ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

A Prospective Randomized Double Blind Study To Compare The Efficacy Of 0.75% Heavy Ropivacaine With 0.5% Heavy Bupivacaine In Caesarean Sections

Dr. Bhagyashree Amingad[1*], Dr. Rashmi H D[2], Dr. Lokesh H C[3], Dr. Hanumanthappa V Airani[4],Dr.Aishwarya Kotagi[5]

[1, 2] Associate Professor, Department of Anaesthesiology, HIMS, Hassan, Karnataka
[3] District Surgeon and Associate professor, Department of General medicine, HIMS, Hassan, Karnataka
[4] Head of the department, Department of Anaesthesiology, HIMS, Hassan, Karnataka
[5] Postgraduate student, Department of Anaesthesiology, HIMS, Hassan, Karnataka

Corresponding Author:Dr Bhagyashree Amingad,

Abstract:

Introduction: Ropivacaine is an 'S' enantiomer of bupivacaine with reduced toxic potential. Its shorter duration of action results in faster recovery of motor function that helps in early ambulation postoperatively. A greater differentiation of sensory and motor block can be observed with it.

Aim: This prospective, randomised, double blinded study was done to compare the efficacy and safety of ropivacaine 0.75% heavy and bupivacaine 0.5% heavy in patients undergoing elective caesarean section.

Methods: This study was done on 80 parturients aged between 18-34years, weighing 50-70kgs, height of 155-174cms undergoing elective caesarean section. The patients were randomly allocated into two groups. Group R received 2ml of 0.75% heavy Ropivacaine and group B received 2ml of 0.5% heavy bupivacaine. The time for onset of sensory, motor blockade, duration of sensory and motor blockade, hemodynamic variability and side effects were recorded.

Results: There was no difference in the time for onset of sensory blockade, onset of motor blockade and the duration of sensory blockade between the two groups. The duration of motor blockade was significantly shorter in group R (74.63+/- 3.920 minutes) than that of group B (126.78+/- 11.441 minutes) with P value <0.01. Minimal variations in hemodynamic parameters were noted with ropivacaine. No side effects were observed in either group.

Conclusion: The authors suggest that ropivacaine is an safer and equally effective alternative to bupivacaine with better haemodynamic and block characteristics.

Keywords: Intrathecal, Bupivacaine, Ropivacaine, Caesarean.

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

Introduction:

Subarachnoid block (SAB) is the preferred technique of anaesthesia for cesarean section, unless contraindicated due to its benefits over general anaesthesia. It is economically feasible, easily administered with rapid onset of action and relatively lower rate of side effects along with better maternal comfort [1]. Bupivacaine 0.5% heavy is a well-known long-acting local anesthetic used since a long time to perform subarachanoid block for caesarean deliveries. It has a higher toxicity profile when used in higher concentrations or on accidental intravenous administration. Hence, newer drugs like ropivacaine, levobupivacaine with all the advantages of bupivacaine and a lower toxicity profile have come into use [2].

Ropivacaine is a long-acting local anesthetic that is structurally related to bupivacaine with a sensory and motor block characteristics comparable to bupivacaine [2]. It provides better sensory-motor differentiation with relatively shorter duration of motor blockade because of its reduced lipophilicity. This characteristic of ropivacaine is useful when motor blockade is desired for shorter duration. The lower lipophilicity of ropivacaine makes it less cardiotoxic and neurotoxic [3].

Several studies have reported the intrathecal use of hyperbaric ropivacaine which was prepared by adding dextrose to isobaric ropivacaine in patients undergoing cesarean section [4-6]. The present study was designed to compare the block and haemodynamic characteristics of hyperbaric ropivacaine with bupivacaine for subarachanoid block in patients undergoing elective cesarean section.

Objectives:

1. To compare the time for onset of sensory and motor block between the two groups.
2. To compare the total duration of sensory and motor block between the two groups.
3. To compare the total duration of post-operative analgesia between the two groups.
4. To compare the hemodynamic variability between the two groups.
5. Intraoperative or postoperative side-effects and complications.

Materials and Methods:

This randomized, prospective and double blinded study was conducted in major operation theatre at Hassan Institute of Medical Sciences, Hassan after the approval of the institutional ethical committee. Informed written consent was obtained from all 80 parturients aged between 18-34 years, weighing 50-70kgs with height of 155-174cms, belonging to American

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

society of Anaesthesiologists physical status (ASA) II undergoing elective caesarean section. Patients with history of allergy to the local anesthetics, bleeding disorders, on anticoagulant therapy, cardiac diseases were excluded from the study. A thorough pre-anaesthetic evaluation for all pregnant mothers was done a day prior to the surgical procedure, and standard ASA fasting guidelines were followed in all of them.

Computer based random allocation of 80 patients was done into two groups:

Group B receiving 2cc of 0.5% hyperbaric bupivacaine.

Group R receiving 2cc of 0.75% hyperbaric ropivacaine.

The study drugs are commercially available solutions and were handed over to the attending anaesthesiologist in a coded form who was blinded to the nature of drug given to him or her.

On arrival at the operation theatre, baseline heart rate, blood pressure, respiratory rate and peripheral oxygen saturation were recorded. An 18G intravenous cannula was secured and intravenous infusion of ringer lactate was started at 10-15ml/kg 30 minutes before block. All emergency drugs and resuscitation kit were kept ready. Under all aseptic precautions, lumbar puncture was done at L3-L4 intervertebral space using 25G Quincke-Babcock's spinal needle in lateral decubitus position. After free flow of clear CSF, the study drug was injected into the subarachnoid space. Patient was positioned supine immediately with table tilt of 15˚ to the left side. Oxygen was supplemented using face mask throughout at 6 litres per minute.

Primary objectives were to evaluate the time for onset of sensory block to highest dermatomal level, duration of sensory blockade, time of onset of motor block, duration of motor block, total duration of postoperative analgesia.

Sensory block was assessed by loss of sensation to pinprick over the desired dermatomes using a 3-points scale [7] which is as follows:

0 - Sharp pain,

1 - Dull pain (analgesia),

2 - No pain (anaesthesia).

Sensory onset time was defined as the time interval between the end of local anaesthetic administration and establishment of score 2 on 3-point scale in all the desired dermatomes. Sensory block duration was defined as the time from injection of local anesthetic to complete recovery from cold and pain sensation in the desired dermatomes.

Onset of motor block: Motor block was assessed using Modified Bromage scale [8].

Grade 1 -- free movement of legs and feet,

Grade 2 -- just able to flex knees with free movement of feet,

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

Grade 3 -- unable to flex knees, but with free movement of feet,

Grade 4 -- unable to move legs or feet.

Motor block onset time was defined as the time interval between the end of local anesthestic (LA) administration to complete motor block (score 2). Motor block duration was defined as the time from injection of local anesthestic study solution to complete recovery of movements of lower limb. Total duration of analgesia was measured till the patient has VAS >3 and rescue analgesia was given. Secondary objectives were hemodynamic parameters and side effects. Hemodynamic parameters such as heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation, and respiratory rate were monitored at every 10 min interval till 1 hour following local anaesthetic injection and then every 20 min till the end of 2nd hour and thereafter every hour till the end of surgery. All side effects such as hypotension (20% reduction in relation to the baseline value), bradycardia (HR), nausea and vomiting were noted in both the groups.

Statistical analysis:

Data was entered in Microsoft excel sheet and SPSS software was used for statistical analysis. All categorical data was expressed in percentages and proportions. Chi Square test was used as the test of significance. All the continuous data was represented as mean and standard deviation. Unpaired t test was the test of significance to identify the mean difference between the two groups. Observations so made were put to stastical evaluation and P value <0.05 was taken as significant.

Results:

Table.1

Table 1. The demographic data of the two groups

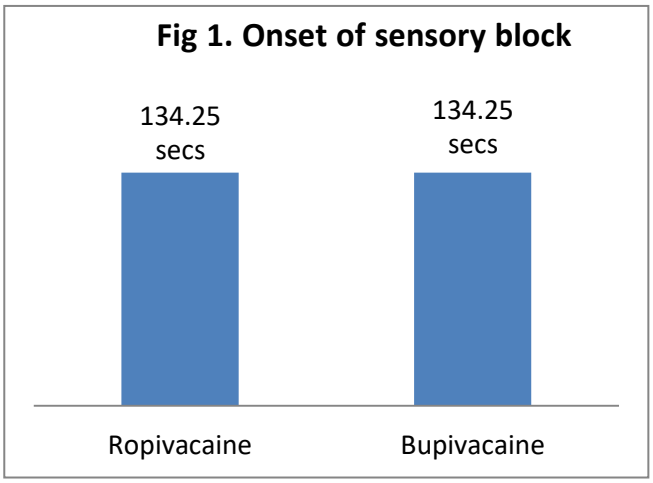
	Group	N	Mean	Std. Deviation	P Value
Age	Ropivacaine	40	24.90	2.898	0.426
	Bupivacaine	40	25.45	3.242	
Gestational Week	Ropivacaine	40	37.25	1.127	0.844
	Bupivacaine	40	37.30	1.137	
Height	Ropivacaine	40	167.28	3.508	0.702
	Bupivacaine	40	167.58	3.485	
Weight	Ropivacaine	40	75.18	5.368	0.716
	Bupivacaine	40	75.63	5.651	
BMI	Ropivacaine	40	26.914	2.408	0.909
	Bupivacaine	40	26.977	2.473	

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

Duration of surgery	Ropivacaine	40	14.28	8.665	0.352
	Bupivacaine	40	16.18	9.481	

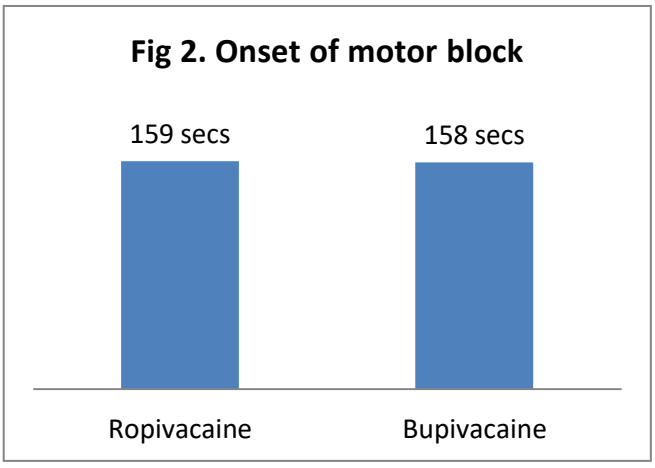
The demographic data in both the groups showed no significant difference in terms of age, weight, height, Body Mass Index (BMI), gestational weeks and duration of surgery.

Figure.1



There was no significant difference in the time of onset of sensory blockade between the two groups (P=1.00).

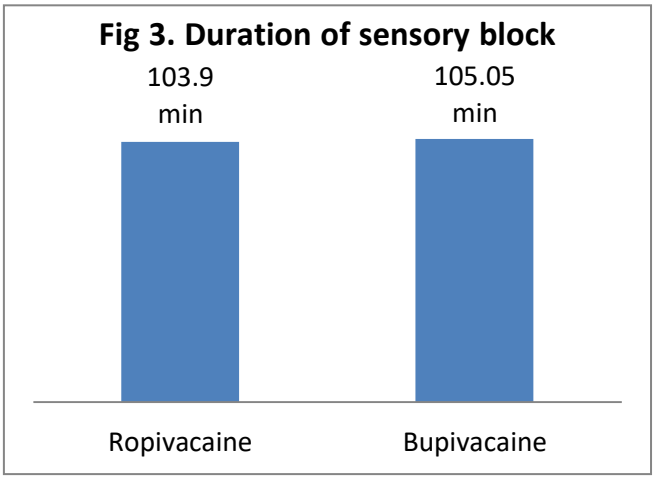
Figure.2



There was no significant difference in the time of onset of motor block between the two groups (P=0.612).

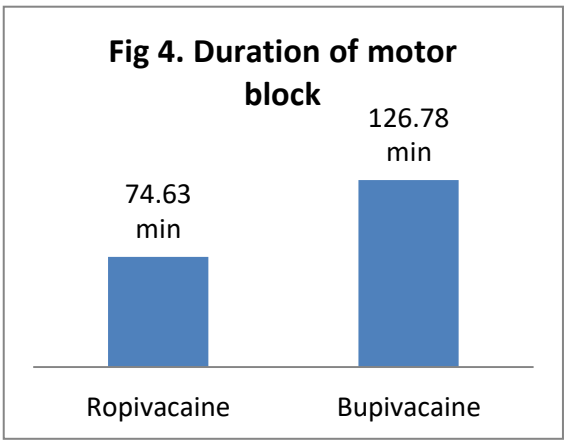
ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

Figure.3



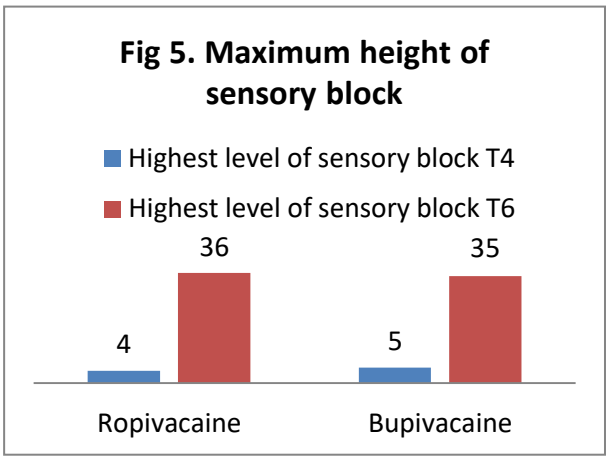
Our study also showed that the duration of sensory blockade was comparable between the two groups with no significant difference (P=0.503).

Figure.4



But the duration of motor blockade was shorter (74.63+/- 3.920 minutes) in group R than that of group B (126.78+/- 11.441 minutes) with P value = <0.01.

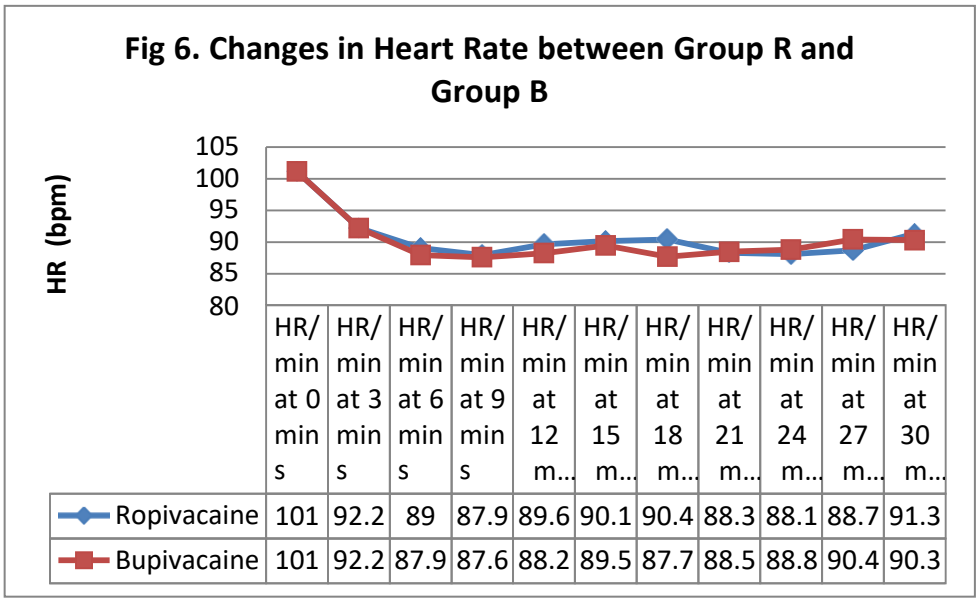
Figure.5



ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

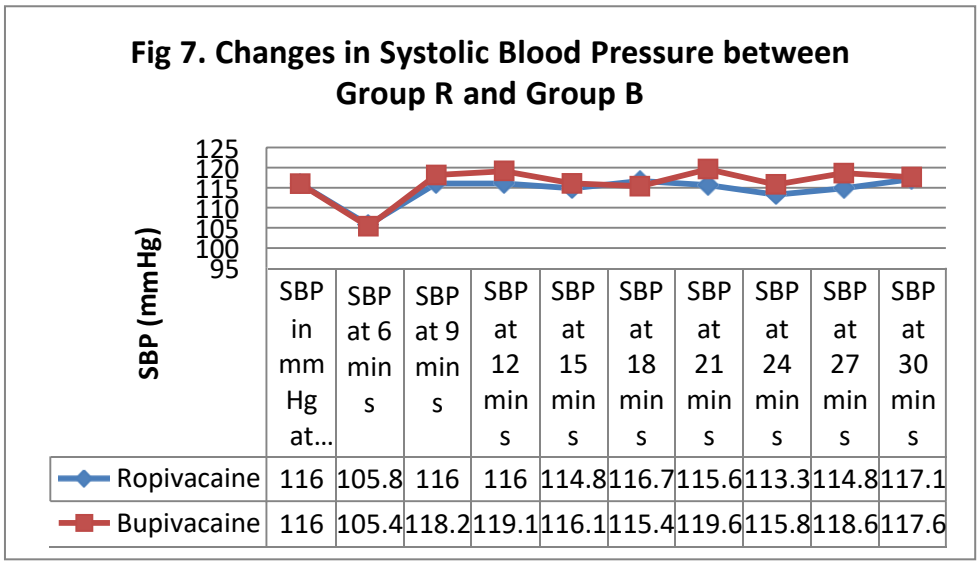
The maximum sensory height of subarachanoid block is shown in **Fig 5**. Our study showed no significant difference between group B and group R in the highest level of sensory block achieved (P =0.723).

Figure. 6



The changes in the heart rate at 0,3,6,9,12,15,18,21,24,27 and 30 minutes were recorded. This study showed no significant changes in heart rate between the two groups.

Figure.7

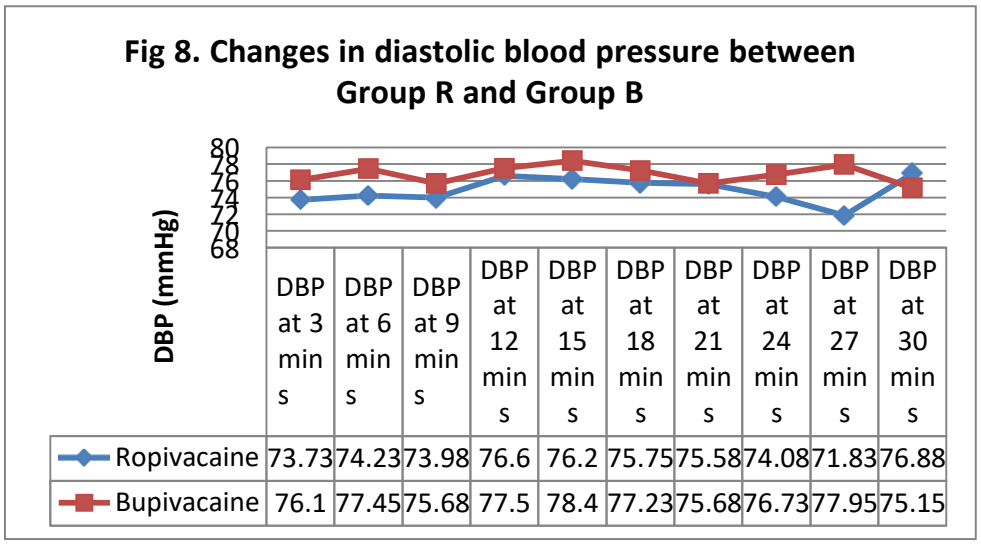


The trend of changes in systolic blood pressure at 0,3,6,9,12,15,18,21,24,27,30 minutes between the two groups showed no significant differences except at 21min and 27min where

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

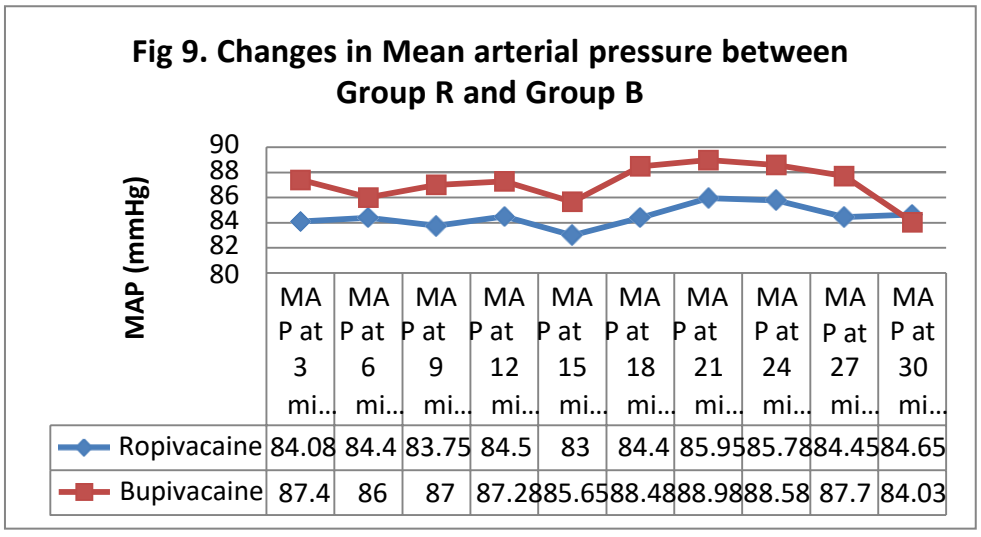
ropivacaine caused slight reduction in the SBP i.e. 115.63+/-8.906 mmHg and 114.83+/-8.345 mmHg respectively.

Figure.8



The trend of changes in diastolic blood pressure at 0.3.6, 9, 12,15,18,21,24,27,30 minutes between the two groups showed no significant statistical differences except at 27 minutes where ropivacaine caused slight reduction in DBP (71.83+/-9.484 mmHg) which did not require any intervention.

Figure.9



Also, the Mean arterial pressure changes between the two groups were recorded at 0,3,6,9,12,15,18,21,24,27,30 minutes. No significant differences were found between the two groups.

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

Side effects like neurological changes, backache, headache, nausea and vomiting were not found within 24 hours of discharge in either group.

Discussion:

Bupivacaine is a long-acting amino-amide local anaesthetic which is most widely used in regional anaesthesia. It is associated with a higher cardiotoxic profile when used at higher concentration or when accidentally administered intravascularly. Hence, newer amino-amide local anaesthetics have been developed with better blocking characteristics and less cardiotoxic potential [9].

Ropivacaine is a pure S (-) enantiomer of bupivacaine with lower toxicity profile and an improved sensory and motor blockade characteristic. A reduced lipid solubility of Ropivacaine results in greater sensory-motor differentiation. Sensory nerve fibres are more readily blocked than that of motor nerve fibres with faster recovery of motor function. This property of ropivacaine provides early ambulation and helps in decreasing the incidence of venous thromboembolism postoperatively [9].

A hospital based, prospective, comparative study by Patil et al[10] in patients undergoing elective lower abdominal surgery showed that isobaric ropivacaine 0.75% can be an alternative to isobaric bupivacaine 0.5%. The results concluded that ropivacaine has better sensory and motor blockade profile with rapid recovery of motor function and early ambulation. But, earlier studies with isobaric ropivacaine showed that the blockade was inadequate. Hence, ropivacaine was made hyperbaric by the addition of glucose to the isobaric ropivacaine [11]. A prospective, randomised, double blinded study by Kulkarni et al [11] on hyperbaric ropivacaine versus hyperbaric bupivacaine in patients undergoing elective lower abdominal, perineal and lower limb surgeries showed that the ropivacaine provides shorter duration of sensory and motor blockade. Also, another prospective, hospital based, comparative study done by Subba et al[12] on hyperbaric bupivacaine 0.5% versus hyperbaric ropivacaine 0.75% in patients undergoing elective Caesarean section by preparing hyperbaric ropivacaine 0.5% by mixing 1 ml of 25% dextrose with 2 ml of 0.75% plain ropivacaine. A total of 3 ml of this solution was drawn and used to perform spinal anaesthesia. It was found that ropivacaine has shorter duration of motor blockade than that of bupivacaine with similar hemodynamic variability and other characteristics. The present study was conducted using commercially available hyperbaric bupivacaine 0.5% versus hyperbaric ropivacaine 0.75% in patients undergoing elective caesarean section. There are very limited studies done on commercially available heavy ropivacaine 0.75% in patients undergoing caesarean section.

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

Also, few studies have been done earlier using hyperbaric ropivacaine 0.75% used intrathecally in patients undergoing caesarean section but with unclear results [12]. The results of the present study showed that there were no differences in the time of onset of sensory (134.25 vs 134.25 secs, P = 1) and motor blockade (159 secs vs 158 secs, P = 0.61) for hyperbaric Ropivacaine 0.75% vs hyperbaric Bupivacaine 0.5% respectively. Also, the duration of sensory blockade was similar in both the groups (103.9 vs 105.5 minutes, P = 0.50). But, the duration of motor blockade was shorter in the group that received hyperbaric ropivacaine (74.63+/- 3.920 minutes) than that of bupivacaine (126.78+/- 11.441 minutes) with a statistically significant P value of <0.01. The haemodynamic variables in both the groups showed no significant differences. No side effects/complications observed in our study. Olapaur et al[13] conducted a prospective, randomized, double blinded study on bupivacaine versus ropivacaine in patients undergoing elective caesarean and observed shorter duration of motor blockade with little influence on hemodynamic variables with ropivacaine. Our observations and results are consistent with the study done by Olapaur et al.

Conclusion:

We conclude that intrathecal hyperbaric 0.75% ropivacaine can be used safely to provide an effective and reliable anaesthesia for patients undergoing elective caesarean section with a lower duration of motor block and possible early ambulation when compared to that of hyperbaric bupivacaine.

References:

1. Gadre AK, Bandypadhyay KH, Dutta C, Nag T. A Comparative study of intrathecal isobaric 0.5% bupivacaine and intrathecal isobaric 0.75% ropivacaine in elective lower segment caesarean section. Journal of Pharmacology and Pharmacotherapeutics. October-December 2019; 10(4): 126-131.
2. Chowdhary J, Bhadrala N, Hussain J. Randomized comparative study of different doses of dexamethasone as an adjuvant to ropivacaine in supraclavicular brachial plexus block in upper limb surgery. International Journal of Scientific Research.April-2019; 8(4): 47-49
3. Mohta M. Ropivacaine: Is it a good choice for spinal anaesthesia? Journal of anaesthesiology, clinical pharmacology. 2015 Oct; 31(4):457-458.
4. Khaw KS, Kee WD, Wong M, Ng F, Lee A. Spinal ropivacaine for caesarean delivery: a comparison of hyperbaric and plain solutions. Anaesthesia & Analgesia. 2002 Mar 1;94(3):680-5

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 05, 2024

5. Chung CJ, Choi SR, Yeo KH, Park HS, Lee SI, Chin YJ. Hyperbaric spinal ropivacaine for caesarean delivery: a comparison to hyperbaric bupivacaine. Anaesthesia & Analgesia. 2001 Jul 1;93(1):157-61
6. Layek, Amitava, Maitra, Souvik, Gozi, Nitish K, Bhattacharjee, Sulagna, Pal, Sugata,Sen, Suvadeep, Hazra, Avijit. Comparison between intrathecal isobaric ropivacaine-fentanyl and bupivacaine-fentanyl in elective infraumbilical orthopaedic surgery-A randomized controlled study. Journal of Anaesthesiology Clinical pharmacology.October-December 2015; 31(4): 542-46.
7. Kathuria S, Gupta S, Dhawan I. Dexmedetomidine as an adjuvant to ropivacaine in supraclavicular brachial plexus block. Saudi journal of anaesthesia. 2015 Apr;9(2):148.
8. Gupta P, Suthar A, Deganwa M, Goyal V, Devgan S. A comparative study of dexmedetomidine versus nalbuphine used as an adjuvant to chloroprocaine for daycare surgeries performed under subarachnoid block. Anesthesia, essays and researches. 2022 Jul;16(3):336
9. Gohil PJ, Panchal P, Panjabi GM, Gohil JJ, Thakar UH, Rathi RR. Anesthetic efficacy and safety of ropivacaine 0.75% versus bupivacaine 0.5% for spinal anaesthesia in patients undergoing lower limb orthopaedic surgery. Asian Journal of Medical sciences. October 2023; 14(10): 9-14.
10. Patil P, Dhulkhed PV, Dhulkhed VK. Isobaric forms of ropivacaine vs. bupivacaine in lower abdominal surgeries: a hospital-based, prospective, comparative study. Medical Gas Research. 2023 Jul; 13(3):123.
11. Kulkarni KR, Deshpande S, Namazi I, Singh SK, Kondilya K. A comparative evaluation of hyperbaric ropivacaine versus hyperbaric bupivacaine for elective surgery under spinal anesthesia. Journal of anaesthesiology, clinical pharmacology. 2014 Apr;30(2):238.
12. Subba S, Chhetri AA, Bhattarai R. Comparison of effects of Bupivacaine and Ropivacaine in patients undergoing elective Caesarean section. Birat Journal of health sciences. Sep-Dec, 2019;4(10):859-63.
13. Olapour A, Akhondzadeh R, Rashidi M, Gousheh M, Homayoon R. Comparing the effect of bupivacaine and ropivacaine in cesarean delivery with spinal anesthesia. Anesthesiology and pain medicine. 2020 Feb;10(1).