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Comparison of Onset and Duration of Sensory and Motor Blockade with Ropivacaine 0.75% and Bupivacaine 0.5% in Epidural Anaesthesia - A Clinical Trial

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***Abstract**:*

***Purpose:** To compare the efficacy of epidural ropivacaine and epidural bupivacaine in surgery requiring sensory level below T6 and to compare the onset, duration, extent of sensory and motor block.*

***Materials and Methods:** 60 ASA I and II adult patients who require sensory block below T6 were enrolled in the trial. They were randomly divided into two groups of each 30 patients. Patients of Group A were injected with 15 ml of commercially available 0.5% bupivacaine solution in the lumbar epidural space, while patients of Group B were injected with 15ml of commercially available 0.75% ropivacaine solution in lumbar epidural space.*

***Results:** In our study we found significant difference between the two groups as regards to the onset of sensory block which was 11.17± 4.676 min in group A and 7.00±4.472 min in group B [P value0.001,(<0.05)] and duration of sensory block is less for group B (186.33 ±52.341 min) than group A (215.50 ± 48.108 min) [P value 0.028 (<0.05)]. Also we found significant difference between the two groups as regards the onset of motor block which was 19.50±5.625 min in group A while was 26.17±4.086 min in group B [p value 0.0001(<0.05)] and duration of motor block is less for group B which was 117.50±23.844 min and 156.00±24.262 min for group A [P value 0.0001 (<0.05)].*

***Conclusion:** Our study has shown that 15 ml of ropivacaine 0.75% can produce predictable and reliable epidural anaesthesia of significantly shorter duration of sensory and motor block, faster onset of sensory block and delayed onset of motor block as compared with bupivacaine 0.5%.*

***Keywords:** Ropivacaine, Bupivacaine, Epidural drug comparison, duration and onset of sensory and motor block*

I. Introduction

Epidural anaesthesia have been shown to blunt the "stress response" to surgery[1], to decrease intraoperative blood loss[2], to lower the incidence of postoperative thromboembolic events[3] and to decrease morbidity and mortality in high risk surgical patients.[4]

Bupivacaine has been in clinical use for more than 50 years. It is widely used for spinal and epidural anaesthesia 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 anaesthetic agents.[5]

Ropivacaine is relatively new long-acting local anaesthetic introduced into the market in the last few years, that has been developed after reports of simultaneous seizure and cardiac arrest with prolonged resuscitation after accidental intravascular injection of bupivacaine.[6]

Due to their three- dimensional structure, local anaesthetics molecules can also have a stereospecificity, with two enantiomer molecules that may exist in two different spatial configurations, like left- and right handed gloves. The molecules of local anaesthetics possess an asymmetric carbon atom which is bound to four different substitutes. The structures of these compounds are defined as chiral. Enantiomers are optically active, and can be differentiated by their effects on the rotation of the plane of a polarized light into dextrorotatory [clockwise rotation (R+)] or levorotatory [counter clockwise rotation (S-)] stereoisomers. A solution of bupivacaine contains equal amounts of the two enantiomers and is called racemic solution, while technological advancements allowed the production of solutions containing only one enantiomer of a chiral molecule, which is optically pure. The physicochemical properties of the two enantiomeric molecules are exactly the same, but the two enantiomers can have substantially different behaviours in their affinity for either the site of action or the sites involved in the generation of side effects.

R- and S- enantiomers of local anaesthetics have been demonstrated to have a different affinity for the different ion channels of sodium, potassium, and calcium[7] and this results in a significant reduction of central nervous system and cardiac toxicity of the S-enantiomer as compared with the R-enantiomer.[8] Ropivacaine is available as optically pure solutions.

Ropivacaine (1-propyl 2`6`-pipecoloxylidide hydrochloride monohydrate) is the s-enantiomer of a new amide local anaesthetic which has been extensively evaluated in adults and older children.[9] Recently, it has been used in adults and several studies have reported its clinical efficacy and safety when administered for spinal anesthesia.[10] 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.[9] The potency of Ropivacaine in terms of sensory block has now been determined in clinical use, whether for infiltration anaesthesia, peripheral nerve block , brachial plexus block, spinal block and lumber extradural block showed that ropivacaine is a long acting local anaesthetic which gave surgical anaesthesia of good quality**.**

The current study was designed in a randomized double blind fashion to compare the clinical effectiveness of Epidural Bupivacaine and Ropivacaine in patients undergoing surgery which require sensory blockade below T6

II. Materials And Methodes

Study was done in the department of anaesthesiology, Academy of medical sciences Pariyaram, Kannur dist, Kerala, India after getting approval from the ethical committee of the institution. After written informed consent, 60 patients of American Society of Anaesthesiologists physical Status I and II, of female sex, in the age group 20-60 years, weight 50-100kg, height 150-180cm posted for planned lower abdominal procedures requiring sensory block below T6 which will last less than 2hour were enrolled in the trial. Patients with coagulopathy, on antiplatelets or anticoagulants, spine deformity, local skin infections known allergy to the trial drugs and pregnant patients were not included in the study.

In this randomized double blind trial, patients were divided into two groups using random number table and 6 block method.

Group A: Comprised of 30 patients who were injected with 15 ml of commercially available 0.5% bupivacaine solution in the lumbar epidural space (L3-4 space).

Group B: Comprised of 30 patients who injected with 15ml of commercially available 0.75% ropivacaine solution in lumbar epidural space (L3-4 space).

Patients were premedicated with tablet Diazepam 5-10mg orally at 10pm on pre operative day. Injection midazolam 1-2mg intravenously immediately prior to epidural block. On arrival in the operation theater patients were reassured and connected to multipara monitor. Baseline hemodynamic parameters were recorded. Intravenous access was achieved and the patients were preloaded with15ml/kg ringer lactate. Group A patients injected with 15 ml of commercially available 0.5% bupivacaine solution and group B patients injected with 15ml of commercially available 0.75% ropivacaine solution in lumbar epidural space (L3-4 space). Injection Mephentermine 6 mg intravenous bolus is given if BP falls less than 20% of the initial Blood Pressure

All patients of both groups were monitored for: Sensory block: Onset, level using pinprick test **(**with a blunt 25G needle every 5min till three consecutive reading is at same level, then every 15 min post operatively till patient complaints of pain). Motor block: Onset (time to attain Bromage score 2 or less), density (maximum Bromage score attained) and duration (time taken to regress motor blockage to Bromage score 3 or more) of block using Bromage score. Data were collected, tabulated, coded then analyzed using SPSS® computer software version 16.0. Numerical variables were presented as mean & standard deviation (SD) while categorical variables were presented as frequency and percent. As regard numerical variables; unpaired student – t test or Mann – Whitney test were used whenever appropriate, while for categorical variables; chi – square test or Fisher exact test were used instead. A difference with significant level <0.05 was considered statistically significant

III. Observations

Patient's characteristics age, weight and height showed no statistically significant differences between the two groups (P > 0.05) (Table -1). All patients were female sex.

Table 1: Demographic characteristics of the study group

	GROUP	N	Mean± Std.Deviation	P value
AGE (yrs)	A	30	42.77±6.942	0.090
	B	30	46.60±9.957	
Height (cm)	A	30	158.53±3.655	0.386
	B	30	159.57±5.335	

Weight (Kg)	A B	30 30	56.47±4.032 56.33±3.387	0.890
Diagnosis	A B	30 30	1.00±000 1.03±0.183	0.326
Surgery	A B	30 30	1.00±.000 1.10±.403	0.184

Twenty Five out of thirty patients were ASA I in Group A and five were ASA ll. Among them 3 patients were hypertensive and 2 were diabetic. Twenty Three out of thirty patients were ASA I in Group B and Seven were ASA ll. Among them 4 patients were hypertensive and 3 were diabetic. There was no statistically significant difference in ASA Physical status between two groups. (Table 2&3, Fig 1)

Table 2: ASA physical status of the study group

ASA status	**Group A (n=30)**	**Group B (n=30)**
ASA I	**25(83.3%)**	**23(76.6%)**
ASA II	**5(16.6%)**	**7(23.3%)**
Hypertension (HTN)	3(10%)	4(13.3%)
Diabetes mellitus (DM)	2(6.6%)	3(10%)

Table 3: physical status of the study group

	GROUP	**N**	**Mean± Std.Deviation**	**Std. Error Mean**	**P value**
ASA	A	30	1.17±0.379	0.069	
	B	30	1.23±0.430	0.079	0.527

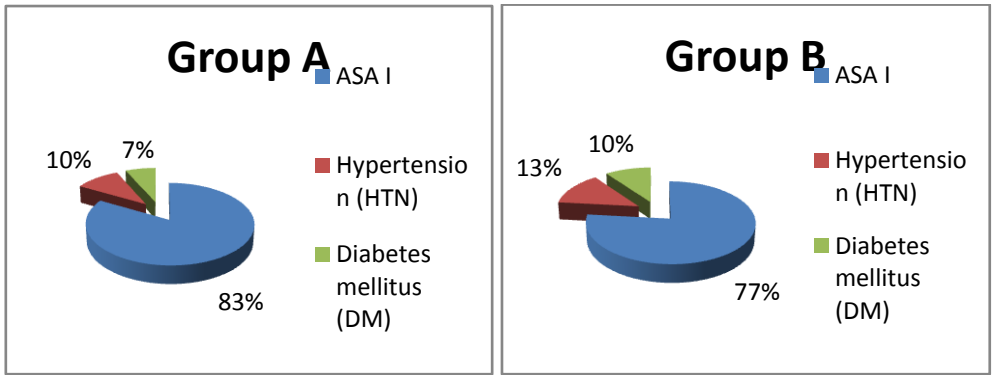

Fig. 1: ASA Physical status and patient's co morbid illnesses group A and group B

3.1. As Regards Sensory Block

3.1.1. Onset

In our study we found significant difference between the two groups as regards the onset of Pin-Prick at T6 which was 11.17± 4.676 min in bupivacaine group while was 7.00±4.472 min in ropivacaine group [P value0.001,(<0.05)] (Table4).

Table 4: Onset of sensory blockade

GROUP		**Mean**	**Std. Deviation**	**P value**
Onset of sensory blockade (min)	A B	11.17 7.00	4.676 4.472	.001

3.1.2. Duration

In our study we found that Ropivacaine has a shorter duration of action less than Bupivacaine, it was 215.50 ± 48.108 min for group A and 186.33 ±52.341 min for group B and it was significantly different [P value 0.028 (<0.05)] (Table 5).

Table 5: Duration of sensory blockade

GROUP		Mean	Std. Deviation	P value
Duration of sensory blockade (min)	A	215.50	48.108	.028
	B	186.33	52.341	

3.2 .As Regards Motor Block

3.2.1. Onset

The results of our study has shown that there was significant difference between bupivacaine (group A) and ropivacaine (group B), in which bupivacaine gave faster onset, 19.50±5.625 min for Bupivacaine group and 26.17±4.086 min for Ropivacaine group [p value 0.0001(<0.05)] (Table 6).

Table 6: Onset of motor blockade

GROUP		Mean	Std. Deviation	P value
Onset of motor blockade (min) Bromage score 2	A	19.50	5.625	.0001
	B	26.17	4.086	

3.2.2. Duration

Ropivacaine shows same degree of motor block which regressed faster than bupivacaine, 156.00±24.262 min for Bupivacaine group and 117.50±23.844 min for Ropivacaine group [P value 0.0001 (<0.05)] (Table 7).

Table 7: Duration of motor blockade

GROUP		Mean	Std. Deviation	P value
Duration of motor blockade (min)	A	156.00	24.262	.0001
	B	117.50	23.844	

There was no significant difference in degree of motor block (P value<0.05). With bupivacaine Out of 30 patients 28 developed grade two block (93%)and one patient developed grade three block, while with ropivacaine group 27 patient developed grade two block (90%),3 patients developed grade three block (10%).

IV. Discussion

This study was done on 60 patients prepared for surgery which require sensory blockade below T6, divided into two groups, Group A and Group B. Group A received 15ml of commercially available bupivacaine 0.5%, while group B received the same volume of commercially available ropivacaine 0.75% epidurally. Our study has shown that 15 ml of ropivacaine 0.75% can produce predictable and reliable epidural anaesthesia, for surgery which require sensory blockade below T6, of significantly shorter duration as regards motor and sensory block without significant difference in degree of motor block but with significant slower onset of motor block and faster onset of sensory block as compared with bupivacaine 0.5%.

As regards sensory block ,in our study we found significant difference between the two groups as regards the onset of Pin-Prick at T6 which was 11.17± 4.676 min in bupivacaine group while was 7.00±4.472 min in ropivacaine group, which was not consistent with the study conducted by M Mantouvalou et al in 2008[11.] Also in our study we found that Ropivacaine has a shorter duration of action than Bupivacaine, it was 215.50 ± 48.108 min for group A and 186.33 ±52.341 min for group B and it was significantly different (P value 0.028), which was consistent with the study conducted by M Mantouvalou et al in 2008[11]

As regards motor block, in our study we have found that patients in ropivacaine group had a slower onset and shorter duration of motor block as well as a faster resolution of sensory block compared to bupivacaine. This is consistent with the study of M Mantouvalou et al in 2008[11] wherein they have found that ropivacaine presented a slower onset and a shorter duration of motor block, as well as a faster resolution of sensory block compared with bupivacaine[11].

Zaric D et al also compared degree of motor blockade between ropivacaine and bupivacaine group, it showed that epidural ropivacaine group had less intense motor blockade compared with bupivacaine group[12] which is not consistent with our study which showed that the degree of motor blockade was of the same intensity with both the groups.

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