IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 14, Issue 4 Ver. VII (Apr. 2015), PP 27-31
www.iosrjournals.org

Comparative Evaluation of Intrathecal Hyperbaric Ropivacaine versus Intrathecal Hyperbaric Bupivacaine in Elective Lower Abdominal and Lower Limb Surgery

Dr Sapna Bansal[1], Dr Babita Ramdev[1], Dr Parul Narula[1], Dr Sachin Bansal[2], Dr Dhanwant Kaur[1], Dr Shivani Rathi[1]
[1](Department of anaesthesiology, MMIMSR, Mullana, INDIA)
[2](Department of respiratory medicine, MMIMSR, Mullana, INDIA)

Abstract:*Spinal anaesthesia is a routine procedure for lower limb and lower abdominal surgeries. Ropivacaine, a long acting amide type of local anaesthetic is newly available in isobaric form.This study was designed to compare the clinical efficacy of hyperbaric ropivacaine versus hyperbaric bupivacaine.100 ASA grade I-II patients undergoing elective lower limb and lower abdominal surgeries under spinal anaesthesia were randomized to receive 18 mg of hyperbaric ropivacaine or 12 mg of hyperbaric bupivacaine. Monitoring of vitals and observation for the block parameters were carried out. The data were presented as mean with standard deviation and frequency with percentage. P value <0.05 was considered as significant.Ropivacaine produced a faster onset of sensory block (ropivacaine 2.9 min; bupivacaine 4.2 min; P < 0.05) but the mean total duration of sensory block in ropivacaine group was significantly less (ropivacaine168.5 min; bupivacaine 196.6 min; P < 0.05). Patients in the ropivacaine group had significantly more rapid recovery from the motor blockade (ropivacaine128.3 min; bupivacaine 148.7 min; P < 0.05). Quality of analgesia and anaesthesia were comparable in both the groups.*
Hyperbaric Ropivacaine 18 mg provides reliable and satisfactory spinal anaesthesia of shorter duration than hyperbaric bupivacaine 12 mg without side effects.
Keywords: *Hyperbaric, bupivacaine, ropivacaine, spinal anesthesia, transient neurologic symptoms.*

I. Introduction

Spinal anaesthesia with lidocaine was widely used for outpatient procedures because of its fast onset and short duration profile; however, it was also associated with a very frequent incidence of transient neurological symptoms. The abandonment of lidocaine in spinal anaesthesia, however, has been a setback for ambulatory anaesthesia, where early recovery is vital. Bupivacaine, the most common alternative to lidocaine, has a low incidence of transient neurologic symptoms (TNS), 0-1% but delays home discharge in ambulatory surgical patients if used in the usual doses[1].For this reason small doses of long acting drugs have been suggested as possible alternatives to lidocaine for outpatient spinal anaesthesia[2].

Ropivacaine is available as the first pure S-enantiomer of local anaesthetics. Ropivacaine, which block sensory nerve fibres more readily than motor fibers, is now gaining popularity due to its reduced cardiac toxicity with overdose. Recent studies with intrathecal ropivacaine have demonstrated low cardiovascular and neurotoxic effects, good tolerability and efficacy[3].Because of sensorimotor dissociation, ropivacaine should be a favourable local anaesthetic for day-case surgery and could be associated with earlier postoperative mobilization than bupivacaine[4].Studies of glucose-free solutions were done primarily to allay concern regarding the safety of ropivacaine in case accidental intrathecal injection occur during epidural block[5]. Studies have shown that plain ropivacaine can produce satisfactory analgesia for surgery but doubt remains about its reliability, as is the case with other agents in plain solution[6].

So, in our study we plan to study the potency, safety and efficacy of intrathecal hyperbaric ropivacaine and also compare it with intrathecal hyperbaric bupivacaine in elective lower limb and lower abdominal surgery.

II. Materials And Methods

The study was carried out in 100 ASA grade I and II adult patients of both genders between 21-70 years of age undergoing lower abdominal and lower limb surgery under subarachnoid block after taking a written informed consent from every patient.

After approval from the ethical committee of the hospital, all patients were selected randomly and were divided into two groups comprising 50 patients each.

Group I(n=50) received an intrathecal injection of 4ml of 0.5% hyperbaric ropivacaine(18mg)
Group II (n=50) received an intrathecal injection of 4 ml of 0.5% hyperbaric bupivacaine (12 mg)

Pre-anesthetic check up including a detailed history and medical examination of each patient was done a day before surgery. All patients were thoroughly investigated as per the requirement of the surgery apart from the routine investigations. All patients were kept fasting overnight and were given premedication i.e. injection 2 mg midazolam intramuscular 45 minutes before anesthesia.

Technique of anaesthesia

Pre-operatively an intravenous line were secured with an 18G intravenous cannula & preloading with Ringer Lactate solution 500ml was done before the initiation of subarachnoid block. After shifting the patient to operation table, a baseline blood pressure, pulse rate, respiratory rate and arterial oxygen saturation were recorded before anesthesia.

Under all aseptic precautions, lumbar puncture was performed with 25 G Quincke's needle by using a midline approach at L2-L3 interspace in lateral decubitus position. Once free flow of clear CSF is obtained, the study drug was injected at the rate of 0.2 ml/sec and the patient was turned supine.Subsequent readings of blood pressure, pulse rate, arterial oxygen saturation and respiratory rate were taken every 5 minutes till 30 minute and then every 30 minutes till the completion of surgery.If surgery was prolonged, then the anesthesia was supplemented with general anesthesia.

Sensory blockadedefined as loss of sharp sensation by using a pin-prick test was recorded at dermatomal level. Time of onset of sensory blockade was defined as time between injection and loss of pin-prick sensation at T10 dermatomal level. Time of maximal sensory block was taken as time between injection and maximal blockade achieved. Duration of blockade was defined as the period between the injection and recovery from sensory blockade. Assessment of sensory block was done every 2 minutes till the level stabilised.

Motor blockwas assessed by Modified Bromage Score. Onset of motor block was taken as the time between the injection and maximum bromage score. Duration of motor block was assessed by recording the time elapsed from the maximum to the lowest Bromage score. Assessment of motor block was done every 2 minutes till 20 minutes.

The quality of anaesthesia was evaluated by the surgeon at the end of the surgery as-

- Excellent – no disturbing muscle stain
- Satisfactory – disturbing, but acceptable muscle strain
- Unsatisfactory – unacceptable muscle strain

The quality of intraoperative analgesia was judged at the end of surgery by the investigator as

- Excellent – no discomfort or pain
- Good – mild pain or discomfort , no need for additional analgeaics
- Fair – pain that required additional analgesics
- Poor – moderate or severe pain that needed high dose analgesics or general anaesthesia.

Intaoperatively any side effects were noted and treated accordingly.
Patients were followed up on post operative days 1 and 5 regarding possible side effects.
All the parameters were recorded in the proforma and satistically analysed at the end of the study. P value <0.05 was considered as significant.

III. Results

Two groups were comparable regarding age, weight, gender and preoperative vitals. There was no significant difference in the type and duration of surgery (table I).

Hyperbaric ropivacaine produced a more rapid onset of sensory block, which ultimately regressed more quickly. The mean time to onset of analgesia at T10 was more rapid with hyperbaric ropivacaine (2.9±0.75 vs 4.2±1.2), (table II). Time to attain maximum level was more with hyperbaric ropivacaine, although maximum level reached was same in both groups (9.5±2.3 vs 8.4±1.9), (table III).

Complete motor blockade i.e. modified bromage score of III was achieved in both groups and mean time taken to reach complete motor block was insignificantly in both groups (8.2±2.1 vs 7.9±2.4), (table IV).

Mean time for two segment regression of sensory block (an indicator of useful duration forsurgery) was lesser in the hyperbaric ropivacaine group (66.1±15.8 vs 75.3±19.1), (table III). Mean time for complete regression of both sensory and motor block was lesser in the hyperbaric ropivacaine group. This difference was statistically significant.

Duration of sensory block was significantly lower with hyperbaric ropivacaine (168.5±44.0 vs 196.6±41.0), (table III). Duration of motor block was also significantly lower with hyperbaric ropivacaine (128.3±38.3 vs 148.7±36.4), (table IV).

The quality of anaesthesia (intraoperative muscle relaxation) and analgesia was similar in both the groups. It was opined to be excellent in 88% of patients in group I and 94% in the group II. This was not

clinically or statistically significant (P value >0.05), (table V and VI). In group I only 18% patients had hypotension as compared to 72% patients in group II which was statistically highly significant (Pvalue <0.01). Incidences of other side effects like bradycardia, shivering, nausea/vomiting and backache were comparable (table VII).

IV. Tables

Table I: Patient characteristics and type of surgery

	Group I	Group II	P-value
Age(years)	41.9±11.4	43.1±14.6	>0.05
Gender M/F	31/19	30/20	
Weight	58.9±8.5	61.2±8.7	
Surgery (lower limb/ lower abdomen)	32/18	34/16	

Table II: Pre-operative vitals

	Group I	Group II	P-value
Heart rate	85.04±9.65	80.16±9.58	>0.05
Mean arterial pressure	77.32±9.25	76.32±7.25	
SpO2	98.28±0.85	98.26±0.96	

Table III: Comparison of Sensory characteristics

	Group I	Group II	P Value
Onset time at T10	2.9±0.75	4.2±1.2	0.00
Time to max sensory block	9.5±2.3	8.4±1.9	0.00
Time for 2 segment regression	66.1±15.8	75.3±19.1	0.01
Duration of sensory block	168.5±44.0	196.6±41.0	0.00

Table IV: Comparison of Motor Characteristics

	Group I	Group II	P Value
Onset	8.2±2.1	7.9±2.4	0.61
Duration of motor block	128.3±38.3	148.7±36.4	0.01

Table V: Comparison of Quality of Anaesthesia

	Group I (n,%)	Group II (n, %)	P value
Excellent	44 (88)	47 (94)	>0.05
Satisfactory	6 (12)	3 (6)	
Unsatisfactory	0	0	

Table VI: Comparison of Quality of Analgesia

	Group I (n, %)	Group II (n, %)	P value
Excellent	44 (88)	47 (94)	>0.05
Satisfactory	4 (8)	2(4)	
Unsatisfactory	2(4)	1(2)	

Table VII: Incident of side effects in both groups

Side effects	Group I (n, %)	Group II (n, %)	P value	Significance
Hypotension	9(18)	36(72)	<0.01	HS
Bradycardia	4(8)	8(16)	>0.05	NS
Nausea/vomiting	2(4)	8(16)	>0.05	NS
Shivering	2(4)	12(24)	>0.05	NS
Backache	10(20)	14(28)	>0.05	NS
Urinary retension	0	0	>0.05	NS
Neurological symptoms	0	0	>0.05	NS
Other side effects	0	0	>0.05	NS

V. Discussion

Bupivacaine, an amino amide compound has been the long acting local anaesthetic agent of choice for lower limb and lower abdominal surgeries. It binds strongly to cardiac cardiac sodium channels leading to a prolonged inhibition of normal conduction. Animals studies[7]has proved that accidental intravascular bupivacaine results in arrhythmias, cardiac depression and cardiac arrest. Ropivacaine, a new amino-amide local anaesthetic agent that has been developed specifically to address the issue of toxicity is similar in chemical structure to bupivacaine[8,9].This drug has a greater margin of safetythan bupivacaine, partly because it is available as a pure form of the S enantiomer. It has been used extensively for the local infiltration, epidural, and peripheral blocks. Extensiveclinical data have shown that ropivacaine is effective and safe for regional

anaesthetics techniques such as epidural and brachial plexus block[10]. However hyperbaric ropivacaine has been little studied in intrathecal anaesthesia.

Ropivacaine is a relatively new local anesthetic that has not been marketed for intrathecal use. In this study, hyperbaric ropivacaine solution was made with 4 mL of 0.75% ropivacaine and 2 mL of 20% dextrose. The specific gravity of 0.5% ropivacaine in 6.7% glucose was 1.030 at 23°C. The specific gravity of 0.5% hyperbaric bupivacaine in 8% glucose was 1.030 at 23°C.

The purpose of this study was to evaluate the efficacy and safety of hyperbaric ropivacaine in spinal anaesthesia and to compare it with hyperbaric bupivacaine in lower limb and lower abdominal surgeries.

The onset time at T_{10} was significantly less in ropivacaine group. Spinal anaesthesia was successful in almost 95% of patients in each group & in none of the patients, conversion to general anaesthesia was required. Previous studies have shown the delayed onset or similar onset time with hyperbaric ropivacaine as compared to hyperbaric bupivacaine. This could be due to the use of equal dose of both drugs. In our study we used higher doses of ropivacaine and bupivacaine in a 3:2 ratio because ropivacaine is not equipotent to bupivacaine for intrathecal anaesthesia[11,12,13,14]. Malinovsky et al. compared intrathecal ropivacaine to bupivacaine in a ratio of 3:2 in patients scheduled for trans-urethral resection of prostrate[12].They found that 15 mg of intrathecal ropivacaine provided similar effects but less potent anaesthesia than 10 mg bupivacaine for endoscopic urological surgery. Whiteside et al.[15] compared 15 mg of intrathecal ropivacaine 0.5% in 10 mg/ml or 50 mg/ml glucose and concluded that the onset time at T_{10} was significantly faster in the glucose 50 mg/ml group. In our study we used 0.5% ropivacaine in 6.7% (67mg) glucose. All patients in ropivacaine group showed sensory block adequate for surgery.

The time to reach maximal sensory level of $T_8$was significantly more in ropivacaine group. Wahedi et al.[16] found that mean cephalad extent of anesthesia was related to dose, T_{10} with 15 mg and T_8 with 22.5 mg of ropivacaine. We found a lower cephalic spread of anesthesia associated with less intense anesthetic blockade in the ropivacaine group. The mean time for two segment regression and duration of sensory block was singnificantly less in ropivacaine group. Time to attain complete motor block of lower limbs was similar in both groups but the motor block regressed faster in ropivacaine group. The results of our study were similar to conclusion of other studies[17,18,19].Faster recovery shows that ropivacaine is less potent than bupivacaine. The lesser lipophilic nature of ropivacaine causes slower penetration the large myelinated A fibers than the more lipid soluble bupivacaine[20].Alsoit has selective action on the pain-transmitting A β and C nerves rather than Aβ fibres, which are involved in motor function.A difference in the potency between ropivacaine and bupivacaine has also been documented in epidural studies[21].Study done by Polly et al[22] described ropivacaine 40% less potent than bupivacaine in epidural anaesthesia.

Main advantage of intrathecal ropivacaine is a shorter duration of action than bupivacaine. Other reason to use intrathecal ropivacaine would be to induce less motor blockade than bupivacaine. Unfortunately, we found complete motor blockade in both the groups. This may be related to the 18mg dose of ropivacaine used. Lower doses of ropivacaine up to 4 mg did not produce motor blockade[23]. Studies regarding the use of intrathecal ropivacaine for ambulatory surgery[11,13] had shown that spinal ropivacaine provides no advantages over bupivacaine for use in day care. Spinal ropivacaine 12 mg proudes motor blockade equivalent to bupivacaine 8 mg and significantly lower quality of analgesia has been seen with ropivacaine 8 or 10mg[13]. However, in this study, hyperbaric ropivacaine 18 mg produced a significantly shorter duration of motor blockade than hyperbaric bupivacaine 12 mg.

Quality of surgical anaesthesia was also comparable among the groups. The quality of muscular relaxation as judged by operating surgeon was satisfactory or excellent in majority of the patients in both the groups. The present study correlates with those of Osama-Al-Abdulhadi et al[19] and J.F Luck et al[24]who also found statistically insignificant difference in quality of anaesthesia between hyperbaric ropivacaine and bupivacaine when given intrathecally.

Ropivacaine is available only as isobaric solution, which has a specific gravity of 0.988 at 37° C. This solution is slightly hypobaric, and therefore has more variable and unpredictable block[6] because gravity has no effect on their spread in the supine position. Addition of glucose leads to a more rapid cephalad spread with less variation in maximum sensory and motor block. Addition of dextrose improves reliability of block[15,18]. In the present study, intrathecal ropivacaine produced excellent intraoperative anaesthesia, indistinguishable from spinal bupivacaine.

Hypotension was the most common side effect in both groups. There was a significant difference in the incidence of hypotension between the two groups. In astudy done by whiteside et al[5]70% patients in hyperbaric bupivacaine group required ephedrine as compared to 15% in ropivacaine group which supports our results of low incidence of hypotension in hyperbaric ropivacaine group. The intraoperative and postoperative complications (bradycardia, nausea, shivering, vomiting) did not differ significantly between the two groups. Transient neurological symptoms were not seen in any patient.

The results of our study points that hyperbaric ropivacaine seeks consideration for use in ambulatory surgery. The ideal agent for day-care anaesthesia is one which produces a rapid onset of a reliable and complete sensory and motor block resulting in adequate surgical anaesthesia followed by a rapid regression of the motor and sensory blocks with minimal or no side-effects or post operative effects. The standard agent for use in this setting has been lidocaine, but concerns persist regarding the incidence of TNS. The incidence of TNS is much lower with ropivacaine than lidocaine[25].

VI. Conclusion

In conclusion, hyperbaric ropivacaine can be used to provide reliable spinal anaesthesia comparable with hyperbaric bupivacaine in terms of quality of block with faster recovery and minimal side effects. However it has few disadvantages. As the hyperbaric solution of ropivacaine is not available commercially, it has to be prepared just before providing anaesthesia. Shorter duration of motor and sensory block may not always correspond with surgical duration which results in shorter duration of postoperative analgesia and early administration of intravenous or intramuscular analgesics. However, this can be improved by adding additives to local anaesthetics.

References

[1]. Pollock JE, Neal JM, Stephenson CA and Wiley CE. Prospective study of the incidence of transient radicular irritation in patients undergoing spinal anesthesia, Anesthesiology 84,1996,1361–7.

[2]. Cappelleri G, Aldegheri G, Danelli G, Marchetti C, Nuzzi M, Iannandrea G et al. Spinal anesthesia with hyperbaric levobupivacaine and ropivacaine for outpatient knee arthroscopy: a prospective, randomized, double-blind study, Anesth Analg 101,2005, 77–82.

[3]. Singh S, Singh V.P. Jain M Gupta K, Rastogi B and Abrol S, Intrathecal 0.75% Isobaric Ropivacaine Versus 0.5% Heavy Bupivacaine for Elective Cesarean Delivery: A Randomized Controlled Trial, JPMS 2, 2012, 75-80.

[4]. Kallio H, Snall E-VT, Kero MP and Rosenberg PH, A comparison of intrathecal plain solutions containing ropivacaine 20 or 15 mg versus bupivacaine 10 mg, Anesth Analg 99,2004, 713 -7.

[5]. White side JB, Bruke D and Wildsimth JAW, Comparison of ropivacaine 0.5% (in glucose 5%) with bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery,Br J Anaesth 90, 2003, 304-308.

[6]. Fettes PDW, Hovking G, Peterson MK, Luck JF and Wildsmith JAW, Comparison of plain and hyperbaric solutions of ropivacaine for spinal anaesthesia, Br J Anaesth 94, 2004, 107-111.

[7]. Clarkson CW and Hondeghem LM, Mechanism for bupivacaine depression of cardiac conduction,Anaesthesiology62, 1985, 396-405.

[8]. Akerman B, Hellenberg and Trossvik C, Primary evaluation of local anaesthetic properties of amino amide agent ropivacaine, Acta Anaesthesiol Scand 32,1988, 571-578.

[9]. Mc Clure JH, Ropivacaine, Br J Anaesth 76, 1996, 300-7.

[10]. McClellan KJ and Faulds D, Ropivacaine, update of its use in regional anesthesia,Drugs 60, 2000, 1065-93.

[11]. McDonnald SB, Liu SS, Kopacz DJ and Stephenson CA, Hyperbaric spinal ropivacaine: a comparison to bupivacaine in volunteers, Anesthesiology 90, 1999, 971-7.

[12]. Malinovsky JM, Charles F, Kick O, Lepage JY, Malinge M, Cozian A et al. Intrathecal anesthesia: ropivacaine versus bupivacaine, Anesth Analg 91, 2000, 1457-60.

[13]. Gautier PE, De Kock M, Van Steenberge A, Poth N, Lahaye B, Fanard L et al. Intrathecal ropivacaine for ambulatory surgery: a comparison between intrathecal bupivacaine and ropivacaine for knee arthroscopy, Anesthesiology 91, 1999, 1239-45.

[14]. De Kock M, Gautier P, Fanard L, Hody JL and Lavand'homme P, Intrathecal ropivacaine and clonidine for ambulatory knee arthroscopy: a dose response study, Anesthesiology 94, 2001, 574-8

[15]. Whiteside JB, Burke D and Wildsmith JA, Spinal anaesthesia with ropivacaine 5mg ml(−1) in glucose 10 mg ml(−1) or 50 mg ml(−1), Br J Anaesth 86, 2001, 241-4.

[16]. Wahedi W, Nolte H and Klein P, Ropivacain zur spinalana¨sthesie. eine dosisfindungsstudie, Anaesthesist 45, 1996, 737– 44.

[17]. Chung CJ, Choi SR, Yeo KH, Park HS, Lee SI and Chin YJ, Hyperbaric spinal ropivacaine for caesarean delivery: a comparison to hyperbaric bupivacaine, Anesth Analg 93, 2001, 157–61.

[18]. Khaw KS, Ngankee WD, Wong M, Ng F and Lee A, Spinal ropivacaine for caesarean delivery: a comparison of hyperbaric and plain solutions, Anesth. Analg 94, 2002, 680 – 5.

[19]. Al-Abdulhadi O, Biehl D, Ong B and Boker A, Hyperbaric spinal for elective caesarean section – Ropivacaine vs bupivacaine, MEJ Anesth 19, 2007, 385 – 397.

[20]. Rosenberg PH, Kytta J and Alila A, Absorption of bupivacaine, etidocaine, lignocaine and ropivacaine into N-heptane, rat sciatic nerve and human extradural and subcutaneous fat,Br J Anaesth 58, 1986, 310–4.

[21]. Zaric D, Nydahl PA, Philipson L, Samuelsson L, Heierson A and Axelsson K, The effect of continuous lumbar epidural infusion of ropivacaine (0.1%, 0.2%, and 0.3%) and 0.25% bupivacaine on sensory and motor block in volunteers: a double-blind study, Reg Anesth 21, 1996, 14 –25.

[22]. Polley LS, Columb M, Naugyton NN, Wagner DS and van de Ven CJ, Relative analgesic potencies of ropivacaine and bupivacaine for epidural analgesia in labor: implications for therapeutic indexes, Anesthesiology 90, 1999, 944 –50.

[23]. Levin A, Datta S and Camann WR, Intrathecal ropivacaine for labor analgesia: a comparison with bupivacaine, Anesth Analg 87, 1998, 624 –7.

[24]. Luck JF, Fettes PDW and Wildsmith JAW, Spinal anaesthesia for elective surgery: a comparison of hyperbaric solutions of racemic bupivacaine, levobupivacaine, and ropivacaine,Br J Anaesth 101, 2008, 705–10.

[25]. Zaric D, Christiansen C, Pace NL and Punjasawadwong Y, Transient neurologic symptoms after spinal anesthesia with lidocaine versus other local anesthetics: A systematic review of randomized, controlled trials, Anesth Analg 100, 2005, 1811-6.