ORIGINAL RESEARCH PAPER

Volume-7 | Issue-5 | May-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

PROSPECTIVE RANDOMIZED DOUBLE BLINDED COMPARISON OF INTRATHECAL ISOBARIC 0.5% ROPIVACAINE AND COMBINATION OF ISOBARIC 0.5% ROPIVACAINE WITH 45 MICROGRAM CLONIDINE IN LOWER LIMB SURGERY

Anaesthesiology

Dr Sumeet chugh Specialist, Department Of Anaesthesia And Intensive Care, Dr Baba Saheb Ambedkar Medical College And Hospital, Delhi, India

Dr Shakti singhal* Senior Resident, Department Of Anaesthesia And Intensive Care, Dr Baba Saheb Ambedkar Medical College And Hospital, Delhi, India *corresponding Author

ABSTRACT

Background: Ropivacaine a long-acting amide local anaesthetic agent was developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. Clonidine, an alpha-2 adrenergic agonist, when added to subarachnoid local anaesthetic improves intensity & duration of sensory & motor block.8

Aims and objectives: To find out the efficacy & safety of 15 mg of 0.5% isobaric Ropivacaine with 45 µg Clonidine for subarachnoid block in patients posted for lower limb orthopaedic surgery.

Materials and methods: 2 equal groups of 30 each were formed by computer generated randomization ; Group R (n=30) received15 mg of 0.5% (3ml), isobaric Ropivacaine + 0.3ml Normal Saline and Group RC (n=30)18 received 15 mg of 0.5% (3ml), isobaric Ropivacaine + 45 µg , (0.3ml) of preservative free Clonidine.

Results: There was statistically significant difference in time required for onset of sensory as well as motor blockade, duration of sensory and motor block and rescue analgesia, in group R and group RC ($P < 0.05$). Conclusion: Addition of intrathecal 45 µg Clonidine prolonged sensory blockade & postoperative analgesia of isobaric Ropivacaine safely.

KEYWORDS

Analgesia, Isobaric, Clonidine, Ropivacaine, Subarachnoid

Introduction

Ropivacaine is a long-acting amide local anaesthetic agent and first produced as a pure enantiomer. It is a pure S (-) enantiomer, unlike Bupivacaine, which is a racemate. Ropivacaine was developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.[3]Isobaric Ropivacaine is commonly used for lower limb orthopaedic surgery[3, 5] However, It was found that Ropivacaine used alone had lesser duration of action, and does not offer adequate pain relief.[6] Hence it was suggested to use an adjuvant that would potentiate the effects of spinal anaesthesia without any side effects[7]. Clonidine, an alpha-2 adrenergic agonist, when added to subarachnoid local anaesthetic improves intensity & duration of sensory & motor block.[8,9] It also prolongs postoperative analgesia.[10] Unlike spinal opioids , Clonidine does not produce pruritus or respiratory depresssion[11].1µg/kg Clonidine is used effectively & safely.[14] Data regarding association of 15 mg isobaric Ropivacaine & intrathecal Clonidine are rare.[14,15]Hence, we carried out a prospective, double blind, randomized study to find out the efficacy & safety of 15 mg of 0.5% isobaric Ropivacaine with 45 µg Clonidine for subarachnoid block in patients posted for lower limb orthopaedic surgery.

Material and Methods

A prospective, randomized, controlled, double blind study was conducted on 60, ASA Gr I & II patients, selected by computer generated randomization in 2 equal groups. Patients selected for the study were all undergoing elective lower limb surgery. Patients with increased intracranial pressure, neuromuscular disorders, cardiorespiratory disease, hemorrhagic diathesis, pregnancy, uncontrolled diabetes and hypertension, infection at the puncture site and allergy to Ropivacaine or Clonidine were excluded from the study. After approval from the ethics committee of the hospital, an informed valid consent of all the patients was taken. Group R (n=30) received 15 mg of 0.5% (3ml), isobaric ropivacaine + 0.3ml normal saline and Group RC (n=30) [12] received 15 mg of 0.5% (3ml), isobaric ropivacaine + 45 µg , (0.3ml) of preservative free clonidine. Universal standard technique was followed in each patient for spinal anaesthesia. The parameters assessed were: Onset, quality and duration of sensory and motor block, time to first dose of rescue analgesic required, level of sedation perioperatively and the evaluation of side effects of Clonidine. Motor block of both the legs was graded as per Bromage scale[17]. Sedation was assessed on a four point scale during the perioperative period.[18]Post-operative pain was assessed using 10 cm Visual analogue scale (VAS) every 30 minutes.[19,20] First dose of rescue analgesic (IV Diclofenac Sodium 75mg) was administered when VAS was > 4.Patients were followed for 48 hours post-operatively.

Statistical Analysis

Students t test was used for quantitative analysis and Chisquare test for qualitative analysis.

Results

Table 1: Onset of sensory block.

Sensory Block	Group R Mean(SD)	Group RC Mean(SD)	P Value
Time required to achieve Maximum level (min)	11.3 (3.66)	5.53 (1.87)	<0.001
Time required to achieve T12 level (Min)	7.9 (2.07)	4.47 (1.9)	<0.001
Time required for Onset of sensory block (Min)	5.13(1.63)	3.63(1.86)	0.002
Height of Block			
T 12	3	3	0.315
T 10	22	17	
T 6- T-8	5	10	

Characteristics of block: As reflected in Table 1, onset of block is quicker when Clonidine is added to intrathecal Ropivacaine.

Table 2 Comparison between onset of sensory and motor level

Onset	Group R Mean(SD)	Group RC Mean(SD)	P Value
Time required for Onset of Sensory block (Min)	5.13(1.63)	3.63(1.86)	0.002
Time required for Onset of Motor block (Min)	3.73 (1.23)	2.23 (1.33)	<0.001

Table 2 reveals that there was statistically significant difference in time required for onset of sensory as well as motor blockade in group R and group RC ($P < 0.001$) and also in the duration of sensory and motor block and rescue analgesia in both the groups (P value < 0.05).In terms of grades of motor block both the groups were comparable. Hypotension was observed in 2 patients of RC group intraoperatively.

One of the patient recovered after administration of fluids, while the other needed (5mg) ephedrine. There was no episode of hypotension postoperatively in both the patients. There were no other side effects reported in any group.

Discussion

Ropivacine, blocks nerve fibers involved in pain transmission (A delta and C fibers) to greater degree than those controlling motor function (A beta fibers).Clonidine potentiates intrathecal block through activation of post synaptic alpha-2 receptors in substantia gelatinosa of spinal cord, blocking the conduction of C and A delta fibers.[15]In our study, we hypothesized that Clonidine as an intrathecal adjuvant with Ropivacaine will improve postoperative analgesia. De kock et al[13] had used 45 mcg of Clonidine and found the results satisfactory. Thus, in our study, we also used 45 mcg of Clonidine to standardize the additive dosage. We added 0.3 ml of Normal Saline in R group to minimize the bias. The demographic data in both the groups were comparable in terms of age, gender, weight, height, and duration of surgery.Onset and quality of analgesia produced by addition of Clonidine was significantly better as compared to Ropivacaine alone in our study. There were no failures observed.Duration of prolongation of sensory blockade by Clonidine is dose dependant.[13]We observed that level of anaesthesia was comparable in both the groups, but maximum level was achieved significantly earlier in RC group. Similar effects were seen with the motor blockade. The grade of motor blockade was also comparable in both groups. The duration of motor block was 1.59 times in RC group as compared to R group. Prolongation of motor blockade was almost same as compared to sensory blockade. None of our patients had bradycardia. Transient hypotension was seen in two patients in our RC. Klimsha et al[23] suggested that when a larger dose of local anaesthetic is used, the hypotensive action of Clonidine is masked by dense axonal blockade produced by the local anesthetic.Striking advantage of intrathecal Clonidine over intrathecal narcotics is absence of respiratory depression and pruritus.[11] None of the patients developed any neurological complications postoperatively. In this study, postoperative analgesia was 1.60 times [225.5 $\pm$20.66/141.1 $\pm$20.54 min] prolonged by addition of 45 µg of Clonidine, without any sedation or cardiovascular compromise. 15 mg of isobaric Ropivacaine (0.5%) has good success rate as observed in our study. 45 µg Clonidine can be added to improve onset, quality and duration of sensory as well as motor block.

Conclusion

We can conclude that addition of intrathecal 45 µg Clonidine prolonged sensory blockade & postoperative analgesia of isobaric Ropivacaine safely. Its postoperative profile was improved by Clonidine. Although 2 patients in RC group had hypotension intraoperatively, but it was managed easily. There was no hypotension reported postoperatively.

References:

1. Macario A, Weinger M, Carney S, Kim A: Which clinical anesthesia outcomes are important to avoid ? The perspective of patients. Anesth Analg 1999; 89: 652-8
2. Luger TJ, Kammerlander C, Gosch M.. Neuroaxial versus general anaesthesia in geriatric patients for hip fracture surgery: does it matter? Osteoporos Int 2010;21:S555-72.
3. Kuthiala G, Chaudhary G Ropivacaine:A review of its pharmacology and clinical use. Indian J Anaesth. 2011 Mar-Apr; 55(2): 104–110.
4. Hansen TG. Ropivacaine: A pharmacological review. Expert Rev Neurother 2004;4:781-91.
5. Mehta A, Gupta V, Wakhloo R, Gupta N, Gupta A, Bakshi R, Kapoor B, Gupta S. Comparative evaluation of intrathecal administration of newer local anaesthetic agents Ropivacaine and Levobupivacaine with Bupivacaine in patients undergoing lower limb surgery. The internet journal of anesthesiology 2007; volume 17: number 1
6. Galea, M. A., et al. "The optimal dose of epidural Ropivacaine for use during labor and delivery." *Anesthesiology*. Vol. 89. No. 3 A. 227 EAST WASHINGTON SQ, PHILADELPHIA, PA 19106 USA: LIPPINCOTT WILLIAMS & WILKINS, 1998.
7. Carli F, Mayo N, Klubien K, Schricker T, Trudel J, Belliveau P. Epidural analgesia enhances functional exercise capacity and health related quality of life after colonic surgery: Results of a randomized trial. Anaesthesiology. 2002; 97:540-9.
8. Dobrydnjov I, Samarutel J. Enhancement of intrathecal lidocaine by addition of local and systemic Clonidine. Acta Anaesth Scand 1999; 43:556-62
9. Grandhe RP, Wig J, Yaddanapudi. LN Evaluation of Bupivacaine-Clonidine Combination for Unilateral Spinal Anaesthesia in Lower Limb Orthopedic Surgery. J Anaesth Clin Pharmacol 2008; 24(2): 155-158.
10. Olfa Kaabachi, Amine Zarghouni, Rami Ouezini, Ahmed Ben Abdelaziz, Olfa Chattaoui, Hannu Kokki. Clonidine 1 g/kg Is a Safe and Effective Adjuvant to Plain Bupivacaine in Spinal Anesthesia in Adolescents Anesth Analg 2007;105:516 –9
11. Strebel S , Jürg A. Gurzeler, Schneider MC, Aeschbach A, Kindler CH. Small- Dose Intrathecal Clonidine and Isobaric Bupivacaine for Orthopedic Surgery: A Dose-Response Study. Anesth Analg 2004;99:1231-12381238
12. Bonnet F, Buisson VB, Francois Y. Effects of oral and subarachnoid Clonidine on spinal anesthesia with bupivacaine. Reg Anesth 1990;15:211–4.
13. Marc De Kock, Phillipe Gautier, Luc Fanard. Intrathecal Ropivacaine and Clonidine for ambulatory knee arthroscopy. Anesthesiology 2001;94(4):574-8
14. Sethi BS, Samuel M, Sreevastava D. Efficacy of Analgesic Effects of Low Dose Intrathecal Clonidine as Adjuvant to Bupivacaine. Journal of Anaesthesia 2007; 51 (5): 415-419
15. Sagiroglu G, Sagiroglu T, Meydan B. The effects of adding various doses of Clonidine to Ropivacaine in spinal anesthesia. Eurasian J Med. 2009 Dec; 41(3): 149-153
16. Neimi L. Effects of intrathecal Clonidine on duration of Bupivacaine spinal anaesthesia, hemodynamics, and post-operative analgesia in patients undergoing knee arthroscopy. Acta Anaesthesiol Scand 1994 Oct; 38(7): 724-8
17. Bromage PR. A comparison of the hydrochloride and carbon dioxide salts of lidocaine and prilocaine in epidural analgesia. Acta Aneaesthesiol Scand Suppl. 1985; 75:193-200.
18. Chia YY, Liu K, Liu YC, Chang HC, Wong CS. Adding ketamine in a multimodal patient-controlled epidural regimen reduces postoperative pain. Anesth Analg. 1998; 86: 1245-1249
19. Katz J, Melzack R. Measurement of pain. Anesthesiology Clinics of North America 1992; 10(2): 229-246.
20. DeLoach LJ, Higgins MS, Caplan AB, Stiff JL. The VAS in the immediate postoperative period. Intrasubject variability and correlation with a numeric scale.
21. Racle JP, Benkhadra A, Poy JY, Gleizal B. Prolongation of isobaric bupivacaine spinal anesthesia with epinephrine and Clonidine for hip surgery in the elderly. Anesth Analg 1987; 66:442-6.
22. Saxena H, Singh S & Ghildiyal S. Low dose Intrathecal Clonidine with Bupivacaine improves onset and duration of block with hemodynamic stability. Internet journal of Anaesthesiology 2010; vol23 (1).
23. Klimscha W, Chiari A, Krafft P, Plattner O, Taslimi R, Mayer N et al. Hemodynamic and analgesic effects of Clonidine added repetitively to continuous epidural and spinal block. Anesth analg 1995 Feb; 80(2): 322-7