A comparative study between the efficacy of fentanyl with bupivacaine 0.5% and buprenorphine with bupivacaine 0.5% for lower abdominal and lower limb surgeries in a Government Tertiary Care Teaching Hospital

V. Muruganantham¹, Nalini²*, Naheed Azar³

¹Junior Resident, ²Associate Professor, ³Professor and HOD
Department of Anesthesiology, Govt. Stanley Medical College, Chennai, Tamil Nadu, India
*Corresponding author email: naliniv1961@gmail.com

Abstract

Background: Pain is one of the most common and uncomfortable consequences of surgery, feared by all. Effective and rapid relief from pain is always a challenge but is necessary for alleviating nociception – induced responses like endocrine-metabolic responses to surgery, autonomic reflexes with adverse effects on organ function, reflexes leading to muscle spasm, and other undesirable results.

Aim of the study: This study was done to compare the efficacy of intrathecal fentanyl with bupivacaine and buprenorphine with bupivacaine for lower abdominal and lower limb surgeries. Materials and methods: Totally 60 ASA I and II patients of both sexes for different lower abdominal and lower limb surgeries were chosen for the study and the patients were divided into two groups of 30 patients in each group. Group F received 3 ml of 0.5% hyperbaric bupivacaine with 25 mcg fentanyl and group B received 3 ml of 0.5% hyperbaric bupivacaine with 75 mcg of buprenorphine. In our study, the time taken to achieve T10 level of the sensory blockade was considered as the time of
onset of sensory block tested with pinprick method, motor block assessed by the onset of Bromage scale 3 and it was found that onset of the sensory block with bupivacaine + Fentanyl was earlier than compared with bupivacaine + Buprenorphine.

**Results:** In the postoperative period VAS scores were significantly low for the buprenorphine group (Group B) when compared with fentanyl group (Group F).

**Conclusion:** To summarize buprenorphine has higher efficacy with intrathecal bupivacaine, prolonged duration of postoperative analgesia and also analgesic-sparing effect in the post-operative period when compared to fentanyl.

**Key words**

Hyperbaric Bupivacaine, Buprenorphine, Fentanyl.

**Introduction**

Spinal anesthesia is the most commonly performed regional anesthesia technique as it is easy to perform, economical and produces rapid onset of anesthesia and complete muscle relaxation [1]. Hyperbaric bupivacaine is the most commonly used intrathecal local anesthetic. However, there is insufficiency with the duration of anesthesia and postoperative analgesia prevails when it is used alone [2]. However, bradycardia and systemic hypotension are the most common side-effects seen with this technique. Marked hypotension may be harmful, particularly in elderly patients with limited cardiac reserve [3]. Levobupivacaine, an amide local anesthetic agent, is the isolated S-enantiomer of racemic bupivacaine. It is the most recent long-acting local anesthetic agent to have been introduced for clinical use [4]. Reports of toxicity with levobupivacaine are scarce, and occasional toxic symptoms are usually reversible with minimal treatment without any fatal outcome. However, levobupivacaine has not entirely replaced bupivacaine in clinical practice [5]. In comparative trials, although its clinical effects were not significantly different from those of bupivacaine, there was some variability in efficacy findings in different clinical populations [6]. The clinical studies available on intrathecal anesthesia with levobupivacaine suggest that it achieves satisfactory surgical anesthesia but with an unpredictable spread of sensory blockade [7]. To improve the block characteristics of intrathecally administered local anesthetics, the addition of adjuvant is widely in practice. Neuraxial opioids are widely used for providing intraoperative and postoperative analgesia without prolonging motor and sympathetic block [8]. Neuraxial administration of opioids along with local anesthetics improves the quality of intraoperative analgesia and also the postoperative analgesia for longer duration [9]. Fentanyl citrate a lipophilic opioid agonist used as an adjuvant to prolong the duration of spinal block. Buprenorphine long acting highly lipophilic opioid used as an adjuvant to prolong the duration of spinal block. Hence the present study was done to compare fentanyl and buprenorphine for the duration of postoperative analgesia [10].

**Materials and methods**

After getting approval from the ethical committee of Government Stanley Medical College, 60 ASA 1 and ASA 2 patients scheduled for elective surgeries and emergency surgeries under subarachnoid block were chosen for the study. The pre-anesthetic check-up was done one day prior to surgery. Patients were evaluated for the systemic diseases and laboratory investigations were done. The procedure of intrathecal block was explained to the patient and written consent was obtained. Patients were educated about the Visual Analog Scale. Preparation of patients included a period of overnight fasting and tablet Ranitidine 150 mg and tablet Alprazolam 0.5mg HS. Speed of onset
and duration of analgesia as determined by lack of appreciation to needle prick at level T10.

Motor Blockade: Speed of onset and duration of the motor blockade as assessed by Bromage scale.

Intraoperative sedation: Assessed using modified Ramsay sedation scale.

Post-operative period: Post-operative pain assessed using the Visual Analog Scale.

**Inclusion criteria:** ASA physical status class 1 and 2 with the age group between 18 – 65 years of either sex were included.

**Exclusion criteria:** Patients with deformities of the spine, hypersensitivity to any of the drugs used in the study, contraindications to subarachnoid block, patient’s refusal, bleeding diathesis were excluded.

**Procedure**

Patients shifted to operating theatre, baseline vitals were recorded. IV access was obtained on the forearm with 18 G intravenous cannula. All patients were preloaded with 15 ml/Kg crystalloid solution 15 minutes before the procedure. Patients were randomly divided into two groups, group F and group B. Under strict aseptic precaution using 23G Quincke needle subarachnoid block was done at level L3 - L4 space. Group F received 15 mg of 0.5% hyperbaric inj. Bupivacaine with 25 mcg of inj. fentanyl; group B received 15 mg of 0.5% hyperbaric inj. bupivacaine with 75 mcg of inj. buprenorphine. Intraoperatively, patients’ vitals HR, NIBP, SpO2, ECG monitored every 2 minutes once for the first 10 minutes, every 10 minutes once for the next 50 minutes, and 15 mins once till the end of surgery. Motor block assessed with modified Bromage Scale.

Bromage 0 – Patient able to move the hip, knee, and ankle.

Bromage 1 – patient unable to move hip, but able to move knee and ankle.

Bromage 2- patient unable to move hip and knee, but is able to move the ankle.

Bromage 3- unable to move hip, knee, ankle.

Intraoperatively if there is hypotension it was treated with a bolus dose of 6 mg inj. Ephedrine intravenously, bradycardia was treated with inj. atropine 0.6 mg intravenously. Postoperatively pain was assessed with a Visual Analog Scale. It is a linear scale with 10 cms line labeled as No pain at one end and worst pain at the other end. 0 = no pain; 10 = severe pain. So the patient simply marks on the line to show the intensity of pain. Analgesics are given if the VAS scores greater than 6.

**Statistical analysis**

Comparative two-group randomized clinical study with 30 patients in each group to study the duration of post-operative analgesia in each group. Statistical analysis was done with student t-test to analyze the data, the p-value was determined. P > 0.05 was not significant, p < 0.05 was significant, and p < 0.001 was highly significant. Data were entered in MS Excel and analysis was done using SPSS 16.0 version. The Independent t-test was used to compare the mean between two groups and ANOVA for more than two groups. Chi-square test was done to find out the association between two categorical variables. P-value of <0.05 was considered as significant.

**Results**

Table - 1 shows that there was no significant difference between the two groups in terms of basic variables.

Table - 2 shows that the mean duration of sensory block was longer among group b compared to group f and it was statistically significant with a p-value of 0.014. The mean duration of motor block was longer among group f compared to group b but it was not statistically significant with a p-value of 0.374. Sensory block onset was shorter in group F. Motor block onset was shorter in group B.

Table - 3 shows Heart Rate, SBP, DBP was significantly lower in group B than group F.
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Table - 1: Demographic details.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Number</th>
<th>Mean (minutes)</th>
<th>Std. Deviation</th>
<th>t</th>
<th>Df</th>
<th>P value</th>
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<tr>
<td>AGE</td>
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<td>30</td>
<td>37.50</td>
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<td>0.134</td>
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<td>160.50</td>
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<td>BMI</td>
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<tr>
<td></td>
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<td>3.43972</td>
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<tr>
<td>GENDER (M/F)</td>
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<td>25/5</td>
<td>CHI-SQUARE = 0.417</td>
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<td>0.519</td>
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<tr>
<td></td>
<td>GROUP F</td>
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<td>23/7</td>
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<tr>
<td>ASA (PS1/PS2)</td>
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<td>5/25</td>
<td>CHI-SQUARE = 0.577</td>
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<td>3/27</td>
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Table - 2: Onset of block.

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<th>STD. DEVIATION</th>
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<td>SENSORY BLOCK</td>
<td>GROUP B</td>
<td>30</td>
<td>3.10</td>
<td>.305</td>
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<td>MOTOR BLOCK</td>
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<td>3.77</td>
<td>.430</td>
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<td>3.87</td>
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Table - 3: Vital signs.

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<td>84.20</td>
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Graph – 1 shows that in Visual Analog Scale – At all hours (6 hours, 12 hours, 18 hours), VAS was significantly lower in Group B than Group F.

Discussion

Levobupivacaine is a relatively new long-acting local anesthetic, with a pharmacological activity very similar to that of racemic bupivacaine but less cardiotoxic and neurotoxic than the racemic bupivacaine [11]. The quest for safer anesthesia procedure with the reduction of local anesthetic dose by addition of adjuvants seems to be never-ending. A large array of opioids ranging from morphine, fentanyl, and sufentanil to hydromorphone, buprenorphine, and tramadol has been used with varying success [12]. Buprenorphine is an opioid of the phenanthrene morphine class with an extremely high binding affinity at the μ and kappa receptors. This high-affinity of buprenorphine for opioid receptors produces a longer duration of action. It is a centrally acting partial opioid agonist with both spinal and supraspinal component of analgesia. It
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is compatible with cerebrospinal fluid and produces no adverse reactions when administered intrathecally. It is highly lipid soluble and diffuses quickly into neural tissue, decreasing the extent of rostral spread leading to a minor risk of respiratory depression in the postoperative period [13]. Subarachnoid block the most commonly performed regional anesthetic technique. It is easy to perform, economical, the patient is awake, and no risk of aspiration, the onset of anesthesia is rapid, complete muscle relaxation [14]. Disadvantages include incomplete block, total spinal anesthesia, urinary retention, spinal cord injury, cauda equina syndrome, intraspinal hematoma. Several adjuvants are added to the local anesthetic to prolong the duration of block and for postoperative analgesia, so that additional postoperative analgesics were not required or only minimally required. In this study adjuvants used are inj. fentanyl and inj. buprenorphine.

Fentanyl is a lipophilic opioid agonist which acts on μ-receptor [15]. Buprenorphine is a lipophilic opioid with a mixed agonist-antagonist activity at both μ (mu) and kappa opiate receptors [16]. Buprenorphine is a lipid soluble drug and rapid absorption into the spinal venous plexus allows a minimal increase in the spinal fluid concentration with minimal risk of respiratory depression associated with the rostral spread [17]. It has a high affinity for the narcotic receptors and therefore produces a longer duration of analgesia compared to fentanyl. All these characteristics were confirmed in our study [18]. Incidence of postoperative nausea and vomiting is higher in group B. Pruritus one of the common side effect seen with opioids [19]. Also, respiratory depression from neuraxial opioids has been the main concern for reluctance in usage intrathecally but in this study, no patients had respiratory depression [20].

Conclusion
Intrathecal midazolam potentiates the effect of intrathecal fentanyl in terms of prolonged duration of analgesia and prolonged motor and sensory block without any significant hemodynamic compromise. Adding buprenorphine significantly prolongs the duration of both sensory and motor blockade compared to fentanyl. Post-operative analgesic requirements were significantly less in the buprenorphine group than the fentanyl group. So intrathecal buprenorphine is the better choice drug when compared with fentanyl for intrathecal adjuvant with inj. Bupivacaine (hyperbaric).

References


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