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ORIGINAL ARTICLE

RANDOMISED CONTROLLED STUDY COMPARING A 0.75% ROPIVACAINE TO A CONVENTIONAL DOSE OF HYPERBARIC BUPIVACAINE FOR CESARIAN SECTION BY EPIDURAL ANALGESIA

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ABSTRACT: Central neuraxial blocked is one of the safest and efficacious methods of anaesthesia and analgesia. It has the added advantage of prolonged pain relief into the postoperative period. Epidural analgesia has increased steadily in popularity when compared to spinal anaesthesia due to its neurological consequences and improved post-operative analgesia with epidural Opioids and as a consequence decreased side effects and prolonged the duration of analgesia. Present study is undertaken to compare hemodynamic and analgesic characteristics using a 0.75% ropivacaine to a conventional dose of 0.5% bupivacaine for cesarean section under epidural anaesthesia. This study was conducted in ASA Grade I 50 singleton parturient to compare hemodynamics, APGAR scores and analgesic characteristics of ropivacaine and bupivacaine. We have observed that the onset of sensory blockade was slower with ropivacaine and the duration of sensory blockade was also less. Whereas there was no significant change in haemodynamics and APGAR scores with both the drugs.

KEYWORDS: Epidural Anaesthesia, Ropivacaine, bupivacaine, caesarean section, APGAR score.

INTRODUCTION: Central neuraxial blocked is an important tool in the armamentarium of the anaesthesiologist. It is one of the safest and efficacious methods of anaesthesia and analgesia; it is cost effective and has the added advantage of prolonged pain relief into the postoperative period.

Epidural Anaesthesia is a central neuraxial technique offering a wide range of applications in the profiles. Context of providing analgesia to the patient. Epidural analgesia has increased steadily in popularity in the second half of the twentieth century, firstly with the decline of spinal anaesthesia owing to their serious neurological sequences and secondly with the advent of improved post-operative analgesia with epidural Opioids and as a consequence decreased side effects and prolonged the duration of analgesia. In 1885, Corning[1] first performed peridural anesthesia with cocaine for relief of pain in an extremity. It was apparently accidental. In 1949, Curbelo[2] first performed continuous peridural anesthesia by means of ureteral catheter. 1951-Crawford[3] used epidural anesthesia for thoracic surgery.

Bupivacaine is a well-established, long-acting regional anaesthetic that, like all amide-type anesthetics, has been associated with cardiotoxicity when used in high concentrations or if accidentally administered intravascularly. Ropivacaine is a long-acting regional anaesthetic that is structurally related to bupivacaine; unlike bupivacaine, which is a race mate, ropivacaine is a pure

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S (–)-enantiomer (of propivacaine) developed for the purposes of reducing the potential toxicity and improving the relative sensory and motor block profiles.

AIM & OBJECTIVES: Present study is undertaken to compare hemodynamic and analgesic characteristics using a 0.75% ropivacaine[4] to a conventional dose of 0.5% bupivacaine[5] for cesarean section under epidural anaesthesia.

MATERIALS & METHODS: The clinical study was carried out in ASA Grade - I patients to compare hemodynamic and analgesic characteristics after the epidural anaesthesia in parturients using 0.75% Ropivacaine in study group (Group-S) to 0.5% bupivacaine in the control group (Group-C) for cesarean section.

This study was conducted in 50 singleton parturients (twenty five patients in Group-S and twenty five patients in Group-C) after taking institutional approval and written consent from each patient. Patients were chosen from Gandhi Hospital, Secunderabad, A. P. Selected patients were in the age group between 18 to 30 years.

EQUIPMENT: The Boyle Anaesthesia machine was checked, appropriate sized endotracheal tubes, two working laryngoscopes, a working suction apparatus with emergency drugs and instruments were kept ready before the procedure started.

Drug Trolley Consists of: Ropivacaine ampoules, Bupivacaine ampoules, Intravenous cannula, 18gauge touhy needle, 18G epidural catheter with filter, Syringes – 2cc, 5cc, 10cc, LOR syringes, I.V. fluids, Emergency drugs like, dopamine, adrenaline, atropine, etc., Mephentermine, Multi-channel monitor with SpO_2, ECG, non-invasive blood pressure monitors, ECG leads, Defibrillator. After confirming the fasting status, the patient was shifted to operating room and transferred onto operating table in left lateral position.

Before performing regional anaesthesia, intravenous access was secured with large bore catheter and Ringers solution infusion was started. Standard monitors such as electrocardiography (ECG), Pulse oximetry and non-invasive blood pressure applied. Before initiation of regional block, base line blood pressure and heart rate readings were taken in the supine position with wedge under the right buttock.

A two operator technique was employed to maintain blinding. Patients were allocated into 2 groups by computer generated random allocation. The enrolling investigator prepared the epidural solution and subsequently had no role in patient's assessment.

Group	GROUP (C) Control	GROUP (S) Study
No. of patients	25 patients	25 patients
Drug injected	15 ml of 0.5% hyperbaric bupivacaine	15 ml of 0.75% isobaric ropivacaine

With patient in sitting position, under sterile conditions L3-L4 interspace was identified with highest point of iliac crest as the anatomical landmark. Local infiltration of 2ml of 1%

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xylocaine given to facilitate introduction of epidural needle. Then stellate was removed and LOR syringe was attached and introduced further. 18G catheter was introduced up to 3-4cm in epidural space[6,7] and confirmed after aspiration and local anesthetic was given.

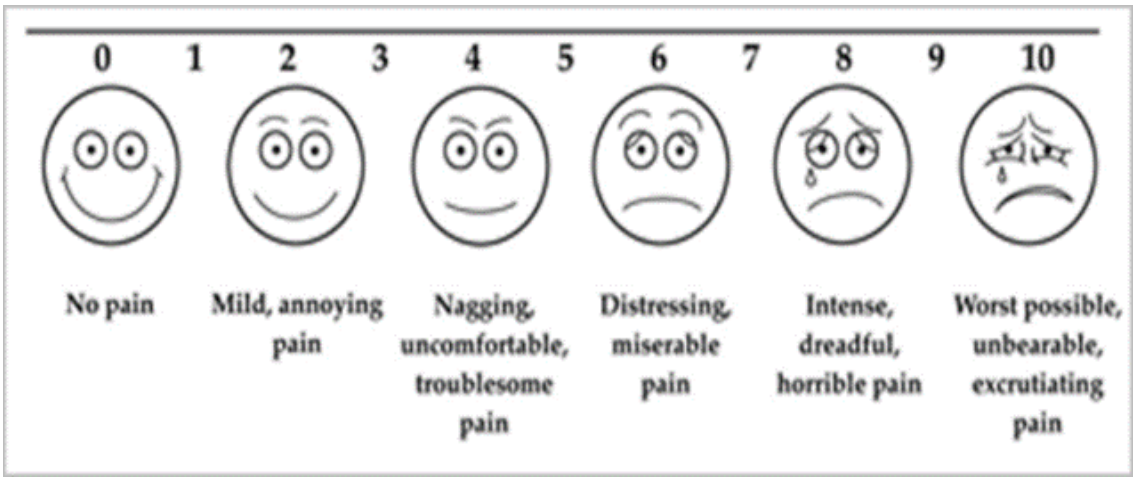
Patients were positioned immediately in supine position. Wedge was placed under patient's right buttock. Oxygen was supplemented by Hudson's mask. An independent investigator, blinded to anaesthetic agent evaluated the effects.

The parameters observed are:

Hemodynamic Status: Systolic blood pressure, diastolic blood pressure, maternal heart rate were recorded every 2 minutes for first 30 minutes and there after every 5 minutes intra operatively. A decrease of systolic blood pressure less than 95 mm. Hg or decrease greater than 25% from baseline was considered as hypotension and treated with 3 to 5 mg. of mephenteramine. Vasopressor requirements were noted.

Sensory level of block was assessed by loss of cold sensation bilaterally at 2 minutes intervals and confirmed by pinprick method. Intraoperative pain assessment was done using visual analogue (VAS) scale (0 to 10 cm)

Visual analogue Score:



Time took to reach sensory block (T10 and T 6) were recorded. Quality of sensory blockade was assessed by following:

Good: no supplementation of analgesia required, when there is exteriorization of uterus or ligation of fallopian tubes.

Satisfactory: if patients require supplementation of analgesia.

Poor: if patient requires General anesthesia for supplementation.

Motor block of lower limb was assessed using modified Bromage scale.

0 = no impairment.

1 = Unable to raise extended legs, but able to move knees and ankles.

2 = Unable to raise extended legs or to flex knees but able to move feet.

3 = Unable to flex ankles, knees or hips.

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Time taken to reach motor block was noted.
Quality of motor blockade was also noted.
Duration for two segment regression of the sensory blockade was noted
APGAR score of babies was recorded at 1 and 5 minutes.

APGAR SCORE: Assessment of baby by the following scores.

	Score of 0	**Score of 1**	**Score of 2**	**Component of acronym**
Skin color/Complexion	Blue or pale all over	Blue at extremities body pink (acrocyanosis)	No cyanosis body and extremities pink	Appearance
Pulse rate	Absent	<100	≥100	Pulse
Reflex irritability	No response to stimulation	Grimace/feeble cry when stimulated	Cry or pull away when stimulated	Grimace
Muscle tone	None	Some flexion	Flexed arms and legs that resist extension	Activity
Breathing	Absent	Weak, irregular, gasping	Strong, lusty cry	Respiration

Side effects, such as nausea, vomiting, pruritus and shivering were noted. Postoperative pain was assessed using VAS scale. Duration of effective analgesia was taken as from time of epidural injection to VAS score > or = 4**.**

Statistical Analysis: Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS 15.0, Chicago, IL). P value is identified by paired t test. Probability values <0.05 were considered as statistically significant.

Exclusion Criteria: Patients with pre-existing or pregnancy induced hypertension requiring treatment, those with cardiac, renal or other end organ disease, patients in active labour, placenta previa and those with contraindication to neuraxial block were not included in the study group. Obese patients and extreme height (<140 cm or >180 cm) were excluded from the study.

Inclusion Criteria: ASA Grade I parturients with height of 140-180 cm, with no co-morbid conditions, without any malformation of placenta and foetus, without any cardiac or renal diseases

RESULTS: The present study was undertaken on 50 ASA grade–I singleton parturients aged between 18 to 30 years of age posted for elective cesarean section. These patients were randomly divided into two groups. each group of 25 each who received either 15ml of 0.5% bupivacaine (control) or 15ml of 0.75% ropivacaine.

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The two groups were comparable with respect to ASA status, age, weight height, as shown in table –I.

	Control Group (C) 10mg bupivacaine	Study Group (S) 7.5mg ropivacaine	P value
No. of patients	25	25	
Age	24.12±1.73	23±1.5	0.73
Weight	64±4.84	68±5.0	
Height	158±2.85	158±2.75	0.98
ASA status	I / II	I / II	

Table I: Demographic profile of two groups with Mean±S.D

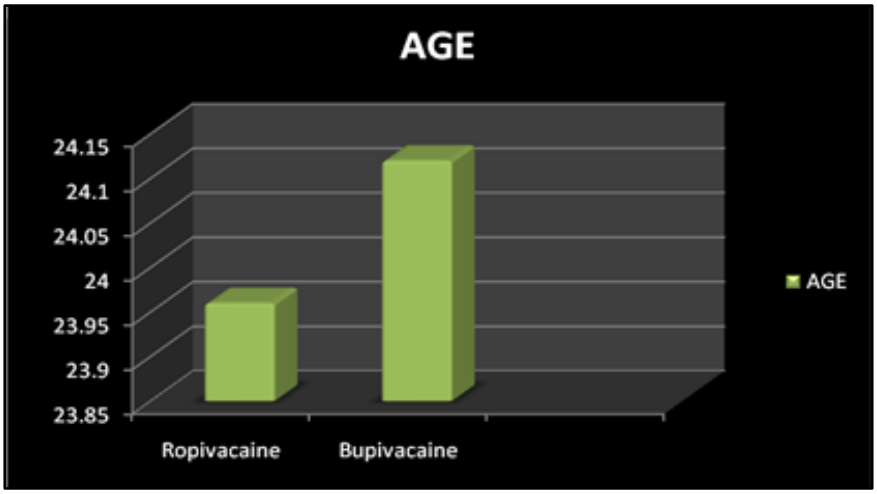

Figure 1: Demographic profile of two groups (AGE)

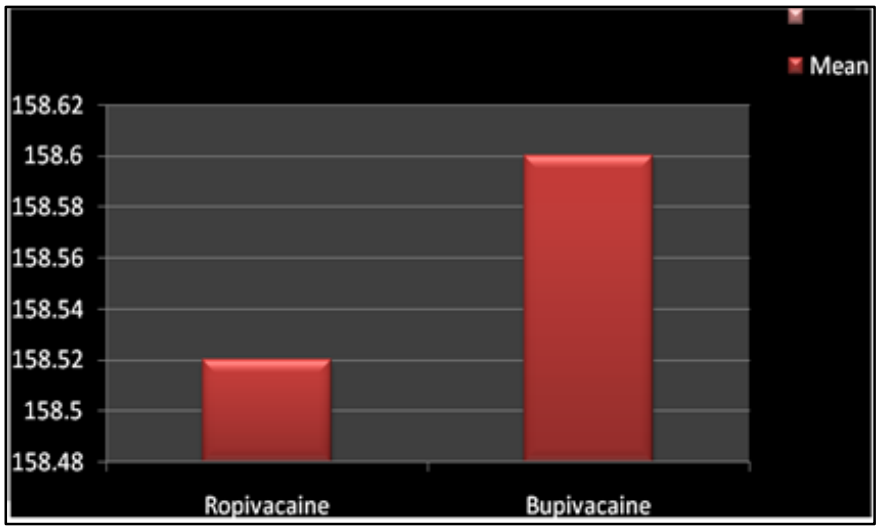

Figure 2: Demographic profile of two groups (HEIGHT)

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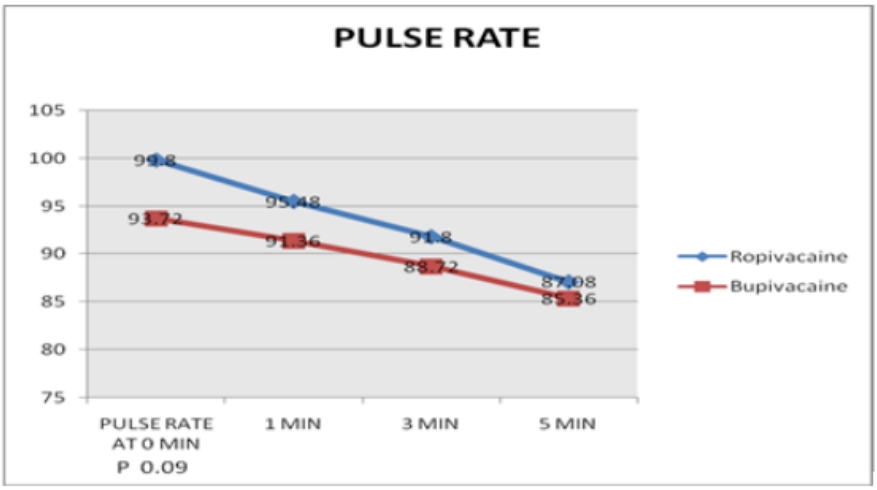

Figure 3: Line diagram showing Heart rate variation

Heart rate variations in min (mean±S.D.)			P value
	Control Bupivacaine	Study Ropivacaine	
At "0" min	93.7±12.6	99±12.5	0.09
At 1 min after epidural	91.3±10.2	95.48±12.4	0.25
At 3min after epidural	88.7±9.5	91.8±12.1	0.32
At 5 min after epidural	85.36±12.7	87.08±9.20	0.58

Table II: Heart rate variation

Heart rate decreased in both the groups after spinal anesthesia but the fall in heart rate was not statistically significant where P value is >0.05.

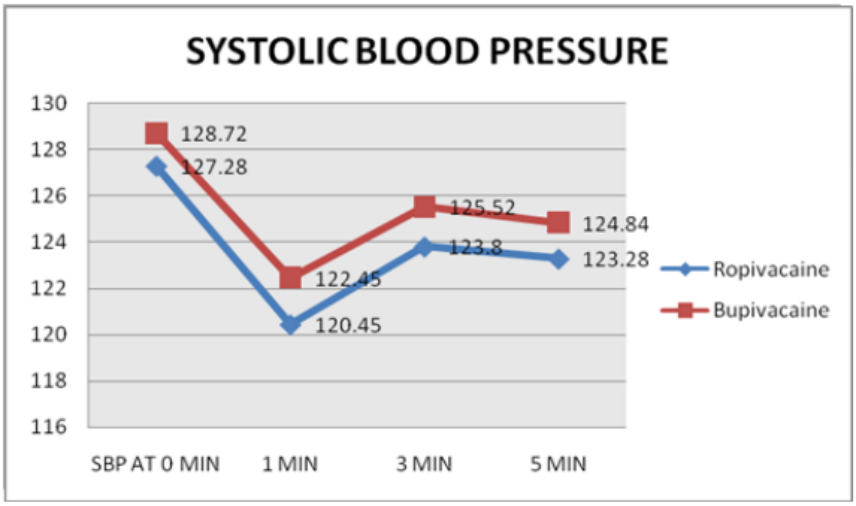

Figure 4: Line Diagram Showing Systolic

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Systolic blood pressure in mmHg (mean±S.D.)			P value p v
	Control	Study	P value
At "0" min	128.8±9.8	127.28±11.2	0.63
At 1 min after epidural	112.4±12.5	117.04±11.8	0.17
At 3min after epidural	120.52±13.1	123.86±9.98	0.21
At 5 min after epidural	124.84±10.2	123.28±9.9	0.80

Table III: Systolic blood pressure changes

Systolic blood pressure decreased in both groups, but the fall in systolic blood pressure at 0 and 1min was not statistically significant as P value was >0.05.

The fall in systolic blood pressure at 3 and 5 min was not statistically significant as P value was >0.05.

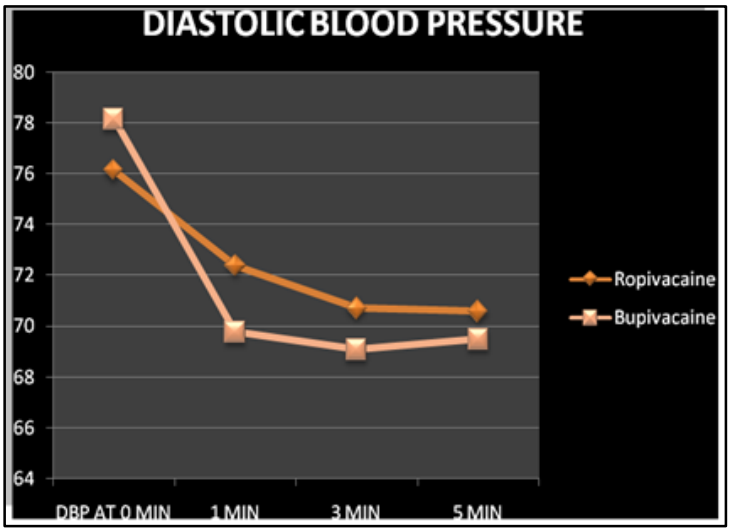

Figure 5: Line Diagram Showing Diastolic Blood Pressure Changes

	STUDY	CONTROL	P VALUE
At 0 min	76.16 ± 11.91	78.16 ± 8.9	0.5
At 1 min after epidural	72.40 ± 11.43	69.76 ± 8.4	0.3
At 3 min after epidural	70.72 ± 8.9	69 ±7.1	0.6
At 5 min after spinal	70.60 ± 9.86	69.48 ± 7.7	0.5

Table IV: Diastolic blood pressure changes

Diastolic blood pressure decreased in both groups, but the fall in diastolic blood pressure at 0 and 1min was not statistically significant as P value was >0.05.

The fall in diastolic blood pressure at 3 and 5 min was not statistically significant as P value was >0.05.

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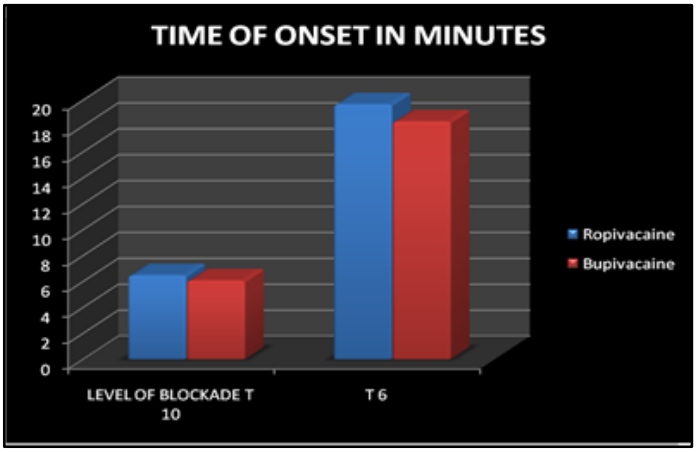

Figure 6: Time of Onset in Minutes

Onset time in minutes (mean±S.D.)			
	Study	**Control**	**P value**
Block till T-10	6.4±0.84	6 ±0.82	**0.03***
Block till T-6	19.6±3.5	18.34 ±2.9	0.1

Table V: Time of onset of sensory blockade

The onset of sensory blockade at the level of T 10 was significantly slower in the study group as p value <0.05.

But at the level of T 6 P value was not statistically significant as P value >0.05.

Time in minutes (mean± S.D.)		
	Study	Control
Duration of sensory blockade	151±7.33	116±14.39

Table VI: Duration of sensory blockade

The two segment regression was faster in study group and was statistically significant being P value <0.05.

Quality of sensory blockade was good referring to no requirement of any analgesia support intra operatively. Quality of motor blockade was also good. Intra operative and early post-operative complications like nausea and vomiting, pruritus, fetal bradycardia, shivering were not seen in both the groups.

	Study	**Control**
At 1 Min	8-9	7-9
At 5 Min	9-10	9-10

Table VII: APGAR scores

There was no difference in neonatal APGAR scores in both the groups.

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DISCUSSION: Ropivacaine is the first long acting, injectable local anaesthetic to undergo testing in more than 20 yr. Although identified as a local anaesthetic in 1957, ropivacaine testing did not begin until 1988 when Albright observed that accidental intravascular injections of bupivacaine resulted in serious cardiac toxic effects with poor outcomes.

Ropivacaine is a well-tolerated regional anaesthetic effective for surgical anaesthesia as well as the relief of postoperative and labour pain. Epidural ropivacaine, administered primarily in the lumbar region, has an effect of anaesthetic for a number of surgical procedures[8]. A majority of studies on epidural ropivacaine are in Caesarean section and although the drug has been investigated as an anaesthetic agent for other abdominal or gynaecological procedures, orthopaedic and vascular surgery, the major use of epidural ropivacaine in the latter procedures is for postoperative pain relief

Clinical trials of epidural anaesthesia for elective Caesarean section indicate that ropivacaine (0.75% or 0.5%) provides a clinically similar onset of sensory and motor block to that of bupivacaine 0.5%.[9] During epidural analgesia for labor, ropivacaine has been found in metanalysis to be equivalent to bupivacaine in terms of quality of pain relief and side effects, mode of delivery and neonatal outcomes.

In our study, the onset of sensory blockade was significantly slower in study group the contol group, the intensity of block in both study and control group was similar. There is no significant decrease in the systolic and diastolic blood pressure ($p > 0.05$) after 3 min and 5min of epidural anesthesia[10] in the control group and the study group.

No serious adverse events were noted in this study. The definition of tachycardia was perhaps too liberal, however, median changes in heart rate varied no more than ±10% from base line in any of the group comparisons and there were no differences noted between the groups. There was not much change in the hemodynamics till 5 min after epidural blockade.

Lierz et al. compared the analgesic, motor block, and haemodynamic effects of single-shot epidural injections of ropivacaine 0.2% 10 mL with bupivacaine 0.125% in outpatients suffering from chronic low back pain in a randomised study involving 36 patients. Bupivacaine 0.125% and ropivacaine 0.2% showed no significant differences in analgesia or in motor blockade or haemodynamic changes. High doses can be complicated by total spinal anaesthesia, severe Arterial hypotension and shock. Excessively small doses may result in spinal anaesthesia failure, either situation may result in conversion to general anaesthesia.

In our study, the onset time of sensory blockade up to T 10 was slower with the ropivacaine than bupicaine. This onset time is statistically significant as the P value was <0.05, which Many clinical studies support duration of sensory block is significantly shorter for ropivacaine the differences in sensory and motor block characteristics between ropivacaine and bupivacaine reported in the literature may also be explained on the basis of a lower, although still adequate, overall potency of ropivacaine compared to bupivacaine.

Complete motor block was achieved in 90–100% of patients with our study, this is in accordance with the results of %, Brown et al[11]. Brown et al (199072:633-6) Compared the effects of epidurally administered ropivacaine 0.5% with bupivacaine 0.5 found both drugs to be clinically similar in both sensory- and motor blocking characteristics, although bupivacaine produced a sensory block of slightly, but statistically significantly longer, duration; the intensity of

motor block in their study was similar, but duration of Bromage Level 1 motor block was significantly longer when using bupivacaine. In our study found no statistically significant difference in intensity and duration of motor block between the two groups.

a double-blind study comparing the effects of epidurally administered ropivacaine 0.75% with bupiva- Caine 0.75% in human subjects, Kerkkamp et al[12] found that both intensity and duration of motor block were significantly less with ropivacaine; although spread and quality of analgesia were similar, their data also show that the duration of sensory block was significantly shorter for ropivacaine.

Similar results were reported by Brockway et al[13] although their data on duration of sensory block when comparing equal concentrations were inconsistent for different dermatomes, and not statistically significant. Quality of motor blockade was good in our study and there was no requirement of supplementation with general anesthesia for inadequate motor blockade while exteriorisation of uterus.

Quality of sensory blockade was good as there was no analgesic supplementation required in study group even when the uterus was exteriorised and pulling of fallopian tubes, but the difference between the groups was not significant. The quality of analgesia was excellent in the both study group and control group in our study. Further, in our study the incidence of nausea and vomiting was not reported in the both groups.

In our study none of the new-born babies had 5min APGAR score <7. Similar observations were made by Balzerena SD, Biswas BN indicating that the dose of fentanyl used may not have significant effect on the new-born., which were also similar with observations of Hunt et al and Shende et al study. The two segment regression of sensory blockade was faster in study group than in control group which was not statically significant (P>0.05) and concurs with the study made by others.

CONCLUSION: The present study was carried out in 50 singleton parturients of ASA grade I/II posted for elective caesarean section under epidural anaesthesia. The hemodynamic and the analgesic characteristics were recorded and statistically analysed.

Onset of sensory blockade was slower in study group. Durations of sensory blockade were shorter with the usage ropivacaine. There was No significant difference in systolic and diastolic blood pressure the both groups. Foetal APGAR scores were not changed with either drugs. The maternal satisfaction and fetal outcome were good.

Hence it is concluded that ropivacaine and bupivacaine have similar heamodynamic and analgesic effects with ropivacine having slower onset and lesser duration of sensory blockade than bupivacaine, combination provides better analgesia and hemodynamic stability.

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