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Original Research Article

Evaluation of Clonidine as an Adjuvant to Ropivacaine in Sciatic Femoral Nerve Block for Lower Limb Surgeries

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Abstract:

Background: The utilization of clonidine as an adjuvant to ropivacaine has demonstrated its ability to extend the duration of peripheral nerve blocks. However, the precise mechanism of action behind this effect remains uncertain. To address this, our hypothesis posits that when clonidine is used as an adjuvant to ropivacaine in an adductor canal block (ACB), the extension of block duration is primarily attributed to a peripheral mechanism. We aim to investigate this hypothesis while controlling for systemic effects.

Methods: This was a randomized, double-blinded study that assigned patients into two groups: Group I, which received ropivacaine, and Group II, which received ropivacaine and clonidine. Each group consisted of n=25 patients, and the surgical procedure was performed under a sciatic femoral nerve block. The patients selected were ASA I and II categories and undergoing elective surgery of lower limbs.

Results: The onset of sensory blockade in group I mean value of 9.5 ± 1.5 minutes in group II, the onset time mean value of 11.5 ± 1.8 minutes. The onset of motor block in the study in group I was 13.25 ± 1.0 minutes in group II was 14.2 ± 1.0 minutes. The duration of sensory block in group I was 11.75 hours which is relatively shorter than group II with a mean duration of 16.10 hours the p values were found to be significant. the duration of the motor block in group I was 10.8 hours as compared to group II with a duration of 12.5 hours and the p values were found to be significant.

Conclusion: When clonidine is added to ropivacaine in a sciatic femoral nerve block, there is no significant difference observed in the onset of sensory and motor blockade compared to using ropivacaine alone. However, the addition of clonidine does lead to a prolongation in the duration of both sensory and motor blockade as well as postoperative analgesia when compared to using ropivacaine alone.

Keywords: Clonidine, Ropivacaine, Sensory block, Motor block, Sciatic Femoral Nerve Block

Introduction

Regional anesthesia techniques, such as nerve blocks, have been widely used to provide effective pain control for various surgical procedures. To prolong the duration of regional anesthesia and improve postoperative pain management, several techniques have been employed. One such technique is the continuous infusion of local anesthetics through catheters placed near the nerves. This method allows for a steady and prolonged release of the anesthetic, providing sustained pain relief.

[1] Continuous nerve blocks are commonly used in orthopedic surgeries, especially in the lower extremities, where postoperative pain can be severe and long-lasting. In addition to local anesthetics, opioids have been used as adjuvants to enhance the analgesic effect of nerve blocks. By combining opioids with local anesthetics in the infusion solution, the duration and quality of pain relief can be improved. Opioids act on specific receptors in the nervous system, enhancing the analgesic effect and reducing the need for additional pain medications. [2] For surgeries involving the leg, a single-shot nerve block can be highly effective in controlling postoperative pain. The sciatic nerve, which provides sensory innervation to a large area of the leg, can be targeted along with other nerves such as the saphenous or femoral nerve. This combination of nerve blocks can provide comprehensive anesthesia for surgical procedures below the knee. One advantage of peripheral nerve blocks, like sciatic nerve blocks, is that they avoid the sympathectomy associated with neuraxial blocks. Sympathectomy refers to the interruption of sympathetic nerve activity, which can lead to changes in hemodynamics. [3] By avoiding this sympathectomy, nerve blocks can be advantageous in situations where hemodynamic stability is crucial. Overall, regional anesthesia techniques, including continuous nerve blocks and the use of opioids as adjuvants, offer effective pain management for postoperative pain, particularly in surgeries involving the leg. These techniques provide prolonged pain relief and can be a valuable alternative to oral medications in controlling pain after surgery.

The effectiveness of using clonidine as a supplementary medication to ropivacaine is still a subject of debate. Some studies indicate that it prolongs the duration of nerve blocks [4-6], while others do not show the same effect [4–6]. In vitro animal studies have shown that clonidine has a local effect, specifically by inhibiting the Ih current in C-fibers, which contributes to the prolongation of the block. [7]. However, clonidine also possesses systemic analgesic properties. Peripheral nerve blocks are commonly employed for surgical procedures, either as the primary anesthetic or as part of a comprehensive pain management strategy to minimize side effects associated with opioids. [8] One limitation of single-injection nerve blocks is their relatively short duration of action. Various methods exist to extend the duration of nerve blocks, such as continuous peripheral nerve blocks [9, 10], the use of long-acting local anesthetics, or the incorporation of different supplementary medications. [11–13] The current study aimed to assess the efficacy of clonidine as an adjuvant to bupivacaine for sciatic nerve blocks.

Material and Methods

This cross-sectional study was conducted in the Department of Anesthesiology, Prathima Institute of Medical Sciences, Naganoor, Karimnagar, Telangana State. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study.

Inclusion criteria

1. All the patients undergoing lower limb surgeries under local anesthesia.
2. Aged 18 – 50 years.
3. Males and Females
4. ASA I and II categories
5. Voluntarily willing to participate in the study.

Exclusion criteria

1. Patients of NSAIDS
2. Patients contraindicated to clonidine.
3. History of Allergy to Local Anesthetics
4. Coagulation disorders, Kidney disorders
5. Peripheral Neuropathy
6. Not willing to participate in the study.

This was a randomized, double-blinded study that assigned patients into two

groups: Group I, which received ropivacaine, and Group II, which received ropivacaine and clonidine. Each group consisted of n=25 patients, and the surgical procedure was performed under a sciatic femoral nerve block. Before the surgery, preoperative investigations were conducted, including measurements of hemoglobin, blood sugar levels, urea, serum creatinine, and urine albumin.

After selecting the cases no premedication was administered. Intravenous access was established, and the anesthesia machine was checked while ensuring the availability of resuscitative equipment and drugs. The sciatic femoral block was performed using the posterior Labat's approach, confirmed with a nerve stimulator. In Group I, patients received 30 ml of 0.75% ropivacaine mixed with 0.4 ml of normal saline. Of this mixture, 18 ml was administered in the sciatic nerve block and 12 ml in the femoral nerve block. In Group II, patients received 30 ml of 0.75% ropivacaine mixed with 0.4 ml of clonidine (60 micrograms). Similarly, 18 ml was administered in the sciatic nerve block and 12 ml in the femoral nerve block. Great care was taken to ensure that the doses of local anesthetics remained within safe limits based on the patient's weight.

The following parameters were observed:

The onset of analgesia: The onset of analgesia was determined by the complete elimination of pinprick pain in the distribution area of the tibial and femoral nerves. This assessment was performed every minute following the administration of the nerve block.

The onset of motor blockade: The onset of motor blockade was assessed every 3 minutes after the block using four-point scales. 0 – Normal power, 1- Weakness but able to move leg 2- Not able to move leg but able to move the toes 3- Complete motor blockade Attaining a score of 2 was considered as the onset of motor Block

Duration of motor Blockade: When (3) in the four-point scale changes to (2) the motor blockade is said to reverse. The duration of the motor block is noted from the time from scale (3) to scale (0)

Duration of analgesia: Pain levels were assessed using a visual analog scale (VAS) that consisted of a 10 cm line with numbers ranging from 0 to 10. Patients were provided with an explanation of the VAS, where 0 represented no pain and 10 represented the worst possible pain. They were then asked to indicate their pain score on the visual analog scale.

Observations were made at regular intervals after the surgery. Patients were monitored every 30 minutes until the motor block was reversed, and subsequently, every hour for 6 hours and every 2 hours for the following 10 hours. The duration of the absolute pain-free period was recorded, indicating the postoperative period during which the patient did not experience any pain (VAS score of 0). The time at which the VAS score exceeded 5 was noted, and the patient received rescue analgesia in the form of an intramuscular non-steroidal anti-inflammatory drug (NSAID) such as diclofenac.

Duration of postoperative analgesia was defined as the length of time from the surgery until the patient required analgesics due to a VAS score higher than 5.

Vital parameters including pulse rate, blood pressure, and SPO2 (oxygen saturation) were monitored. The Ramsay sedation score was recorded, and potential side effects such as hypotension and bradycardia were also noted.

Statistical analysis: All the available data was uploaded on an MS Excel spreadsheet and analyzed by SPSS version 19 in Windows format. Continuous variables were represented as Mean, standard deviations, and percentages. Categorical variables were calculated by Fischer's Exact test and p-values of (<0.05) were considered significant.

Results

Out of the n=25 cases included in each group; we found the most commonly involved age group was 41 – 50 years with 38% of all the cases. The distribution of cases based on age have been depicted in Table 1. The range of age in group I was from 22 – 46 years and the mean age was 45.5 ± 5.5 years. Similarly, for group II the range of age was 21 – 59 years and the mean age was 49.5 ± 3.5 years. The p values were found to be greater than 0.05 hence the distribution of cases in the groups was found to be even based on the age of the cases.

Table 1: Age and group-wise distribution of cases in the study

Age group	*Group I*	*Group II*	*Total (%)*
18 – 30	4	3	7 (14%)
31 – 40	6	8	14 (28%)
41 – 50	10	9	19 (38%)
51 – 60	5	5	10 (20%)
Total	25	25	50 (100%)

In group I cases out of n=25 cases n=18 were males and n=7 were females and in group II out of n=25 cases n=19 were males and n=6 were females. The distribution of cases based on the sex in each group was found to be even with p-values of 0.896.

The average weight of patients in group I was 54.5 ± 8.5 kgs, while in group RC it was 56.8 ± 6.2 kgs. The statistical analysis revealed a p-value of 0.325, indicating that the difference in weight between the two groups is not statistically significant. In group I, n=6 patients were ASA I and n=19 patients were ASA II. In Group RC, n=5 patients were ASA I and n=20 patients were ASA II. Both the groups were comparable in respect to ASA classification with a "p" value of 0.875 which is statistically insignificant.

Table 2: Showing the onset of sensory block in minutes in both groups.

Onset of sensor block (Min)	*Group I*	*Group II*
7	2(8%)	0(00%)
8	4(16%)	2(8%)
9	7(28%)	4(16%)
10	5(20%)	5(20%)
11	4(16%)	8(32%)
12	3(12%)	3(12%)
13	0(00%)	2(8%)
14	0(00%)	1(4%)
15	0(00%)	0(00%)
Total	25	25

Based on the results in Table 2, it appears that two groups (group I and group II) were compared in terms of the onset of sensory blockade. The onset time in group I ranged from 7 to 12 minutes, with a mean value of 9.5 minutes and a standard deviation of 1.5 minutes (Table 2). In group II, the onset time varied from 8 to 14 minutes, with a mean value of 11.5 minutes with a standard deviation of 1.8 minutes. The p-value of 0.338 suggests that there is no statistically significant difference between the two groups.

Table 3: Showing the onset of Motor block in minutes in both groups.

Onset of motor block (min)	*Group I*	*Group II*
10	1(4%)	1(4%)
11	2(8%)	0(00%)
12	3(12%)	4(16%)
13	11(44%)	8(24%)
14	6(24%)	4(16%)
15	2(8%)	3(12%)
16	0(00%)	2(8%)
17	0(00%)	2(8%)
18	0(00%)	1(4%)
Total	25	25

The onset of motor block in the study in group I varied from 10 to 15 minutes and the mean value was 13.25 ± 1.0 minutes and the mean values of onset of motor block in group II varied from 10 to 18 minutes and the mean values were 14.2 ± 1.0 minutes (table 3). The p-values between the two were found to be 0.158 and insignificant.

Table 4: Duration of sensory and motor block in hours between the groups

	Duration of Block in Hours			
	Sensory Block		Motor Block	
	Group I	Group II	Group I	Group II
Range	9 – 13	13 – 17	8 - 12	10 - 14
Mean	11.75	16.10	10.8	12.5
± SD	1.75	1.85	1.95	1.55
P value	0.0128*		0.0321*	

* Significant

The duration of sensory block in group I was 11.75 hours which is relatively shorter than group II with a mean duration of 16.10 hours the p values were found to be significant depicted in Table 4. Similarly, the duration of the motor block in group I was 10.8 hours as compared to group II with a duration of 12.5 hours, and the p values were found to be significant. Therefore, based on the given information, there is a statistically significant difference between the two groups in terms of both the duration of sensory blockade and motor blockade. Group II had longer durations in both sensory and motor blocks compared to Group I. The Duration of analgesia was significantly longer in group II (16.5 ± 0.75 hours) than in group I (12.25± 0.85 hours). 'p-value was 0.04. The difference between the two groups was statistically significant. In all the cases (n=25) in the group I had a sedation score of 1. But only n=5 cases in group II had a score of 1 and the remaining 20 had a score of 2. The difference between the two groups was statistically significant with a p-value of 0.0258. There were no significant differences between group I and group II based on SBP, DBP, MAP, Heart Rate, and SPO_2.

Discussion

The significance of alpha-2 agonists like clonidine increases when used as an adjuvant in anesthesia and as an analgesic. Its primary action is sympathectomy, as it decreases the release of norepinephrine in

the peripheral system by activating inhibitory alpha-2 adrenoreceptors located before the junction. [14] Additionally, it inhibits neural transmission in the dorsal horn of the central nervous system through both presynaptic and postsynaptic mechanisms. It also directly affects spinal preganglionic sympathetic neurons. [15] While traditionally employed as an antihypertensive medication, its potential applications as a sedative, anxiolytic, and analgesic are currently being explored. In this study, the addition of 60µg of clonidine to a combined sciatic femoral block did not result in any statistically significant differences between the two groups in terms of age, sex, weight, and ASA status. In group I, the sensory block onset occurred at approximately 9.5 ± 1.5 minutes, while the motor block onset occurred at approximately 13.25 ± 1.0 minutes. In group II, the sensory block onset occurred at approximately 11.5 ± 1.8 minutes, and the motor block onset occurred at approximately 14.2 ± 1.0 minutes. The addition of clonidine did not have a significant impact on the onset of sensory and motor blocks. The duration of surgery was similar in both groups. The mean duration of sensory block in group I was 11.75 ± 1.75 hours, while in group II, it was 16.10 ± 1.85 hours. The difference between the two groups was statistically significant, with a p-value of 0.0128 ($P < 0.05$), indicating that the addition of clonidine in group II resulted in a significantly longer duration of sensory block compared to group I.

Previous trials in this field have typically utilized a two-group design, where one group received a block with both ropivacaine and clonidine, while the other group received only ropivacaine [4-6, 16-18]. While this design examines the overall impact of clonidine on the duration of the block, it does not provide conclusive evidence regarding its site of action. Consequently, the results from these trials have been inconsistent. Four of the trials found no extension of the sensory nerve block, suggesting that clonidine has no effect at all [18, 19]. In contrast, other trials discovered that the addition of clonidine to ropivacaine did prolong the block duration [19, 20]. This effect could potentially be attributed to a peripheral mechanism of clonidine or the systemic absorption and redistribution of perineurally administered clonidine, which exerts its properties systemically.

In the study conducted by Helayel et al., [21], intramuscular clonidine was utilized as a systemic adjuvant to ropivacaine in a sciatic nerve block for foot and ankle surgery. Similarly, Culebras et al., [22] included a group that received intramuscular clonidine as an adjuvant to bupivacaine in an interscalene block for rotator cuff repair. In both trials, no significant difference was observed in the duration of analgesia between the perineural (local administration), systemic (intramuscular administration), and placebo groups. These findings suggest that there is no notable effect of clonidine when used as an adjuvant in these contexts. However, our study found a significant difference between the ropivacaine group and the ropivacaine and clonidine group. The systemic adverse events reported in various studies vary from no side effects [3, 5] to mild sedation, lower heart rate, and lower blood pressure. [23] These findings are consistent with the results obtained in our study.

Conclusion

When clonidine is added to ropivacaine in a sciatic femoral nerve block, there is no significant difference observed in the onset of sensory and motor blockade compared to using ropivacaine alone. However, the addition of clonidine does lead to a prolongation in the duration of both sensory and motor blockade as well as postoperative analgesia when compared to using ropivacaine alone. The incidence of adverse reactions was not found in any of

the groups at the given dose used for the patients.

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