Pre-emptive Incision Infiltration Versus Post-Operative Wound Infiltration with 0.5% ropivacaine in Patients Undergoing Lumbar Laminectomy

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ABSTRACT

Background: *Post-operative pain relief after lumbar laminectomy and stabilization surgery is related to soft tissue and muscle dissection, manipulation and removal at the operating site.*

Aims & Objectives: *The present study is designed to evaluate the pre-emptive effect of 0.5% Ropivacaine infiltration in patients undergoing lumbar laminectomy*

Materials and Methods: *In this prospective, randomized study, seventy five patients belonging to ASA I and ASA II were randomly allocated to three groups as group A, group B and group C. After conventional general anesthesia, patients were kept in prone position. Patients belonging to group Areceived 2 mg/kg of 0.5% ropivacaine before incision and patients belonging to Group B received the same as wound infiltration before closure and group C patients received 10 ml saline infiltration at closure. Injection diclofenac sodium intravenous was given as a rescue analgesia when required. We observed pain intensity with Visual Analogue Scale (VAS) at 0, 30 minutes and 1,3,6,12,16 hrs, time for first analgesic requirement, total diclofenac sodium consumption and incidence of nausea and vomiting.*

Results: *Mean VAS score immedietly after the surgery for group A was (2.3±1.8) significantly lower than group B(5.0±1.9, P=0.0001) and group C(6.6±2.3,P=0.0001). First analgesic dose requirement time was longer in group A (120±21min) than group B(60.3±20.1min,P=0.0001) and group C(10±19.3min,P=0.0001). Total amount of diclofenac sodium required in group A(65.8±20.8mg) was less than group B(110±25.8mg,P=0.0001) and group C(141±22.1mg,P=0.0001). Incidence of nausea and vomiting were equal in all the groups.*

Conclusion: *Infiltration with 0.5% Ropivacaine significantly decreses post-operative pain intensity and diclofenacsodium consumption. Infiltration has better effect when given pre-emtively.*

Keywords: *Infiltration, Post-operative analgesia, Pre-emptive, Ropivacaine*

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INTRODUCTION

Laminectomy is associated with considerable pain due to soft tissue and muscle dissection and to manipulations and removal at the operation site. Most patients experienced severe pain at rest and during movement during first 12 hour after surgery[1]. Different modalities including IV, IM, epidural, spinal, instillation and infiltration routes of analgesia have been evolved. Tissue injury causes an increase in the excitability of dorsal horn neurons in the central nervous system[2]. This is normal physiological response which contributes to pain in post-operative period. Prevention of this central sensitization to pain may result in better post-operative analgesia[3-5]. This can be achieved with pre-emptive incision infiltration with local anesthetic agent.

Numerous clinical studies have reported wound infiltration with local anesthetics as safe and effective for post-operative analgesia following lumbar laminectomy under general anesthesia[6]. It reduces opioid consumption in remarkable portion of patients and may be sufficient as single method of postoperative analgesia[7]. Studies performed have not provided data of optimal method and time for infiltration and the optimal dosage/volume of local anesthetic agent, regarding systemic absorption and toxicity which may increase during the large surgical incisions. Ropivacaine is an ideal drug for infiltration for its vaso-constrictive properties and decreased neuro and cardio-toxicity[8,9].

The present study is designed to evaluate the pre-emptive effect of ropivacaine infiltration in patients undergoing lumbar laminectomy.

METHODS

After hospital ethical committee approval and informed consent 75 patients of ASA I and II undergoing elective lumbar spine surgery were selected

randomly and blinded for study. Patients with pregnancy, obesity, allergy to local anesthetic agent, concurrent treatment with antidepressant, anti-coagulant or analgesics were excluded from study.

All patients were induced with inj. propofol 2-2.5 mg/kg and inj.vecuronium bromide 0.1mg/kg for standard general anesthesia. All patients were intubated with proper sized flexometalic cuffed tube and kept on mechanical ventilator. General anesthesia was maintained with oxygen, nitrous oxide and isoflurane 1.0 MAC and vecuronium as required. Inj. fentanyl 1-1.5 mcg/kg was given for intraoperative analgesia. All patients were given prone position. After painting and draping planned surgical incision was marked with permanent marker. Patients of group A received 2mg/kg of 0.5% ropivacaine injected just before incision in skin, subcutaneous tissue and muscle. Patients of group B received 2mg/kg of 0.5% ropivacaine as wound infiltration into the paravertebral muscles on either side by the operating surgeon before closure. Patients of group C received 10 ml saline as wound infiltration. During intraoperative period ECG, NIBP, SPO_2, $ETCO_2$ were observed.

All patients were reversed from muscle relaxation and were extubated and were transferred to post-operative ward(POW). Pain was assessed by patient with a Visual Analog Scale(VAS) score system (0-10 cm 0=no pain 10=worst pain)

Pain score was evaluated by a blinded observer anesthesiologist at the time of arrival in POW and 30min, 1, 3, 6, 12, 16hoursthereafter using VAS score. VAS score, the time for first analgesic, number of dosage of analgesic given and total analgesic requirement for the first 24hours were recorded. Rescue analgesic given with inj. diclofenac sodium 75mg intravenously to a maximum of three doses when pain score exceeded 4. Any complications such as nausea, vomiting, sedation were recorded.

STATISTICAL ANALYSIS

Data were expressed as mean±sd. Repeated data were analyzed using repeated analysis of variance (ANOVA). All statistical analysis were done using SPSS version 17 in Chicago, IL and considered statistically significant when $P<0.05$. VAS score were compared between the two groups using kruskal-Wallis test.

RESULT

Demographic data of all the groups of patients as shown in table 1 were without significant difference. There was no significant difference among the groups with respect to mean arterial blood pressure (MAP) or heart rate(HR) before induction, during surgery or in first 24 hours after surgery.VAS score was lower in group A than group B and group C at all the time. However VAS score was lower in group B as compared to group C as shown in table 2 and table 3. The difference was not statistically significant between group B and group C. 22(88%) patients required second dose in group C, 11(44%) patients required that in group B whereas no patient required second dose in group A.

As shown in table 4 group A and group B had significantly longer mean time to first analgesic demand than the control group (group C) [Pvalue< 0.001]. The mean time to first analgesic in group A was significantly longer than group B (P value<0.001) and group C. Table 4 shows total diclofenac sodium requirement was higher in group C (141±22.1mg) than group A (65.8±20.8mg) and group B (110.4±25.8mg). It was lowest in group A. Number of incidence of nausea and vomiting were without significant difference in all groups. There were no side effects or adverse effects in any of the groups.

Table: 1 Demographic and vital data of patients.

Variable	GROUP A	GROUP B	GROUP C
Age(years)	49.5±8.2	48.3±7.6	48.2±5.2
Sex(M/F)	12/8	11/9	11/8
Weight(kg)	60.6±12.3	59.8±11.8	59±10.4
Height(cm)	165±5.9	170±4.9	163±5.5
Duration of surgery(minutes)	130±26.7	122±35.8	128±28.8
Level of surgery	Lumbar spine	Lumbar spine	Lumbar spine
Pre-operative MAP (mm of hg)	80±16.4	84±10.9	83±13.9
HR	76	72	75

MAP: Mean Arterial Blood-pressure HR: Heart rate

Data are presented as mean±sd. There were no significant difference between the groups.

Table: 2 Visual Analog Scale score at different intervals

Time	GROUP A	GROUP B	GROUP C
0 hr	2.3±1.8	5.9±1.9	6.6±2.3
30 mins	2.6±1.2	3.9±2.5	7.2±2.2
1 hr	3.3±1.6	5.6±3.8	6.4±2.2
3 hr	4.2±2.8	6.6±2.3	7.4±2.4
6 hr	4.3±16	5.6±2.4	6.2±3.5
12 hr	4.0±1.8	5.9±2.9	6.6±3.4
16 hr	3.0±1.2	3.9±2.7	4.3±2.2

Data are presented as mean±sd.

Table: 3 P value for visual analog scale score between the groups

Time	GROUP A and B	GROUP A and C	GROUP B and C
0 hr	0.0001	0.0001	0.2465
30 mins	0.0233	0.0025	0.6544
1 hr	0.0076	0.0016	0.2
3 hr	0.0018	0.0004	0.5
6 hr	0.0288	0.0172	0.48
12 hr	0.0077	0.0015	0.43
16 hr	0.1343	0.0125	0.56

P < 0.05 is significant. Significant difference between group A and Group B till 12hours in postoperative period, between group A and Group C at all time intervals.

Table: 4 Rescue analgesic requirement

Variable	GROUP A	GROUP B	GROUP C	P VALUE A & B	P VALUE A & C	P VALUE B & C
1ST analgesic requirement	120.8±21	60.3±20.1	10±19.3	0.0001	0.0001	0.0001
No. of pts. requiring 2nd dose(% of pts.)	Non	11(44%)	22(88%)			
Amt. of inj. diclofenac sodium(mg)	65.8±20.8	110.4±25.8	141±22.1	0.0001	0.0001	0.0001
No. of inj. diclofenac sodium	0.5±0.4	1±0.5	2.6±0.3	0.0109	0.0001	0.0001
Inci. Of nausea % vomiting(no. of pts %)	3(12%)	4(16%)	4(16%)			

Values are represented as number of patients and as mean±sd.
P < 0.05 is significant

DISCUSSION

Poorly managed pain may inhibit the early ability to mobilize the patient and may influence the overall outcome. Infiltration analgesia by local anesthetic agent has been increasing in practice for post-operative pain management. After infiltration into the surgical wound, these drugs modulate peripheral pain transduction by inhibition of the transmission of noxious impulses from the site of injury. Many studies have been carried out on the quality of post-operative analgesia obtained with continuous infusions, instillations and infiltration of ropivacaine in surgical wounds. These new technique have led to a better quality of analgesia and a significant decrease in the consumption of systemic analgesics in the first 24 post-operative hours. Pre-emptive analgesia is the administration of analgesics before starting the painful stimulation to prevent the establishment of central neuronal sensitization, thus decreasing post-operative pain intensity[10].In our study pre-emptive and post-operative ropivacaine infiltration both has decreased pain intensity in the first 16 hours P<0.001 as compared to the group not receiving infiltration. However pain was better managed with pre-emptive infiltration. This may be because pre-emptive infiltration probably blocks central sensitization. The pre-emptive group even after anesthetic blockade regression, remained comfortable because their nervous receptors were not sensitized, which promoted better pain control, delaying the first rescue demand.

The agent must have a faster onset and enough long duration of action to cover the operative and post-operative period. The onset of action of ropivacaine is about 1-5 minutes and its duration of action is 692-793

minutes when injected intradermal[11]. In a study of ropivacaine in tumescent anesthesia found that the mean duration of absence of pain was 15.6 hours with a maximum of 30 hours[12]. This long duration of anesthesia should be adequate to cover the pain during lumbar laminectomy and during the post-operative period. Incisional infiltration has a limited duration of action (less than 5 hours) but it contributes to the decrease in demand for systemic analgesics thereafter. The use of this technique does not lead to any increase in wound dehiscence or infection. N.K. Nguyen and colleague had done a study using 7.5mg/ml ropivacaine incision infiltration before skin closure in patient for caesarean section under spinal anesthesia and their technique had best adapted to their practice, because of its indisputable efficacy and the simplicity[13].

A study done by Bianconi et al reveals that post-operative pain control after spine fusion surgery at rest and on mobilization was better with 0.5% ropivacaine wound infiltration and continuous ropivacaine 0.2% wound perfusion than with systemic analgesia[14]. This is in consistant with our study. Studies by Johnson B et al with pre-emptive ropivacaine infiltration using 200 mg and 175 mg doses for herniorrhaphy and cholecystectomy and found reduction in pain limited to 6 hours post-operatively[15,16].

Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate myelinated motor fiber, resulting in a reduced motor blockade, and also the reduced potential for central nervous system toxicity and cardio toxicity. Thus it has greater degree of motor sensory differentiation and greater degree of safety margin[17]. In vitro studies shows thatropivacaine induces vessel contractility there by induces vasoconstriction[9]. These finding suggests that the vaso-constrictive property of ropivacaine makes it an ideal agent for infiltration.

The recommended dose of ropivacaine used for infiltration is 2-225 mg. one study has demonstrated 300 mg of ropivacaine (~5mg/kg) was well tolerated by 37 patients and significantly reduced post-operative pain after inguinal hernia repair till 7th post-operative day[18]. We used 2mg/kg of 0.5% ropivacaine and found significantly lower VAS score in both pre-emptive and post-operative infiltration group as compared to control group. A study by Horn et al, found infiltration followed by drain lavage with 30 ml of 0.75% ropivacaine significantly decreased post-operative pain and did not observed toxic effects[19].

In the study done by Johansson A et al preoperative ropivacaine infiltration done for breast surgery with 0.3 ml/kg of 3.75 mg/ml before surgery and found no significant difference between VAS scores[20]. This may be because of low dose (average patient weighing 60 kg will receive 65mg with this protocol) of ropivacaine which might not sufficient to affect post-operative pain. A comparative study done by M.A.I. Rica and et al with pre-emptive versus post-operative ropivacaine wound infiltration found the pre-emptive group had wider angles of shoulder abduction in post-operative period[21].

Single shot intra operative wound infiltration reduces the median time to first analgesic, the VAS scores, the use of analgesic medication on the first post-operative day and increases number of patients using no analgesic[22,13]. This issimilar to data obtained by our study. Alp Gurbet and et al had done study with levobupivacaine infiltration with and without methylprednisolone at before incision versus before closure of wound. The data of their study showed that all four groups had significantly lower values for PCA demand and boluses than control group. Furthermore time to first PCA demand was longer in pre-emptive groups than their corresponding groups[23]. Andre Laranjeira et al[24] studied 2mg/kg 0.75% ropivacaine before incision and after incision. The data of the study shows that morphine consumption was significantly lower in pre-incisional group (1.5mg) as compared to the pre-closure group(5.5mg) or the control group (17mg). Time for first analgesic requirement was also longer with lowest pain intensity in pre-incisional group. Similar to this our data also shows ropivacaine infiltration before incision or at wound closure has decreased post-operative pain intensity, rescue analgesic consumption as compared to control group. The time for first analgesic dose requirement was significantly longer in pre-emptive infiltration group as shown in table 2 and 4 than at wound closure and control group. Number of doses of rescue analgesia required less in group A.

Decreased analgesic consumption and increased time for rescue drug request with bupivacaine infiltration before incision as compared to post-operative infiltration has been shown in meta-analysis[25]. A study with bupivacaine infiltration before and after tonsillectomy has obtained better results with pre-emptive infiltration [26].

CONCLUSION

Ropivacaine infiltration was effective for post-operative pain control with better results when done before incision. It has significantly decreased pain intensity and diclofenac consumption and has delayed first rescue requirement.

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