Original Article

Spinal anesthesia with ropivacaine: A double-blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing perineal and lower limb surgeries

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Abstract

Background: Ropivacaine, a long-acting amide local anaesthetic agent, is less lipophilic than bupivacaine. Intrathecally, it has been used for day care procedures as it provides adequate sensory block with early motor recovery. It has an improved safety profile over bupivacaine with a reduced central nervous system and cardio toxic potential. This double blind randomized study was conducted to compare efficacy and safety of two different concentrations of intrathecal ropivacaine in perineal and lower limb surgeries. **Material And Methods:** A total of 100 patients were randomly divided into two equal groups. Group I received 0.5% and Group II received 0.75% isobaric Ropivacaine.After spinal anesthesia, the patient's pulse rate, systolic, diastolic and mean BP along with sensory and motor block were recorded at every three minutes. Sensory and motor blocks were assessed by pin prick test and Bromage scale respectively. **Results:** Heart rate, systolic and diastolic blood pressure in both the groups did not vary significantly. Cardiovascular changes were unremarkable throughout. We found that the 0.75% ropivacaine solution resulted in a higher frequency of complete motor block and a longer duration of motor block in the lower limbs than 0.5%. **Conclusion:** Intrathecal administration of 22.5mg of 0.75% isobaric Ropivacaine produced better quality and longer duration of analgesia, reliable quality of motor block, better postoperative outcome with minimum side effects as compared to 15mg of isobaric 0.5% ropivacaine in perineal and lower limb surgeries.

Key Word: Ropivacaine, spinal anaesthesia, lower limb surgeries, efficacy, safety.

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Received Date: 05/06/2016 Revised Date: 10/07/2016 Accepted Date: 03/08/2016

Access this article online	
Quick Response Code:	Website: www.medpulse.in
	DOI: 24 August 2016

INTRODUCTION

Ropivacaine is a pure S-enantiomer of the parent drug racemic bupivacaine, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. It is a long-acting regional anaesthetic with lower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system toxicity, lesser motor block and greater differentiation of sensory and motor block.[1] Spinal anaesthesia is the most convenient anaesthetic technique that offers many advantages over general anaesthesia, including reduced stress response and improved post-operative pain relief.[2] Intrathecally, ropivacaine has been used for day care procedures as it provides adequate sensory block with early motor recovery.[3] It has an improved safety profile over bupivacaine with a reduced central nervous system and cardio toxic potential and hence is gaining favour.[4] This double blind randomized study was conducted to compare efficacy and safety of two different concentrations of

How to site this article: Harish K, Sunil K S, Sudhaprasad. Spinal anesthesia with ropivacaine: A double-blind study on the efficacy and safety of 0.5% and 0.75% solutions in patients undergoing perineal and lower limb surgeries. *MedPulse – International Medical Journal.* August 2016; 3(8): 806-808. http://www.medpulse.in (accessed 27 August 2016).

intrathecal ropivacaine in perineal and lower limb surgeries.

MATERIAL AND METHODS

After approval of Institutional Ethical Committee and written informed consent from all patients, a prospective, randomized, double-blind study was conducted on 100 patients undergoing perineal and lower limb surgeries. Patients of American Society of Anaesthesiologists physical Status I or II of either sex, aged between 20 and 60 years, presenting for perineal or lower limb surgeries were included. Whereas, patients with severe systemic disease, coagulopathies, sepsis at the site of spinal injection, or allergic to local anaesthetic agent were excluded. Patients were allocated into two groups viz; Group-I: 50 patients receiving 3ml of isobaric Ropivacaine 0.5% and Group-II: 50 patients receiving 3ml of isobaric Ropivacaine 0.75%. A total of 100 envelopes were divided into two groups of 50 each. The drug to be given was mentioned inside the envelope. An envelope was randomly picked up just before the surgery. The envelope was opened by an anesthesiologist and the drug was loaded by that person. Another person conducted the procedure of spinal anaesthesia and theobservations were done by a third person who did not know what drug was given. Following arrival into the operation theatre, intravenous access was established, multipara monitor (electrocardiogram, non-invasive blood pressure and pulse oximeter) was attached and baseline parameters were recorded. After ensuring sterile conditions, spinal anaesthesia was performed, and the patient received one of the two study drugs. After spinal anesthesia, the patient's pulse rate, systolic, diastolic and mean BP along with sensory and motor block were recorded at 0, 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 45, 60, 75, 90, 120, 150 and 180 minutes. A decrease of more than 25% from the baseline or < 90 mm Hg in the systolic blood pressure (SBP) was considered hypotension and decrease in the heart rate below 55 beats/min was considered bradycardia and treated with intravenous ephedrine and atropine respectively. The sensory block level was evaluated with the pin prick test, and the motor block level was determined according to the Bromage Scale [5].Patients were observed for shivering, hypotension, bradycardia, high spinal blockade, breathing difficulty, nausea and vomiting. Statistical evaluation was performed using paired and unpaired *t*-test and analysis of variance. Data are presented as mean ± standard deviation and $P< 0.05$ was considered significant. Categorical data were analyzed using the Chi-square test.

RESULTS

The patients studied across the group did not vary much with respect to age, sex, weight and ASA grade. (Table1).

Table 1: Demographic data

Parameters	Groups (n=100)	
	Group I (n=50)	Group II (n=50)
Age (yrs)	37.80±11.78	35.08±9.73
Sex (M/F)	42/8	43/7
Weight (Kgs)	60.02±6.92	59.28±7.45
ASA Grade (I/II)	37/13	40/10

Heart rate, systolic and diastolic blood pressure in both the groups did not vary significantly (Table 2). Cardiovascular changes were unremarkable throughout, and similar in the two groups, as were the volumes of fluid and administered. One patient in group I who received 0.5% ropivacaine had a transient bradycardia of <50 bpm, which was treated with 0.6mg atropine and improved immediately. His blood pressure at that time was 130/90mmHg. Otherwise all the other patients' hemodynamics were stable.

Table 2: Comparison of study parameters in both groups

Parameters	Heart rate (bmp)		Mean arterial pressure (mmHg)	
Groups	Group I	Group II	Group I	Group II
Baseline	76.30±13.16	74.68±7.22	77.26±8.53	73.72±11.25
3 minutes	76.98±13.77	72.82±6.79	79.18±9.96	74.28±9.53
6 minutes	76.94±12.41	70.14±7.64	80.00±8.68	74.64±9.41
9 minutes	77.04±12.02	70.36±7.94	78.42±10.63	72.64±9.14
12 minutes	76.22±12.17	69.32±8.58	79.04±10.5	71.58±9.35
15 minutes	75.84±14.29	68.02±8.02	75.88±9.57	69.72±6.91
18 minutes	72.82±12.45	65.34±6.66	77.50±12.02	70.80±8.15
21 minutes	69.12±13.00	66.64±6.73	76.96±12.28	71.42±8.09
24 minutes	72.60±10.23	66.14±7.98	75.78±12.4	67.22±10.79
27 minutes	71.44±10.23	66.68±10.36	77.44±11.88	69.54±8.99
30 minutes	69.22±09.39	66.88±9.62	76.00±8.57	69.40±8.10
45 minutes	72.18±09.79	66.36±8.23	77.54±8.28	70.84±8.40
60 minutes	71.70±10.29	68.36±8.71	76.06±10.19	73.56±7.42
75 minutes	70.64±10.57	67.54±9.23	77.96±8.51	73.68±7.77
90 minutes	72.20±09.76	68.44±6.39	76.92±6.93	74.34±7.73
120 minutes	73.80±10.09	67.02±6.6	77.58±7.06	73.30±7.87
150 minutes	73.48±09.30	66.62±8.05	79.40±6.83	71.76±7.96
180 minutes	74.76±08.04	66.96±6.6	77.26±8.53	73.72±11.25

The onset of sensory blockade was delayed by about 60 seconds in Group-I and theonset of motor blockade was delayed by about 30-90 seconds in Group-I compared to Group-II. The time for two dermatomal segments regression of sensory level was prolonged in Group-II compared to Group-I and also time for regression of sensory level to T10 dermatome was prolonged in Group-II compared to Group-I thus increasing the duration of analgesia. The time of first request of analgesics by the patients in Group-II is prolonged compared to Group-I thus prolonging the duration of analgesia (Table 3).The adverse effects observed in the study were minimal (Table 4).

Table 3: Comparison of Sensory block and Motor block characteristics in two groups of patients studied

Criteria	Group I	Group II	P value
SENSORY BLOCK			
Onset	2.34±0.56	1.60±0.67	<0.001
Time To Max Cephalad Spread	19.24±6.10	16.22±4.59	0.006
Duration At T10	47.16±15.03	92.38±37.60	<0.001
Total Duration	**155.00±26.95**	**187.10±19.67**	**<0.001**
MOTOR BLCOK			
Onset	2.22±0.68	1.68±0.71	<0.001
Time To Max Degree	17.54±6.85	11.24±4.69	0.025
Total Duration	**118.50±12.71**	**153.60±20.01**	**<0.001**

Table 4: Comparison of adverse effects in two groups of patients studied

Side effects	Group I(n=50)	Group II(n=50)	P value
Shivering	11(22.0%)	14(28.0%)	<0.001
Hypotension	0	0	-
Nausea	0	0	-
Vomiting	0	0	-
Bradycardia	1(2.0%)	0	1.000
Neurological Sequelae	0	0	-

DISCUSSION

Ropivacaine, a new long-acting amide local anaesthetic, is considered to block sensory nerves to a greater degree than motor nerves. Because of sensorimotor dissociation ropivacaine should be a favorable local anesthetic for day-case surgery and could be associated with earlier postoperative mobilization than bupivacaine. This double blind randomized study was conducted to compare two different concentrations of intrathecal ropivacaine in perineal and lower limb surgeries. In present study, ropivacaine in both groups was efficient and tolerable with minimal side effects. Recent studies with intrathecal ropivacaine have demonstrated low cardiovascular and neurotoxic effects, good tolerability and efficacy.[3] Our findings of stable hemodynamics during surgery and low incidences of inadequate analgesia (time of first request of analgesics)and other adverse effects such as shivering arein agreement with Wong et al.[6] We found that the 0.75% ropivacaine solution resulted in a higher frequency of complete motor block and a longer duration of motor block in the lower limbs, whereas, the 0.5% ropivacaine solution with its shorter duration of analgesia and often relatively moderate motor block of the lower limbs could be useful for transurethral procedures or minor orthopedic surgery, where the degree of motor block is not of critical importance.Previous studies also found that better motor block was obtained with 0.75% ropivacaine than 0.5% ropivacaine.van Kleef et al reported that 3 mLof 0.5% (15 mg) glucose-free ropivacaine was suitable fortransurethral procedures or minor orthopedic surgery whenthe degree of motor block was not of critical importance,and 3 mL of 0.75% (22.5 mg) glucose-free ropivacaineprovided the most satisfactory conditions for lower limbsurgery of intermediate duration.[7] Wahedi et al alsoconcluded that a dose of 3 mL of 0.75% isobaric ropivacaine seemed to be suitable for gynecologic and urologic operations.[8] To conclude, intrathecal administration of 22.5mg of 0.75% isobaric Ropivacaine producedbetter quality and longer duration of analgesia, reliable quality of motor block, better postoperative outcome with minimum side effects as compared to 15mg of isobaric 0.5% ropivacaine in perineal and lower limb surgeries.

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Source of Support: None Declared
Conflict of Interest: None Declared