3 A CASE STUDY OF COMPARATIVE STUDY OF EPIDURAL ANESTHESIA USING 0.5% BUPIVACAINE AND 0.75% ROPIVACAINE IN CAESAREAN SECTION

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Abstract

Background: Early studies suggested that Ropivacaine had clinical advantages over Bupivacaine with respect to cardio toxicity and motor block, and that it was suitable for epidural caesarean section. This study was set up to compare epidural 0.75% Ropivacaine with a popular 0.5% Bupivacaine for elective caesarean section.

Methods: 60 women having elective caesarean section under epidural anaesthesia were randomly allocated to receive 18- 20 mL of either 0.75% Ropivacaine or 0.5% Bupivacaine.. Times were recorded for onset of sensory block, density and duration of motor block, and the need for supplementation.

Results: The mean time taken to achieve sensory block at T10 was 9.33+/-2.54 min in group B and 11.33+/-2.60minutes in group R . . In group B 93.33% patients had achieved T10 level with in 10 min as against 76.67%in group R. In group B 6.67 % patients had achieved T10 level after 10 min as against 23.33 % patients in group R. However, Ropivacaine produced a
motor block that was denser time to achieve modified bromage score 3 was10 to 25 minutes in group and 10-30 minutes in group R . The mean time taken to achieve modified bromage score 3 was 15.83+/-2.96 minutes in group Band 16.33+/- 3.7 min in group R

Conclusions: This study suggests that epidural 0.75% Ropivacaine may be used as an alternative to
Bupivacaine 0.5% for elective caesarean section, with a denser and prolonged motor block. With the onset time of anaesthesia

Keywords: Epidural Anaesthesia; Caesarean section; bupivacaine; ropivacaine

Introduction

Neuraxial analgesia is frequently administered to women in for LSCS. The choice of anaesthesia depends on the indications for the surgery , the degree of urgency , maternal status (full stomach) and the desire of the patient for the type of anaesthesia as well as whether to stay awake during child birth or not [5].

Most caesarean section are now performed with single –shot spinal anaesthesia . Epidural anaesthesia provides segmental block of spinal sensory and sympathetic nerve fibres with partial block of motor fibres. Lumbar epidural analgesia is a gold standard and widely used technique for providing labour analgesia[5].It can provide analgesia for both stages of labour and can be extended to provide anaesthesia for caesarean section or instrumental delivery if need arises. It has some advantages over spinal like lower incidences of hypotension ,lower risk of high spinal block since it provides segmental block , then there is no risk of post dural headaches , the risk os spinal cord injury is less , top of doses can be given to extend post operative analgesia though motor block is less pronounced

For many years, bupivacaine has been used because of its long duration of action, limited placental transfer, and minimal neonatal effects. Compared with older local anesthetics such as tetracaine, bupivacaine provided better analgesia without excessive motor block. In addition, compared with lidocaine, there was less tachyphylaxis with long-term administration. However, Bupivacaine is more cardio toxic than other local anesthetics and motor blockade accompanies the analgesia especially at higher concentrations. Many local anesthetics such as Bupivacaine exist in 2 forms, levorotatory and dextrorotatory. Ropivacaine is an amide local anesthetic produced in the pure levorotatory form. Its use may address some of the concerns related to bupivacaine.[7,9,14]

The **AIM of this study** was to assess whether there is an advantage to the use of either of these local anesthetics for neuraxial analgesia, so we compared 0.5% Bupivacaine with 0.75% Ropivacaine as local anaesthetic agents in caesarean section Sensory and motor blocking properties , hemodynamic properties and intraoperative and postoperative complications and side effects of equal concentrations of Bupivacaine and Ropivacaine was compared .

Methods

Sixty pregnant women posted for elective caesarean section were selected after taking written informed consent. All women ASA I or II, at P36 weeks of gestation over 18 years old were randomly allocated into two groups(n=30) each and received 18-20ml

Group B : Inj. bupivacaine. 0.5%

Group R : Inj Ropivacaine 0.75 %.

Women in labour,with known contraindication to regional anaesthesia like who had significant back surgery,injury or scoliosis,coagulopathy , psychiatric illness local infection and those known to have an allergy to amide local anaesthetics were **excluded**. Women in whom there was any concern about fetal wellbeing were also excluded.

All women were premedicated with oral ranitidine150 mg and Ondansetron 8mg and On arrival in the Operation theatre were preloaded with Ringer lactate solution 500 mL intravenously. The epidural was performed by anaesthetist or with the patient in left lateral position. The epidural space was identified according to normal practice in the L2-3 or L3-4 interspace with a 18-gauge Tuohy needle, bevel cephalad, using a midline approach, with loss of resistance to either air or saline. An epidural catheter was inserted with 3 cm left in the epidural space, and patients were then positioned supine with approximately 15° uterine tilt to the left (ensuring that the abdominal bump looked displaced) . A second anaesthetist, not involved in the study, prepared and administered the study solution according to instructions found within a pre-randomised, sealed, numbered envelope. Subjects were randomly allocated to receive either 18- 20 mL of 0.75% ropivacaine (group R) or 18- 20 mL of 0.5% bupivacaine . Five minutes after a 3-mL test dose of 2% plain lidocaine had been given by the investigator, the study solution was given The solution was given slowly over 2 min . All assessments (preoperative, intraoperative and postoperative) were made The timing period for the study began once all the study solution had been given. Electrocardiogram (ECG) and pulse oximetry were started upon arrival in theatre. An automated sphygmomanometer

recorded maternal blood pressures every 5 min. Hypotension (systolic pressure <100 mmHg, or a 20% drop from baseline, or symptoms of nausea, dizziness or faintness) was treated using additional fluids and/or ephedrine 3–6 mg boluses.

Evaluation

Sensory Block : was assessed by using pinprick test every 5 min after injection of drug through epidural catheter till sensory block at T10 and after surgery every hourly till regression of sensory block below T10.

Onset of sensory Blockade :Time required to produce loss of pinprick sensation at dermatome at T10

Duration of sensory block : Time of regression of analgesia to pin prick below T10 dermatome

Motor blockade : It was assessed by using modified bromage score every 5 min after injection of drug through epidural catheter till patient was unable to perform straight leg rise (modified bromage score 3) and surgery every hourly till patient was able to perform straight leg rise test (modified bromage score 6)

Modified Bromage score by Breen et.al[1,2]

1 Complete block (able to move hips, knees, feet and lift legs up)

2 Almost complete block(able to move knees and feet)

3 Partial Block (only able to move feet)

4 Detectable weakness of hip flexion while supine (full flexion of knees)

5 No detectable weakness of hip flexion while supine

6 Able to perform partial knee bend

During surgery, all women received oxygen (8 L min_1) via a mask until delivery of the baby, whereupon Syntocinon 10 units (in two divided doses) - were given intravenously. Assessment
of the baby, according to obstetric and neonatologist protocol, included routine preoperative fetal heart monitoring using a cardiotocograph, Apgar scores at 1, 5 and 10 min after delivery .
The postoperative analgesic regimen used for all women was standard for this hospital at the time of
the study. This comprised 50mg tramadol via epidural route .At the end of surgery, time was noted . pulse rate blood pressure and level of sensory and motor blockade were evaluated hourly till six hours and then at 12 and 24 hours after surgery.

Time of regression of analgesia of analgesia to pin prick below T10 dermatome was considered as duration of sensory block and the time at which patient was able to perform straight leg rise was considered as duration of motor block .Nausea , vomiting ,

bradycardia , hypotension and urinary retention were assessed . Epidural catheter was removed 24 hours after surgery .
Data were analysed using unpaired 't'test with P< 0.05 considered statistically significant and presented as mean values and mean +/- SD .

Results

Both groups were demographically comparable in terms of mean age (26.93yr,25.57yr), mean weight (62.63kg, 59.83 kg), mean height (152.53cm, 151.9 cm)in group Bupivacaine and Ropivacaine respectively.

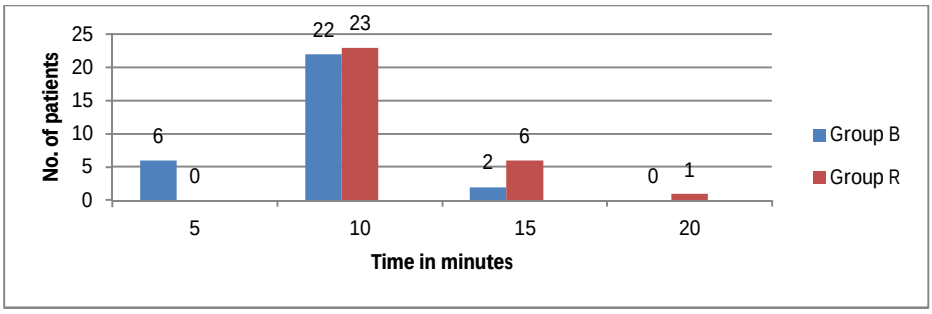
Table 1. Demographic Data

Demographic Data	Group B (Mean±SD)	Group R (Mean±SD)
Age (years)	26.93±3.96	25.57±3.66
Weight (kg)	62.63±5.57	59.83±6.46
Height (cm)	152.535.33	151.9±5.52

Table 2 : Time taken for onset of sensory block

	Group B (no. of patients)	**Group R (no. of patients)**
5	**6**	**0**
10	**22**	**23**
15	**2**	**6**
20	**0**	**1**
Total	**30**	**30**
Mean +/- SD	**9.33+/- 2.54**	**11.33+/-2.60**

Figure - 1 Time taken for onset of sensory block at T10

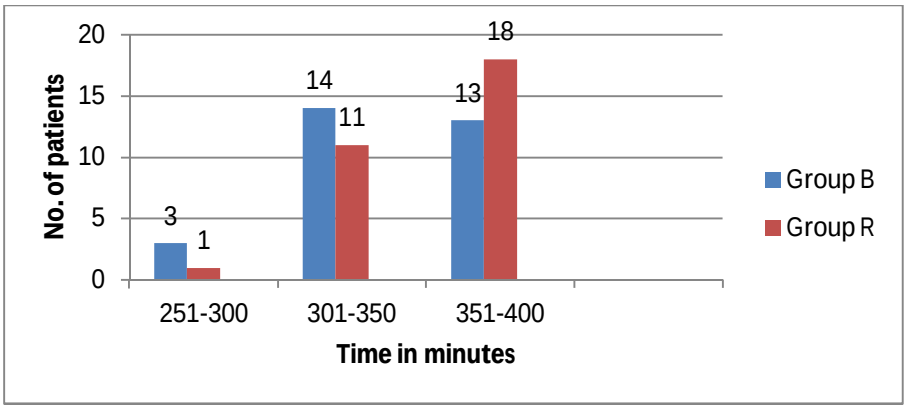


The range of time taken to achieve sensory block at T10 was 5-15 minutes in group B and 10-20 min in group R . The mean time taken to achieve sensory block at T10 was 9.33+/-2.54 min in group B and 11.33+/-2.60minutes in group R . . In group B 93.33% patients had achieved T10 level with in 10 min as against 76.67%in group R. In group B 6.67 % patients had achieved T10 level after 10 min as against 23.33 % patients in group R showing a statistically significant difference between the two groups ($p < 0.05$).

Table 3 Duration of Sensory Block

Duration(min)	Group B (No. of patient)	Group R (No. of patient)
251-300	3	1
301-350	14	11
351-400	13	18
Total	30	30
Mean±SD	340.67±40.42	352.67±34.95

Figure 2 Duration of Sensory Block



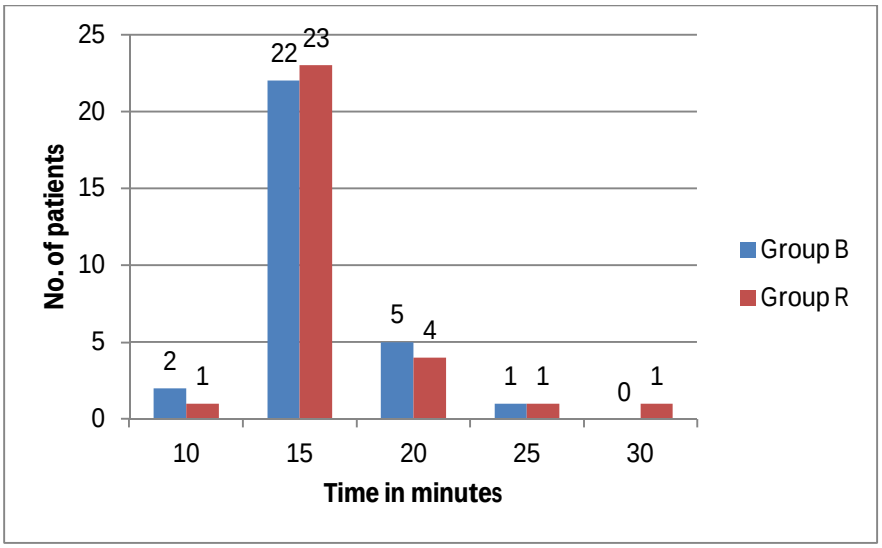
The range of Duration of sensory was 255 to 380 minutes in group B and 250 to 380 min in group R. The mean time for duration of sensory block was 340.67 +/-40.42 min and group B and 352.67 +/- 34.95 minutes in group R showing no statistically significant difference between the two groups (P>0.05)

Table 4 Time for onset of Motor Block

Time(min)	Group B (No. of patient)	Group R (No. of patient)
10	2	1
15	22	23
20	5	4
25	1	1
30	0	1
Total	30	30
Mean±SD	15.83±2.96	16.33±3.7

t =0.5780, p=0.5655(>0.05) not significant

Fig 3. Time for Onset of Motor Block Modified bromage score 3



The range of time to achieve modified bromage score 3 was10 to 25 minutes in group and 10-30 minutes in group R . The mean time taken to achieve modified bromage score 3 was 15.83+/-2.96 minutes in group Band 16.33+/- 3.7 min in group R showing no ststistically significant difference between the two groups . p.0.05

Table 5 Degree of motor block at the time of onset of sensory block at T10 by modified bromage score

Modified bromage score	Group B (No. of patient)		Group R(No. of patient)	
	No.	%	No.	%
5	7	23.33	2	6.67
4	23	76.67	24	80
3	0	0	4	13.33
Total	30		30	

At time of onset of sensory block at T10, modified bromage score was 5 in 23.33% patients of group B and 6.67% patients of group R , 4 in 76.67 % of group B and 80 % of Group R and 3 in 0 patientof group B and 13.33 % of group R .

The range of duration of motor block was 185 to 375 minutes in group B 255 to 440 minutes in group R. the mean time for duration of motor block was 306.17 +/-47.83 min in group B and 369.67+/-42.51 min in group R showing a statistically significant difference between the two groups ($p<0.05$).

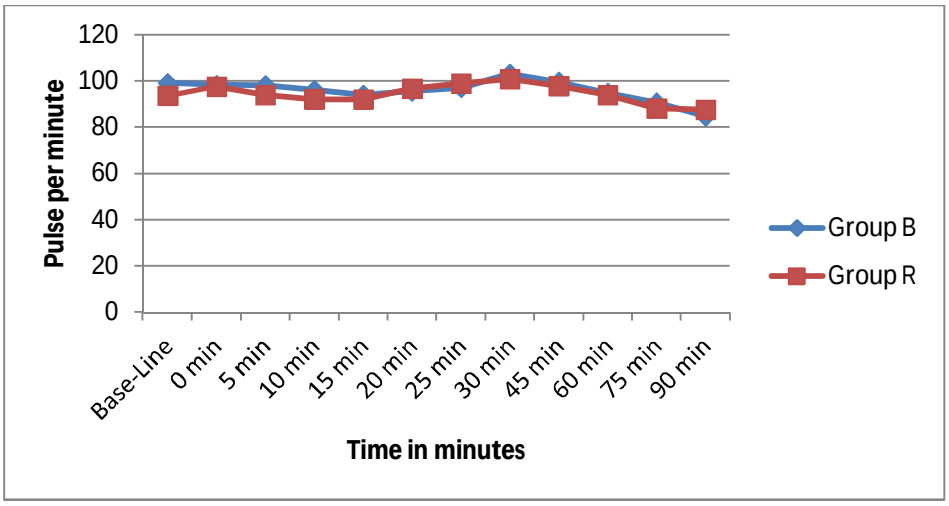
Table 6 : Pulse Rate Changes

Time interval	Group B		Group R		T Test	P Value
	Mean	±SD	Mean	±SD		

Base-Line	99.10	20.26	93.63	12.71	1.252	0.216
			Intra Operative			
0 min	98.27	20.08	97.60	15.54	0.141	0.886
5 min	98.03	17.4	93.90	18.16	0.900	0.372
10 min	96.03	19.28	92.13	13.62	0.905	0.369
15 min	93.87	19.47	92.07	11.09	0.440	0.662
20 min	95.63	16.22	96.63	12.73	0.266	0.791
25 min	97.10	17.46	98.83	12.63	0.440	0.661
30 min	103.07	17.82	100.77	13.54	0.563	0.576
45 min	99.60	14.48	97.83	14.2	0.477	0.635
60 min	94.83	12.7	93.93	14.70	0.254	0.801
75 min	90.67	8.84	88.03	12.20	0.957	0.342
90 min	84.77	8.76	87.60	10.63	1.127	0.265
			Post Operative			
1st hr	89.6	12.33	85.87	8.56	1.362	0.179
2nd hr	87.20	11.23	84.93	9.36	0.849	0.399
3rd hr	84.60	11.29	83.77	7.24	0.340	0.735
4th hr	82.47	9.58	83.07	5.45	0.298	0.767
5th hr	80.60	8.77	83.07	5.95	1.301	0.198
6th hr	80.27	6.55	81.93	4.41	1.156	0.253
12th hr	78.13	5.12	76.47	3.63	1.455	0.151
24th hr	78.07	5.32	78.47	4.48	0.315	0.754

The changes in pulse rate between the two groups were not statistically significant during intraoperative as well as post operative period

Figure 4:intraoperative pulse rate changes



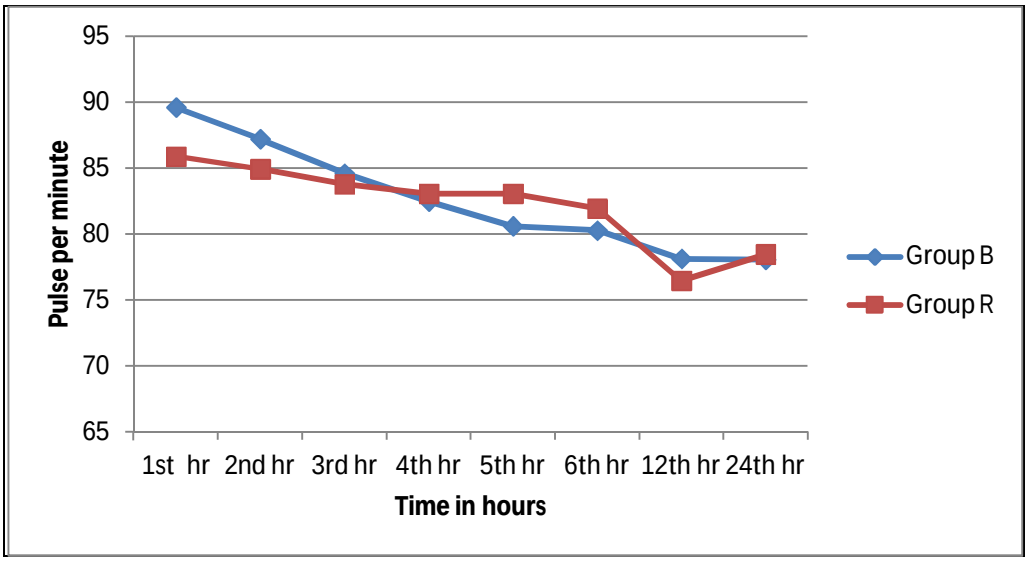


Figure – 5 Pulse rate changes during post op period

Changes in Systolic blood pressure between the two groups were not satistically significant during intraoperative period p> 0.05 but in post operative period at 2nd , 3rd and 4th hour , changes in systolic blood pressure between the two groups were statistically significant .p<0.05

Figure 6: Changes in Systolic blood pressure

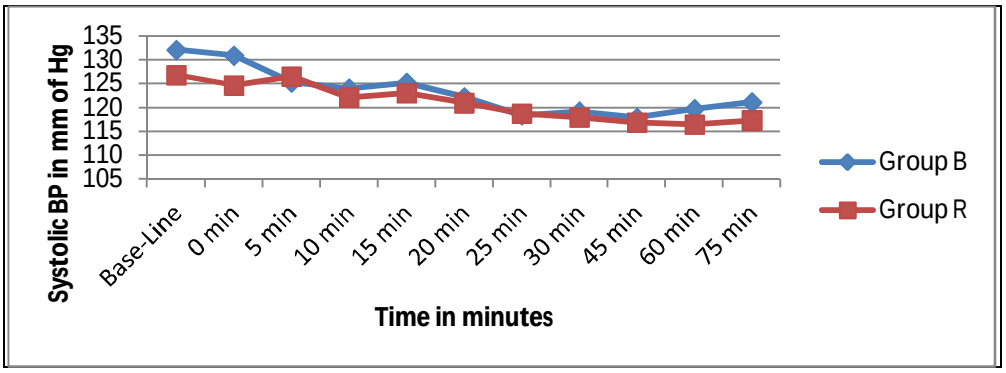


Figure – 7 Systolic Blood Pressure Changes during intra op period

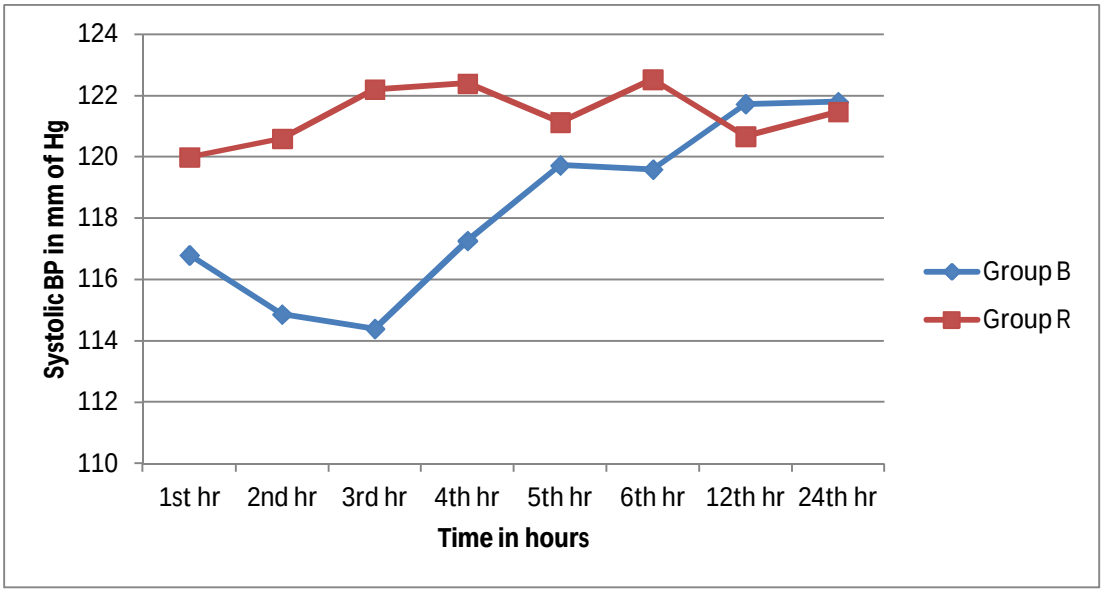
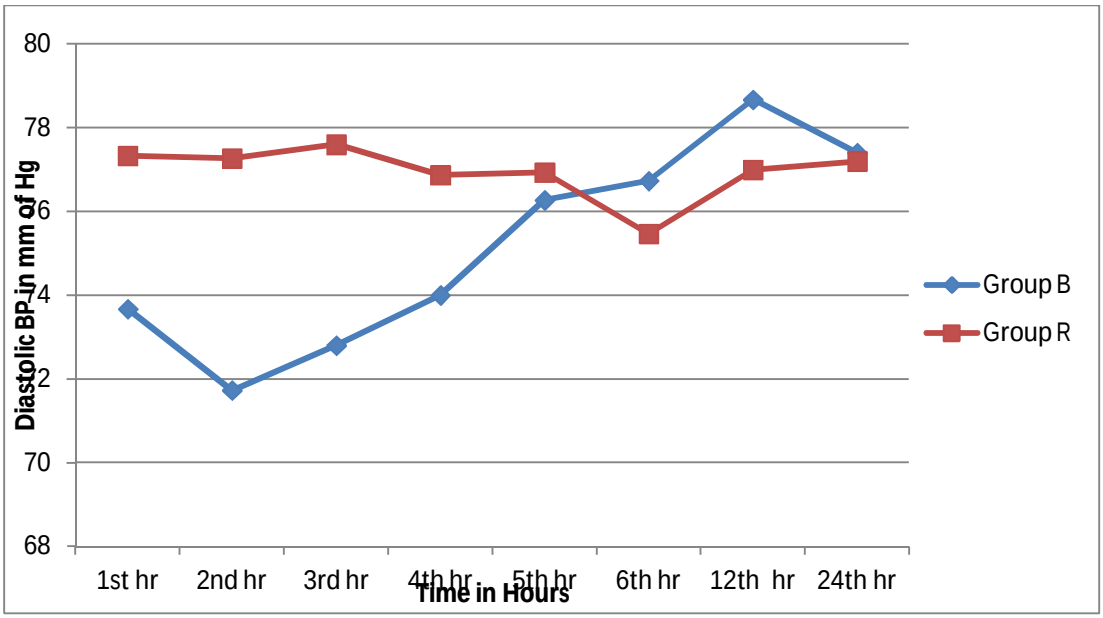


Figure – 8 Systolic Blood Pressure Changes during intra op period

Changes in diastolic blood pressure between the two group were not statistically significant during intraoperative period $p>0.05$ but in post operative period at 2nd and 3rd hour , changes in diastolic blood pressure the two groups were statistically significant $p<0.05$

Figure9: Diastolic Blood Pressure changes during post op period



Side Effects : During intraoperative hypotension was noted in one patient of both groups . there was no incidence of any other side effects in intraoperative period . no other side effects were noted in either group during post operative period like nausea vomiting hypotension ,bradycardia and urinary retention .

Side effects	Group B	Group R
Nausea/Vomiting	0	0
Bradycardia	0	0
Hypotension	1	1
Urinary retention	0	0

Discussion

When ropivacaine was first released it was widely promoted as a potentially superior agent to bupivacaine because of lower toxicity and less motor block. Studies suggested that ropivacaine is less cardiotoxic than Bupivacaine. Ropivacaine is a long acting amide type local anaesthetic relased for clinical use in 1996 . In comparison with Bupivacaine it is equally effective for subcutaneous infiltration,epidural and peripheral nerve block for surgery , obstetric procedures and post operative analgesia . Ropivacaine because of its pure S- enantiomer form is less cardiotoxic than Bupivacaine . the motor blocking characteristics it is less potent than Bupivacaine .
In our study , Both groups were demographically comparable in terms of mean age (26.93yr,25.57yr), mean weight (62.63kg, 59.83 kg), mean height (152.53cm, 151.9 cm)in group Bupivacaine and Ropivacaine respectively

David L. Brown , Randall L.Carpenter, Gale E. Thompson [6]observed onset of sensory block at T10level in 10.7 +/- 5.6 min in 0.5% . Ropivacaine and 13.0+/- 10.7 min in 0.5% Bupivacaine, at T5 level in 20.5 +/-7.9 in o.5% Ropivacaine and 19.5+/- 10.2 min in 0.5%. Bupivacaine, duration of sensory block 333+/- 54 min for Ropivacaine and 394 +/- min for Bupivacaine. Our study supports these in which, onset of sensory block at T10 was9.33 +/- 2.55 min in group B and 11.33+/-2.60 minutes in group R . Duration of sensory block was 340.67 +/-40.42 min in group B and 352.67 +/- 34.95 min in group R.

Increasing the concentration of Ropivacaine resulted in greater degree and longer duration of motor block . A positive correlation was noted between the total dose of Ropivacaine and the sensory block profile by **Brendan T. Finucane, et al in 1994**[3], did a double – blind comparative study of Ropivacaine 0.5%,0.75%,!% and Bupivacaine 0.5%,in 125 patients of abdominal hysterectomy . It was the first study to test the efficacy of Ropivacaine when injected epidurally for major abdominal surgery . Increasing doses of Ropivacaine were associated with an increased clinical effect .The main difference between Ropivacaine 1.0 % and Bupivacaine 0.5% was in sensory duration and between different doses of Ropivacaine in motor duration.

Our study supports this Duration of motor block for 0.75 % Ropivacaine is longer and more intense .The mean time taken to Ropivacaine is longer and more intense .The mean time taken to achieve modified bromage score 3 was comparable in both groups . Degree of motor block was observed and considered as the modified bromage score at that time of onset of sensory block at T10 . It was 5 in 23.33% patients of group B and 6.67% patients of group R, 4 in 76.67% of group B and 13.33% of group R at time of onset of sensory block.

The range of duration of motor block was 185 to 375 minutes in group B and 255 to 440 min in group R . The mean time for duration of motor block was 306.17 +/-47.83 min in group B and 369.67 +/- 42.51 min in group R which was statistically significant $p<0.05$

In 2005 , N.Christelis , J. Harrad , P.R Howell[10] did a comparative study of epidural Ropivacaine 0.75% and Bupivacine o.5% fentanyl mixture for elective caesarean section .and suggested that epidural 0.75% ropivacaine without opioid could be used as an alternative to bupivacaine 0.5% with fentanyl for elective caesarean section, but it did not induce anaesthesia any faster but resulted in a denser, more prolonged, motor block our study supported this study .

I**n 2011, Sara Korula,et al**[13], found that duration and intensity of motor block with 0.75% Ropivacaine was comparable to 0.5% Bupivacaine .

In our study we found that epidural 0.5% Bupivacaine and 0.75% were similar in both sensory and motor blocking characterstics for Caesarean section , with the the exception that Ropivacaine produced slightly longer and dense motor blockade . As Ropivacaine is less cardiotoxic and neurotoxic than Bupivacine , it is recommended for epidural anaesthesia in caesarean section .

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