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International Journal of Current Research
Vol. 7, Issue, 06, pp.16955-16958, June, 2015

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

COMPARATIVE STUDY OF ISOBARIC BUPIVACAINE AND ISOBARIC LEVOBUPIVACAINE IN SPINAL ANAESTHESIA

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ARTICLE INFO

Article History:
Received 20th March, 2015
Received in revised form
07th April, 2015
Accepted 25th May, 2015
Published online 27th June, 2015

Key words:
Bupivacaine,
Levo-bupivacaine,
Total abdominal hysterectomies.

ABSTRACT

Study Objective: To compare the clinical effects of 3.5ml of 0.5% isobaric bupivacaine and 3.5ml of 0.5% isobaric levo-bupivacaine intrathecally in total abdominal hysterectomies.
Design: A prospective randomized study.
Materials and Methods: 100 patients belonging to ASA physical status I & II (each group 50 patients n=50) were randomly selected for the study. The time of onset of sensory and motor block, hemodynamic status, duration of analgesia and adverse effects if any were compared in both the groups.
Group I patients received 3.5ml of 0.5% isobaric Bupivacaine.
Group II patients received 3.5ml of 0.5% isobaric levo-bupivacaine.
Results: The time of onset of sensory block of levobupivacaine was 8± 3.5 and bupivacaine was 7.2± 2.6 min (P< 0.05). Onset time of motor block of levobupivacaine was 12 ±1.5 and bupivacaine was 10±1.7 min (P< 0.01). Hemodynamic changes did not differ in patients of either group (p >0.05).The duration of analgesia in group I was 280±40 minutes and in group II was 248±46 minutes which was statistically significant (p<0.001). The side effects were minimal in both the groups.
Conclusion: Intrathecal administration of isobaric bupivacaine 0.5% produces rapid onset of anesthesia, longer duration ofanalgesia compared to isobaric levo-bupivacaine.

***Citation*:** Dr. Nirmala, B.C., Dr. Sindhu Sabapathy, Dr. Manju Vijayan and Dr. Faliya Mitesh, 2015. "Comparative study of isobaric bupivacaine and isobaric levobupivacaine in spinal anaesthesia", *International Journal of Current Research*, 7, (6), 16955-16958.

INTRODUCTION

Spinal anesthesia is one of the most popular and commonly used method of regional anaesthesia worldwide. Spinal anesthesia is advantageous as it uses smaller dose of anesthetic, is simple to perform, offers rapid onset of action, reliable surgical analgesia and good muscle relaxation. Spinal anesthesia is performed by local anesthetics with or without additives that allow control over the level, the time of onset and the duration of spinal anesthesia (David L Brown, 2010). The type of local anesthetic solutions within the subarachnoid space determines the extent of the neural blockade produced by spinal anesthesia. There are number of studies which compare levobupivacaine, an S(−)-enantiomer of bupivacaine, with racemic bupivacaine, either isobaric or hyperbaric. However there are no conclusive data, especially in lower abdominal surgery. There are very few studies about spinal anesthesia in gynecological surgery with abdominal incision which requires a higher level of sensory block.

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Therefore the quality of anesthesia, sensory and motor block characteristics and hemodynamics in patients requiring a higher level of spinal block for lower abdominal approach with isobaric levobupivacaine was interesting. Anesthesiologists generally use the hyperbaric form of local anesthetics for intra-abdominal surgery.

MATERIALS AND METHODS

Institutional Ethical Committee approval was obtained. This prospective randomized control study was conducted in the Department of Anesthesiology, MVJ MC & RH. Patients with ASA physical status I & II aged between 30-60 years who were posted for total abdominal hysterectomy were included in the study. Patients who are hypersensitive to amide local anesthetic and patients with history of bronchial asthma, epilepsy disorders were excluded from the study.Any general contraindications for spinal anaesthesia, BMI more than 35 kg/m^2 and height less than 150 cm were also excluded from the study. Investigations like complete hemogram, urine examination, fasting blood sugar, ECG, chest X-ray, blood grouping, blood urea, serum creatinine were done. Patients were prepared by overnight fasting and oral tablet alprazolam

0.5mg and tablet ranitidine 150mg was given at night before the day of surgery. The procedure of anesthesia was explained to the patients and informed written consent was obtained. Patients were allocated to receive either isobaric bupivacaine or isobaric levobupivacaine using a computer-generated randomization sequence. Patients were allocated to groups based on computer-generated randomization sequence numbers.

- Group A (n=50): received 3.5ml 0.5%of isobaric bupivacaine.
- Group B (n=50): received 3.5ml 0.5%of isobaric levobupivacaine.

I.V line with 18G I.V. cannula was established. Standard monitoring like continuous electrocardiogram (lead II), heart rate, non-invasive arterial blood pressure and pulse oximetry (SpO2) were done. All patients were preloaded with 10 mL/kg of lactated Ringer's solution intravenously before giving spinal anaesthesia. Under all aseptic precautions, after local infiltration of the skin with 2% lignocaine, 25 G Quincke's spinal needle was inserted at the L3-4 interspace in the right lateral decubitus position in the midline approach. Correct needle placement was identified by free flow of cerebrospinal fluid and the drug was injected at the rate of 0.2ml/s. The patient was immediately turned supine. Throughout the procedure OT table was kept straight. Onset of sensory block was assessed by pin prick sensation every 1min till no sensation (grade 2) in anterior axillary line. Sensory block was graded according to Gromley and Hill scale 1996, {Normal sensation - 0, Blunted sensation -1, No sensation -2}.Operation was performed once the sensory level of T6 was achieved and was taken as onset time. The time of regression to L1 is taken as the duration of the sensory block.

Onset of Motor block assessed every 1 min till complete motor block is achieved (grade 3). Motor block was graded according to Modified Bromage scale {0 = no paralysis, able to flex hips/knees/ankles; 1 = able to move knees, unable to raise extended legs; 2 = able to flex ankles, unable to flex knees; 3 = unable to move any part of the lower limb}. Bradycardia was defined as pulse rate 20 % less of the baseline and was treated with IV atropine. Hypotension was taken as 20% less than the baseline reading of blood pressure and was treated with IV boluses of 5 - 10 mg ephedrine and additional IV fluids. Differences between the groups were presented as mean and SD and statistically analyzed using students t test and Fisher's exact test and presented as number and percentage. The intervals sensory block level was compared using Kaplan-Meier curve and log rank test. Using SPSS 17.0 for all statistics, we considered a *P* value <0.05 as statistically significant.

RESULTS

There was a slight decrease in mean heart rates and arterial blood pressures after spinal anesthesia, which however was not statistically significant. Both between the group and inside the group differences in hemodynamics were not statistically significant. Spo_2 remained between 98%-99%, none of the patients required supplemental oxygen. Hemodynamic and respiratory variables remained within normal limits throughout the surgical procedure. No patient required blood replacement.

Demographic data (mean±SD)

	Group A	Group B	P value
No of patients	50	50	
Age (years)	40.09±8.76	42.73±7.80	0.25 ns
Weight(kg)	52.59±6.7	50.77±7.2	0.69 ns
Height(cm)	150.31±4.5	151.75±3.9	0.66 ns

Each group was allocated fifty patients equally. There were no differences with respect to age, height, weight between the groups.

Sensory blockade in either group

	Group-A Mean ±SD(min)	Group -B Mean ±SD(min)	P Value	Remarks
Sensory onset T6	7.2±2.6	8±3.5	<0.05	Significant
Duration for the block regression to L1	280±40	248±46	0.001	Highly significant
Maximum level achieved	T3(T5-T2)	T5(T6-T3)	0.01	Significant

The difference between the groups was statistically significant.

Motor blockade in either group

	Group –A Mean ±SD(min)	Group -B Mean ± SD(min)	P Value	Remarks
Motor onset	10±1.7	12±1.5	<0.05	significant
Duration of motor block	250±36	190±45	0.01	significant

Complete motor blockade was observed in all patients in both groups.

Side Effects

Side Effect	Group -A	Group -B	p-value
Nausea &Vomiting	3(6%)	0	0.23
Urinary retention	1(2%)	1(2%)	0.99
Desaturation	No	No	0.99
Hypotension	16(32%)	13(26%)	0.62
Bradycardia	0	1(2%)	0.99

DISCUSSION

The spread of solution in the spinal canal is obtained by observing the following:

- Amount of drug and type of drug
- Volume of injection
- Rate of injection
- Site of injection
- Baricity.

With greater amounts of drug there is an increase in the duration, height and intensity of spinal anesthesia. There is an upper limit to the total amount of agent that may be used regardless of the volume and is determined by that amount that may produce neurological damage. The amount of drug remains constant than the extent of anesthesia may be increased by increasing the volume. If the total volume is small the effect of volume augmentation is limited. With slow injections, the levels are low and very rapid injection may

cause anesthesia to reach well up into the thoracic area with hyperbaric solution. The slow injection of isobaric solution will produce longer duration than resulting from rapid injection. Selection of one or two spaces higher than the usual L4-L5 interspace provides higher levels of anesthesia when all other conditions are constant (David L Brown, 2010 and Greene, 1985). Baricity is defined as ratio of density of local anesthetic solution divided by density of cerebrospinal fluid (CSF). Solutions that have the same density as CSF have baricity of 1.0000 and are termed isobaric; solutions that are denser than CSF are termed hyperbaric, whereas solutions that are less dense than CSF are termed hypobaric. Baricity is important in determining local anaesthetic spread and block height, because gravity causes hyperbaric solutions to flow downward in CSF to most dependent regions in spinal column, whereas hypobaric solutions tends to rise in CSF. In contrast, gravity has no effect on distribution of isobaric solutions. Hyperbaric solutions travel to the most dependent part of the subarachnoid space depending on the patient's position. Isobaric solutions are considered not to spread with changes in position and the levels of anesthesia are independent of positioning. Hypobaric solutions in contrast to hyperbaric solutions are influenced by gravity and position of the patient.

They are administered while patient is in the prone position with 8 degree head down tilt of the table. High spinal block with hypobaric solutions can be achieved with the patients in the sitting position (Stienstra *et al*., 1990 and Connolly and Wildsmith, 1998). The present study demonstrates that levobupivacaine, the pure S(−)-enantiomer of racemic bupivacaine, is an effective local anesthetic for spinal anaesthesia. Onset time and duration of the sensory and motor blocks, peak block height was slightly lesser with isobaric levobupivacaine compared to isobaric bupivacaine and hemodynamics was similar to those obtained with racemic bupivacaine. Levobupivacaine has very similar pharmacokinetic properties to those of its parent drugbupivacaine; several studies support the notion that its faster protein-binding rate reflects a decreased degree of toxicity. The decreased cardiovascular and central nervous system toxicity make levobupivacaine an interesting alternative to racemic bupivacaine, despite the fact that spinal anesthesia achieved was of shorter duration. Levobupivacaine is also worth considering for its anesthetic potency and hemodynamic effects in the event of inadvertent intrathecal or intravenous administration during epidural anesthesia.

G. A McLeod Concluded from his study that the density of local anaesthetics decreases with increasing temperature and increases in a linear fashion with the addition of dextrose. Levobupivacaine 5 mg/ml has a significantly higher density compared with bupivacaine 5 mg/ml and ropivacaine 5 mg/ml at 23 and 37°C both with and without dextrose. Levobupivacaine 7.5 mg/ml is an isobaric solution with all patient groups at 37°C (McLeod, 2004). Glaser *et al.* performed this prospective randomized double-blinded study to evaluate the anesthetic potencies and hemodynamics of intrathecal levobupivacaine compared with racemic bupivacaine. Eighty patients undergoing elective hip replacement received either 3.5 mL levobupivacaine 0.5% isobaric or 3.5 mL bupivacaine 0.5% isobaric. Intergroup differences between levobupivacaine and bupivacaine were insignificant both with regard to the onset time and the duration of sensory and motor blockade (11 +/- 6 versus 13 +/- 8 min; 10 +/- 7 versus 9 +/- 7 min; 228 +/- 77 versus 237 +/- 88 min; 280 +/- 84 versus 284 +/- 80 min). Both groups showed slight reductions in heart rate and mean arterial pressure, but there was no intergroup difference in hemodynamics. They conclude that intrathecal levobupivacaine is equal in efficacy to, but less toxic than, racemic bupivacaine (Glaser *et al*., 2002) conducted this study to examine the clinical effects of the subarachnoid administration of levobupivacaine, the S(-)-enantiomer of racemic bupivacaine. It was non-comparative study performed on 20 patients undergoing elective lower limb surgery. Three milliliters of a plain solution of 0.5% S(-)-bupivacaine (15 mg) was administered via the L2 or L3 interspace with the patient in the sitting position.

Following injection, the patients were immediately placed supine. Spread of sensory analgesia, degree of motor block, and hemodynamic parameters were recorded. Satisfactory surgical anesthesia was achieved in 18 patients. The median time to onset of analgesia was 2 minutes (ranging 2-10 minutes) and the median duration of analgesia was 388 minutes (range, 295-478 minutes). This group of patients achieved complete motor block, with a median onset time of 5 minutes (2-10 minutes) and duration of 266 minutes (range, 170-415 minutes). They concluded that S(-)-bupivacaine can provide satisfactory surgical anesthesia, but the spread of the plain solution is unpredictable (Burke *et al*., 1999). J.F. Luke *et al* compared the clinical effects of 'hyperbaric' bupivacaine for spinal anaesthesia with those of similar preparations of levobupivacaine and ropivacaine.

Sixty ASA grade I–II patients undergoing elective surgery under spinal anaesthesia were randomized to receive 3 ml of bupivacaine, levobupivacaine, or ropivacaine, each at 5 mg/ml and made hyperbaric by the addition of glucose 30 mg/ml. There were no significant differences between the groups with regard to the mean time to onset of sensory block at T10, the extent of spread, or mean time to maximum spread. Regression of sensory block in the ropivacaine group was more rapid. There were no significant differences between the bupivacaine and the levobupivacaine groups. They concluded that 'Hyperbaric' ropivacaine provides reliable spinal anaesthesia of shorter duration than bupivacaine or levobupivacaine, both of which are clinically indistinguishable (Luck *et al*., 2008).

Conclusion

The results of this study shows that levobupivacaine had less potency for spinal anaesthesia, both with regard to the onset time and the duration of sensory and motor blockade compared to racemic bupivacaine. Bupivacaine showed a more sustained sensory and motor blockade. Hemodynamic changes were similar regardless of whether levobupivacaine or racemic bupivacaine was used. We conclude that intrathecal isobaric levobupivacaine is less efficient to isobaric racemic bupivacaine. But still levobupivacaine seems to be an interesting alternative to bupivacaine for spinal anaesthesia.

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