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Original Research Article

Ropivacaine and Ropivacaine with Dexamethasone as an adjuvant for postoperative analgesic efficacy in Lumbar Paravertebral block in lower limb surgery: A Randomized Comparative Observational study

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Abstract

Background: Pain during the postoperative period has an impact on the quality of recovery and the length of hospital stay, which is a point of concern both for the surgeon and patients. Many modalities for reducing postoperative pain have been evaluated, with Lumbar paravertebral Block being associated with reduced postoperative pain, significantly reduced postoperative analgesic requirements.

Aim: The primary objective of the present study was to assess the analgesic effectiveness of Lumbar paravertebral block given with Ropivacaine alone and Ropivacaine with Dexamethasone (as adjuvant) for elective lower limb surgery.

Material and Methods: This was a single-centre, double blinded, hospital-based comparative observational study conducted among a total of 60 patients undergoing lower limb elective surgery given Lumbar paravertebral block given with Ropivacaine alone (30 patients) and Ropivacaine with Dexamethasone, as adjuvant (30 patients). Evaluation of Postoperative pain, with the first demand of analgesia and total analgesic required, was recorded.

Results: There was no statistically significant difference between the two groups regarding the distribution of age, weight, gender or BMI. The mean VAS score at 0,6, 12-, 24-, 36- and 48 hours after surgery among patients given lumbar paravertebral block with Ropivacaine alone was 0, 2.6, 4.1, 3.9 and 4.1, respectively. The mean VAS score at 0, 6, 12-, 24-, 36- and 48 hours after surgery among patients given Lumbar Paravertebral Block with Ropivacaine and Dexamethasone was 0, 1.1, 2.5, 3.4, and 3.6, respectively. The mean duration of the first request for analgesia was 14.6 hours and 19.2 hours among the patients given only Ropivacaine in comparison to those given both Ropivacaine + Dexamethasone ($p<0.0001$).

Conclusion: Lumbar paravertebral nerve block given with both Dexamethasone & Ropivacaine for elective lower limb orthopedic surgery improves postoperative analgesic quality and decreases the requirements of analgesia in comparison to patients given Ropivacaine alone.

Keywords: Dexamethasone, ropivacaine, lumbar paravertebral block

Introduction

The Lumbar paravertebral block(L-PVB) rising popularity can be attributed to its several merits *viz.* analgesic effectiveness and safety [1]. The PVB is suited as the new standard for

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perioperative analgesia following abdominal and lower limb surgeries due to the deployment of different technical modifications as well as the improved efficacy and safety. Paravertebral block has been utilized for perioperative analgesia in an increasing variety of procedures, including those involving the lumbar and thoracic region [2, 3]. Few adjuncts have been tried to extend the duration of analgesia, Dexamethasone, fentanyl, and morphine are a few examples of drugs that have been shown to extend the duration of PVB analgesia with varied degrees of effectiveness. Dexamethasone when combined with local anaesthetics (LA) also prolonged the duration of the intercostal blockade and was shown to possess anti-inflammatory action [4, 5].

Traditionally, the PVB is given with local anaesthetics. To further increase the analgesic effectiveness of PVB, a combination of LA with various adjuvants can be tried. Therefore, we conducted the present study intending to compare and study the analgesic effectiveness of Lumbar paravertebral block given for postoperative analgesia with Ropivacaine alone and Ropivacaine along with Dexamethasone in lower limb surgeries.

Material and Methods

Study design: This was a single centre, hospital (in-patient) based, Randomized comparative observational study.

Study settings: The present study was conducted at the Department of Anaesthesiology, Maharishi Markandeshwar Medical College & Hospital, Solan Himachal Pradesh. The data collection for the present study was initiated after the research protocol was approved by the Institute's Ethical Committee on Human Research.

Study duration: The total duration of the study was 6 months.

Primary outcome

i) First requirement of analgesia during the postoperative period (defined as VAS score ≥3 at any time point)
ii) Number of doses of analgesic required in 48 hours of the postoperative period.

Secondary outcome

i) Side effects, complications and adverse events.

Inclusion criteria

i) Patients aged 18-75 years.
ii) ASA I & II.
iii) Patients posted for lower limb surgery.
iv) Patients who gave written informed consent to participate in the study.

Exclusion criteria

i) Local site infection.
ii) Known allergy to any local anaesthetic.
iii) History of Neurological disorder.
iv) Spine abnormalities.

Informed consent: A bi-lingual (Hindi & English) consent form was drafted following the prescribed guidelines for research on human participants to obtain written informed consent for the study.

Study groups: 60 patients were randomly allocated into 2 groups of 30 patients each.

Group A: Patients in group A received post-operative analgesia with 20 ml 0.25%

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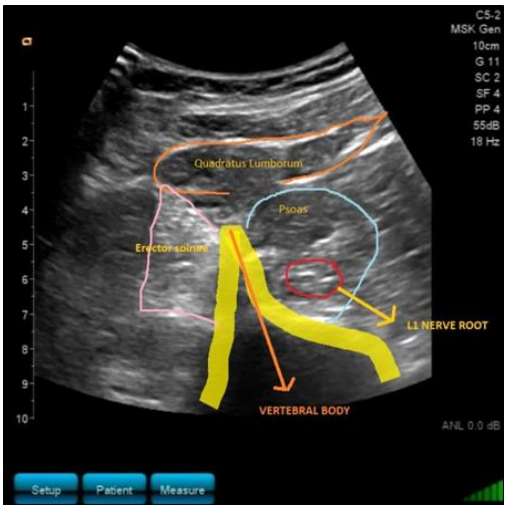
Ropivacaine + distilled water (2ml).
Group B: Patients in group B received post-operative analgesia with 20ml 0.25% Ropivacaine + 8mg dexamethasone (2ml).

Technique of Lumbar paravertebral block: Under all aseptic precautions, US-PVB was carried out using a high-frequency 10-12 MHZ linear or curvilinear ultrasound transducer on Phillips Innosight Diagnostic Ultrasound System. USG lumbar paravertebral using a trident view**,** a paramedian sagittal scan was done putting the patient in the lateral decubitus position, with the side to be blocked uppermost, once an exquisite view of the lumbar ultrasound (US) trident was obtained, then 8cm long Tuohy's needle was inserted in plane from the caudal end of the US transducer. The block needle was guided through the acoustic window of the lumbar US trident, that is, through the space between the transverse process of L2 and L3 into the posterior aspect of the psoas major muscle, a 19-gauge catheter was inserted through the Touhy's needle and advanced approximately 4cms caudally within the compartment. Subarachnoid block was performed using 25-gauge Quincke's needle at L2-L3 space by midline approach after confirming clear flow of CSF. Then 15 mg of 0.5% heavy Bupivacaine was given at the rate of 0.2 ml per second. The patient was turned supine and the level of block was assessed using pin prick method and was not allowed to exceed T7. Post-operative analgesia was provided by intermittent lumbar paravertebral bolus to the patients on VAS>3 via the *in-situ* catheter with 20 ml Ropivacaine 0.25% with distilled water(2ml) in Group A & 0.25% Ropivacaine + 8mg dexamethasone(2ml) in Group B, VAS scale was explained to the patient prior to the procedure. The in-situ catheter was removed 48 hours after the end of the surgery.



"Trident View" of Lumbar Paravertebral space
Sampling Methodology: We employed a non-probability, convenience sampling method to recruit participants for the study. All patients posted for elective lower limb surgery were screened using the selection algorithm to recruit participants.

Statistical analysis plan: The primary outcome was the analgesic efficacy of the drug(s) used for lumbar paravertebral block. The coded data was imported into Stata 17.1 version for analysis. Continuous variables in the two comparison groups were analysed using a student's t-test. Categorical variables were analysed using chi-square (χ^2) tests (9, 10). A *P*-value < 0.05 was considered statistically significant.

Funding: There was no external funding from the study and no conflict of interest.

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Observations

A total of 60 participants were enrolled in the present study: 30 participants were given Lumbar Paravertebral block with Ropivacaine and the remaining 30 were given Lumbar Paravertebral block with Dexamethasone + Ropivacaine. There was no statistical difference between the two groups regarding the distribution of age, weight, gender or BMI (Table 1).

Table 1: Descriptive characteristics of the participants

Variable	Group A(n=30)	Group B(n=30)	P-value
Mean Age (SD)	49.83 (15.43)	48.33(15.37)	0.78
Male	13 (43.3)	15 (50.0)	0.546
Female	17 (56.7)	15 (50.0)	
Weight	63.9 (8.96)	64.0 (9.93)	0.612
BMI	23.4	24.5	0.571

Table 2: VAS score during the postoperative period (n=60)

Time Points	Group A (n=30)		Group B (n=30)		
	Mean	Range	Mean	Range	P-value
0 Hour	0	0-0	0	0-0	0.001
6 Hours	0	0-0	0	0-0	0.006
12 Hours	2.6	2-4	1.1	0-2	0.012
18 Hours	3.7	2-5	2.3	1-4	0.009
24 Hours	4.1	3-5	2.5	1-4	0.003
30 Hours	3.7	3-5	2.9	2-5	0.014
36 Hours	3.9	3-6	3.4	2-5	0.016
42 Hours	4.4	3-6	3.5	2-5	0.014
48 Hours	4.1	4-6	3.6	3-6	0.019

Table 2 illustrates the mean and range of VAS scores among the participants during the first 48 hours of the postoperative period. As can be inferred from table 2, the mean VAS score gradually increased in both the groups during the postoperative period, however, the VAS score was comparatively lower among the patients given ropivacaine and dexamethasone than patients given ropivacaine alone at all-time points ($p<0.05$). None of the participants in the groups complained of any pain during the first 12 hours of the postoperative period. The mean VAS score at 12-, 24-, 36- and 48 hours after surgery among patients given lumbar paravertebral block with ropivacaine alone was 2.6, 4.1, 3.9 and 4.1, respectively. The mean VAS score at 12-, 24-, 36- and 48 hours after surgery among patients given Lumbar Paravertebral block with Ropivacaine and Dexamethasone was 1.1, 2.5, 3.4, and 3.6, respectively.

Table 3: Requirement of analgesic during the first 48 hours of the postoperative period

Requirement of Analgesic	Group		P-value
	Group A (n=30)	Group B (n=30)	
0-6 Hours	0 (0%)	0 (0%)	-
6-12 Hours	0 (0%)	0 (0%)	-
13-18 Hours	9 (30%)	3 (10.0%)	0.0012
18-24 Hours	11 (36.7%)	7 (23.3%)	0.003
25-30 Hours	13 (43.3%)	8 (26.7%)	0.013
31-36 Hours	15 (50%)	11 (36.7%)	0.037
37-42 Hours	14 (46.7%)	10 (33.3%)	0.041
43-48 Hours	16 (53.3%)	12 (40%)	0.068
Mean Time (Hours)	14.6	19.2	<0.0001

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Table 3 illustrates the 6 hourly requirements of the analgesic among the participants in the two groups. The mean duration of the first request for analgesia was 14.6 hours and 19.2 hours among the patients given only ropivacaine in comparison to those given both Ropivacaine + Dexamethasone (p<0.0001). Comparatively, the requirements of analgesic were higher among the patients given only Ropivacaine in comparison to those given both Ropivacaine + Dexamethasone at each of 6 hourly intervals during the 48 hours of the postoperative period. There were no untoward complications or adverse events in any participants in either group.

Discussion

Tormenting agony, moderate pain, is expected 30%-40% of the time after orthopedic surgery [6, 7]. Safe and effective postoperative pain management in orthopedic patients presents unique challenge. Despite its prevalence, postoperative pain is often dismissed or improperly handled. This is probably due to difficulties in determining an appropriate postoperative pain management regimen with manageable side effects. Improper postoperative pain management can have far reaching consequences for an orthopedic patient and has a wide range of potential adverse effects. Inadequate care of acute postoperative pain is associated with higher long-term morbidity and mortality, highlighting the importance of providing these patients with the best pain management. Multimodal analgesia focuses on many pain pathways to treat perioperative pain in orthopaedic surgery. Multimodal analgesia maximizes analgesic efficacy while minimizing side effect [8, 9].

Dexamethasone is a long-acting drug with anti-inflammatory, anti-allergic, analgesic effects, in addition, it has been widely used as a local anaesthetic adjuvant [10]. Thus, we conducted this study with an aim of determine the analgesic efficacy of Dexamethasone as an adjuvant to Ropivacaine for Lumbar Paravertebral Block for providing postoperative analgesia for elective lower limb surgery. We observed that the mean duration of the first request for analgesia was significantly longer (by about 5 hours) among the patients given both Ropivacaine + Dexamethasone in comparison to Ropivacaine alone. In additions, we also observed that the requirements of analgesic were higher among the patients given only Ropivacaine in comparison to those given both Ropivacaine + Dexamethasone during the 48 hours of the postoperative period. The study results showed that there were significant differences in the time to first postoperative remedial analgesia, perioperative analgesic consumption and postoperative pain score between Ropivacaine combined with Dexamethasone.

Dexamethasone has been tried as an adjuvant to local anaesthetic drugs in regional blocks since long, but broad research of literature revealed no study where Dexamethasone has been used with Ropivacaine to prolong the duration of analgesia in Lumbar paravertebral block in patients undergoing elective lower limb surgery. To the best of author's knowledge this was the one of the first study to compare the analgesic efficacy of Lumbar Paravertebral Block with local anesthetic alone and along with adjuvants for lower limb surgery. Similar to our study, Gupta *et al*., reported that Ropivacaine plus Dexamethasone could significantly prolong the postoperative analgesic time during an abdominal transverse plane block [11]. Pande *et al*., also reported that the analgesic time of a supraclavicular brachial plexus block could be significantly prolonged by adding a low dose of dexamethasone to the local anaesthetic solution [5]. Mao *et al*., also reported that, as an adjuvant of ropivacaine for Thoracic Lumbar paravertebral Block dexamethasone could significantly reduce the dosage of perioperative anaesthetic drugs, effectively control postoperative acute pain, reduce postoperative complications, shorten rehabilitation time, and reduce the incidence of chronic pain [12]. Our findings are also similar to the results reported by Song *et al*., [13] and Yaghoobi *et al*., [14] which revealed that dexamethasone as local anaesthetic adjuvants had superior analgesic effects in Thoracic PVB when compared to local anaesthetic alone. Kumar *et al*., revealed that adding 8 mg of Dexamethasone in 0.375% Ropivacaine for an ultrasound-

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guided serratus anterior plane block could prolong time for patients undergoing a modified radical mastectomy [15]. Baloda *et al*., revealed that adding 8 mg of Dexamethasone to 0.5% levobupivacaine for a supraclavicular brachial plexus nerve block could shorten the onset time of sensory and motor nerve block and prolong the duration of analgesia [16]. Similarly, 5 mg Dexamethasone added to 0.375% Ropivacaine for popliteal block in hallux valgus surgery, increased the duration of both sensory and motor block by 12 hours (25 ± 7 hours, 46%) and 13 hours (36 ± 6 hours, 55%), respectively [17]. Kumar *et al*., in a study evaluated that Dexamethasone prolonged the time to first analgesic request when added to Bupivacaine for thoracic lumbar paravertebral block in patients undergoing modified radical mastectomy [18]. No significant side effect was seen among both the groups.

Conclusion

When combined with Ropivacaine, Dexamethasone has an adjuvant effect for postoperative pain relief in Lumbar Paravertebral block for lower limb elective orthopaedic surgery. Dexamethasone prolonged the duration of the first analgesic demand while decreasing total analgesic requirements during the postoperative period.

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