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Research Article

A Randomized Control Trial to Compare the Onset and Duration of Sensory and Motor Blockade with Intrathecal Isobaric Ropivacaine versus Isobaric Ropivacaine-Clonidine for Infraumbilical Surgeries

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ABSTRACT

Background: To investigate the onset and duration of sensory and motor blockade in isobaric 0.75% Ropivacaine and isobaric 0.75% Ropivacaine - Clonidine in patients undergoing infra umbilical surgeries.
One year double-blinded randomized controlled trial.
Methods: A total of 70 patients undergoing infra umbilical surgeries were allocated into two groups namely, Group I (n=35; Patients received 3 ml of isobaric 0.75 % ropivacaine intrathecally) or Group II (n=35; Patients received 3 ml of isobaric 0.75 % ropivacaine + 15 mcg of clonidine intrathecally). Onset and duration of Sensory and motor block and hemodynamic parameters were noted and compared.
Results: The demographic parameters were comparable in both groups. The onset of sensory block was similar in both groups but the duration of sensory block was prolonged in group II (191.7±19.21 minutes) than in group I (180.8 ±13.08 minutes). The motor block onset was faster in group II (11.4±2.29 minutes) than in group I (13.6±2.29 minutes). Duration of motor block was prolonged in group II (271.3±18.32 minutes) than in group I (224.5±16.46 minutes).
Conclusion: The addition of clonidine to 0.75 % isobaric ropivacaine intrathecally prolonged the duration of sensory and motor block but with no effect on the sensory onset but the faster onset of the motor block with no significant hemodynamic changes.

Introduction

Spinal anaesthesia is a widely used technique for surgeries of the abdomen, pelvis and lower limbs due to its quick onset and effective sensory and motor blockade. When compared to Bupivacaine, Ropivacaine is less toxic and similar in terms of the level of the block but with a later onset of motor block and for a shorter duration [1-2].

Different drugs, like phenylephrine, epinephrine, adenosine, magnesium sulfate, fentanyl and clonidine, have been used with local anaesthetic to prolong the duration of spinal analgesia intrathecally.

Alpha-2 adrenergic agonists with its analgesic and sedative properties, not only potentiates the effect of local anaesthetic but can also reduce the dose needed when used with local anesthetics [3-4]

The use of such adjuvants reduces the need for anesthetic and analgesic requirement to a significant extent due to their analgesic properties and also as they cause hyperpolarization of nerve tissue by altering

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transmembrane potential and ion conductance at locus coeruleus in the brainstem which enhances local anesthetic effect [3].

Clonidine is a partial α2 agonist used intrathecally with demonstrated safety. When used with local anesthetics, it prolongs the duration of motor and sensory spinal blockade [5-8].

Several studies have shown the effect of Clonidine on Bupivacaine. There are only a few studies showing the effect of clonidine as an adjuvant to 0.5 % isobaric ropivacaine intrathecally [6]. However there is no study evaluating the effect of clonidine in addition to 0.75 % isobaric ropivacaine.

Hence this study attempted to compare the onset and duration of sensory and motor block following intrathecal isobaric ropivacaine and intrathecal isobaric ropivacaine supplemented with clonidine.

Methods

Source of Data

A computerized randomization process was used to separate the 70 patients scheduled for infraumbilical surgery into two groups for a one-year randomized control experiment.

Sampling procedure

The duration of the motor block was used to calculate the sample size using the findings of the earlier study and standard statistical formula.

$$Sample\ Size\ = \frac{2\ (\mathrm{Z}\alpha\ +\ \mathrm{Z}\beta)^2\ (S_1{}^2\ +\ S_2{}^2)}{(\ \overline{x_1}\ -\ \overline{x_2})^2}$$

The Level of significance is taken as 5%

The Power of the test used is taken as 80%

Hence, Zα= 1.96 $\overline{x_1}$ =112

Zβ= 0.84 $\overline{x_2}$ =127

S_1= 11 S_2 =19.5

Where:

- S_1 is S.D of the Ropivacaine group
- S_2 is S.D of the Ropivacaine-clonidine group
- $\overline{x_1}$ is the duration of motor block in the Ropivacaine group
- $\overline{x_2}$ is the duration of motor block in the Ropivacaine-clonidine group

The sample size obtained was 35 in each group.

Selection Criteria:

Inclusion

- Patients undergoing infraumbilical surgeries under spinal anaesthesia.
- Age: 18 to 60 years.
- ASA Grade I and Grade II patients.
- Height: 150 cm - 180 cm

Exclusion

- Patient's refusal.
- Contraindications to subarachnoid block like coagulopathy, local skin infection, raised intracranial pressure, spinal deformity, etc.
- ASA grade III or IV patients.
- Patient allergic to study drugs.

After obtaining approval from the Ethics Commission, patients were randomly assigned to one of the two groups of 35 patients each based on a computer-generated randomization table after meeting inclusion and exclusion criteria and obtaining informed consent. Patients belonging to ASA Grade I and II of either gender between the age group of 18-60 years scheduled for infraumbilical surgeries were studied.

- Group I: Received 3ml of isobaric 0.75% Ropivacaine.
- Group II: Received 3 ml of isobaric0.75% Ropivacaine + 15mcg Clonidine.

An Anaesthesiologist involved in the data collection as well as the patient was blinded to the content of the study solution.

The patient's intravenous (IV) line was set up prior to surgery with either an 18 G or 20 G cannula, and 15 ml/kg of IV ringer lactate solution was begun 30 minutes before spinal anesthesia. The patient was then moved to the operating room, where baseline values were taken and monitors such an electrocardiograph (ECG), pulse oximeter, and non-invasive blood pressure were attached. The patient was positioned on his or her lateral side.

The study medication was injected at the rate of 1ml/15 seconds into the L3-L4 subarachnoid space using a 23 G Quincke's spinal needle under thorough aseptic conditions. The patient was then immediately placed in supine position.

The sensory block was assessed using an alcohol swab in the mid clavicular line. T10 was taken as the level for onset of the sensory blockade and recovery time for the sensory blockade was defined as two dermatome regressions of anaesthesia from the highest level. Following the evaluation of sensory block, the motor block was evaluated using a modified Bromage scale.

The time to achieve a modified Bromage score of 3 was taken as onset of motor block and the time to return to a modified Bromage score of 0 was taken as duration of the motor block.

Sensory and motor block was assessed at time intervals: 0, 5, 10, 15, 20, 25 and every 15 minutes till there was two segment regression in sensory block and motor block regressed completely (i.e., modified bromage score= 0). The time of injection was used as the starting point for all calculations.

Until the end of the procedure, blood pressure and heart rate were monitored every 15 minutes and at intervals of 5, 15, 30, 45, and 60 minutes. A bolus intravenous fluid infusion and incremental intravenous boluses of mephentermine sulphate 3 mg were used to treat hypotension, which was defined as a 30% reduction in systolic blood pressure from baseline values or a systolic blood pressure less than 90 mm of Hg. Bradycardia was described as a heart rate reduction of less than 60 beats

per minute and was treated with intravenous Atropine Sulphate 0.6 mg. Supplementary oxygen was given through a face mask.

Statistical Analysis

Mean±Standard deviation were used to express all data.

Student's unpaired t-test was used to compare Quantitative data while Qualitative data were compared using the chi-square test.

The p-value of <0.05 was considered significant.

Results

There were no statistically significant variations between the two groups' patient demographics.

The onset of sensory block was comparable in both the groups but the duration of sensory block was prolonged in group II (191.7±19.21 minutes) than in group I (180.8 ±13.08 minutes). Onset of motor block was faster in group II (11.4±2.29 minutes) than in group I (13.6±2.29 minutes). Duration of motor block was prolonged in group II (271.3±18.32 minutes) than in group I (224.5±16.46 minutes). The mean heart rate was significantly lower in group II than in group I. Mean arterial pressure was comparable in most of the recordings between both groups. No other side effects like sedation, delayed mobilization and micturition were seen.

Table 1- Onset and Duration of Block

Parameters	Group I (minutes)	Group II (minutes)	P value
Sensory- Onset	10.8±2.56	10.6±2.02	0.067
Sensory-Duration	180.8±13.08	191.7±19.21	0.007
Motor- Onset	13.6±2.29	11.4±2.29	<0.001
Motor- Duration	224.5±16.46	271.3±18.32	<0.001

Table 2- Hemodynamic parameters - Heart rate

Time interval	Group I (n=35)		Group II (n=35)		P value
	Mean	SD	Mean	SD	
Baseline	88.13	13.88	77.87	8.03	0.936
4 minutes	82.80	12.27	75.80	07.52	0.005
10 minutes	79.80	09.91	74.80	06.31	0.014
15 minutes	79.50	10.25	74.20	06.85	0.014
20 minutes	81.20	10.56	74.80	07.61	0.005
25 minutes	81.40	09.84	74.70	07.24	0.002
30 minutes	80.90	09.71	74.90	06.89	0.004
40 minutes	80.80	09.51	74.80	07.02	0.004
50 minutes	82.20	09.65	74.80	07.56	0.001
60 minutes	80.90	08.31	76.40	07.04	0.017

Discussion

Intrathecal isobaric ropivacaine is more cardio-stable than Bupivacaine which is the widely used drug for spinal anaesthesia. But its drawbacks are its slower onset and shorter duration of blockade when compared to bupivacaine [9-10]. So, to hasten the onset, lengthen the duration, and provide effective analgesia, numerous adjuvants, including fentanyl and clonidine, have been added to ropivacaine. Clonidine has lately been thoroughly investigated because it has no opioid-related adverse effects such respiratory depression, nausea, or itching [11].

In a study by McNamee et al, different intrathecal ropivacaine doses and concentrations were investigated, and a comparison between intrathecal administration of 7.5 mg/ml (18.75 mg) ropivacaine and 10 mg/ml (25 mg) ropivacaine was done. The time to reduction to T10 and the duration of total motor block were both longer with 10 mg/ml (25 mg) intrathecal ropivacaine [12].

In a separate study by Van Kleef et al. [13], intrathecally administered ropivacaine at concentrations of 0.5% (1.5 ml) and 0.75% (1.5 ml) were compared. It was discovered that the total motor block rate (90%) and duration of motor block (268 min) were significantly higher and longer in the group receiving 0.75% ropivacaine.

Therefore, in our study, 0.75 % isobaric Ropivacaine was used but a larger volume (3ml) was chosen as infra

umbilical abdominal surgeries may require larger volume than used for lower limb surgeries for a better quality of motor blockade.

In our study 15mcg of Clonidine was used as an adjuvant to 3ml of 0.75% Ropivacaine as higher doses of clonidine were associated with significant adverse effects as demonstrated in a study by De Kock et al. [7] who observed comparable effects on the objective parameters of anaesthesia, i.e., duration of sensory and motor blockade on the addition of 15, 45, and 75 mcg of Clonidine to isobaric Ropivacaine but the dose of 45 and 75 mcg Clonidine were associated with increased cardiovascular and other side effects.

In our study, the mean onset of sensory blockade was 10.8± 2.5 minutes in plain Ropivacaine (group I) and10.6±2.02 minutes in Ropivacaine with clonidine (group II), this difference was statistically insignificant (p=0.067). The duration of sensory blockade in our study was 180.8±13.08 minutes in group I and 191.7±19.21 minutes in group II (with Clonidine) and this difference was statistically significant (p= 0.007). Similar findings were reported in a study done by G Sagiroglu et al [8,10].

In our study, the mean onset of motor blockade was 13.6±2.29 minutes in the plain Ropivacaine group and 11.4±2.29 minutes in Ropivacaine with Clonidine and the difference was statistically significant (p<0.001). However, another study done by C Ogun et al 6 didn't find any statistically significant difference because the study compared a lower dose of Ropivacaine with an adjuvant with that of the higher dose of Ropivacaine i.e., between 15mg Ropivacaine with 30 mcg Clonidine and 17.5 mg Ropivacaine (higher dose of ropivacaine).

The mean duration of motor block (complete motor recovery) was 224.5±16.46 minutes in the Ropivacaine group and 271.3±18.32 minutes in Ropivacaine with Clonidine group and the difference was statistically significant (p<0.001). Similar results were found in the study done by De Kock et al. [7] in patients undergoing knee arthroscopy. The quality and duration of the anesthesia produced by local anesthetic are improved when intrathecal Clonidine is combined with isobaric Ropivacaine. Through the activation of postsynaptic -2 receptors in the substantia gelatinosa of the spinal cord, its intrathecal injection produces an analgesic action that is spinally mediated. Additionally, it intensifies the motor blockage as it causes direct inhibition of impulse conduction in motor nerve fiber [14].

Overall, the current study demonstrated that intrathecal 15 mcg Clonidine administered as an adjuvant to 0.75% isobaric Ropivacaine prolonged the duration of sensory and motor block, which was statistically significant, with a similar onset of sensory block (statistically insignificant), and without any statistically significant side effects when compared to intrathecal plain 0.75 % isobaric Ropivacaine.

Conclusion

Addition of 15mcg clonidine to 0.75% Isobaric ropivacaine intrathecally significantly prolonged the duration of sensory and motor block without any increase in adverse effects.

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