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Comparison of the Efficacy Of 0.5% Hyperbaric Ropivacaine With 0.5% Hyperbaric Bupivacaine for below Umbilical Procedures under Spinal Anaesthesia- A double blinded randomized prospective study

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Original Research Article

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Abstract: Our aim was to compare the clinical efficacy of 0.5% hyperbaric ropivacaine and 0.5% hyperbaric bupivacaine with regard to onset of sensory and motor blockade, total duration of blockade and recovery profile of patients undergoing below umbilical procedures under spinal anaesthesia. Eighty subjects were randomized into 2 groups .40 patients in group A received 3 ml of 0.5% hyperbaric ropivacaine with glucose 8.33% and 40 patients in group B received 3 ml of 0.5% hyperbaric bupivacaine. Intraoperative vitals were recorded. Onset of sensory block after 5 minutes and time taken to achieve maximum sensory blockade was assessed. Time to complete motor block and total duration of motor block were compared during the procedure. Total duration of sensory block was also noted. We found that onset of sensory and motor block was earlier with bupivacaine as compared to ropivacaine ($P<0.001$). The total duration of sensory and motor blockade was less with ropivacaine ($P<0.001$).The time taken for mobilization and first micturition was earlier with ropivacaine ($P<0.001$). The incidence of hypotension was lower with ropivacaine ($P<0.05$).Thus, 0.5% hyperbaric ropivacaine seems to be a promising agent for intermediate duration day care procedures under spinal anaesthesia.
Keywords: Hyperbaric, Bupivacaine, Ropivacaine, sensory and motor block, recovery.

INTRODUCTION

The aim of anaesthesiologists is to make spinal anaesthesia a safe option to provide adequate analgesia, facilitate early ambulation and voiding post surgery.

Among the local anaesthetics, bupivacaine is more popular because of its longer duration of action and differential sensory-motor blockade but its accidental intravascular injection can lead to cardiac arrhythmias resulting in death [1]. Also the prolonged motor blockade can interfere with early ambulation and voiding thus delaying discharge from hospital [2].

With increasing trend towards day care surgery, a drug which has better sensory-motor differentiation along with cardiac stability is the need of the hour and this is the reason for the increasing popularity of ropivacaine.

Baricity is one of major factors which ensures predictable spread of local anaesthetics in the intrathecal space. Commercially, hyperbaric ropivacaine is not available as it is difficult to maintain pharmacological stability [3]. Also, isobaric ropivacaine produces less intense, unpredictable and variable height of block [4].

Thus, our study was aimed at comparing the efficacy of hyperbaric ropivacaine and hyperbaric bupivacaine for below umbilical procedures performed under spinal anaesthesia. To match with commercially available hyperbaric bupivacaine, dextrose was added to isobaric ropivacaine to make it a hyperbaric solution.

MATERIAL AND METHODS

After approval by the Ethics and Scientific committee of G. Kuppuswamy Naidu Memorial Hospital, Coimbatore a written informed consent was taken from all subjects prior to the procedure. Eighty

patients scheduled for elective below umbilical procedures under spinal anaesthesia were divided into two groups- group A -Ropivacaine and group B-Bupivacaine by computer generated randomization. Duration of the study was 2 years (October 2014 to September 2016).

Inclusion criteria

Patients between 18 to 65 years of age; ASA grade I and II; undergoing below umbilical procedures under spinal anaesthesia and able to give consent for the procedure.

Exclusion criteria

Patients with ASA grade III and above; not willing for spinal anaestheisa, infection at site and coagulopathy; patients undergoing caesarean section; longer duration procedures.

Venous access was established on dorsum of hand with 18/20 G and patients were co loaded with Ringer Lactate 10 ml/kg. Hyperbaric ropivacaine was prepared aseptically by adding 2 ml of autoclaved 0.75% ropivacaine to 1 ml of 25% dextrose (3 ml of 0.5 % hyperbaric ropivacaine with 8.33% glucose concentration) [5].

In the operation theatre an anaesthetist who was not involved in the anaesthetic management loaded the drugs based on randomization number using sterile technique.

Under aseptic precautions spinal anaesthesia was performed using a 25G Whitacre needle in L3-L4 or L4-L5 interspace. For group A, 0.5% hyperbaric ropivacaine and for group B commercially available 0.5% that was being administered.

Intraoperative sedation with 1 mg bolus dose of Midazolam was given at the discretion of anaesthetist.

Level of sensory blockade was assessed using alcohol swab and motor blockade by James modified Bromage scale

- Grade 0- Full movement
- Grade 1- inability to raise extended leg, can bend knee
- Grade 2- Inability to bend knee can flex ankle
- Grade 3- No movement

Level of sensory and motor block, Heart rate (HR), Blood Pressure (BP) was recorded at 2, 5, 10,15,20,25,30 min intervals and then every 30 min interval till completion of procedure.

Sensory block after 5 min (onset of block), time taken to achieve maximum sensory level and total duration of sensory block was assessed.

Time taken to grade 3 motor block and total duration of motor block was recorded. Vital parameters were recorded at 30 min intervals in post anaesthesia recovery unit (PACU) until complete regression of sensory and motor block. Then patients were motivated to mobilize and pass urine and discharged from PACU.

Adverse effects like hypotension, bradycardia, respiratory depression, nausea and vomiting were noted and treated.

STATISTICAL ANALYSIS

The sample size was calculated using t-test – difference between two independent means (two groups) at 80% power and alpha error 0.05.It was further enhanced and rounded off to 40 cases equally divided into each group.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables. Dichotomous outcomes were compared by Chi square test with continuity correction or Fisher's exact test as applicable Numerical variables were compared by Student's t test or Mann Whitney U test depending on distribution. Analysis was done using SPSS version 21.Microsoft word and MS excel was used to generate graphs and tables.

RESULTS

Table-1: Comparison of Sensory Block Parameters (Mean) across the Study Groups (N=80)

Parameters	Group A	Group B	P value
Sensory Block at 5 min (T)	6.75 ± 1.73	4.98 ± 1.38	<0.001
Maximum sensory level achieved (T)	4.90 ± 0.85	4.05 ± 0.59	<0.001
Time taken for maximum sensory level (min)	9.62 ± 2.89	7.75 ± 2.98	0.005
Sensory level at 90 min (T)	6.90 ± 1.65	4.28 ± 0.784	<0.001
Total duration of sensory block (min)	209.23 ± 25.27	274.50 ± 25.91	<0.001

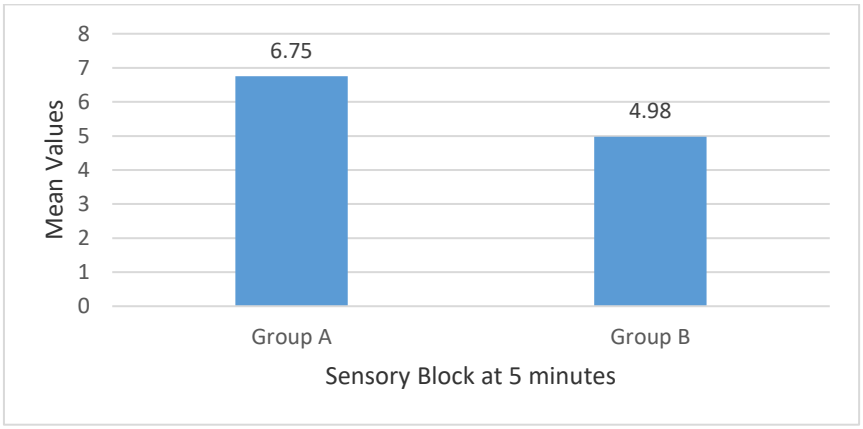

Fig-1: Bar Chart for Sensory Block at 5 Minutes (Mean) across the Study Groups (N=80)

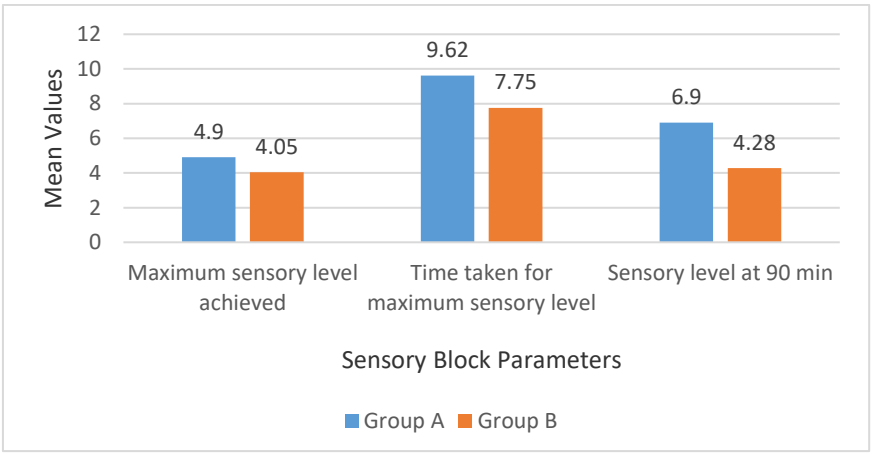

Fig-2: Bar Chart for Sensory Block Parameters across the Study Groups (N=80)

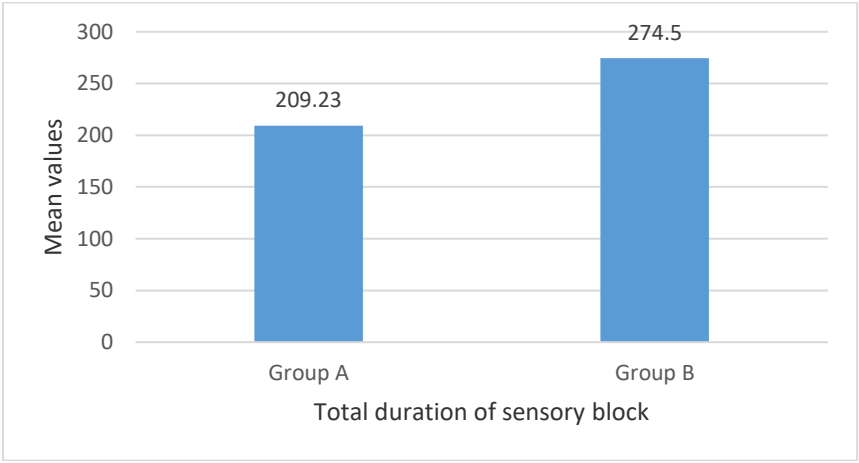

Fig-3: Bar Chart for Total Duration of Sensory Block across the Study Groups (N=80)

Table-2: Comparison of Motor Block Parameters across the Study Groups (N=80)

Parameters	Group A	Group B	P value
Time taken for grade 3 motor block (min)	6.97 ± 2.93	4.23 ± 1.67	<0.001
Total duration of motor block (min)	174.85 ± 24.78	243.00 ±30.23	<0.001

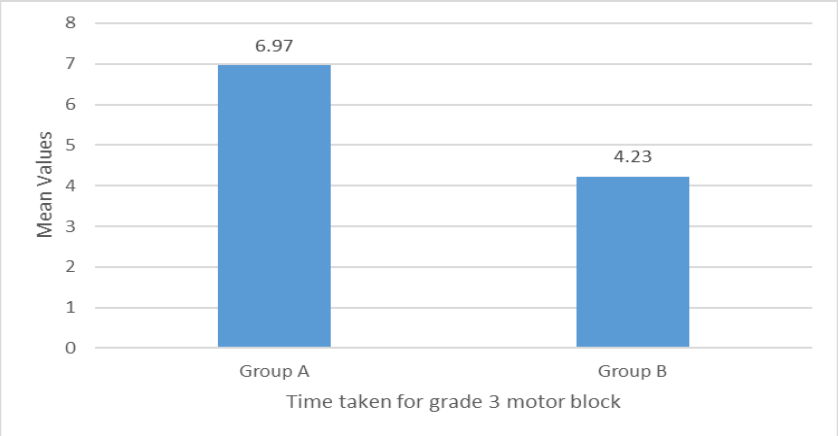

Fig-4: Bar Chart for Time taken for Grade 3 Motor Block across the Study Groups (N=80)

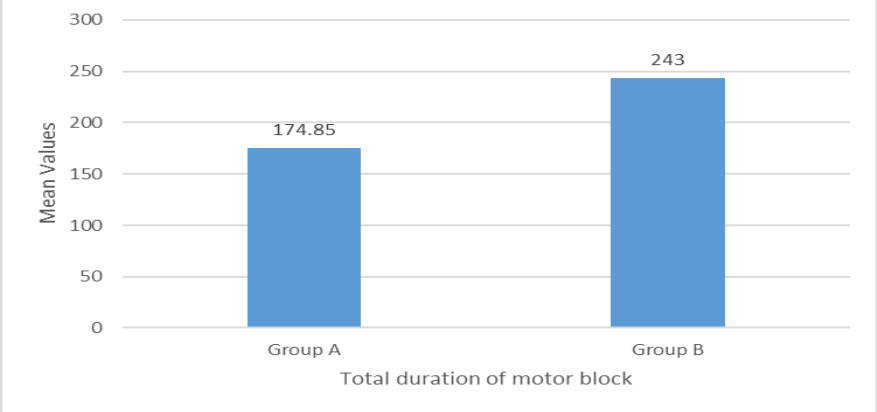

Fig-5: Bar Chart for Total Duration of Motor Block across the Study Groups (N=80)

Table-3: Comparison of Intraoperative Parameters across the Study Groups (N=80)

Parameter	Group A	Group B	Chi Square value	P value
Intra operative Hypotension				
Yes	6 (15.0%)	16 (40.0%)	6.270	0.012
No	34 (85%)	24(60.0%)		
Intra operative Sedation Requirement				
Yes	8 (20%)	2 (5%)	4.114	0.043
No	32 (80%)	38 (95%)		

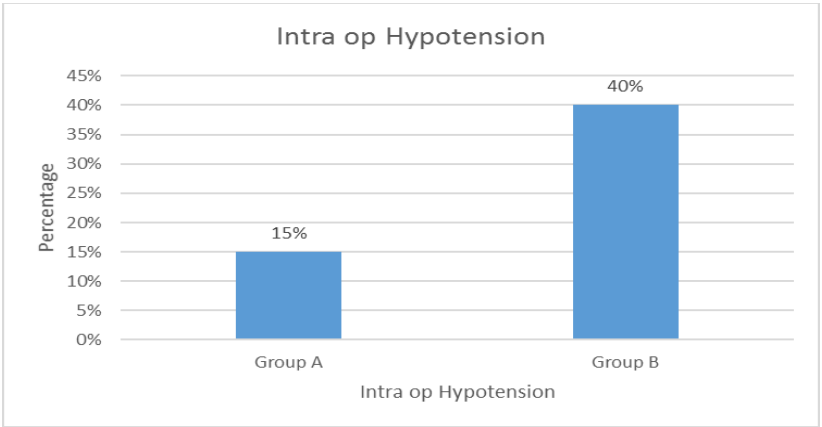

Fig-6: Bar Chart for Intra Operative Hypotension across the Study Groups (N=80)

Table-4: Comparison of Recovery Parameters across the Study Groups (N=80)

Parameters	Group A	Group B	P value
Time taken for mobilization (min)	249.23 ± 29.11	325.94 ± 39.42	<0.001
Time taken for first micturition (min)	344.24 ± 42.20	459.70 ± 54.91	<0.001

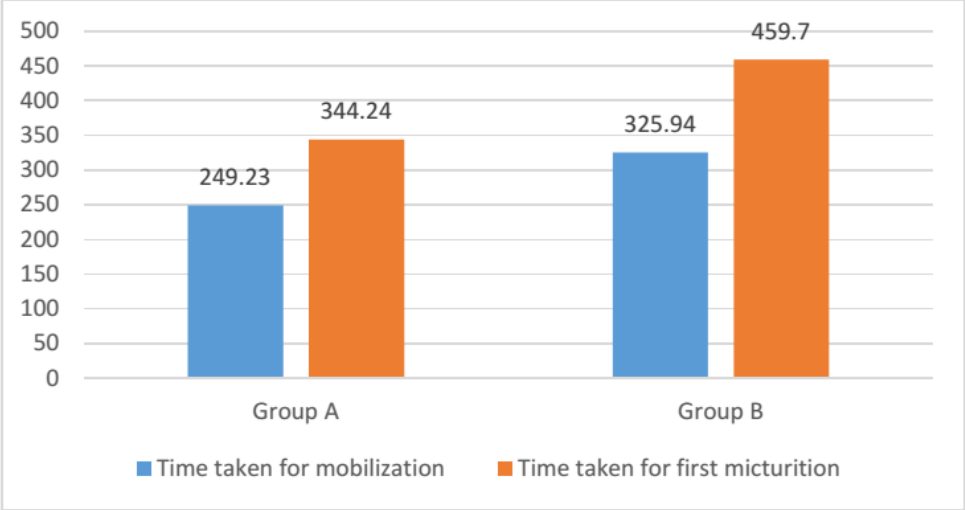

Fig-7: Bar Chart for Recovery Parameters across the Study Groups (N=80)

RESULTS

Table 1 - shows the onset of sensory block was delayed in group A as compared to group B(P<0.001); the mean time taken for maximum sensory block was 9.62 min in group A and 7.75 min in group B(P=0.005); Also, the total duration of sensory block which is the time taken from intrathecal injection to the complete regression of block till S2 was less in group A than group B (P<0.001).

Table 2- shows the mean time taken for grade 3 motor block was 6.97 min in group A and 4.23 min in group B(P<0.001). Though the mean total duration of the block was prolonged in group B (243 min) than group A (174.85 min); (P<0.001).

Table 3 –The proportion of subjects with intraoperative hypotension were 15% in group A and 40% in group B (P=0.012).

Table 4- The mean time taken for mobilization was 249.23 min in group A and 325.94 min in group B (P<0.001). Also the mean time taken for first micturition was 344.24 min in group A and 459.70 min in group B(P<0.001).

DISCUSSION

With the advances in technology, better drugs and infrastructure for surgery and anaesthesia there is a shift in trend from in patient procedures to day care [6]. Day care surgeries facilitate early discharge of the patient from hospital, reducing nosocomial infections and complications associated with immobilization like thromboembolism. Thus a delay in discharge of the patient following uneventful surgery due to anaesthetic agents with prolonged motor block and recovery is not desired [2].

Ropivacaine is 30-40% less potent than bupivacaine [3]. As a result, ropivacaine produces shorter duration of motor and sensory blockade; this facilitates early ambulation and recovery of the patient especially in day care procedures [7].

In order to compare the efficacy of two drugs effectively, hyperbaric ropivacaine was prepared under aseptic conditions. This was comparable to commercially available 0.5% hyperbaric bupivacaine in terms of its specific gravity, volume and dose. Similar results were seen in study done by KR Kulkarni *et al.* [3] and J B Whiteside *et al.* [8] who also compared similar concentration of solutions.

Our study was a double blinded randomized prospective study wherein the two groups were similar with regards to demographic characteristics and baseline vital parameters. Also, the mean duration and type of surgery performed in these 80 patients was comparable.

In our study the mean time taken for the maximum sensory level was 9.62 ±2.89 min in group A and 7.75 ±2.98 min in group B and was statistically significant. This correlates with a study conducted by C.J Chung *et al.* (42) where ropivacaine group (A) took more time to achieve maximum sensory level. On the contrary, KR Kulkarni et al. [3] and Leena Ingale *et al.* [5] found the

time to maximum sensory level was more with bupivacaine.

The mean total duration of sensory block was shorter in group A and was significant .Similar results were observed by J B Whiteside *et al*. [8] and JF Luck *et al*. [10] in which regression of sensory block was faster in group A as compared to group B.

The time of onset of complete motor block was taken as time taken to achieve grade 3 motor block which was longer in group A ropivacaine than group B. These results were comparable with study done by K R Kulkarni *et al*. [3].

In our study, the results were comparable to a study by C K Narena *et al*. [11] where in the time of total duration of motor block i.e. regression of complete motor block was faster with ropivacaine. This is because of lower lipid solubility of ropivacaine than bupivacaine.

We also found that the incidence of hypotension was lower in group A (15%) as compared to group B (40%) and the result was statistically significant. Other hemodynamic parameters were comparable in both the groups. No patient had bradycardia or respiratory depression during or after the procedure.

The time taken for mobilization was taken as time from spinal anaesthesia to patient mobilization and it was observed that patients mobilized faster in group A. During recovery, patient voided sooner in group A as compared to bupivacaine group and similar results were observed by K R Kulkarni *et al*. [3].

There were certain limitations to the study such as small sample size, non availability of commercial ropivacaine hence extreme aseptic care was needed. Also due to non availability of densitometer we relied for specific gravity on other studies.

CONCLUSION

Our study revealed that the total duration of spinal anaesthesia was shorter with ropivacaine when compared to bupivacaine but it was adequate for proposed intermediate duration procedures. Regression of sensory block to S2 dermatome was faster and duration of motor block was shorter with ropivacaine as compared to bupivacaine. The time taken for mobilization and first micturition was significantly earlier with ropivacaine. Thus it was concluded that 0.5% hyperbaric ropivacaine may be a better alternative to 0.5% hyperbaric bupivacaine for intermediate duration day care procedures under spinal anaesthesia.

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