COMPARISON BETWEEN ROPIVACAINE (0.5%) 10mg WITH 45µg CLONIDINE AND ROPIVACAINE (0.5%) 10mg ALONE INTRATHECALLY FOR POSTOPERATIVE ANALGESIA IN LOWER LIMB ORTHOPEDIC SURGERY

Sadhana Kulkarni¹, Poornima Sonkamble², Mukund Parchandekar³, Hrishikesh Khadilkar⁴, Vineet Jadhav⁵

HOW TO CITE THIS ARTICLE:

Sadhana Kulkarni, Poornima Sonkamble, Mukund Parchandekar, Hrishikesh Khadilkar, Vineet Jadhav. "Comparison between ropivacaine (0.5%) 10mg with 45µg clonidine and ropivacaine (0.5%) 10mg alone intrathecally for postoperative analgesia in lower limb orthopedic surgery". Journal of Evolution of Medical and Dental Sciences 2013; Vol2, Issue 33, August 19; Page: 6290-6299.

ABSTRACT: BACKGROUND: Data regarding effect of low dose clonidine on subarachnoid block with 10 mg isobaric ropivacaine are meager. **AIMS:** To evaluate association of 10 mg isobaric subarachnoid ropivacaine with 45 µg of intrathecal clonidine for lower limb orthopedic surgery. Evaluation of effect on duration of sensory block was primary outcome and secondary outcomes included onset, intensity, duration of block, time for first rescue analgesic and patient safety. **PATIENTS & METHODS:** After Institutional Ethical Committee approval, double blind, prospective study was conducted. 70 ASA grade I patients (18-50 years) were equally randomized into group R (receiving 10 mg of isobaric ropivacaine) and group RC (receiving 10 mg of isobaric ropivacaine with clonidine 45 µg). Standard technique of administration and evaluation of subarachnoid block and postoperative analgesia were followed. Onset, duration and intensity of block and complications, time for first dose of postoperative analgesic were recorded. **STATISTICAL ANALYSIS:** Fox Pro 2.6 model. **RESULTS:** There was significantly early onset of sensory block, adequate and prolonged sensory & motor blockade in RC group when compared with R group. Time for first analgesic required was also significantly delayed in RC group. Sedation level and cardiovascular changes were comparable in both groups. **CONCLUSION:** Addition of intrathecal 45 µg clonidine prolonged sensory blockade & postoperative analgesia of isobaric ropivacaine safely. **KEY WORDS:** - Spinal anaesthesia, isobaric 10 mg ropivacaine 0.5%, 45 µg clonidine. **KEY MESSAGE:** - clonidine 45µg with 10 mg isobaric ropivacaine

INTRODUCTION: Subarachnoid block using isobaric ropivacaine is commonly used for lower limb orthopedic surgery. Clonidine, alpha-2 agonist, when added to subarachnoid local anaesthetic improves intensity & duration of sensory & motor block. ^[1, 2] It also prolongs postoperative analgesia. ^[3] Unlike spinal opioids, clonidine does not produce pruritus or respiratory depression. ^[4]

Clonidine has been used orally, ^[5] intramuscularly ^[6] along with subarachnoid local anaesthetic and in subarachnoid block with local anaesthetic agent ^[7]. Various doses of clonidine have been tried. 75µg clonidine, when added to local anaesthetic prolongs the duration of subarachnoid block but produces fall in blood pressure & causes sedation. ^[8] However 1µg/kg clonidine is used effectively & safely. ^[9] Data regarding association of 10 mg isobaric ropivacaine & intrathecal clonidine are rare. ^[8,10] So we carried out a prospective, double blind, randomized study

to find out efficacy & safety of 10 mg of 0.5% isobaric ropivacaine with 45 µg clonidine for subarachnoid block in patients posted for lower limb orthopedic surgery.

PATIENTS & METHOD: This prospective, randomized, study was carried out after approval by ethical committee. Informed, valid, written consent was obtained from the patients.

Seventy ASA Gr I patients of age between 18 to 50 years, weighing 50-90 kg, height > 150 cm scheduled for elective orthopedic surgery of lower extremities for tibia or femur nailing or fixator were enrolled in the study. Patients with increased intracranial pressure, neuro-muscular disorders, cardio-respiratory disease, hemorrhagic diathesis, pregnancy, infection at the puncture site and allergy to ropivacaine or clonidine were excluded from the study.

70 patients were divided by computer generated randomization in 2 equal groups. Even numbered patients received 10 mg of 0.5% (2ml), isobaric ropivacaine [Naprod life sciences Pvt. Ltd] – Group R (n=35). Odd numbered patients received 10 mg of 0.5% (2ml), isobaric ropivacaine + 45 µg, (0.3ml) of preservative free clonidine[8] [Cloneon-Neon laboratory] - Group RC (n=35).

Difference of 0.3 ml volume does not affect spread of subarachnoid block. ^[11]

I.V. access was established and infusion of RL (4ml/kg) was started. Patients were monitored with cardiac monitor, pulse oximeter and non-invasive blood pressure. Under all aseptic precautions Sub-arachnoid block was given in midline at L2-3 or L3-L4 space with 25 G Quincke spinal needle in lateral position. Group R patients received 10 mg of Ropivacaine and Group RC patient received 45 µg Clonidine along with 10 mg of Ropivacaine

Following parameters were assessed:

1. Onset and quality of sensory and motor block,
2. Duration of sensory and motor block.
3. Time to first dose of rescue analgesic required and
4. Evaluation of side effects of clonidine were secondary outcomes measured.

Onset of sensory block was tested with pinprick every two minutes till maximum level was achieved. Duration of sensory block was defined as period between injection of drug and recovery of pin prick in S-2 dermatome. Sensory block was assessed every 10 minutes till recovery of pin prick sensation in S-2 dermatome.

Quality of sensory block was assessed as follows

- a] Adequate: Neither sedation or analgesic required to complete the procedure
- b] Inadequate: Need for additional analgesic (fentanyl 1 µg /kg IV) required
- c] Failed block: Sensory block not achieved bilaterally up to T12 in 20 min and/or duration of block was less than 50 minutes & patient required general anaesthesia to complete the surgical procedure ^[12].

Patients with inadequate or failed block were excluded from study.

Motor block of both the legs was graded as per Bromage scale ^[3]

Grade 0 - Able to flex ankle, knee & hip

Grade 1 - Inability to raise extended leg, can flex knee & ankle

Grade 2 - Ability to flex hip & knee, can flex ankle

Grade 3 - Complete block of lower limbs.

Patients with grade 0 block were excluded from study as movement of limb during surgery may hinder the surgical procedure.

Onset of motor block was considered as inability to raise extended leg with movement possible at knee and ankle joints. Motor block duration was defined as period between injection and complete recovery from motor block (Bromage grade 0). Vital parameters were recorded every 5 min in operating room and every 15 min in PACU and at least 6 hourly in ward for 24 hours.

Any adverse events like hypotension, bradycardia, sedation, nausea and vomiting, shivering and respiratory insufficiency during peri-operative period were noted. Hypotension was defined as decrease in mean arterial blood pressure by 25% or more from baseline values [13] and treated with oxygen, 300 ml of additional IV fluid (RL). If this proves to be ineffective, an IV bolus of ephedrine 5mg was administered. Clinically relevant bradycardia, heart rate < 50/min or decrease in rate more than 20% from baseline [3] was treated with 0.6 mg IV Atropine.

Sedation level was assessed by sedation score. [14]

- I. Awake and Nervous
- II. Awake and Calm
- III. Sleepy and easily arousable
- IV. Sleepy and difficult to arouse

Post-operative pain was assessed using 10 cm Visual analogue scale (VAS) every 30 minutes. First dose of rescue analgesic (IV Diclofenac Sodium 75mg) was administered when VAS was > 4. [2] This duration was noted as duration of post-operative analgesia.

Patients were followed for 48 hours post-operatively and their ability for ambulation, urination & defecation and adverse effects like nausea, vomiting, headache, backache, tingling or pain in the legs and other symptoms were noted.

STATISTICS: Sample size was determined with the help of Open-Epi software version 2.3, May 2009 developed by Minn M. Soe and Kevin M. Sullivan, Emory University. Total sample size of 26(13 in each group) was derived from observations of De Kock et al. [8] Data was analyzed with statistical tests. Students T test for quantitative analysis and χ^2 (Chi square) test for qualitative analysis.

RESULTS: There were no significant differences in patient demographics and surgical data in both groups (Table 1).

16 patients from R group & one from RC group were excluded from study as they had failed spinal block or grade 0 motor block. 10 patients in R group had no sensory or motor blockade, 3 patients in R group & 1 patient in RC group had level less than T- 12 and 3 patients from R group had level above T 12 but had grade 0 motor block and required general anesthesia for achieving immobility needed for surgical procedure. So we have excluded 16 patients from each group for comparison of rest of the parameters.

First 19 patients from RC group were included in the study group. This number exceeds the sample size needed for this study (13 patients in each group). Patients' demographic data and quality of block was analyzed in 35 patients of each group while rest of the data was analyzed in 19 patients.

Quality of sensory & motor block was better in RC group (Table 2 & 3). Adequate sensory block was seen in 34 patients in RC group as compared to 19 patients in R group. Onset of sensory block at L 5 & time required for level of block up to T 12 ($5.09+3.62/2.17+2.14$ minutes & $8.34+3.62/3.89+1.14$ min.) In R group was earlier as compared to that in RC group ($P<0.05$). Maximum level achieved (T10 -T 12) was comparable in both groups. (Table 2). Duration of sensory block was prolonged by 2.4 times ($4.11+0.99/1.70+1.19$ hours) in RC group. Duration varied between 2.5 -7 hours in RC group as opposed 1-2 hours in R group. Quality of motor block was better in RC group. None of the patients in RC group had grade 0 block. 33 patients had grade II - III block. The difference in R and RC group motor block quality and duration was statistically significant. (Table 3)

Changes in pulse rate & mean arterial pressure (Table 4) were comparable in both groups. None of the patients in either group had bradycardia. Two patients in RC group had transient hypotension, 5-8 min after administration of the drug and needed 5 mg ephedrine. None of the patients were sleepy. One patient in RC group had shivering lasting for 8-10 min and did not require any additional treatment. (Table 5). Duration of postoperative analgesia was 2.34 times (Table 2) in RC group than that of R group ($3.92+0.66/1.84+1.3$ hours). No other complication was seen in postoperative period till 48 hours (Table 5).

DISCUSSION: Clonidine potentiates sub-arachnoid block through activation of post synaptic alpha - 2 receptors in substantia gelatinosa of spinal cord, blocking the conduction of C and A delta fibers, increasing potassium conductance in isolated neurons in vitro and intensifies conduction block of local anesthetic. [18]

De Kock^[8] et al observed prolongation of sensory blockade 1.38 times ($132+38/183+52$ min) as opposed to 2.4 times ($4.11+0.99/1.70+1.19$ hours) in our study. This might be due to difference in dosages of Ropivacaine (8mg vs 10 mg). Gonul et al ^[10] observed prolongation of duration 1.2 times only as the dose of clonidine used was 30 micrograms. Duration of prolongation of sensory blockade by clonidine is dose dependant. [8]

Onset and quality of analgesia produced by addition of clonidine was significantly better as compared to ropivacaine alone in our study. 28.5% patients (10/35 patients) in R group did not have sensory or motor blockade in our study. Ying Y. Lee et al ^[12] also reported 17% failure when 10 mg ropivacaine was used. Van Kleef Jack W. et al ^[15] have used 3 ml of 0.5% isobaric ropivacaine (15 mg) for minor lower limb surgery & observed inadequate anaesthesia in 5% patients. In our study, one patient in RC group had adequate analgesia but the level was less than T-12. So this patient was excluded from study. McNamee et al ^[16] observed excellent anaesthetic conditions in all the patients when 10mg ropivacaine was used.

Evaluation for sensory block was done by using loss of sensation to cold by McNamee et al. We have used loss of sensation to pin prick criteria. This can produce significant discrepancy in the assessment of sensory block following intrathecal block. [17] De Kock et al ^[8] also observed adequate anaesthesia in all patients with 8 mg ropivacaine (4ml). The difference in the volume used might be responsible as isobaric 2ml ropivacaine was used in our study. We observed that level of anesthesia was comparable in both the groups, but maximum level was achieved significantly earlier in RC group ($9.54+4.86/4.05+3.27$ min in R and RC group respectively).

Similar effects were seen with the motor blockade. The grade of motor blockade was inferior (Table 3) in R group as compared to RC group as also observed by De Kock et al. [8] The duration of motor block was 2.18 times in RC group as compared to R group ($3.32 \pm 0.70 / 1.52 \pm 1.15$ hours). Prolongation of motor blockade was less as compared to sensory blockade. This might be useful for patients undergoing day care surgery. Potentiation of intensity and duration of motor block may be ascribed to local anesthetic effect of clonidine itself. [8] Alpha 2 adrenoreceptor agonists induce cellular modification in the ventral horn of spinal cord and facilitate the local anesthetic action. [8]

Our patients were calm & awake (Gr. II). Excessive sedation was also not observed by Grandhe et al. [2] Olfa Kaabache et al [3] observed sedation in 2% patients while using 1 µg /kg of clonidine intrathecally. None of our patients had bradycardia. Gonul et al [10] used 30 µg clonidine along with 10 mg ropivacaine and observed significant bradycardia and hypotension. Transient hypotension was seen in two patients in our RC group requiring 5 mg ephedrine. However De Kock et al [8] have observed relative reduction in arterial blood pressure lasting from 60 to 150 minutes but none of the patients required vasopressor. The fact that we had used a relatively high dose of ropivacaine (10 mg) may explain why less incidence of hypotension was evident in the RC group of our study. Klimsha et al [19] suggested that when a larger dose of local anesthetic is used, the hypotensive action of clonidine is masked by dense axonal blockade produced by the local anesthetic. The relatively low dose of ropivacaine (8mg) used with 45µg clonidine by De Kock et al [8], might have unmasked the effect of clonidine. Grandhe et al [2] have suggested that hypotension is more commonly associated with use hyperbaric local anesthetic. Early hypotension observed in our RC group patients might be because of inhibition of spinal cord pre-ganglionic neural tone. [20] Hypotension was less likely to be due to systemic effect of clonidine. As plasma drug concentrations were uniformly undetectable when 50-100µg of clonidine was used intrathecally by Siddal et al. [21] Vasodepressor and cardio-inhibiting effects of clonidine are produced by an action on chemosensitive zones at ventral surface of medulla oblongata. [22] Striking advantage of intrathecal clonidine over intrathecal narcotics is absence of respiratory depression and pruritus. [4] None of the patients developed any neurological complications postoperatively.

In this study, postoperative analgesia was 2.34 times ($3.92 \pm 0.66 / 1.84 \pm 1.3$ hours) prolonged by addition of 45 µg of clonidine, without any sedation or cardiovascular compromise. Grandhe et al [2] observed 1.65 times prolongation of duration of analgesia while using 1 µg /kg of clonidine along with bupivacaine.

10 mg of isobaric ropivacaine (0.5%) has variable success rate as observed in our study and by Ying et al. [12] 45 µg clonidine can be added to improve onset, quality and duration of sensory as well as motor block. If the duration of surgery is more than 90 min & particularly if adequate muscle relaxation is needed, addition of 45 µg clonidine will be beneficial to avoid need for supplementation of general anesthesia. 17/50 patients had sensation at site of surgery even when dose of ropivacaine was increased to 15 mg by Malinovsky et al in patients undergoing bladder surgery. [13] So addition of clonidine can be better alternative than increasing dose of ropivacaine.

If only improvement in quality with low dose ropivacaine subarachnoid block without prolongation of sensory and motor block is needed, smaller dose of clonidine (15µg) can be used. [8]

We have analysed data of 19 patients. A large scale further study is planned.

CONCLUSION: In conclusion, intrathecal 45µg of clonidine added to 10 mg of isobaric 0.5% of ropivacaine for lower limb orthopedic surgery significantly improved onset, quality and duration of sensory as well as motor blockade along with improvement in postoperative analgesia, safely.

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Table No. 1:

PATIENT CHARACTERISTICS

Demographic data Mean $\pm$ SD	GROUP R N=35	GROUP RC N=35	P VALUE
Age (years)	35.5 $\pm$ 10.5	37.73 $\pm$ 8.74	0.486
Weight (kg)	56.22 $\pm$ 10.19	$\pm$ 7.85	0.316
Height (cm)	166.8 $\pm$ 9.56	163.15 $\pm$ 5.09	0.147
Duration of surgery (hrs)	1.52 $\pm$ 0.42	1.49 $\pm$ 0.59	0.807
Type of surgery			
External fixator	17	14	X ² = 0.66 P >0.05
Femur nailing	13	14	
Tibia nailing	05	07	

Table No. 2:
CHARACTERISTICS OF SENSORY BLOCK

Sensory block	R *	RC*	P VALUE
	MEAN ± S.D.	MEAN ± S.D.	
Time required to achieve maximum level (min)	9.5±4.86	4.05±3.27	0.000
Time required to achieve T12 level (min)	8.34±4.32	3.89±1.14	0.023
Time required for onset of sensory block (min)	5.09±3.62	2.17±2.14	0.003
Height of block†	No of patients ‡	No of patients	X ² =0.23 P value >0.05
<T-12	3	1	
T-10 to T-12	21	32	
T-6	1	2	
Grades of block † (Adequate/Inadequate/Failed)	19/4/12	34/0/1	X ² =17.55 P value <0.01
Duration of sensory block in hours	1.70±1.19	4.11±0.99	0.000
Time to first rescue post-operative analgesic (Hours)	1.84±1.3	3.92±0.66	0.000

* In R group 16 patients were excluded as 10 patients did not have any sensory effect, 3 patients had sensory block less than T12 level and 3 patients had sensory level more than T 12 but motor block was grade 0. So data of 19 patients were compared.

† This data is for 35 patients in R and RC group.

‡ 10 patients in R group did not have any sensory blockade

Table No. 3:
CHARACTERISTICS OF MOTOR BLOCK

Motor block	R (n=35)	RC (n=35)	P VALUE
	MEAN ± S.D.	MEAN ± S.D.	
Grades of motor block†			X ² =52.50 P value <0.01
III	0	3	
II	22	30	
I	0	2	
0	13	0	
Time required for onset of motor block (min)*	2.31±2.37	1.10±0.32	0.035
Duration of motor block in hours*	1.52±1.15	3.32±0.70	0.000

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* In R group 16 patients were excluded as 10 patients did not have any sensory effect, 3 patients had sensory block less than T12 level and 3 patients had sensory level more than T 12 but motor block was grade 0. So data of 19 patients were compared.

† This data is for 35 patients in R and RC group.

Table No. 4:
CHANGES IN PULSE RATE AND SYSTOLIC BLOOD PRESSURES

TIME	PULSE RATE (PER MIN)		P VALUE	MEAN ARTERIAL BLOOD PRESSURE (mm Hg)		P VALUE
	R group Mean±SD	RC group Mean±SD		R group Mean±SD	RC group Mean±SD	
0 min	90.47±12.68	79.89±7.90	0.000	92.4±7.36	92.14±6.8	0.88
1 min	91.2±11.56	80.31±7.84	0.000	91.77±7.5	91.54±6.72	0.89
5 min	92.4±11.4	81.89±11.80	0.000	91±7.58	89±6.82	0.25
10 min	91.37±12.34	83.68±11.47	0.000	91.34±8.15	89.48±6.66	0.3
15 min	91.51±11.86	82.10±8.44	0.000	91.08±7.52	90.25±6.49	0.62
20 min	90.82±70.72	81.05±8.80	0.000	91.11±7.47	90.25±6.82	0.61

*Data of 19 patients

TABLE 5:
INTRAOPERATIVE AND POSTOPERATIVE ADVERSE EVENTS

	R group	RC group	P Value
Intraoperative			P value could not be calculated
Bradycardia	0	0	
Hypotension	0	2	
Sedation	0	0	
Shivering	0	1	
Postoperative			
Nausea, Vomiting	0	0	
Headache	0	0	
Transient radiating pain	0	0	
Difficulty in passing urine	0	0	
Muscle weakness	0	0	

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AUTHORS:

1. Sadhana Kulkarni
2. Poornima Sonkamble
3. Mukund Parchandekar
4. Hrishikesh Khadilkar
5. Vineet Jadhav

PARTICULARS OF CONTRIBUTORS:

1. Professor and Head, Department of Anaesthesiology, Government Medical College, Aurangabad.
2. Assistant Professor, Department of Anaesthesiology, Government Medical College, Aurangabad.
3. Assistant Professor, Department of Anaesthesiology, Government Medical College, Aurangabad.
4. Assistant Professor, Department of Preventive & Social Medicine, Government Medical College, Aurangabad.

5. Junior Resident, Department of Anaesthesiology, Government Medical College, Aurangabad.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Poornima Sonkamble,
254, "Anubhuti",
Nandanvan Colony,
Aurangabad (Maharashtra),
PIN – 431002.
Email- pathadepoornima@rediffmail.com

Date of Submission: 20/05/2013.
Date of Peer Review: 27/05/2013.
Date of Acceptance: 10/08/2013.
Date of Publishing: 19/08/2013