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TO Compare Between Intrathecal Hyperbaric Ropivacaine and Intrathecal Hyperbaric Bupivacaine in Lower Abdominal Surgeries

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Abstract

Present study was undertaken to see the comparsion between intrathecal hyperbaric ropivacaine and Intrathecal hyperbaric bupivacaine in lower abdominal surgeries.

Material& methods: The Present study was undertaken in indoor patients admitted at NSCB, Medical College Hospital, Jabalpur (M.P.) after institutional and ethics committee approval and informed consent 80 patients of ASA physical status I & II aged between 20 and 60 years, undergoing lower abdominal surgeries were enrolled for the study.

Exclusion Criteria : Patient refusal, Patients with coagulopathy, Hypovolemia or shock.

Materials: 25 G Top spinal needle, Disposable 5 ml syringe. Sterile gloves sterile drapes. Sterile bowl with betadine and spirit, of 0.5% bupivacaine , of 0.75% plain ropivacaine

Group 1 (ropivacaine group): Received intrathecally 3ml of 0.5% hyperbaric ropivacaine in dextrose 5%.

Group 2 (bupivacaine group): Received Intrathecally 3ml of 0.5% hyperbaric bupivacaine (available commercially).

Results: we observed in our study that more number of patients in bupivacaine group (20 out of 40) developed hypotension immediately after intrathecal injection, which responded to fluid administration and i.v. ephedrine, if required.

The mean time taken for achieving maximum level of sensory block in group 1 was 20.08 min as compared to 15.0 min in group 2 (statistically significant).

The mean time taken for sensory regression to L1 was 67.88 min in group 1 as compared to 110.38 min in group 2 (statistically significant).

Conclusion: From our study we concluded that hyperbaric ropivacaine is comparable to hyperbaric bupivacaine in terms of quality of block, but with a short recovery profile. Patients in the ropivacaine group were able to mobilize and pass urine sooner than those in the bupivacaine group. Ropivacaine may be suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage. We therefore recommend that intrathecal hyperbaric ropivacaine is a suitable

alternative to intrathecal hyperbaric bupivacaine in short duration surgeries where early ambulation is desirable.

Keywords: Bupivacaine, Ropivacaine

Introduction: Spinal anesthesia is a simple technique that provides a deep and fast surgical block through the injection of small doses of local anesthetic solution into the subarachnoid space. Intrathecal anesthesia allows for the production of an ideal operating condition in large part of the body through the relatively simple injection of a very small amount of local anesthetic.

The first report on clinical use of spinal anesthesia was performed in 1899 by Dr August Bier, who described the intrathecal administration of cocaine. Since then, a lot of experience and data had been achieved on physiology, pharmacology, and clinical application of spinal anesthesia. In its long history, it has gained both enthusiastic acceptance and outright condemnation. It has withstood extensive critical analysis which has proved beyond doubt that if applied with proper skill and scrupulous care to properly selected patient, it offers numerous advantages.

In the last years, the improvement in technology and central nervous system imaging allowed to improve our knowledge of some anatomical and pathophysiological aspects of spinal nerve block. These important advancements forced us to change the indications and clinical use of intrathecal anesthesia techniques; while the development of new drugs and special techniques for spinal anesthesia requires further studies to improve the efficacy and safety of this old but evergreen technique.

The technique of subarachnoid block is quite simple and is single injection results in ideal operating conditions with complete analgesia, profound muscular relaxation, decreased blood loss and minimal ventilatory disturbances. Spinal anaesthesia is induced by injecting small amounts of local anaesthetic into the cerebro-spinal fluid (CSF). The injection is usually made in the lumbar spine below the level at which the spinal cord ends (L2). Spinal anaesthesia is easy to perform and has the potential to provide excellent operating conditions for surgery below the umbilicus.

Spinal anaesthesia has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anaesthetic. However, the greatest challenge of the technique is to control the spread of that local anaesthetic through the cerebrospinal fluid (CSF), to provide block that is adequate (in both extent and degree) for the proposed surgery but without producing unnecessarily extensive spread and so increasing the risk of complications.

Bupivacaine has been in clinical use for more than 30 years. It is widely used for spinal anesthesia but it is associated with a number of side effects, including motor weakness, cardiovascular and central nervous system toxicity. This has resulted in the continuing search for new and safer local anesthetic agents[1.] In the last few years, it's pure S-enantiomers, ropivacaine and levobupivacaine, have been introduced into clinical practice because of their lower toxic effects for heart and central nervous system.

Ropivacaine (1-propyl- 2,6-pipecoloxylidide hydrochloride monohydrate) is the s-enantiomer of a new amide local anesthetic which has been extensively evaluated in adults and older children[2]. Use of ropivacaine for spinal anesthesia has been described for obstetric and nonobstetric patients. Recently, it has been used in adults and several studies have reported its clinical efficacy and safety when administered for spinal anesthesia[3].

Ropivacaine has several properties which may be useful in practice, namely the potential to produce differential neural blockade with less motor block and reduced cardiovascular and neurological toxicity[4].

The potency of Ropivacaine in terms of sensory block has now been determined in clinical use, whether for infiltration anesthesia, peripheral nerve block, brachial plexus block, spinal block and lumber extradural block showed that ropivacaine was a long acting local anesthetic which gave surgical anesthesia of good quality[5].

Ropivacaine is well tolerated after intrathecal use, and was found to have a shorter duration of action than bupivacaine, making it a possible alternative to lidocaine for ambulatory surgery because of the low incidence of transient neurological symptoms (TNS).

Previous studies with other local anesthetics have shown that the addition of glucose improved the cephalic spread and reliability of anesthesia and also shortened the duration of sensory and motor block.[6,7]

The current study was designed to compare the clinical efficacy of hyperbaric solution of ropivacaine with that of commercially available preparation of hyperbaric bupivacaine in spinal anesthesia in lower abdominal surgeries.

Materials & Method

The Present study was undertaken in indoor patients admitted at NSCB, Medical College Hospital, Jabalpur (M.P.) After institutional and ethics committee approval and informed consent 80 patients of ASA physical status I & II aged between 20 and 60 years, undergoing lower abdominal surgeries were enrolled for the study.

Method

- Preoperative evaluation and preparation
- A thorough preanaesthetic check up was done before the surgery. Routine investigation like Complete blood count, Blood sugar and electrolytes were done. Any special investigations as per requirement was carried out.
- All the Patients were informed regarding the procedure and a written consent was obtained from all the patients.
- Age, Height, weight, Pulse Rate, Blood Pressure and respiratory rate were recorded. Usual overnight starvation regime was followed for the routine cases.
- The patients were randomly allocated by envelope method into two groups having 40 patients each.

Group 1 (ropivacaine group)

Received intrathecally 3ml of 0.5% hyperbaric ropivacaine in dextrose 5%.

Group 2 (bupivacaine group)

Received Intrathecally 3ml of 0.5% hyperbaric bupivacaine (available commercially)

Technique

All patients were placed on the operating table in sitting position, before starting the procedure all monitors (NIBP cuff, pulse oxymeter, ECG) were attached and baseline value of BP, HR, SpO_2 and RR were recorded An 18 G IV Cannula was inserted. All patients received preloading with 10 ml/kg of lactated Ringer solution. Lumbar puncture was carried out using 25G Quincke needle in sitting position at L_3-L_4 Interspace and the drug prepared as per group of patients was injected with a uniform speed. All the patients were placed supine thereafter. All patients received supplemental oxygen. Immediately after administration of spinal anesthesia PR, BP, RR, SPO_2 were recorded every 3 minute for first 15 min and then at 5 min interval thereafter till the duration of operation. Any reduction of mean arterial pressure more than 20 % from baseline was recorded & treated with 3mg ephedrine IV and HR <50/min was treated with incremental doses of atropine 0.3 mg.

Monitoring of Complications

The following complications were looked out:

1. Bradycardia HR < 50/min.
2. Hypotension Systolic Arterial Blood Pressure < 20% from baseline.
3. Nausea and vomiting.
4. Pruritus.
5. T.N.S.

Postoperatively patients were followed up for 24 hrs for any complications like nausea, vomiting, pruritus, respiratory depression, hypotension, bradycardia, post spinal headache and urinary retention.

The data of the present study were recorded into the computers and after its proper validation, check for error, coding & decoding were compiled and analysed using the software SPSS 18 for windows. Appropriate univariate and bivariate analysis were carried out using the Student *t* test for the continuous variable (age) and two-tailed Fisher exact test or chi-square (χ^2) test for categorical variables. All means are expressed mean ± standard deviation. The critical levels of significance of the results were considered at 0.05 levels i.e. $P < 0.05$ was considered significant.

Results: 80 patients of either sex of ASA physical status 1 & 2 aged between 0 & 60 years undergoing lower abdominal surgery were enrolled. The patients were randomly allocated by envelope method to one of two groups having 40 patients each.

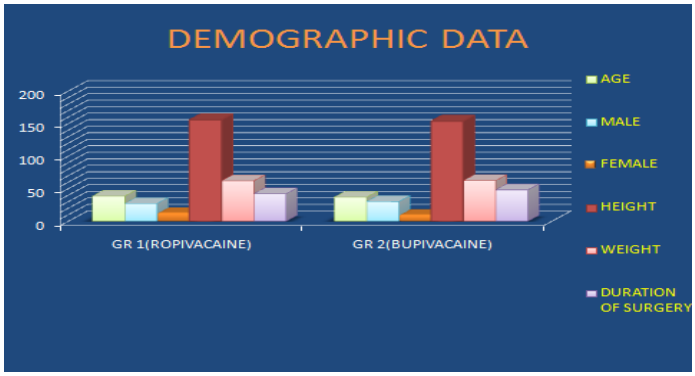
Group 1: 40 patients who received 3 ml of hyperbaric ropivacaine (0.5% in dextrose 5%).

Group 2: 40 patients who received 3 ml of hyperbaric bupivacaine (available commercially, 0.5% in dextrose 8%).

All data pertaining to demographic characteristics, sensory block, motor block and adverse effects in the study group was recorded and subjected to statistical analysis .All data has been recorded in mean +-standard deviation.

Table No. 1: Showing demographic data in various groups

Variables	Group1(ropivacaine)	Group2(bupivacaine)
Age(in years)	38.92+-14.37	37.55+-13.97
Weight(in kg)	62.42+-7.82	62.33+-6.53
Height(in cm)	155.58+-6.00	154.64+-5.86
Male(in no.)	27	28
Female(in no.)	13	12
Duration of surg. (in min.)	42+-13.21	50.13+-14.43



The mean age of patients in group 1 (ropivacaine) was 38.92 years while in group 2 it was 37.55 years.

The mean height of patients in group 1 was 155.58 cm while in group 2 it was 154.64 cms.

The means weight of patients in group 1 was 62.42 kgs and 62.33 kgs in group 2.

The male: female ratio in group 1 was 27:13 while in group 2 it was 28:12.

The mean duration of surgery in group 1 was 42 mins and 50 mins in group 2.

There was no significant difference in the demographic data in the two groups.

The mean onset of the sensory block at T10 was 5.30 min as compared to 2.48 min in group 2 (statistically significant<0.0005).

The mean number of dermatomes blocked in group 1 was T7 as compare to T5 in group 2(statistically significant).

Table no. 2: Showing mean pulse rate at different time intervals

Mean pulse rate at different time intervals (in min)	Group1 (ropivacaine) N=40	Group2 (bupivacaine) N=40
0	85.70+_16.08	85.95+-15.66
3	83.70+-15.24	81.90+-14.75
6	80.30+-14.99	78.25+-14.32
9	79+-14.63	77.80+_13.28
12	78.67+-14.07	77.4+-12.89
15	77.90+-12.95	77.3+-12.71
20	77.25+-12.56	77.05+-13.39
25	77.10+-12.24	77.15+-13.19
30	77.13+-12.09	77.20+-12.16
40	77.20+-12.16	76.25+-12.93
50	76.90+-12.25	75.75+-12.33
60	76.85+-12.03	75.65+-12.34
70	77.15+-12.58	76.10+-12.39
80	77+-12.69	76.15+-12.29
90	76.68+-12.40	76.80+_12.16

As is evident from the above table, mean pulse rate of group 1 (ropivacaine) patients show little variation (85.70 mins to 76.68 mins) from their baseline pulse intraoperatively, which signifies that ropivacaine is hemodynamically stable as regards heart rate.

Patients in group 2 (bupivacaine) show a greater degree of decline in mean pulse rate as compared to group 1 patients. Mean pulse rate in group 2 patients ranged from 85.95 mins (baseline) to 76.8 mins (at the end of surgery). This signifies that bupivacaine hemodynamically less stable than ropivacaine as regards pulse rate.

Table no. 3: Showing mean of systolic blood pressures at different time intervals

Mean of systolic blood pressure at different time intervals(in min)	Group1 (ropivacaine) N=40	Group2 (bupivacaine) N=40
0	122.75+_12.09	119.45+_17.72
3	118.4+_9.44	117.2+_9.84
6	114.45+_9.19	110.6+_8.95
9	122.10+_8.94	109.8+_9.28
12	111.55+_8.14	110.1+_7.94
15	111.15+_7.69	110.05+_7.15
20	111.85+_7.25	110.05+_6.63
25	110.80+_6.26	110.58+-6.35
30	111.1+_7.57	110.88+-5.90
40	111.25+_7.99	110.8+-5.9
50	111.20+_7.52	110.5+-6.6
60	110.83+_6.81	110.45+-6.49
70	111+_7.21	110.98+-6.56
80	110.85+_7.61	111.45+-5.87
90	110.68+_6.78	110.60+-5.16

As it is clearly evident from above table that in both the groups, mean of systolic blood pressures show a similar degree of decline over time. Baseline systolic blood pressure in ropivacaine group declined from 122.75 mm of Hg to 110.68 mm of Hg at the end of surgery. In bupivacaine group baseline systolic blood pressure declined from 119.45 mm of Hg to 110.6 mm of Hg at the end of surgery. This suggests that both drugs are comparable as regards to intraoperative hemodynamics.

But we observed in our study that more number of patients in bupivacaine group (20 out of 40) developed hypotension immediately after intrathecal injection, which responded to fluid administration and i.v. ephedrine, if required.

Table no. 4: Showing mean of diastolic blood pressures at different time intervals

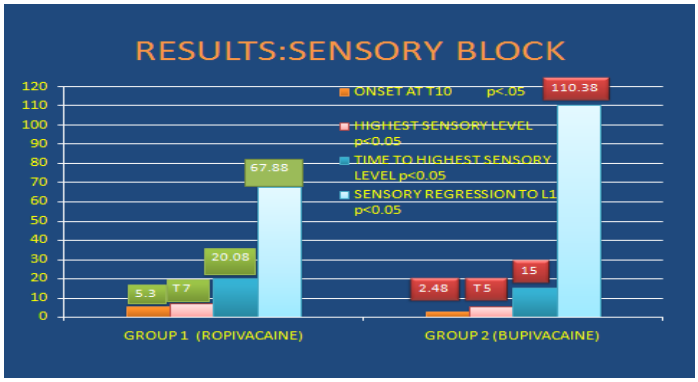
Mean of diastolic blood pressure at different time intervals (in min)	Group1 (ropivacaine) N=40	Group2 (bupivacaine) N=40
0	76.75+_8.84	78.7+_9.06
3	73.75+_8.58	72.95+_8.85
6	70.45+_9.43	69.35+_8.28
9	68.9+_8.32	69.50+_7.98
12	69.25+_8.42	69.15+_8.22
15	69.48+_7.87	69.2+-7.9
20	69.35+_7.87	69.4+_8.21
25	69.35+_7.87	69.4+_8.21
30	69.15+_7.73	69.5+_7.73
40	69.3+_8.18	69.15+_7.9
50	69.1+_7.93	69.1+_7.83
60	69.28+_8.35	69+_7.91
70	69.4+_7.79	69.45+-7.73
80	68.75+_8	69.95+-7.99
90	68.95+_7.96	70+_8.02

Comparison of mean diastolic blood pressures of the two groups has shown that mean diastolic BP of group 1 patients declined from 76.75 mm of Hg at the start of surgery to 68.95 mm of Hg at the end of surgery. This is statistically as well as clinically in significant.

In group 2 patients, mean diastolic BP at start of surgery was 78.7 mm of Hg which declined to 70 mm of Hg at the end of surgery. Again it was observed that 50% of patients developed hypotension which responded well to fluid and i.v. ephedrine.

Table no. 5: Showing onset of sensory block, maximum block height achieved and time taken for the same

Characteristics	Group1 (ropivacaine) N=40	Group2 bupivacaine) N=40	Significance
Onset at T10	5.30+-1.24	2.48+-0.67	T=12.60 P< 0.0005
Time to highest sensory level	20.08+-1.84	15.00+-1.19	T=14.58 P<0.0005
Regression to L1	67.88+-7.67	110.38+-8.92	T=26.01 P<0.0005



The mean time taken for achieving maximum level of sensory block in group 1 was 20.08 min as compared to 15.0 min in group 2 (statistically significant).

The mean time taken for sensory regression to L1 was 67.88 min in group 1 as compared to 110.38 min in group 2 (statistically significant).

Table No. 6: Showing characteristics of motor block

Characteristics	Group1 (ropivacaine) N=40	Group 2 (bupivacaine) N=40	significance
Onset of grade 3 motor block	14.98+-1.94	10.90+-1.24	T=15.22 P<0.0005
Duration of grade 1 motor block	92.75+-2.45	230.0+-9.54	T=55.33 P<0.0005

The mean onset of grade 3 motor block was 14.98 min in group 1 & 10.90 min in group 2(statistically significant).

Discussion: Spinal anesthesia is a simple technique that provides a deep and fast surgical block through the injection of small doses of local anesthetic solution into the subarachnoid space. Spinal anesthesia can be considered adequately safe and severe complications are reasonably rare. The cardiovascular effects associated with sympathetic block are more frequent, but successfully treated with volume expansion and administration of vasoactive drugs.8

Ropivacaine is a local anesthetic with lower cardiotoxic potential than racemic bupivacaine. The majority of published data on ropivacaine concerns its use in the epidural space. Use of ropivacaine for spinal anesthesia has been described for obstetric and nonobstetric patients. Previous studies with other local anesthetics have shown that the addition of glucose improved the cephalic spread and reliability of anesthesia and also shortened the duration of sensory and motor block.[9] J. B. Whiteside, D. Burke and J. A. W. Wildsmith compared the clinical efficacy of hyperbaric ropivacaine with that of the commercially available hyperbaric preparation of bupivacaine and found that ropivacaine 15 mg in glucose 50 mg/ml provides reliable spinal anaesthesia of shorter duration and with less hypotension than bupivacaine. They concluded that the recovery profile for ropivacaine may be of interest given that more surgery is being performed in the day-case setting.

Present study, 80 patients of either sex of ASA physical status 1 & 2 aged between 20 & 60 years undergoing lower abdominal surgery were enrolled. The patients were randomly allocated by envelope method to one of following two groups having 40 patients each.

Group 1: 40 patients who received 3 ml of hyperbaric ropivacaine (0.5% in dextrose 5%).

Group 2: 40 patients who received 3 ml of hyperbaric bupivacaine (available commercially, 0.5% in dextrose 8%).

The mean age of patients in group 1 (ropivacaine) was 38.92 years while in group 2 it was 37.55 years.

The mean height of patients in group 1 was 155.58 cm while in group 2 it was 154.64 cms.

The means weight of patients in group 1 was 62.42 kgs and 62.33 kgs in group 2.

The male: female ratio in group 1 was 27:13 while in group 2 it was 28:12.

The mean duration of surgery in group 1 was 42 mins and 50 mins in group 2.

Since all the groups were demographically similar ($p>0.05$ in all the comparision), it can be presumed

that the groups are comparable for the purpose of the study. No premedication was used in study population it can therefore be presumed that recording of parameters pertaining to sensory analgesia were consistently accurate. All the patients were preloaded to offset the effect of relative hypovolemia or hypotension.

Onset of sensory block in the present study was defined as time taken for loss of pain sensation at T10 (periumbilical region). The mean onset of sensory block in group 1 was 5.3 min as compared to 2.48 min in group 2 which is statistically significant.

The mean no. of dermatomes blocked in group 1 was T7 as compared to T5 in group 2 which is statistically significant. The mean time taken for achieving maximum level of sensory block was 20 min as compared to 15 min in the group 2.

Duration of sensory block for the purpose of present study was defined as time taken for sensory regression to reach L1. The mean duration of sensory block in the group 1 was 67.88 min as compared to 110.38 min in group 2 which is statistically significant. These findings are in corroboration with the findings of J. B. Whiteside et al, who compared the clinical efficacy of hyperbaric ropivacaine with that of the commercially available hyperbaric preparation of bupivacaine and found that the onset of pinprick analgesia at T10 was more rapid with bupivacaine (2 min as compared to 5 min in ropivacaine group, $p<0.005$), although the time to maximum extent of cephalad spread was similar in both groups. In their study, they found that median block height with time was slightly higher throughout in the bupivacaine group, and the maximum block height achieved was significantly higher (T7 as compared to T5 in ropivacaine group). The total duration of sensory block was shorter with ropivacaine (180 min vs 255 min in bupivacaine group).

In our study, onset of motor block was defined as time taken for motor block to reach a score of 3 on the modified Bromage scale. The mean onset of motor block in group 1 was 14.98 min as compared to 10.90 min in group 2 which is statistically significant. All patient achieved complete motor block . The mean time of duration of grade 1 motor block was 92.75 min as compared to 230 min which is statistically significant. These findings are in corroboration with the findings of J. B. Whiteside et al, who compared the clinical efficacy of hyperbaric ropivacaine with that of the commercially available hyperbaric preparation of bupivacaine and found that the degree and duration of motor block were significantly greater with bupivacaine than with ropivacaine. Median time to complete regression of motor block was 180 min (range 120-210 min) with bupivacaine compared with 90 min (60-180 min) with ropivacaine.

In our study, the no. of patients who developed hypotension in group 1 was 6(15%) as compared to 20(50%) in group 2 which is statistically significant. These findings goes against the findings of J. F. Luck who reported a higher incidence of

hypotension in ropivacaine group while comparing hyperbaric solutions of Racemic bupivacaine, levobupivacaine, and ropivacaine in spinal anaesthesia for caesarian section.

No. of patients who experienced nausea /vomiting was 2 in group 1 as compared to 13 in group 2, which is statistically significant.

Finally, to appraise the clinical relevance of our findings, we would like to say that a solution of ropivacaine that is hyperbaric relative to cerebrospinal fluid can be used to provide reliable spinal anaesthesia that is comparable to that with hyperbaric bupivacaine in terms of quality of block, but with a shorter recovery profile. This suggests that ropivacaine may be suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage.

Conclusion

Intrathecal hyperbaric ropivacaine is better than Intrathecal hyperbaric bupivacaine in lower abdominal surgeries. Ropivacaine may be suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage.

We therefore recommend that intrathecal hyperbaric ropivacaine is a suitable alternative to intrathecal hyperbaric bupivacaine in short duration surgeries where early ambulation is desirable.

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