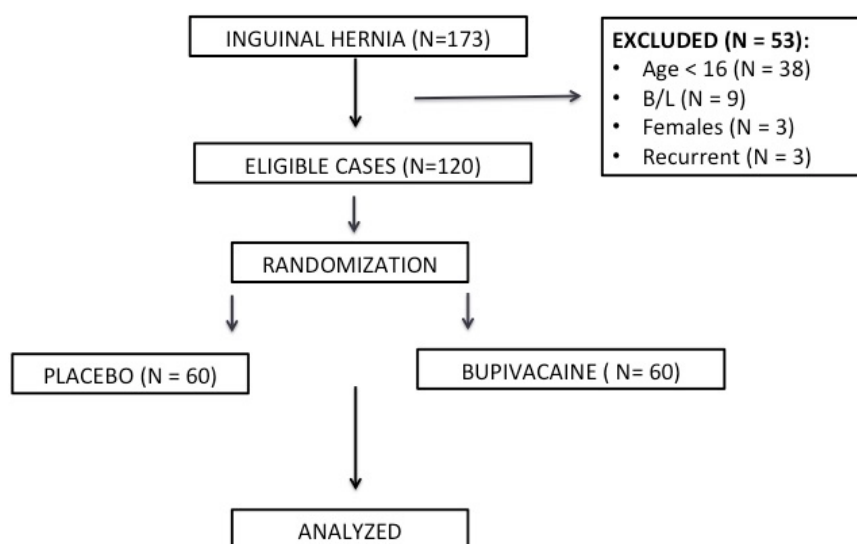


Figure 1. The CONSORT flow diagram of the study

suffering, to promote the healing process to prevent complications. However, clinical pain management after surgery is far from being successful. It is a well-documented fact that post-operative pain is undertreated [2]. Opioids are the mostly used medicine for post-surgical pain control [3]. Among the many other options available for the control of post-operative pain, analgesia delivered through an indwelling epidural catheter or local infiltration of wound site by an anesthetic agent is a safe and effective method for the management of acute postoperative pain [2].

Inguinal hernia repair is one of the most commonly performed surgical procedures. In fact, it is the bread and butter of surgeons. Approximately 800,000 are performed each year in the United States, 100,000 in France, and 80,000 in the United Kingdom [4]. Most patients suffer from pain after inguinal hernia surgery and many develop chronic pain after surgery, which might be, at least in part, a result of undertreated acute postoperative pain [5]. Bupivacaine is a potent agent that belongs to the amide group of local anaesthetics and blocks the generation of pain related action potentials by increasing the threshold of the nerve fibers [6]. The aim of the present study was to compare local infiltration of bupivacaine versus normal saline for post-operative pain relief after inguinal hernioplasty.

MATERIALS AND METHODS

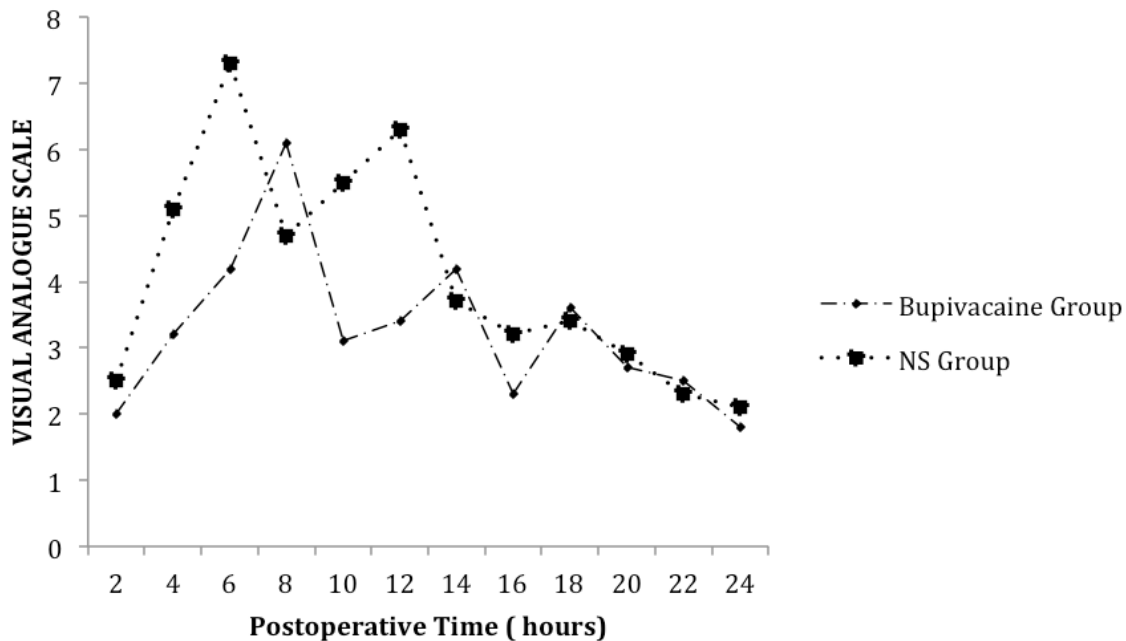
Ours was a prospective randomized controlled trial comprising of a cohort of patients undergoing Lichtenstein hernioplasty with the primary outcome of comparing the post-operative analgesic effects of bupivacaine infiltration versus placebo. Between March 2017 and March 2020, a total of 173 patients with groin hernias were treated by Lichtenstein tension free repair at a district level hospital of

Health Services Kashmir. The sample size of the study was not calculated. All of the cases were admitted on an elective basis and only the uncomplicated hernias were taken up for the study. Exclusion criteria included patients with bilateral hernias, recurrent hernias, females, age less than 16 years and those with who refused to participate in the study. All of the patients were advised to empty their urinary bladder just before surgery. The patients were operated under spinal anaesthesia.

After excluding the patients who were not meeting the study criteria, we were left with 120 eligible patients. The patients were randomly divided into two groups of 60 each by a computer-generated table of random numbers (**Figure 1**). The first author did all the surgical procedures. The hernia defects were classified in accordance with the EHS classification and the defect sizes were measured intra-operatively. After hernioplasty, the first group received infiltration with 10 mL bupivacaine 0.25% below the external oblique aponeurosis (under ultrasound guidance) and 15 mL bupivacaine 0.25% subcutaneously after completion of the surgical procedure. The other group received an equal amount of normal saline infiltrated in the similar manner. Identical containers were used for bupivacaine and saline as a method of allocation concealment. Postoperative pain was measured by visual analog scale (VAS). The pain scores were obtained at 1, 2, 4, 6, 8, 12 and 24 hours postoperatively. Rescue analgesics (Diclofenac 50 mg tablet) were administered if the VAS score was > 6 or on demand. The total diclofenac consumption and time to first request for rescue analgesic were recorded. As the primary endpoint of this study was immediate post-operative pain and analgesic requirement, so long-term follow-up was not done.

Table 1. Baseline Parameters of the two groups

PARAMETER		BUPIVACAINE (n = 60)	PLACEBO (n = 60)	P Value
Mean Age (Years)		53.34 ± 9.42	55.72 ± 8.39	0.9821
Mean BMI (Kg/m ²)		22.45 ± 0.22	23.02 ± 0.31	0.8665
European Hernia Society (EHS) Type (N)	Medial	11 (18.33%)	13 (21.67%)	0.9132
	Lateral	40 (66.67%)	39 (65%)	0.8954
	Combined	9 (15%)	8 (13.34%)	0.8748
Defect Size (N)	I (< 1.5 cm)	10 (16.67%)	11 (18.34%)	0.9231
	II (1.5 – 3 cm)	42 (70%)	43 (71.67%)	0.8986
	III (> 3 cm)	8 (13.34%)	6 (10%)	0.5324

**Figure 2.** The pain scores (VAS) in the two groups over 24 hours revealed a significant difference ($P < 0.05$)

An approval from the institutional ethical committee was obtained for the purpose of this study. This clinical trial was registered with the local trials registry (DHB-13 of 2017). A written and informed consent was taken from the patients for publication and analysis of their data after explaining to them the protocol of the study in their own language. The data thus collected was compiled and analyzed using SPSS version 22 for Mac (IBM Corporation, 2012). To calculate the P-value, Fisher's exact test and Pearson's chi-square test were applied to compare the frequencies for categorical parameters, and the unpaired t-test was used to compare the means (2-tailed) among continuous variables. A P-value < 0.05 was considered significant.

RESULTS

The baseline parameters were similar in both the groups and all efforts were made to minimize the confounding factors (**Table 1**). Our study included cases of direct, indirect and combined uncomplicated primary inguinal hernias. All the cases were operated under spinal anesthesia. Postoperative pain was significantly decreased in patients receiving bupivacaine compared to saline (**Figure 2**, $p < 0.05$). There

was no difference in the post-operative hospital stay of the two groups ($p > 0.05$), and almost all the patients in either of the groups were discharged on the first post-operative day.

There were two peaks above VAS score of 6 in the placebo group as compared to only one peak in the bupivacaine group. Mean time to first request for rescue analgesic was increased from 245 ± 19.42 minutes to 472 ± 19.42 minutes ($p < 0.05$) in the bupivacaine group. The consumption of supplementary analgesics during the 24-hour study period reduced from a mean of 2.8 ± 0.12 to 1.7 ± 0.09 doses in bupivacaine group as compared to saline group ($p < 0.05$). No untoward side effects were noted in either of the groups and none of our patients developed a seroma.

DISCUSSION

To the serious and dedicated surgeon, it would be unthinkable to expect a career without being competent enough in the performance of repair for inguinal hernias. Accounting for 75% of all abdominal wall hernias, and with a lifetime risk of 27% in men and 3% in women, inguinal hernia repair is one of the most commonly performed surgery in the world [7,8]. It is imperative that such a surgery

remains pain free in the post-operative period. Optimizing postoperative analgesia improves clinical outcomes and increases patient satisfaction while uncontrolled postoperative pain can result in significant morbidity and mortality. Infiltration of wounds with local anesthetics not only provides analgesia but also appears to reduce the local inflammatory response to trauma or surgery [3]. The current paper is an attempt to determine the effect of bupivacaine infiltration on post-operative pain in patients with elective inguinal hernioplasty.

The aim of post-operative analgesia is to provide subjective comfort with minimum side effects [9]. It also helps to blunt autonomic and somatic reflex responses to pain and allows early ambulation and restoration of function. If the post-operative pain is not controlled, it leads to detrimental acute and chronic effects [10]. The nociceptive input to the central nervous system leads to activation of neuroendocrine stress response mainly involving the hypothalamic-pituitary-adrenocortical axis. This results in tachycardia, hypertension, and increased myocardial oxygen consumption [11]. In addition, it can decrease the myocardial oxygen supply through coronary vasoconstriction leading to myocardial ischemia and infarction in vulnerable patients. The metabolic changes occurring lead to sodium and water retention, increased blood glucose, and lactate levels. Hyperglycemia leads to poor wound healing and immunosuppression. Nausea and vomiting occur due to nociceptive impulses from viscera and somatic structures [10-12].

The major causes of postoperative pain are the stretching of the wound during surgery and the total length of the fascial incision [13]. Incision leads to an acute inflammatory response in which neutrophils, mast cells and other cells are recruited that secrete various cytokines and lead to stimulation of nociceptors. The stretching of the wound also leads to activation and sensitization of peripheral nociceptors and spinal dorsal horn neurons [5]. Bupivacaine is a long acting local anesthetic agent, which helps in pain alleviation by blocking these nociceptive impulses. In a study by Dierking et al, pain at rest, during mobilization and during cough was significantly decreased in patients receiving bupivacaine compared to placebo [14]. They reported that median time to first request for morphine was increased from 25 minutes to 135 minutes, and the consumption of supplementary morphine during the twenty-four hour study period reduced from four to two doses of 0.1 mg/kg IV or 0.125 mg/kg IM, in patients who received bupivacaine compared to placebo [15]. Ding et al advocated the use of an ilioinguinal-hypogastric nerve block

with bupivacaine 0.25% as an adjuvant during inguinal herniorrhaphy under monitored anaesthesia care for decreasing the pain and analgesic requirements [16]. Our study supplemented these results. Less postoperative pain demonstrated added advantages as it translated into early ambulation, acceptance of orals, and discharge of patients in the bupivacaine group.

In our study, the consumption of supplementary analgesics during the twenty-four hour study period reduced from a mean of 2.8 ± 0.12 to 1.7 ± 0.09 doses in bupivacaine group as compared to saline group. Harrison et al reported that the combination of nerve block and wound infiltration reduced consumption of morphine in the first twenty-four hours after herniorrhaphy, but they failed to show any effect of 0.5% bupivacaine beyond the first six hours after operation [17]. Our patients demonstrated a sustained effect as the first dose of rescue analgesia was given at an average time of 472 ± 19.42 minutes in the bupivacaine group as compared to 245 ± 23.17 minutes in the saline group. The maximum scores of pain were observed at 4 hours postoperatively in the placebo group, presumably due to exhaustion of the effects of spinal anesthesia; however, the maximum scores of pain were observed at 8 hours postoperatively in the bupivacaine group.

The present study has some potential limitations. The sample size was small and the population was homogenous, so extrapolation of results to other parts of the globe may not be valid. Our study was not a double-blinded one. However, the postoperative pain assessment was somewhat blinded as all scoring was performed by the attending nurse who was unaware of the ongoing study. Our study can also be criticized on the plea that cost/benefit ratio was not done. We did not do it as bupivacaine and diclofenac was available free of cost in the hospital as per the hospital health policy. The strength of our study is it being randomized and thus eliminating selection bias.

CONCLUSION

Local infiltration of bupivacaine is an effective modality for post-operative pain relief after Lichtenstein inguinal hernioplasty. It also helps to reduce the overall post-operative systemic pain medication.

DECLARATION OF CONFLICT OF INTEREST

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