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"Comparative Study Of Efficacy And Safety Of Intrathecal Hyperbaric Ropivacaine 0.75% And Intrathecal Hyperbaric Bupivacaine 0.5% In Patients Undergoing Elective Infra-Umbilical Surgeries."

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ABSTRACT
Introduction*: The primary goal of ambulatory Anaesthesia is rapid recovery with minimal side effects. Ropivacaine, due to its sensory-motor dissociation property, may be useful when quicker recovery of motor function is desirable.*
Objectives*: This study was designed to compare the efficacy and safety of equal volume of Hyperbaric Ropivacaine (0.75%) with Hyperbaric Bupivacaine (0.5%) for SAB in patients undergoing Infra-Umbilical surgeries.*
Methods*: Sixty patients, ASA I/II, were randomized to receive equal Intrathecal injection of Ropivacaine or Bupivacaine. Group R (n=30) received 3.2ml of Hyperbaric Ropivacaine 7.5mg/ml (24mg). Group B (n=30) received 3.2ml of Hyperbaric Bupivacaine 5mg/ml (16mg). The onset and duration of sensory block, time for complete motor block, duration of Motor-blockade, and time for rescue analgesia were recorded.*
Results*: The average Sensory onset in group B was 194.3sec and in Group R was 256.0sec (p<.001). The Average time for complete motor blockade (in min) in group B was 11.10 and in group, R was 14.28(p<.001). The average duration of motor blockade (in min) in group B was 193.67 and in group, R was 123.50(p<.001). The average duration of sensory blockade (in min) in group B was 198.167 and in group, R was 127.50(p<.001)*
Conclusions*: Intrathecal administration of either 24mg Ropivacaine or 16mg bupivacaine was well tolerated and adequate block was achieved in all patients. More rapid postoperative recovery of sensory and motor function was seen in Group R compared with Group B.*
Keywords*: Bupivacaine, Infraumbilical, Intrathecal, Hyperbaric, Regional anaesthesia, Ropivacaine*

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I. INTRODUCTION

Subarachnoid block (SAB) with a local anaesthetic not only makes the patient insensible to the pain of tourniquet, incision, and surgery but also it makes the surgeon comfortable by providing adequate muscle relaxation. Spinal anaesthesia is gradually gaining momentum over GA in various surgeries.

The primary goal of ambulatory Anaesthesia is quick recovery with the minimal hospital stay. With the availability of rapid, short‑acting anaesthetic, analgesic, sympatholytic and muscle-relaxant drugs, as well as improved monitoring devices, it has been possible to minimize the adverse effects of Anaesthesia during the recovery process.[1]

Ropivacaine, a new long-acting local anaesthetic amide agent that is structurally and physiochemically similar to Bupivacaine, but less potent (30-40%) than it and has reduced potential for neurotoxicity and cardiotoxicity[2] which causes sensory nerve blockade to a greater extent than motor nerves.[3–6]

Intrathecal Ropivacaine was found safe with a shorter duration of action than Intrathecal Bupivacaine[7].

Intrathecal use of hyperbaric Local-Anaesthetic agents produces predictable block characteristics and reliable Spinal-Anesthesia (SA) hence has become more popular. Early recovery along with early ambulation and minimal side effects after surgeries under SA is required in today's scenario.

So, this prospective randomized comparative study was aimed at comparing and evaluating the efficacy and safety of intrathecally injected Hyperbaric-Ropivacaine and Hyperbaric-Bupivacaine in patients undergoing Infra-Umbilical surgeries under SA.

Our primary objectives is to find whether Intrathecal Hyperbaric Ropivacaine is superior to Hyperbaric Bupivacaine in terms of early sensory and motor recovery or not, and our secondary objective is to find whether Hyperbaric Ropivacaine provides greater haemodynamic stability than Hyperbaric Bupivacaine or not.

II. METHODS

This prospective, randomized double-blinded study was conducted on 60 adult patients of both genders of the American Society of Anaesthesiologists (ASA) physical statuses l to II, aged between 18 to 60 years, scheduled for Infra-Umbilical surgeries under SA. Patients with known allergies to any study drugs, contraindications to neuraxial block, Local infection at site of spinal, patients having bleeding diasthesis,patients having Raised Intracranial pressure and those patients in whom informed consent could not be obtained were excluded from the study.

The study was conducted from March 2022 to August 2022 at YCM Hospital, Pimpri Pune after obtaining from the institutional ethics committee approval and taking patients written informed consent.

Sixty sealed envelopes labelled inside for Group R (n = 30) and Group B (n = 30) were mixed. Patients who met the inclusion criteria were randomized in a double-blind fashion by picking up the sealed envelope to receive 3.2ml of Hyperbaric-Ropivacaine 7.5mg/ml in Group R or 3.2ml of Hyperbaric-Bupivacaine 5mg/ml in Group B.

On the night before Surgery, all the patients received a tablet of Ranitidine 150mg and a tablet of Alprazolam 0.5mg. On arrival at the pre-anaesthetic room, baseline Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial pressure (MAP) & Respiratory Rate (RR) were taken. A suitable peripheral intravenous (IV) assess was performed with an 18-gauge cannula. Injection Metoclopramide 10mg IV and Injection Ranitidine 50mg IV were given 1.5 hours before operation. All the patients were asked to void before shifting to the operation theatre. In the operation theatre, standard monitoring with an electrocardiogram (ECG), non-invasive arterial blood pressure (NIBP), and pulse oximetry (SPO2) were started, and baseline readings were assessed. Then, in the sitting position and under all aseptic precautions, a lumbar puncture was performed using a midline approach at the third and fourth lumbar Intrathecal space (L3-L4) using a 25G Quinke spinal needle (B-Braun Melsungen AG, Germany) with bevel-end facing cephalad. The Local-Anaesthetic drugs were injected over 14-16sec. Co-loading was done with Ringer Lactate at the rate of 8-10ml/kg. The study drugs with calculated volume were given by an anaesthetist who is not aware about the study. Just after Intrathecal injection of drugs (taken as 0min), all the patients were kept in a supine horizontal position. The degree of motor block onset in the lower limbs was assessed at 5min, 10min, and 15min using a Modified Bromage scale (MBS). Intraoperative hemodynamic parameters (HR, SBP, DBP, MAP and RR) were assessed at 5min, 10min, 15min, 30min, 45min, 60min, 120min and 180min. Upon arrival at the postoperative care unit (PACU), postoperative hemodynamic parameters (BP, HR and MAP) were recorded at 0 min (Time taken when patients just arrived at the PACU), and then at 10min, 20min, 30min, and 40min. Motor block regression in the lower limbs was assessed by using MBS at 0-60min, 60-120min and 120-180min intervals. Sensory blockade regression time up to S2 was checked in the mid-clavicular line bilaterally by using the pinprick method without piercing the skin. Then, assessments were continued until complete regression of motor lock within the lower limbs, and sensory block to S2.

Hypotension, defined as a fall in SBP >20% from the baseline was treated with an IV injection of Mephentermine 3mg. A fall in HR <50 beats/min was considered as Bradycardia and treated with injection .

Modified Bromage scale

0 - No motor block
1- Inability to raise extended leg but able to move knee and foot
2- Inability to raise extended leg and move knee but able to move foot
3- Complete block of motor limb

Sample Size

Formula Used: $n = (Z\alpha/2+Z\beta)^2 * 2*\sigma 2 / d2$,
Where,

$Z\alpha/2$ =1.95 at 95% confidence level
$Z\beta$ =0.84 at 95% confidence level
$\sigma 2$ is the population variance, and
d is the difference you would like to detect

Statistical Analysis

The primary outcome variable was the Duration of Sensory blockade and the results of Kulkarni and co-workers[8] were used to estimate the sample size.

With 95% confidence level, 80% power and taking the mean difference in duration of sensory block of two groups equal to 35.5 (SD=48.99)1, the minimum required sample size is 30 per group.

Data were analysed using InStat computer software. Numerical variables were presented as mean and standard deviation for patient characteristics such as age, weight, hemodynamic changes, block parameters such as onset, duration and recovery time of sensory block, time to maximum motor blockade, duration of motor blockade and the time to first micturition. Categorical variables were presented as frequency and per cent for patients' characteristics such as sex distribution, ASA status and type of surgery, Bromage grade of motor blockade and incidence of adverse events such as Hypotension, Bradycardia, Backache, Post-Dural puncture headache (PDPH) and for the need of General-Anaesthesia (GA) supplementation.

III. RESULTS

In this double-blind prospective study, groups were comparable with regard to age, sex, weight, ASA status and type of surgery.

Table No. 1 - Use of Ropivacaine and Bupivacaine in different age groups)

Age-wise distribution									
Drug	<30		30-40		40-50		50-60		Total
	n	%	n	%	n	%	N	%	
BUPIVACAINE	14	46.7%	8	26.7%	3	10.0%	5	16.7%	30
ROPIVACAINE	10	33.3%	12	40.0%	4	13.3%	4	13.3%	30
Total	24	40.0%	20	33.3%	7	11.7%	9	15.0%	60

Table No. 2 - Gender-wise distribution of Ropivacaine and Bupivacaine

Gender-wise distribution					
Drug	Male		Female		Total
	n	%	n	%	
BUPIVACAINE	16	53.3%	14	46.7%	30
ROPIVACAINE	15	50.0%	15	50.0%	30
Total	31	51.7%	29	48.3%	60

Table No. 3 - Use of Ropivacaine and Bupivacaine in different ASA groups)

	ASA 1	ASA 2
ROPIVACAINE Group	16	14
BUPIVACAINE Group	16	14

Table No.4 – Use of Ropivacaine and Bupivacaine in number of patients undergoing different surgical procedures

Surgery	BUPIVACAINE	ROPIVACAINE
TIBIAL #	8	8
FEMUR SHAFT #	2	4
APPENDICECTOMY	8	6
VAGINAL HYSTERECTOMY	3	2
ACL REPAIR	2	4
ANKLE BIMALLEOLAR	7	6
Total	30	30

The between-group comparison of study parameters was done using an independent sample t-test.

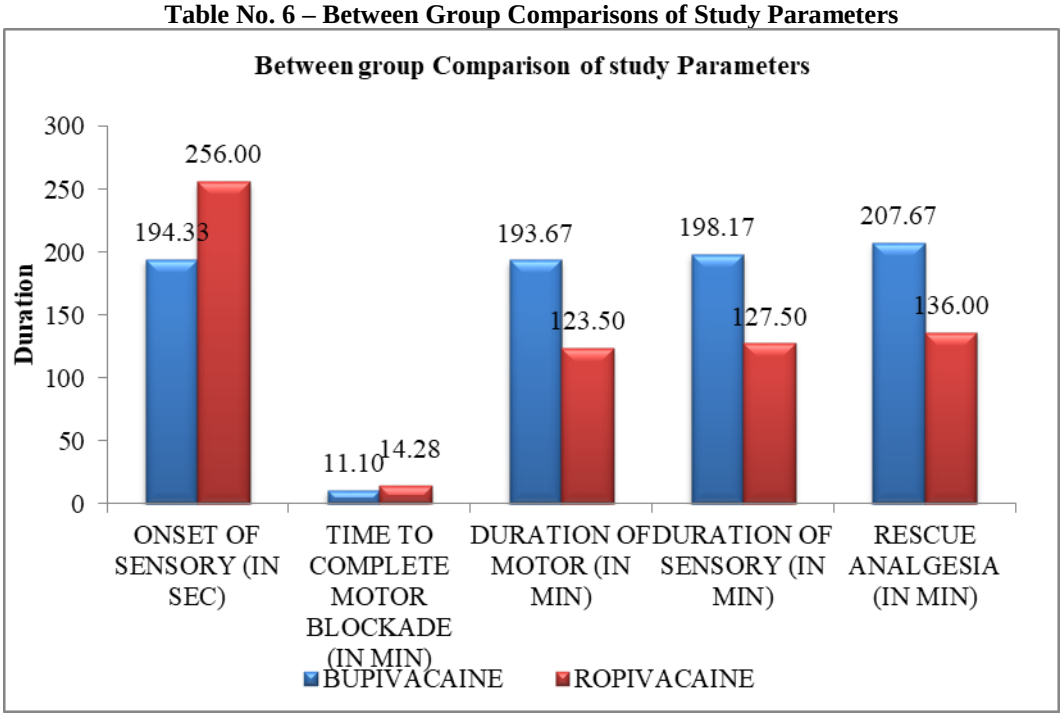
Onset of sensory block and time for complete motor block was rapid with significant differences between the two groups.

Table No.5 - Between-group Comparison of study Parameters

Drug		N	Mean	SD	SEM	Mean Diff	t-stat	df	p-value
ASA	BUPIVACAINE	30	1.467	0.507	0.093	0.000	0.000	58	1.00, NS
	ROPIVACAINE	30	1.467	0.507	0.093				
ONSET OF SENSORY (IN SEC)	BUPIVACAINE	30	194.333	15.241	2.783	-61.667	-14.873	58	<.001**
	ROPIVACAINE	30	256.000	16.836	3.074				
TIME TO COMPLETE MOTOR BLOCKADE (IN MIN)	BUPIVACAINE	30	11.100	0.855	0.156	-3.183	-14.396	58	<.001**
	ROPIVACAINE	30	14.283	0.858	0.157				
DURATION OF MOTOR (IN MIN)	BUPIVACAINE	30	193.667	8.703	1.589	70.167	34.962	58	<.001**
	ROPIVACAINE	30	123.500	6.715	1.226				
DURATION OF SENSORY (IN MIN)	BUPIVACAINE	30	198.167	7.598	1.387	70.667	38.964	58	<.001**
	ROPIVACAINE	30	127.500	6.399	1.168				
RESCUE ANALGESIA (IN MIN)	BUPIVACAINE	30	207.667	11.502	2.100	71.667	25.812	58	<.001**
	ROPIVACAINE	30	136.000	9.948	1.816				

**: Significant at 1% level of significance, NS" Not Significant

Table No. 6 – Between Group Comparisons of Study Parameters



The average onset of sensory in group B was 194.3 sec and in Group R it was 256.0sec (p<.001).
The average time to complete motor blockade (in min) in group B was 11.10 and in group R it was 14.28 (p<.001).
The average duration of motor blockade (in min) in group B was 193.667 and in group R it was 123.50(p<.001).
The average duration of sensory blockade (in min) in group B was 198.167 and in group R it was 127.50(p<.001).
The average time to Rescue Analgesia (in min) in group B was 207.667 and in group R it was 136.0(p<.001)
In our study urinary retention is not found in Ropivacaine group but in Bupivacaine group.
There is delayed micturition and urinary retention is found in 3 patients in Bupivacaine group.

Table no.7 - Complications

	Bupivacaine	Ropivacaine
Hypotension	4	2
Bradycardia	2	1
Backache	3	3
PDPH	1	1
Conversion to GA	0	0
Urinary Retention	3	0

IV. DISCUSSION

We found that Intrathecal Hyperbaric Ropivacaine is superior to Hyperbaric Bupivacaine in terms of early sensory and motor recovery. And Hyperbaric Ropivacaine provides greater haemodynamic stability than Hyperbaric Bupivacaine.

Subarachnoid-block is a commonly employed anaesthetic technique for performing Infra-Umbilical surgeries as it is simple, safe, inexpensive and easy-to-administer technique which also offers a rapid onset of action and high level of post–Anaesthesia satisfaction for patients [9,10]

Both Ropivacaine and Bupivacaine are effective and well‑tolerated local-anaesthetic agents for SA[10]

SA with Hyperbaric-Ropivacaine 0.75%, 24mg (3.2ml) resulted in significantly faster recovery of both motor and sensory block, as well as shorter time to first voluntary micturition and ambulation in comparison with 16mg (3.2ml) of Hyperbaric-Bupivacaine 0.5%.

Earlier studies with Isobaric-Ropivacaine reported having variable or inadequate block patterns for surgery[11,12]

Earlier studies made Isobaric Ropivacaine to become Hyperbaric by the addition of Dextrose as commercially Hyperbaric-Ropivacaine was not available, but in our study, we used commercially available Ropivacaine (0.75%) (By NEON.[8]

It is known that Ropivacaine is 30-40% less potent and its effects are short-lived than Bupivacaine making it advantageous for short to intermediate-duration of surgeries or ambulatory surgeries.[13–15]

Nema et al[16] also observed that onset of sensory block was faster in Bupivacaine group than in Ropivacaine group as observed in our study

The average duration of sensory blockade in Bupivacaine group was 198.16min and it was 127.5min in Ropivacaine group. This is supported by Kumar et al[2] who observed significant differences between both groups.

We observed that Ropivacaine has a less potent effect on motor nerves and the degree of sensory-motor separation is more as compared with Bupivacaine, but can produce reliable

SA, which has been supported by similar observations of other studies[17, 18] .The findings were similar to the study carried out by Ghimire et al[15] who observed mean time for complete motor blockade and total Motor duration of 13.1min and 97min for Ropivacaine and 8.7min and 146.5min for Bupivacaine Respectively, Adhikari et al[7] also observed less degree and duration of motor blockade as observed in our study.

Hypotension is a common side effect with both Intrathecal Ropivacaine and Intrathecal Bupivacaine[19]. The Bupivacaine group was associated with a numerically higher incidence of hypotension without significant difference between the two groups. MAP and RR did not differ in the study groups at any time point. In another study,[19] incidence of hypotension was significantly more, whereas bradycardia was numerically higher with Bupivacaine than Ropivacaine.

Ropivacaine is less lipophilic as compared with Bupivacaine. Lesser lipophilicity of Ropivacaine is associated with reduced risk of cardiovascular toxicity[20] Overall, because of greater margin of safety than Bupivacaine, [19] Ropivacaine can be preferred agent for SA in patients undergoing Infra-Umbilical surgeries.[21]

V. CONCLUSION

Commercially available Intrathecal Ropivacaine is superior to Bupivacaine in terms of early sensory and motor recovery, an advantage which encourages early ambulation. Greater hemodynamic stability was observed in the Ropivacaine group. Based on these findings, 0.75% Hyperbaric-Ropivacaine may be preferred over 0.5% Hyperbaric-Bupivacaine for subarachnoid-block, especially in cases where early ambulation is desired.

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