WOUND INSTILLATION OF LOCAL ANESTHETIC BUPIVACAINE FOR POSTOPERATIVE ANALGESIA FOLLOWING LUMBAR LAMINECTOMY

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Abstract

Purpose: Lumbar laminectomy is a commonly performed procedure in neurosurgical and orthopedic practice. Postoperative pain relief helps in early mobilization, initiation of physiotherapy, provides satisfaction to the patients and plays an important role in reducing the morbidity and mortality. This prospective study investigated the simple technique of instillation of wound with bupivacaine and leaving a contact time of 60 seconds on postoperative pain following lumbar laminectomy.

Methods: 32 ASA I and II patients scheduled for laminectomy were randomly allocated to receive either 20 ml of normal saline (group I) or 0.25% of bupivacaine (group II) into the wound after securing hemostasis. After a dwell time of 60 sec the wound was closed in layers without mopping or suctioning. After extubation, the pain scores were evaluated by visual analog scale at every 4 hrs. for 24 hrs and also the time for first demand of analgesia, number of analgesic demands and the total amount of analgesia consumed were noted by an independent observer.

Results: The median duration of analgesia in group I was 8.8 [5-11] and in group II 13 [8.5-16] hrs. with a p=0.04. The number of demands and the amount of analgesia consumed was also statistically significant.

Conclusion: Wound instillation technique is simple, safe and effective in management of acute pain management after lumbar laminectomy and can be used as one among the multimodal armamentarium in pain management.

Keywords: lumbar laminectomy, bupivacaine, postoperative pain, wound instillation.
Introduction

Lumbar laminectomy is a commonly performed procedure in neurosurgical and orthopedic practice. Patients usually suffer significant pain after lumbar laminectomy. Postoperative pain relief helps in early mobilization, initiation of physiotherapy, provides satisfaction to the patients and plays an important role in reducing the morbidity and mortality. There has been an increased attention in the understanding of the pathophysiology of acute pain and development in newer modalities of analgesic treatment. Currently several postoperative analgesic options are available. Intravenous opioids, NSAIDs, intrathecal administration of opioids and local anesthetics have been evaluated. Epidural or paravertebral administration of drugs using catheter for continuous infusions have also been studied. Regional techniques offer many advantages: pain is cured at close to damaged tissue and when local anesthetics are used, they provide analgesia and substantially reduce the need for opioids. Most of these techniques may be limited by potentially high failure rates, high cost, technically challenging, and labor intensive, adverse/toxic effects, and procedure-related complications. Wound site infiltration is an efficient method in acute post-operative pain management, but has a potential theoretical risk of wound site infection. Instillation of local anesthetic drug into the wound was found to provide postoperative analgesia in certain surgical procedures like hernia repair and laparoscopic cholecystectomy. The role of wound instillation with local anesthetic has not been studied. Simple technique of instillation of wound with bupivacaine and leaving a contact time of 60 seconds may alleviate postoperative pain following lumbar laminectomy.

Aims and objectives:

The aim of the current study is to evaluate the duration and analgesic efficacy of 0.25% bupivacaine on wound instillation following lumbar laminectomy.

Methods

Institutional ethics committee approval and informed consent from the patient was taken for this prospective randomized double blind study. This study was undertaken in 32 patients of ASA physical status I and II scheduled for lumbar laminectomy who were planned to have single level lumbar disc surgery. Patients with instrumentation due to spondylolisthesis or spinal stenosis, and are planned to have multiple distance or double site laminectomy, patients who underwent prior lumbar disc surgery, have ASA III-IV status, prior neurological deficits, preoperative opioid use or any history of substance abuse or on steroids, infection, have known local anesthetics allergy were excluded from the study. Patients with bleeding, cerebrospinal fluid leak, or requiring placement of drain were excluded after initial recruitment.

Patients were randomized into two groups of 16 each by computer generated random numbers (figure1). All patients received standard general anesthesia with endotracheal tube of appropriate size. Paracetamol 1 gram IV was administered after induction of anesthesia for intraoperative analgesia. Once the surgical procedure was completed and hemostasis was secured-patients in group I received 20ml of normal saline instillation which remained in the wound for a dwell time of 60 seconds and patients in group II received 20ml of 0.25% bupivacaine for the same contact period and the wound was closed in layers without mopping or suctioning.

Patients were assessed for postoperative pain score by visual analog scale, a 10 point scale ranging from “0” minimum or no pain to “10” the maximum pain score perceived by the patient. Postoperative pain was assessed by an independent observer blinded to the study first at 0 hours i.e., immediately after extubation and then at every 4 hours intervals for 24 hours. The duration of analgesia was considered from the time the study drug was instilled to the time for first demand of analgesia. When the pain score exceeded 3 rescue analgesia (diclofenac 75mg deep IM) was given with a lock-out period of 8 hr and maximum dose of 225mg in 24hrs. The number of analgesic demands and the amount of analgesia administered were also noted.

Statistical Analysis

Sample size was based on a pilot study of 20 patients with 10 in each group. A group sample size of 12 each achieves 86% power to detect a difference
of 4hrs between the null hypothesis that the means of both the groups are 7.7 hrs and alternate hypothesis that the mean of group II is 11.8 with standard deviation of 3.1 and 3.5 at a significance level of 0.05% using a 2 sided independent sample t-test. Hence a sample size of 32 was studied to allow for possible exclusions after initial inclusion. Statistical analysis was performed by using SPSS version 17. Data was expressed as median and Inter Quartile Ratio for continuous variables and percentages for categorical variables. Continuous variables and ordered categorical variables were compared between the groups using Mann Whitney U test. Categorical variables were compared between the 2 groups using Chi square test. A two sided p of <0.05 was considered as statistically significant.

Table I
Patient Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group I</th>
<th>Group II</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>40 [30-53]</td>
<td>43.5 [38.2-48.3]</td>
<td>0.579</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>60 [57-70]</td>
<td>50 [50-60]</td>
<td>0.143</td>
</tr>
<tr>
<td>Gender (M/F)</td>
<td>10/5</td>
<td>9/6</td>
<td></td>
</tr>
<tr>
<td>Duration of surgery(Min)</td>
<td>120 [120-187]</td>
<td>90 [60-120]</td>
<td>0.796</td>
</tr>
<tr>
<td>Duration of Analgesia(Hrs)</td>
<td>8.8 [5-11]</td>
<td>13 [8.5-16]</td>
<td>0.04*</td>
</tr>
<tr>
<td>Number of Demands</td>
<td>2 [1.75-3]</td>
<td>1 [1-1]</td>
<td>0.05*</td>
</tr>
<tr>
<td>Amount of Analgesia(mg)</td>
<td>150 [131.5-225]</td>
<td>75</td>
<td>0.05*</td>
</tr>
</tbody>
</table>

Data is presented as Median [Interquartile] except for gender.
* Statistically significant.


**Results**

Demographic data was comparable between the groups. (Table I). Two patients (one from each group) were excluded due to surgical complications. The median duration of analgesia in group I was 8.8 [5-11] hrs. and in group II 13 [8.5-16] hrs. which was statistically significant with a p 0.04. (Fig. 1) The number of demands and the amount of analgesia consumed was also significantly lower in the group II as compared to group I (p=0.05). The pain scores were significantly lower in group II at all-time intervals (figure 2).

**Discussion**

In this prospective study, the results showed that patients who received wound instillation with 20ml of 0.25% bupivacaine experienced better postoperative analgesia as compared with patients who received saline. In the current study, the study drug was instilled and allowed a dwell time of 60 seconds; the probable mechanism of pain relief could be due to the anesthetic effect of bupivacaine acting on the pain receptors distributed in the soft tissues and the nerve endings exposed in the wound right from the skin to the dura meninge (skin, paraspinal muscle, posterior longitudinal ligament, dorsal annulus, facet joint capsule, nerve root which was under compression and the spinal meninges the dura supplied by recurrent nerve of Von Luschka). The pain scores were low at all points of time in the study group. The time to first demand of analgesia was prolonged in the study group. Cumulative rescue analgesic consumption and number of demands for analgesia in the first 24 h was significantly lower in the bupivacaine group.

Wound infiltration with local anesthetics with or without adjuvant drugs has for long been known to produce efficient postoperative analgesia. Cherian and co authors in their study evaluating the efficacy of wound infiltration with bupivacaine after lumbar laminectomy found significant analgesia compared to placebo group. The mean time before administration of the first dose of analgesic postoperatively in the bupivacaine and placebo recipients was 807.7 (567.6) minutes and 181.4 (110.1) minutes. In another study by Milligan et al where patients received injection of 10 ml of 0.5% bupivacaine into the wound found less pain scores and longer duration of analgesia following lumbar discectomy. Hernández-Palazón and colleagues studied wound infusion of 0.25%
bupivacaine and 0.25% ropivacaine into the paraspinal muscle and skin before closure of wound following lumbar laminectomy and found mean time until the first request for analgesia was significantly longer in bupivacaine group than in ropivacaine or control group (164 +/- 53 min versus 68 +/- 31 and 38 +/- 14 min, respectively). Continuous wound infusion with ropivacaine was found to be effective following spinal instrumentation, iliac crest bone graft and shoulder surgery. A single time instillation of local anesthetic into the laminectomy wound has not been evaluated earlier. Unlike the present study; all these studies involved injection, infiltration or infusion of the study drug bupivacaine or ropivacaine for analgesia. But the present study is different, here it involved only instillation of the study drug and allowing it for a dwell time of 60 seconds and the analgesia was unremarkable.

Local tissue instillation of local anesthetic bupivacaine is a simple, safe and low cost technique. Whenever a peripheral tissue injury occurs it results in two kinds of responsiveness in the CNS: a peripheral and a central sensitization. The central sensitization leads to an increased excitability of spinal cord neurons that is triggered by nociceptive afferent inputs which results in an increase in the response to pain. The local infiltration of anesthetic blocks C-fiber input to the dorsal horn and may thereby inhibit central sensitization. It can also have potential benefits such as inhibition of both the early inflammatory response (edema, fibrin formation, capillary dilatation, leukocyte aggregation) and the late effects of this process (proliferation of capillaries and fibroblasts, collagen formation and scarring). It has been shown that adequate relief of acute postoperative pain can result in improved long term outcomes.

In the present study the median duration of analgesia was 13hrs with instillation of local anesthetic bupivacaine with good quality of analgesia was good. None of our patients developed side effects typically associated with spread of local anesthetic to nerve roots or intrathecal space with resultant problem with mobility and differences in wound infection rates. However the concentration of bupivacaine used was 0.25% where it can mostly cause sensory blockade.

Wound instillation technique is simple, safe and effective in management of acute pain management after lumbar laminectomy and can be used as one among the multimodal armamentarium in pain management.
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**Predictable and complete reversal**
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- 97% of BRIDION patients recovered to a TOF \(^{-1}\) ratio of 0.9 from 1 to 2 PTCs \(^1\) within 5 minutes\(^3\)

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- BRIDION rapidly reversed patients from reappearance of \(T_2\) \(^1\) in 1.4 minutes\(^2\)
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**Important safety information**

BRIDION is not recommended in patients with severe renal impairment. Studies in patients with hepatic impairment have not been conducted and, therefore, patients with severe hepatic impairment should be treated with great caution. Caution should be exercised when administering BRIDION to pregnant women as no clinical data on exposed pregnancies are available.

BRIDION has not been investigated in patients receiving rocuronium or vecuronium in the Intensive Care Unit (ICU) setting.

If neuromuscular blockade is required within 24 hours of BRIDION administration, a nonneostigmine neuromuscular blocking agent should be used instead of rocuronium or vecuronium. The most commonly reported adverse reactions were dysgeusia (metal or bitter taste) and anesthetic complications (movement, coughing, grimming, or suctioning on the endotracheal tube). In patients treated with BRIDION, a few cases of awareness were reported. The relation to BRIDION was uncertain. In a few individuals, allergic-like reactions (ie, flushing, erythematous rash) following BRIDION were reported. Clinicians should be prepared for the possibility of allergic reactions and take the necessary precautions. In a trial of patients with a history of pulmonary complications, bronchospasm was reported in 2 patients and a causal relationship could not be fully excluded.

Volunteer studies have demonstrated a slight (13%-22%) and transient (<30 minutes) prolongation of the prothrombin time/activated partial thromboplastin time (PT/aPTT) with BRIDION; however, clinical studies have demonstrated no clinically relevant effect on peri- or postoperative bleeding complications with BRIDION alone or in combination with anticoagulants. As BRIDION has demonstrated an in vitro pharmacodynamic interaction with anticoagulants, caution should be exercised in patients on anticoagulation for a pre-existing or comorbid condition. This pharmacodynamic interaction is not clinically relevant for patients receiving routine postoperative prophylactic anticoagulation. Although formal interaction studies have not been conducted, no drug interactions were observed in clinical trials. Preclinical data suggest that clinically significant drug interactions are unlikely with the possible exceptions of toremifene, fusidic acid, and hormonal contraceptives.

\(^1\) Train-of-four  
\(^2\) Post-tetanic count  
\(^3\) Second twitch

**REFERENCES**:  
1. BRIDION Summary of Product Characteristics (SPC)  

Please see summary of product characteristics for full prescribing information.
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