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Anaesthesia Section

Comparison between Plain Ropivacaine, Ropivacaine with Buprenorphine and Ropivacaine with Clonidine for Intrathecal use in Lower Limb Orthopaedic Surgeries: A Randomised Controlled Trial

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ABSTRACT

Introduction: Ropivacaine is an amide local anaesthetic agent. The lower limb surgeries involves the great somatic pain. By using these adjuvants such as buprenorphine and clonidine with local anaesthetic agent to know the effective intraoperative and postoperative analgesia.

Aim: To compare the anaesthetic characteristics in terms of quality of blockade when intrathecal ropivacaine with buprenorphine and ropivacaine with clonidine as adjuvant.

Materials and Methods: The present double-blinded randomised control trial was carried out at a tertiary care hospital, Ammapettai, Tamil Nadu, India, from December 2019 to June 2021. Total of 75 subjects were divided into three groups, with 25 per group-group R (Inj. ropivacaine 0.75% 3 mL with 0.2 mL sterile water), group RB (0.2 mL buprenorphine with Inj. ropivacaine 0.75% 3 mL), and group RC (0.2 mL Clonidine with Inj. Ropivacaine 0.75% 3 mL). Onset and duration of blocks were observed. Haemodynamic parameters and pain score were monitored intraoperatively and postoperatively. Data was entered in Microsoft excel sheet and analysed using Statistical Package for the Social Sciences (SPSS) software version 16.0. The p-value <0.05 were considered as statistically significant.

Results: The onset time of sensory and motor blockade for group RC was significantly more in comparison to R and RB groups (sensory block-5 minutes 50 seconds vs 3 minutes 39 seconds vs 3 minutes 50 seconds); and (motor block-6 minutes 52 seconds vs 4 minutes 39 seconds vs 4 minutes 74 seconds). Group RC had significantly longer duration of sensory block than R and RB groups (327 minutes 88 seconds vs 166 minutes 60 seconds (167 minutes) vs 222 minutes 44 seconds).

Conclusion: Ropivacaine with clonidine showed significantly more duration of sensory block, motor block and time for first rescue analgesia with haemodynamic stability than ropivacaine and ropivacaine with buprenorphine.

Keywords: Adjuvants, Local anaesthetic, Opioids, Spinal anaesthesia

INTRODUCTION

In recent years, with increase in number of lower limb orthopaedic surgeries. It has become crucial for practitioners in the field of anaesthesia to search for appropriate practices that reduce the complications caused by anaesthesia for patients with lower limb surgery [1]. The term "neuraxial anaesthesia" implies the placement of local anaesthetic in or around the central nervous system. Spinal anaesthesia is a neuraxial anaesthesia procedure in which local anaesthetic is placed completely in the intrathecal space (subarachnoid space). Other neuraxial techniques comprise epidural and caudal anaesthesia [2,3]. The selection of local anaesthetic is based on the potency of the agent, onset and period of anaesthesia, and adverse reactions to the drug [4]. Ropivacaine is a newer amide local anaesthetic that is being utilised more frequently in spinal anaesthesia. Ropivacaine has the tendency of reversible inhibition of sodium ion influx in nerve fibres. The drug is less lipophile, which make it less lethal to the cardiovascular and central nervous system. It has reduced motor blocking potency with a powerful analgesic effect, because it selectively prevents nerve fibres engaged in pain conduction (A-delta and C fibres) to a superior degree than those controlling motor purpose (A-beta fibres) [5,6].

The addition of an adjuvant extends and reinforces the sensory blockade produced by local anaesthetics with reduction in dose of the latter, thus dipping the side-effects. Adjuvants are drugs that enhance the efficacy or potency of other drugs when given concurrently [7]. Buprenorphine is a centrally acting lipid soluble analogue of alkaloid thebaine. It displays analgesic property both at spinal and supraspinal levels. It has constantly proven to lengthen the duration of anaesthesia. At higher doses, it triggers pruritus, drowsiness, nausea and vomiting [8-12]. Clonidine is a partial alpha-2 adreno-receptor agonist and also centrally acting. Its analgesic impact is expected to be mediated by attaching post-synaptic α-2 receptors in the dorsal horn of the spinal cord, ensuing in lessened nociceptive transmission. It does not affect proprioception or create a motor blockade. When utilised as a neuraxial accessory for pain support after caesarean delivery, key abdominal and orthopaedic surgery, clonidine lengthens the period of analgesia and anaesthesia. Ropivacaine is less cardiotoxic than bupivacaine [13-16]. To compare the effects of ropivacaine, ropivacaine with buprenorphine and ropivacaine with clonidine for intrathecal use in lower limb orthopaedic surgeries. The primary outcomes were time taken for the onset and duration of sensory and motor blockade. The quality of analgesia, postoperative analgesic requirement and the haemodynamic variables were the secondary outcomes.

MATERIALS AND METHODS

This double-blinded randomised control trial was carried out at atertiary care hospital, Ammapettai, Tamil Nadu, India, from December 2019 to June 2021. The trial is registered under clinical trial registry of India with the registration number CTRI/2020/02/023197. Institutional Ethical Committee approval was obtained (IEC

NO:2019/559). Informed written consent was obtained from each participant.

Inclusion criteria: American Society of Anaesthesiologists (ASA) physical status I and II, age between 18-60 years, both male and female gender, patient undergoing lower limb orthopaedic surgery.

Exclusion criteria: Patient refusal, allergic to opioids/local anaesthetics, Body Mass Index (BMI) >30 kg/m^2, patient with recent history of cardiovascular accident, coagulation disorder, recent Cardio Vascular System (CVS) abnormalities, poorly controlled hypertension, poorly controlled diabetes mellitus, emergency orthopaedic surgery.

Sample size calculation: The sample size was calculated based on the study by Singh AP et al., [17]. The sample size required for each group was 25. The total sample considering the mean and standard deviation of buprenorphine+ropivacaine time to reach Bromage 3 as 2.75±0.42, mean and standard deviation of fentanyl+ropivacaine time to reach Bromage 3 as 3.1±0.47, at 95% confidence interval with 80% power was:

$N=(Z_{1-\alpha/2+}Z_{1-\beta})^2 * 2* \sigma^2/(\mu1-\mu2)^2$

where, $Z_{1-\alpha/2-}$ two tailed probability for 95% confidence interval=1.96

$Z_{1-\beta}$-two tailed probability for 80% power=0.84

μ1-mean of buprenorphine+ropivacaine time to reach Bromage 3=2.75

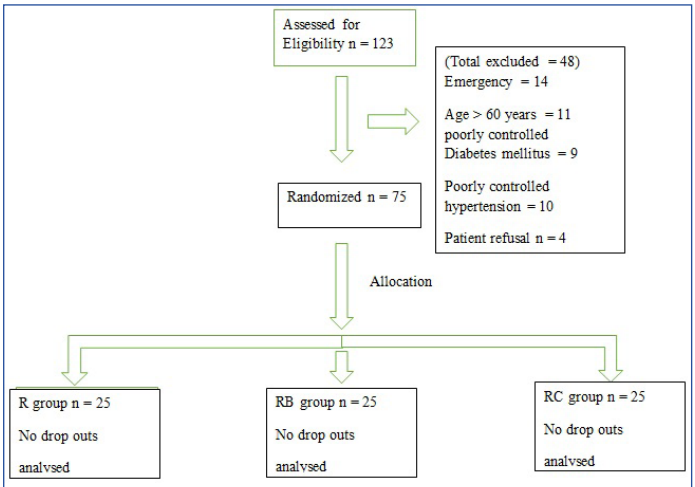
μ2-mean of fentanyl+ropivacaine time to reach Bromage 3=3.1

σ-average standard deviation of buprenorphine+ropivacaine time to reach Bromage 3 and fentanyl+ropivacaine time to reach Bromage 3=0.45

$N=(1.96+0.84)^2 *2* 0.445^2/(2.75-3.1)^2$

N=25.38

However, the total number of patients recruited was 75. They were randomly divided into three groups of 25 each, by computer generated list of random numbers. Group "R"-patients who received only local anaesthetic-Inj. Ropivacaine 0.75% 3 mL. Group "RB"-patients who received 0.2 mL (60 mcg) of preservative free intrathecal buprenorphine with local anaesthetic-Inj. ropivacaine 0.75%-3 mL. Group "RC"-patients who received 0.2 mL (30 mcg) of preservative free intrathecal clonidine with local anaesthetic-Inj. ropivacaine 0.75% 3 mL. The patient and performing anaesthetist were blinded to group allocation [Table/Fig-1].



[Table/Fig-1]: CONSORT flowchart.

Study Procedure

Patients were explained the procedure of spinal anaesthesia after an IV access secured with 18G or 20G cannula. Baseline heart rate, blood pressure and oxygen saturation were recorded. Patients were explained about Visual Analogue Score (VAS) and taught how to express the degree of pain on the scale [18]. Under strict aseptic precautions through midline approach, intrathecal block was preformed between L2-L3 or L3-L4 intervertebral space using 23 or 25G quincke spinal needle in sitting position. After free flow of cerebrospinal fluid, 3 mL of 0.75% ropivacaine with 0.2 mL of sterile water for group R patients and 3 mL of 0.75% ropivacaine with (0.2 mL) 60 mcg of buprenorphine for group RB patients were injected in to subarachnoid space. The dose of intrathecal buprenorphine was measured by using insulin syringe. A 3 mL of 0.75% ropivacaine with (0.2 mL) 30 mcg of clonidine for group RC patients were injected in to subarachnoid space. The dose of intrathecal clonidine was measured by using insulin syringe. The time of intrathecal injection was noted.

The onset of analgesia was assessed as the time taken from the drug injected to the onset of sensory blockade (absence of pin prick sensation). The two segment dermatomal regression of sensory block was recorded at various intervals. The duration of analgesia was assessed using VAS 0-10 score from no pain to worst painat 15,30,60 minutes and thereafter at four hour interval for 24 hours postoperative period. Patients above VAS score 3 received rescue analgesia in the form of Inj. paracetamol 1g IV in the postoperative period. Time of first rescue analgesic required and VAS score at that time was noted. Quality of analgesia was assessed depending on number of doses of rescue analgesia given in 24 hours from the time of injection of drug in intrathecal space this was noted below and compared between the three groups.

During intraoperative and postoperative monitoring, Mean Arterial Pressure (MAP) >15% was taken as hypotension then treated Inj. ephedrine 6 mg IV with adequate fluid replacement and pulse rate <60/min taken as bradycardia then treated with Inj. atropine 0.6 mg IV.

Sensory blockade was tested by pin prick method and the time of onset was taken from time of injection of the drug into the subarachnoid space to loss of pin prick sensation. The time to achieve maximum sensory block was noted from time of injection of drug to loss of pin prick sensation at highest dermatomal level T6. Motor blockade was assessed using the Bromage scale [19]. Abdominal muscle relaxation was assessed by using the Rectus Abdominis Muscle (RAM) score useful in assessing the onset of maximum motor blockade. The time to achieve maximum motor blockade was noted from time of injection of the drug to maximum degree of motor block [Table/Fig-2] [20].

Muscle power	RAM score	Criteria
100%	0	Able to rise from supine position with hands behind the head
80%	1	Can sit only with arms extended
60%	2	Can lift only head and scapula off the bed
40%	3	Can lift only shoulder off the bed
20%	4	An increase in abdominal muscle tension can be felt
0%	5	Full abdominal muscle relaxation

[Table/Fig-2]: Rectus abdominus muscle score [20].

STATISTICAL ANALYSIS

Data was entered in Microsoft excel sheet and analysed using SPSS software version 16.0. Analysis variance by One-way Anova test or Kruskal-Wallis test (variable is not normally distributed) across different times. Paired t-test was used to find the statistical difference. The p-values <0.05 were considered statistically significant.

RESULTS

The mean age among R group was higher than RB and RC group but the difference was not statistically significant (p-value=0.27). The mean BMI among R group was higher than RB and RC group but the difference was not statistically significant (p-value=0.40) [Table/Fig-3]. The mean onset of sensory block in group R was significantly lower than groups RB and RC. The mean onset of motor block among R was also significantly lower than groups RB and RC [Table/Fig-4]. The mean duration of sensory block and motor block in group RC was significantly longer [Table/Fig-5]. The intraoperative pulse rate and MAP were compared among the groups [Table/Fig-

6,7]. The VAS score in group RC was significantly lesser than groups RB and R, in the first four hours of postoperative period and for 0, 15 and 30 minutes VAS scores were 0 [Table/Fig-8]. RC group had hypotension and bradycardia were present for a few patients.

Variable	Group	Values	p-value
Age (years) (Mean±SD)	R	41.56±7.73	0.27
	RB	37.28±9.52	
	RC	38.92±10.48	
BMI (Kg/m^2) (Mean±SD)	R	26.86±1.97	0.40
	RB	25.93±1.73	
	RC	26.54±1.47	
Gender (n, %)	R	Male 16 (64%)	0.97
		Female 9 (36%)	
	RB	Male 9 (36%)	
		Female 12 (48%)	
	RC	Male 13 (52%)	
		Female 12 (48%)	

[Table/Fig-3]: Demographic variables.

Variable	Group	Mean±SD	p-value	95% CI
Onset of sensory block (mins)	R	3.39±0.56	<0.001*a	3. 31-3.78
	RB	3.50±0.33	<0.001*a	3. 78-4.05
	RC	5.50±0.49	<0.001*a	5. 45-5.86
Onset of motor block (mins)	R	4.39±0.56	<0.001*a	4. 16-4.62
	RB	4.74±0.34	<0.001*a	4. 59-4.88
	RC	6.52±0.43	<0.001*a	6. 10-7.20

[Table/Fig-4]: Distribution of onset of sensory and motor block with drug group among study population.
*- p value<0.05 is significant; a- One way Anova test expressed as mean (standard deviation)

Adverse events	R Group	RB Group	RC Group	p-value
Presence	Mean±SD	Mean±SD	Mean±SD	
Duration of sensory block	166.60±9.91	222.44±22.54	327.88±17.03	<0.001
Duration of motor block	145.88±8.74	189.52±16.85	279.64±17.98	<0.001
Time for first rescue analgesia	193.84±11.9	273.72±24.02	372.48±18.11	<0.001
Total number of doses of Inj. paracetamol 1g IV	3.4±0.44	2. 48±0.65	2.20±0.41	<0.001

[Table/Fig-5]: Distribution of duration of sensory and motor block, rescue analgesia with drug group among the study population.

Mean Arterial Pressure (MAP)	R Group	RB Group	RC Group
	Mean±SD	Mean±SD	Mean±SD
MAP baseline	91.08±6.01	90.12±5.40	91.35±4.83
MAP 5 mins	84.80±5.30	77.81±6.71	84.93±6.56
MAP10 mins	82.32±5.68	79.61±4.30	85.72±3.65
MAP 15 mins	83.92±5.66	81.93±4.79	86.16±3.95
MAP 30 mins	86.20±3.80	84.03±3.88	88.03±3.66
MAP 45 mins	88.16±4.40	85.87±4.51	89.65±4.02
MAP 60 mins	89.21±3.71	81.96±4.82	90.28±3.0
MAP 75 mins	90.58±3.72	94.48±3.49	90.13±3.35
MAP 90 mins	91.80±3.70	94.44±4.45	92.63±2.92
MAP 105 mins	94.67±1.53	93.75±4.03	92.50±1.00
MAP 120 mins	-	95.50±3.54	93.00±2.83
MAP 135 mins	-	-	-

[Table/Fig-6]: Mean Arterial Blood Pressure (MAP) distribution among the population between the groups based on time period.

DISCUSSION

The search for safer subarachnoid block with lesser dose local anaesthetic agent by adding adjuvant seems to be never ending. ropivacaine is amide group of local anaesthesia with lesser cardiotoxic than bupivacaine. Buprenorphine is an opioid adjuvant which acts on

In per minute	R Group	RB Group	RC Group
Pulse Rate (PR)	Mean±SD	Mean±SD	Mean±SD
PR baseline	81.80±6.22	81.68±6.41	79.12±5.61
PR 5 mins	88.92±5.42	86.40±5.37	82.28±6.19
PR10 mins	88.20±2.58	87.80±4.45	81.20±7.80
PR 15 mins	84.00±3.24	83.88±4.30	78.08±8.40
PR 30 mins	82.28±3.31	81.88±3.94	76.04±8.45
PR 45 mins	81.36±2.94	82.64±3.73	75.64±8.48
PR 60 mins	80.50±2.70	80.92±3.07	75.48±8.24
PR 75 mins	80.74±2.70	81.35±2.54	76.70±6.72
PR 90 mins	82.00±2.45	81.44±1.74	76.40±6.82
PR 105 mins	81.00±2.65	81.75±1.71	71.50±7.94
PR 120 mins	-	83.00±1.41	66.00±5.66

[Table/Fig-7]: Pulse rate (PR) distribution among the population between the groups based on time period.

In scores	R	RB	RC	p-value
	Mean±SD	Mean±SD	Mean±SD	
VAS 60 mins	1.33±0.56	0.6±0.51	0±0	<0.001*
VAS 4th hour	3.44±0.51	3.16±0.69	0.32±0.48	<0.001*
VAS 8th hour	2.80±0.71	2.84±0.75	2.76±0.72	0.03
VAS 12th hour	2.84±0.75	2.96±0.73	2.92±0.81	0.05
VAS 16th hour	2.76±0.52	2.92±0.64	2.92±0.76	0.60
VAS 20th hour	3.04±0.73	3.00±0.71	3.00±0.71	0.04
VAS 24th hour	3.04±0.54	3.12±0.60	3.32±0.69	0.26

[Table/Fig-8]: Distribution of VAS pain score fourth hourly postsurgery with drug group among the study population.

μ and κ receptors. Clonidine is a partial agonist alpha 2 adrenoceptor which used as analgesic and is sedative. The impact of buprenorphine or clonidine when used as adjuvant with ropivacaine intrathecally were observed. Buprenorphine and clonidine subsequently increased the duration of both sensory and motor block. This reduced the conversion of subarachnoid block in to general anaesthesia due to faster level regression and better postoperative analgesia in lower limb orthopaedic surgeries. The onset and duration of sensory block for RC group was significantly more in comparison to R and RB group. According to this study RC group had longer duration of sensory block.

Chhabra AR et al., showed that in ropivacaine clonidine group, there was significant extension of sensory block and motor block. Time to reach peak sensory level were statistically significantly more in ropivacaine clonidine group in comparison to ropivacaine fentanyl group (6.86±3.73 vs. 8.61±7.18). Time to reach peak motor level also was more in ropivacaine clonidine group in comparison to ropivacaine fentanyl group (6.02±2 vs.7.05±3.2). Hypotension and bradycardia was seen in 8.6% patients in ropivacaine clonidine group, whereas pruritus was reported by 8.6% patients in ropivacaine fentanyl group [21]. The study shows similar result as indicated in this present study in terms of onset of action.

Singh M et al., showed that period taken for beginning of the sensory and motor block was considerably shorter in ropivacaine with clonidine category in contrast with ropivacaine category. Mean value of extent of analgesia was suggestively elevated in subjects who got clonidine as an adjuvant which was contrast to the result obtained from this present study [22].

The RC group showed significantly more duration of sensory block motor block and time for first rescue analgesia. Also total number of doses of Inj. paracetamol 1g IV from time of injecting the spinal drug till 24 hours was significantly more group. The haemodynamic changes among the groups shows the RC showed significant bradycardia, increased systolic blood pressure and mean arterial pressure in comparison to R and RB group.

Studies have shown that clonidine addition have prolonged the duration of motor block in comparison to other adjuvants like Kumar N et al., showed that in ropivacaine clonidine group had extended duration of

analgesia. The duration of motor block was significantly more in clonidine group in comparison to only ropivacaine group (281.25±25.58 min vs. 244.88±6.51 min) and the mean duration of sensory analgesia was (4vs.51.10±13.79 362.60±5.96 min). The incidence of bradycardia and hypotension was meaningfully more in ropivacaine clonidine category as compared to only ropivacaine group [23].

Verma O et al., showed buprenorphine and fentanyl with bupivacaine in spinal anaesthesia offered good quality intraoperative and postoperative analgesia. Bupivacaine with buprenorphine considerably extends sensory and motor block. Duration of analgesia and sedation were longer in buprenorphine group than fentanyl group [24]. In this present study, sedation was not seen with RB group.

Shruthijayaram BA, showed that duration of sensory and motor block was significantly extended with dexmedetomidine group in comparison with buprenorphine or saline. Dexmedetomidine delayed the time for first analgesic need postoperatively [25]. The study results were similar as present study in terms of onset of action.

This study was also a quest for safer local anaesthetic agent along with an adjuvant for intrathecal use. The anaesthetic fraternity moving towards the opioid free analgesia to over come its adverse effects. No study previously compared the buprenorphine and clonidine intrathecally with ropivacaine. The results of this study, shows that clonidine is no longer a lesser adjuvant than buprenorphine and also had superior sensory and motor block. This encourages to use clonidine than buprenorphine for safer anaesthesia practice and lesser conversion of general anaesthesia because of block regression.

Limitation(s)

This was a single centre study. The duration of surgery and nature of procedure might have an influence in postoperative pain. By studying the outcome for single orthopaedic produce may give a better reliable postoperative pain score and its management.

CONCLUSION(S)

Clonidine when used as an adjuvant, in addition to prolonging duration of sensory and motor block and also delays the time of requirement for first rescue analgesia thereby reduces the consumption of postoperative analgesia than the control and buprenorphine groups. The side effects like hypotension and bradycardia were observed in clonidine group but was minimal. Hereby, concluding that clonidine usage as adjuvant has significant advantage over using plain local anaesthetic drug or with buprenorpine intrathecally.

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- For any images presented appropriate consent has been obtained from the subjects. NA

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