



COMPARATIVE EVALUATION OF IV KETOROLAC VS BUPIVACAINE 0.25% IN LUMBAR PLEXUS BLOCK FOR POST OPERATIVE ANALGESIA FOLLOWING HIP ARTHROPLASTY

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Abstract:

Pain levels are higher in the first few days after orthopaedic surgery compared to those of patients who had undergone other types of surgery.¹ Lower limb pain post-operatively in orthopaedic surgery can be treated by various methods, such as an epidural, a posterior or anterolateral lumbar plexus block, or a combination of these and multimodal analgesia.² It has been argued by many experts to be an effective analgesic option that can reduce the use of opioids and other analgesics, along with their associated negative effects, as part of a multimodal approach. Our study will be focusing on comparing IV analgesia and peripheral nerve block. *Aim:* To evaluate and efficacy of IV Ketorolac and 0.25% Bupivacaine in lumbar plexus block for postoperative following hip arthroplasty done in the patient under spinal anesthesia. *Method:* A prospective, randomized, single-blind, controlled study where a total of 60 ASA 1 & 2 adult patients of either gender undergoing elective total hip arthroplasty under spinal anesthesia were randomized and either were administered IV Ketorolac or were given lumbar plexus block postoperatively for post-operative analgesia. VAS score was evaluated every 2 hours for 12 hours postoperatively and the time of the requirement of the first rescue analgesia was also noted also hemodynamic parameters including heart rate and non-invasive blood pressure were monitored. *Results:* There was not much change in the hemodynamics of the patient. Whereas it was noted that the VAS score for lumbar plexus block was less compared to the IV ketorolac, also the requirement of rescue analgesia was less in patients with the lumbar plexus block. *Conclusion:* From the study, it was concluded the lumbar plexus block provides better postoperative analgesia as compared to IV ketorolac in patients undergoing total hip arthroplasty.

Keywords: Lumbar plexus block, IV ketorolac, VAS score, first rescue analgesia

Introduction

Pain levels are higher in the first few days after orthopaedic surgery compared to those of patients who had undergone other types of surgery.¹ Lower limb pain post-operatively in orthopaedic surgery can be treated by various methods, such as an epidural, a posterior or anterolateral lumbar plexus block, or a combination of these and multimodal analgesia.² However, best way to treat pain has yet to be discovered. Psoas compartment nerve blocks,

however, have been argued by many experts to be an effective analgesic option as part of a multimodal approach.³

The iliohypogastric nerve, ilioinguinal nerve, genitofemoral nerve, femoral nerve, obturator nerve, and lateral cutaneous nerve of the thigh are all blocked by the LPB (from the first lumbar nerve to the fourth lumbar nerve).⁴ In contrast, the 3IN1B is a method for simultaneously blocking three nerves in the thigh: the femoral, the lateral cutaneous, and the medial obturator.

When it comes to orthopaedic surgery of lower limb, there is still some debate about whether single-shot LPB or 3IN1B is more effective. For most lower limb orthopaedic procedures, including open reduction and internal fixation (ORIF), wiring of knee fractures, intramedullary nailing, Sequestrectomy, screw and plating femoral fractures, those blocks have been used routinely for pain management.⁵ Peripheral nerve blocks (PNBs) are utilised for both perioperative and postoperative pain relief. PNB has many advantages over GA, such as more effective pain management, fewer complications from the anaesthesia, etc.⁶

To provide post operative pain relief, regional analgesic is administered. It is possible to achieve local analgesia with a nerve block, which can be very helpful in relieving post operative pain.⁷ Local anaesthetics, in general, function by penetrating the nerve and preventing pain signals from reaching the brain.⁸ However, the adverse effect on the heart and brain increases with increasing local anaesthetic dosage. Systemic toxicity from the local anaesthetic, a hematoma, an allergy, an infection, and, extremely rarely, peripheral nerve injury are all possible side effects of PNB.⁹

Hip surgery recovery pain can be very taxing on a person's emotional and physical well-being. Joint and slow progress in physiotherapy due to inadequate pain treatment can have a negative impact on recovery. Infusions of nonsteroidal anti-inflammatory drugs (NSAIDs), epidural analgesia, intravenous morphine, and peripheral nerve blocks are just some of the methods used to alleviate pain after surgery. After hip replacement surgery, NSAIDs such as intravenous ketorolac has been shown to be very helpful for patients. In comparison to opioids, nonsteroidal anti-inflammatory drugs (NSAIDs) have analgesic and anti-inflammatory effects with significantly less potential for addiction and dependence.¹⁰

Lumbar plexus is the web of nerves which is present in the lumbar region of the body. The major branches of the lumbar plexus are Genitofemoral nerve, lateral femoral cutaneous nerve, femoral nerve and obturator nerve.^{7,9,11}

The chemical structure of bupivacaine is an amide bond between a tertiary amine and a substituted aromatic ring. The action mechanism of bupivacaine is to prevent an action potential from being generated by blocking the entry of sodium ions across the neuronal membrane.² Bupivacaine's affinity for nerve tissue is thought to be responsible for its prolonged effects.¹¹

A novel chiral NSAID, ketorolac is being offered as the racemate for analgesia. The medicine is the water-soluble tromethamine salt, and it may be used orally or intravenously. Ketorolac undergoes substantial glucuronidation and oxidation metabolism, with very little of the medication being excreted in an unaltered form.¹²

This study was done to evaluate and efficacy of IV Ketorolac and 0.25% Bupivacaine in lumbar plexus block for post operative pain relief following hip arthroplasty done in patient under spinal anaesthesia.

Materials and method

Following institutional ethical committee approval and written informed consent, a prospective, randomized, comparative study was conducted with 60 patients in the Department of Anaesthesiology, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune, India.

Inclusion Criteria:

1. ASA grade I, II and III patients.
2. Ages between 25 and 80 years of either sex.
3. Patients undergoing hip arthroplasty under spinal anaesthesia.
4. Haemodynamically stable patients with all routine investigations within normal limits.
5. Patients who are not on any cardiac related drugs.
6. Availability of informed consent.

Exclusion Criteria:

1. Patients with ASA physical status IV or more.
2. Patients with below 25 years and above 80 years.
- 3 Patients posted for emergency procedures.
4. Patients with major neurological, cardiac, respiratory, metabolic, renal, hepatic disease or with coagulation abnormalities.
5. Patients contraindicated for regional technique.
6. Patients with known allergies to the study drugs.

Methodology

Institute Ethics Committee Clearance was obtained before start of study. Study was carried out on 60 patients meeting all the inclusion and the exclusion criteria and scheduled for elective surgeries for hip arthroplasty. A computer-generated balanced allocation sheet was used to randomly allocate the 60 patients into two groups, 30 cases in each group.

- Group LPB 30 cases – 0.25% Bupivacaine via lumbar plexus block
- Group Ketorolac 30 cases – IV Ketorolac 0.5 mg/kg (max 30mg)

Pre-operative visit was done on the day prior to surgery and detailed history and complaints was done with thorough general and systemic examination. Routine laboratory investigations such as haemogram, liver function tests (LFTs), renal function tests (RFTs), serum electrolytes, urine routine, bleeding time and clotting time (BT-CT) was done.

Patients were kept nil by mouth from midnight prior to surgery. Informed consent was taken. Preoperative pulse, non-invasive blood pressure, ECG and oxygen saturation was

noted. Peripheral venous access was secured with a 20G intravenous (IV) cannula and IV fluids was infused, preloading the patient with 20ml/kg of Ringer's lactate.

With the patient in seated position and while maintaining appropriate aseptic precautions, spinal anaesthesia was administered in L3-L4 intervertebral space using 26 G Quincke's babcock spinal needle with drug administered intrathecally after confirming free and clear flow of CSF. In Group LPB, following spinal anaesthesia, each patient was taken in lateral decubitus position with operated side upright. Thigh was flexed with flexed knee (Sim's position). Lumbar plexus blockade was achieved using Winnie's posterior approach^[21], in which Intercostal line was determined through the two iliac crests (line 1), which is positioned over the L4 transverse process in most adults. Another line linked the lumbar spinous processes. We identified the posterior superior iliac spine.

The posterior superior iliac spine was crossed by a second line parallel to the lumbar spines (line 2). The intersection of lines (1 and 2) is where we placed our needle. Lumbar plexus was located using a 21-gauge 10cm stimuplex needle connected to a peripheral nerve stimulator. The nerve stimulator was set initially at 1.0 to 1.5 mA, and needle was advanced at right angles to skin until the transverse process of L4 was encountered. Once bone was contacted the needle is brought back towards the skin and redirected caudally to walk off the transverse process. The twitching of quadriceps muscle was taken as a sign that the needle was close to the lumbar plexus, and the needle was then gently advanced caudally for no more than 20mm (this twitch is usually encountered at a depth of 5 to 8 cm from the skin). The stimulator current was reduced to 0.5 mA and once the twitch remained evident with the decreased current, local anesthetic dose was injected with frequent aspiration.

In Group Ketorolac, each patient was given IV Ketorolac 0.5mg/kg for reducing the pain post operatively.

All patients were monitored for 24 hours.

The Visual Analog Scale was recorded at rest for every 2hrs over a duration of 12 hour postoperatively. During the postoperative period, patients was given Inj. Ketorolac IV 0.5mg/kg stat on demand for rescue analgesia when the pain score is more than 7 on the basis of the Visual Analog Scale. Subsequent rescue analgesics were given if the patient had a pain score of 5 or more than 5. Time of administration the rescue analgesic was noted and chart was maintained.

Statistical analysis

SPSS version 25.0 analyzed the Excel data when it was loaded. Quantitative (numerical variables) data was given as mean and standard deviation, whereas qualitative (categorical variables) data was provided as frequency and percentage. The student t-test was used to compare the two groups' mean values, while the chi-square test analyzed their frequency differences. If $p < 0.05$, it was statistically significant.

Results:

Both groups were comparable with respect to their age, weight and ASA grade and there was no significant difference seen.

Table 1: Comparison between LPB group and KETOROLAC group as per first rescue analgesia

| Groups | First Rescue Analgesia (hours) | | |
|-----------------|--------------------------------|-----------------|---------|
| | Mean±S.D. | Mean Difference | p-value |
| Group LPB | 8.80±1.17 | 5.36 | 0.001* |
| Group Ketorolac | 3.44±0.61 | | |

The comparison of mean time to First Rescue Analgesia (hours) between Group LP and Group Ketorolac using the unpaired t-test showed that the mean time to First Rescue Analgesia (hours) was significantly more among Group LPB compared to Group Ketorolac.

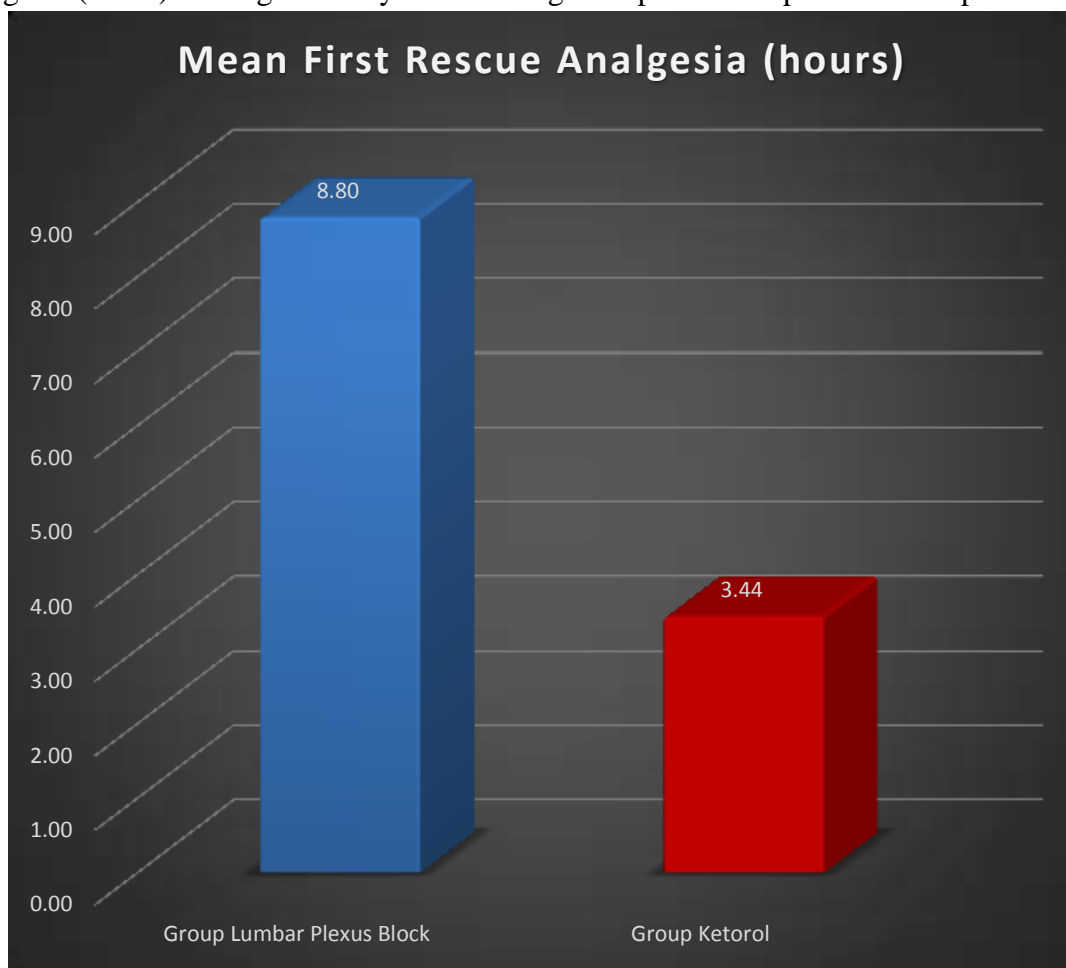


Chart suggestive of requirement of first rescue analgesia in LPB and Ketorolac group

Table 2: Comparison between LPB group and KETOROLAC group as per VAS score

| VAS score | Group LPB | Group Ketorolac | Mean Difference | p-value |
|----------------------------|-----------|-----------------|-----------------|---------|
| | Mean±S.D. | Mean±S.D. | | |
| At 2 hours post operative | 2.07±0.37 | 3.43±0.50 | -1.36 | 0.001* |
| At 4 hours post operative | 2.10±0.55 | 4.83±0.59 | -2.73 | 0.001* |
| At 6 hours post operative | 3.80±0.89 | 4.40±0.50 | -0.60 | 0.002* |
| At 8 hours post operative | 4.57±0.73 | 5.20±0.61 | -0.63 | 0.001* |
| At 10 hours post operative | 4.37±0.67 | 4.60±0.68 | -0.23 | 0.048* |
| At 12 hours post operative | 4.77±0.68 | 5.43±0.73 | -0.66 | 0.001* |

The comparison of mean VAS score 2 hour, 4 hour, 6 hour, 8 hour, 10 hour and 12 hours post operative between Group LP and Group Ketorolac using the unpaired t-test showed that the mean VAS score was significantly more among Group Ketorolac compared to Group LPB.

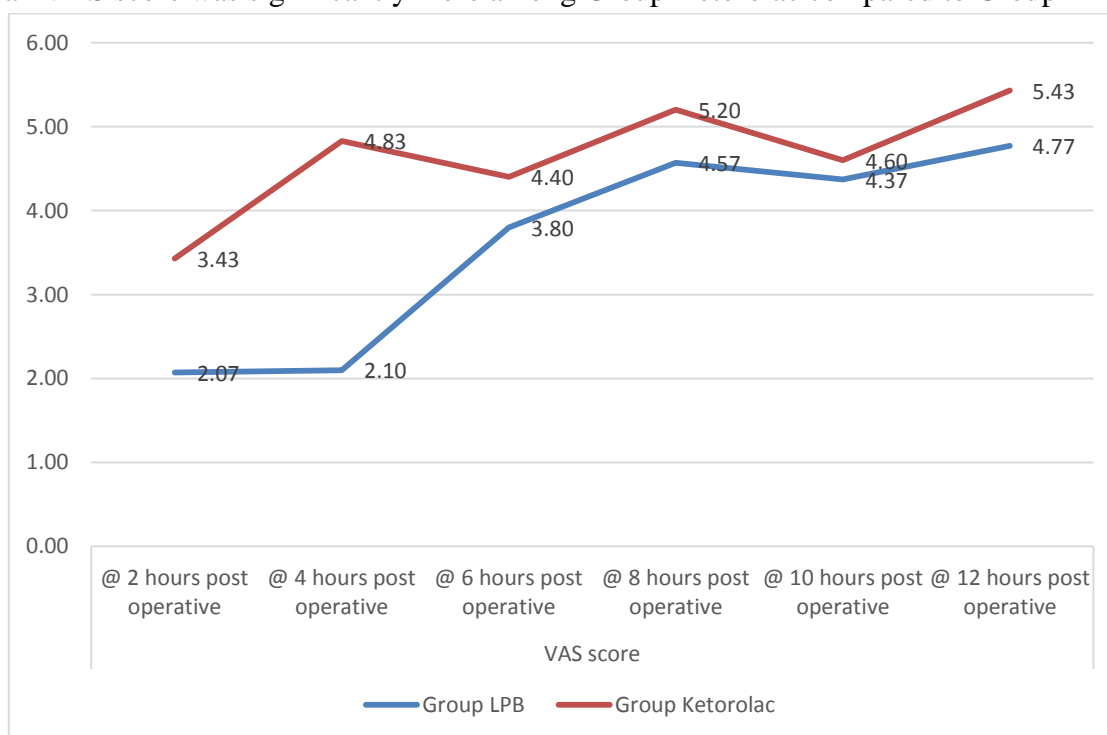


Chart suggestive of VAS score postoperatively in LPB group and Ketorolac Group

Table 3: Comparison between LPB group and KETOROLAC group as per heart rate:

| Heart rate | Group LPB | Group Ketorolac | Mean Difference | p-value |
|---------------|-------------|-----------------|-----------------|---------|
| | Mean±S.D. | Mean±S.D. | | |
| Before block | 94.00±13.05 | 88.13±11.68 | 5.87 | 0.072 |
| At 10 minutes | 89.03±13.75 | 87.37±10.90 | 1.67 | 0.605 |
| At 20 minutes | 85.73±12.44 | 87.10±10.79 | -1.37 | 0.651 |
| At 30 minutes | 83.70±12.34 | 87.87±10.39 | -4.17 | 0.162 |

The comparison of mean heart rate before block, at 10 minutes, at 20 minutes and at 30 minutes between Group LPB and Group Ketorolac using the unpaired t-test showed no significant difference in mean Heart rate Before block, at 10 minutes, at 20 minutes and at 30 minutes between Group LPB and Group Ketorolac.

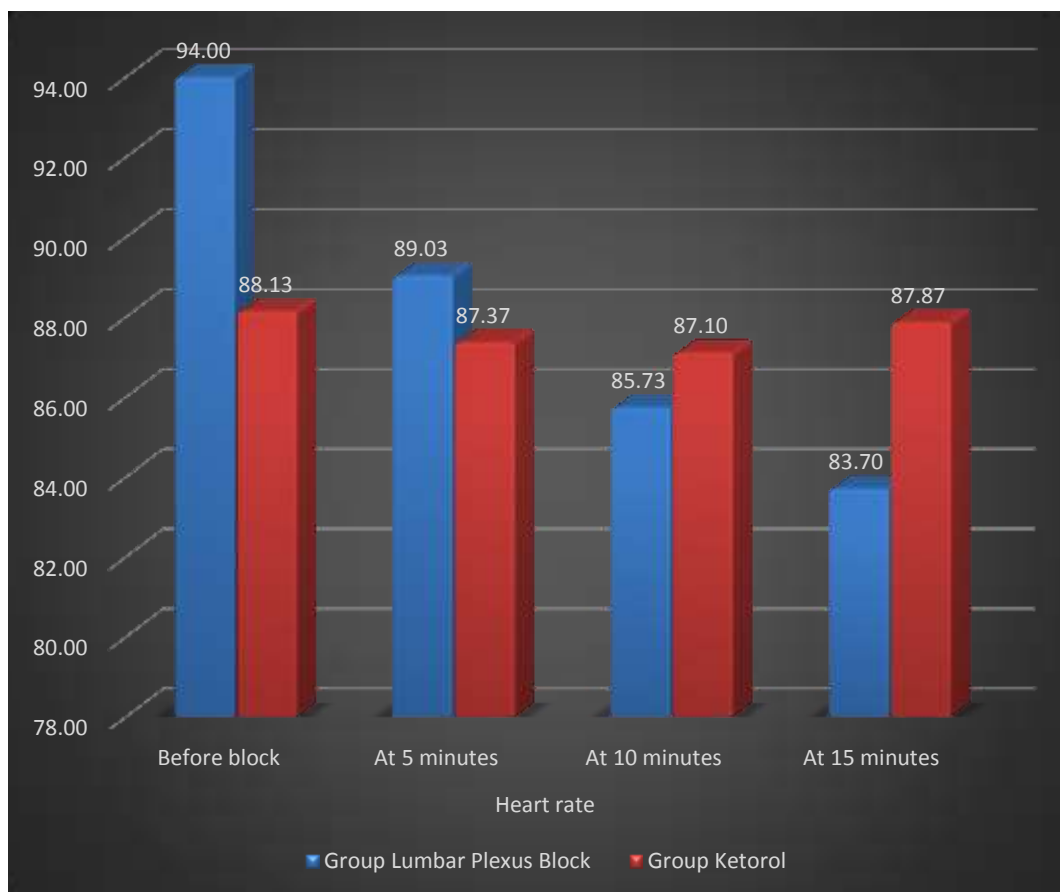


Chart suggestive of comparison between Heart Rate between LPB and Ketorolac group.

Table 4: Comparison between LPB group and KETOROLAC group as per mean arterial pressure:

| | Group LPB | Group Ketorolac | Mean Difference | p-value |
|---------------|------------|-----------------|-----------------|---------|
| MAP | Mean±S.D. | Mean±S.D. | | |
| Before block | 99.63±7.41 | 101.97±6.57 | -2.33 | 0.202 |
| At 10 minutes | 99.87±5.92 | 100.43±6.03 | -0.57 | 0.715 |
| At 20 minutes | 98.50±6.12 | 99.50±5.86 | -1.00 | 0.521 |
| At 30 minutes | 98.20±5.73 | 99.00±5.36 | -0.80 | 0.579 |

The comparison of mean MAP Before block, at 10 minutes, at 20 minutes and at 30 minutes between Group LPB and Group Ketorolac using the unpaired t-test showed no significant difference in mean MAP Before block, at 10 minutes, at 20 minutes and at 30 minutes between Group LPB and Group Ketorolac.

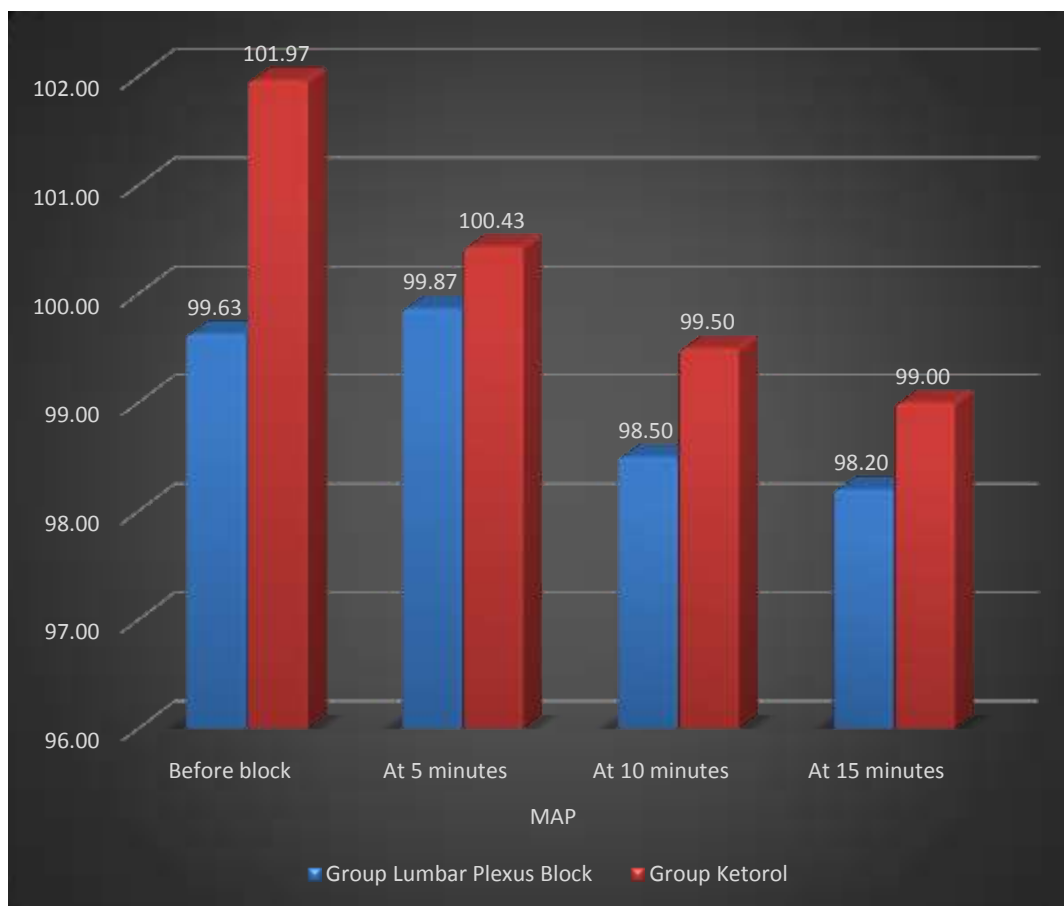


Chart suggestive of comparison of MAP between LPB and ketorolac group

Discussion

Lower limb orthopaedic surgery causes significant postoperative pain that may be treated using regional analgesic methods. When compared with other regimens, regional anesthesia provides superior pain relief and may favorably influence outcomes such as reduced blood loss and low incidence of thromboembolic events. Blocks are appreciated for the superlative and long-lasting analgesia they provide. Moreover, when compared with other types of anesthesia, a nerve block may enhance intraoperative hemodynamic stability.^[13]

For lower limb orthopaedic surgery three branches of the lumbar plexus need to be blocked namely the lateral femoral cutaneous nerve of the thigh, obturator nerve, and femoral nerve. These are the branches of the lumbar plexus. Lumbar plexus block is used as post-operative analgesia and leads to less use of NSAIDs, epidurals and opioids. There was no significant difference in mean age, weight, and No. of days since fracture between Group Lumbar Plexus Block and Group Ketorolac.

In our study, the mean VAS score for 2-hour, 4-hour, 6-hour, 8-hour, 10 hours and 12 hours post-operative was significantly more among Group Ketorolac compared to Group LPB. The mean in Group LPB patients in our study was (2.07±0.37, 2.10±0.55, 3.80±0.89, 4.57±0.73, 4.37±0.67, 4.77±0.68) and the mean in group Ketorolac was (3.43±0.50, 4.83±0.59, 4.40±0.50, 5.20±0.61, 4.60±0.68, 5.43±0.73). Similar to our study, Kundu *et al.*,^[14] did a study in which the VAS score in Group B (lumbar plexus and sciatic nerve block) was observed to be much lower for a significantly longer period of

time into the postoperative period than it was in Group A (Bupivacaine and Fentanyl). This was in line with our findings as well. According to *Luber et al.*^[15] they found comparable results, lumbar plexus block appears to give advantages for early postoperative analgesia, resulting in improved patient comfort and satisfaction. The requirement for the first rescue analgesia in this study was approximately after 8 hours postoperatively.

VAS score in our study is suggestive of the fact that the action of lumbar plexus block is longer than the action of IV ketorolac. According to *Ankur et al.*^[16] two groups were taken as per the study it was found that in Group 2 which was the LPB group VAS score at 30,60,90 and 120 mins (1.5 ± 0.51 , 1.8 ± 0.58 , 2.2 ± 0.65 , 1.72 ± 0.54) interval was less than the group 1. Also, the requirement of the first rescue analgesia in group LPB (8.80 ± 1.17) hour postoperatively, whereas in group ketorolac requirement of the first rescue analgesia was (3.44 ± 0.61) hours postoperatively. Hence proving that the lumbar plexus block provides better analgesia as compared to the IV ketorolac. According to *Ankur et al.*^[16] it was found that the requirement of the first rescue analgesia in the patients in group LPB was after 7 hours approximately postoperatively. It was found in the current research that the mean time to First Rescue Analgesia (hours) was significantly more among Group Lumbar Plexus Block compared to Group Ketorolac. This was in similarity to the findings by *Kundu et al.*^[15] it was revealed that Group B (lumbar plexus and sciatic nerve block) had a substantially longer duration of analgesia compared to Group A (Bupivacaine and Fentanyl), since p value is 0.002 which shows that there is significant difference between the two groups. We also found a study by *Moreno et al.*^[17] which reported excellent and prolonged postoperative analgesia thereby significantly decreasing the need for opioids. Which was in comparison to our study.

Aytolign et al.^[19] found that both single-shot LPB and the 3IN1B were equivalent in terms of the mean time to 1st request of analgesia, and the total amount of analgesic intake for the first twenty-four hours following thigh orthopedic surgery.

Tokat et al.^[20] concluded that LPB is more effective than 3IN1B. In terms of total analgesic consumption, it was higher in the 3IN1B group than in the LPB group, but the mean time to the first request for analgesia was the same in both groups. The fact that the prior study incorporated sciatic block in both groups for intra-operation anesthetic and postoperative analgesia might be a potential reason for these findings.

A study done by *Masoumi et al.*^[21] in 2017 used ketorolac for femur fracture patients for pain relief. Here, 10 mg iv ketorolac was given as a loading dose followed by 5 mg every 5 minutes to 10 minutes if $VAS \geq 4$. The mean VAS score at 30-minute intervals was 2.39 ± 0.81 whereas in our study where ketorolac was given at a dose of 0.5mg/kg (maximum of 30 mg) had a VAS of (3.43 ± 0.50 , 4.83 ± 0.59 , 4.40 ± 0.50 , 5.20 ± 0.61 , 4.60 ± 0.68 , 5.43 ± 0.73) post operatively at 2-hour interval for 12 hours. This study by *Masoumi et al.*^[21] was done on a patient with femur fracture and compared VAS score at different time intervals while patients were at rest.

There was no significant difference in mean Heart rate before block, At 10 minutes, at 20 minutes, and 30 minutes between Group Lumbar Plexus Block (94.00 ± 13.05 , 89.03 ± 13.75 , 85.73 ± 12.44 , 83.70 ± 12.34) and Group Ketorolac (88.13 ± 11.68 , 87.37 ± 10.90 , 87.10 ± 10.79 ,

87.87±10.39). There was no significant difference in mean MAP Before block, at 10 minutes, at 20 minutes, and 30 minutes between Group Lumbar Plexus Block (99.63±7.41,99.87±5.92,98.50±6.12,98.20±5.73) and Group Ketorolac (101.97±6.57,100.43±6.03,99.50±5.86,99.00±5.36). According to Ankur et al. [16] in Group 2 i.e LPB group changes were insignificant at all the intervals from the baseline. Between groups, blood pressure changes were statistically significant at time intervals of 15, 30, 45, 60, 75, 90, 105, and 120 min mean ±SD (152.66 ± 16.7 148.44 ± 15.58 147.12 ± 14.53 148.3 ± 15.6 146.6 ± 15.3 147.92 ± 15.0 146.08 ± 12.5 147.28 ± 15.63 151.5 ± 12.4) and p-value (0.37,0.23,0.36,0.20,0.31,0.13,0.26,0.83)

There was no significant difference in mean SpO₂ before block, at 10 minutes, at 20 minutes, and 30 minutes between Group Lumbar Plexus Block (98.93±1.20, 99.13±1.04, 99.17±0.87, 99.00±0.91) and Group Ketorolac (98.90±0.76, 99.00±0.70, 99.00±0.74, 98.93±0.91). There was no significant difference in mean Respiratory rate before block, at 5 minutes, at 10 minutes, and 15 minutes between Group Lumbar Plexus Block and Group Ketorolac.

Conclusion

Lumbar Plexus Block provides superior postoperative analgesia in patients undergoing surgery for total hip replacement under spinal anaesthesia. Also, patients who were given Lumbar Plexus Block required less amount of rescue analgesia as compared to those who were administered IV Inj. Ketorolac as post operative analgesic agent. There was no side effect from the drugs or complication of LPB was reported in our study.

Limitation

- The intensity of pain perceived can vary from patient to patient depending on the pain threshold.
- As the block was given immediately after surgery under spinal anaesthesia, time required by the block to achieve peak analgesia could not be assessed.

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