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COMPARATIVE STUDY OF ROPIVACAINE (0.75%) AND BUPIVACAINE (0.5%) FOR EPIDURAL ANAESTHESIA IN PATIENTS UNDERGOING LOWER ABDOMINAL AND LOWER EXTREMITY SURGERIES

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ABSTRACT

Background: Epidural analgesia has become the most commonly used technique which not only provides perioperative surgical anaesthesia but also postoperative analgesia following lower abdomen and lower limb procedures is epidural anaesthesia. Present study was aimed to compare ropivacaine (0.75%) versus bupivacaine (0.5%) for epidural anaesthesia in patients undergoing lower abdominal and lower extremity surgeries. **Material and Methods:** Present study was Randomized, single blinded, interventional study, conducted patients aged 20-60 years, any gender, body weight between 50 to 100 kgs, height between 150-180 cm, ASA I & II, undergoing lower abdominal and lower extremity surgeries. Patients were randomized into either of two groups by computer-generated software as B group (Received bupivacaine) & R group (Received ropivacaine). **Results:** There was no significant difference between two groups in the time of onset of sensory block, time of onset of Motor block & two segment regression. There was a significant difference between two groups in duration of motor block (more in B group) & duration of analgesia (more in R group). There was slight decrease in heart rate & systolic blood pressure at 5 and 10 min in group B. There was slight decrease in systolic blood pressure & mean arterial pressure at 10 and 15 min in group B. There was stability in oxygen saturation among patients of both groups. **Conclusion:** Duration of motor block was more in Bupivacaine group and duration of analgesia were more in Ropivacaine group patients. This implies that Ropivacaine has more efficacy compared to Bupivacaine.
Keywords: bupivacaine, ropivacaine, postoperative analgesia, epidural anaesthesia

INTRODUCTION

According to “International Association for the study of pain”, pain is defined as an unpleasant sensory and emotional experience connected with existing or potential tissue damage. Pain has been demonstrated to alter the physiology of nearly all systems, with the exception of psychological trauma, including the cardiovascular, respiratory, and metabolic profiles, increasing morbidity.[1]

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Epidural analgesia has become the most commonly used technique which not only provides perioperative surgical anaesthesia but also postoperative analgesia following lower abdomen and lower limb procedures is epidural anaesthesia.[2] By providing dynamic analgesia, it even permits patients to resume their regular activities, pain-free.[3] The addition of opioids to long-acting local anaesthetics during epidural analgesia provides a dose-saving benefit that is advantageous for the low occurrence of negative side effects.[4]

Studies comparing Bupivacaine with Ropivacaine in developing countries like India are less. So, the evidence already available was not sufficient to draw conclusions on their safety and efficacy in our local settings. Present study was aimed to compare ropivacaine (0.75%) versus bupivacaine (0.5%) for epidural anaesthesia in patients undergoing lower abdominal and lower extremity surgeries.

MATERIAL AND METHODS

Present study was Randomized, single blinded, interventional study, conducted in department of Anaesthesiology, NRI Medical College & General Hospital, Mangalagiri, Andhra Pradesh, India. Study duration was of 2 years (November 2020 to September 2022). Study was approved by institutional ethical committee.

Inclusion criteria

- Patients aged 20-60 years, any gender, body weight between 50 to 100 kgs, height between 150-180 cm, ASA I & II, undergoing lower abdominal and lower extremity surgeries & willing to participate in present study

Exclusion criteria

- ASA III and IV
- Patients with known allergies to drugs used in the study
- Pregnant and lactating women
- Patients with coagulation disorders
- Patient's refusal for surgery
- Prior history of neurological disorders
- Psychiatric patients
- Patients on antiarrhythmic medications

Study was explained to participants in local language & written informed consent was taken. After complete clinical workup for all the cases which include detailed history, physical examination, vitals & systemic examination patients were randomized into either of two groups by computer-generated software.

B group: Received bupivacaine (0.5%) for epidural anaesthesia

R group: Received ropivacaine (0.75%) for epidural anaesthesia

In surgical theatre, Boyle's anaesthesia machine was checked. Appropriate size endotracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus were kept ready before the procedure. Patients were shifted to the OT and ASA standard monitors attached which are pulse oximetry, ECG leads, and NIBP cuff.

Venous access was secured with 18G and 16G cannula. Epidural anaesthesia was given with the patient in the lateral position using 18-gauge Touhy needle at the L2–3 or L3–4 interspaces. The study medication (20ml) was administered.

After the epidural block, HR, SpO2 and NIBP to be measured every 5 min for the first hour and then every 15 min till the end of surgery. Supplementary oxygen was given through a facemask. The level of sensory anaesthesia, time for onset of block at T8, maximum block

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height, total duration of analgesia, time to request for analgesia, time of onset of motor block, degree of motor block, total duration of block, and analgesics supplements were given if any were noted. Time of first complaint of pain and request for rescue analgesia was recorded.

Vital parameters like HR, NIBP, MAP, and SPo2 were recorded at intervals of every five min for 30min. ECG was monitored continuously throughout the procedure. Intravenous Paracetamol or Diclofenac or opioid to be used as a rescue analgesia, if needed.

The data collected was entered in MS Excel 2019 and analysis was carried out by EPI INFO software. Chi-square test was used to test the presence of association between various parameters. T test was used to compare numerical values between two groups. P value less than 0.5 was considered as statistically significant.

RESULTS

The current study was conducted on 60 patients. They were randomized into 2 groups. Mean age, gender, mean body weight, mean height, ASA grade & type of surgery were comparable in both groups & no statistically significant difference was noted.

Table 1: General characteristics

Characteristics	Group B	Group R	P value
Mean Age (in years)	39.26 ± 10.96	35.3 ± 8.4083	0.52
Gender			
Female	13	13	1
Male	17	17	
Mean weight (kgs)	75.86 ± 7.45	76.1 ± 6.0876	0.89
Mean Height (cms)	163.5 ± 6.7198	162.1 ± 7.0288	0.43
ASA grade			
1	17	21	0.184
2	13	9	
TYPE OF SURGERY			
Fracture of patella	2	3	0.88
Surgery for fracture of tibia	8	9	
Inguinal hernia	4	5	
Implant removal	10	9	
Varicose vein stripping	6	4	

The mean onset of sensory block for group B was 6.76min and for group R, it was 6.81 min. There was no significant difference between two groups in the time of onset of sensory block as per the t test (P= 0.73).

The mean Motor time of onset for group B was 10.22 min and it was 10.30 min for group R. There was no significant difference between two groups in the time of onset of Motor block as per the t test (P= 0.73).

The mean motor block duration in group B was 315.3 and the mean motor block duration in group R was 310.6 min. There was a significant difference between two groups in duration of motor block as per the t test (P= 0.04).

The mean time for two segment regression in group R was 160.6 min and for group B, it was 160.26 min. There was no significant difference between two groups in time for two segment regression as per the t test (P= 0.84).

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The mean duration of analgesia for group B was 363 min and it was 387 min in group R. It was more in group R, which indicates Ropivacaine has more efficacy. There was a significant difference between two groups in time duration of analgesia (P= 0.002).

Table 2: Anaesthesia characteristics

Characteristics	**Group B**	**Group R**	**P value**
Sensory block time of onset (minutes)	6.76 ± 0.6095	6.81 ± 0.6157	0.737
Motor block time of onset (minutes)	10.22 ± 0.9335	10.30 ± 0.9292	0.73
Motor block duration (minutes)	315.36 ± 10.31	310.63 ± 9.63	0.046
Time for two segment regression (minutes)	160.6 ± 5.53	160.26 ± 7.18	0.8412
Duration of analgesia (minutes)	363.96 ± 7.76	387.36 ± 9.69	0.002

There was slight decrease in HR at 5 and 10 min in group B

Table 3: Mean HR in both groups

Intervals	**Mean HR B**	**Mean HR R**	**P value**
Baseline	83.6	86	0.13
5 min	75	89	**0.03**
10 min	77	86	**0.04**
15 min	82	88.8	0.67
30 min	83.8	86	0.34
45 min	82	80.7	0.32
60 min	80.93	86	0.23
120min	82.1	89	0.11

There was slight decrease in SBP at 5 and 10min in group B

Table 4: Mean SBP in both groups

Intervals	**Mean SBP B**	**Mean SBP R**	**P value**
Baseline	128.1	128.9	0.41
5 min	118.1	122.46	0.02
10 min	110	118	0.002
15 min	117	120	0.52
30 min	122	125	0.15
45 min	123.2	123	0.12
60 min	123.3	122	0.87
120min	121	119.5	0.18

There was slight decrease in DBP at 10 and 15 min in group B

Table 5: Mean DBP in both group

Intervals	**Mean DBP B**	**Mean DBP R**	**P value**
Baseline	77.4	75.6	0.16
5 min	71.6	72	0.23
10 min	67.8	72.3	**0.003**
15 min	69.3	72	0.04
30 min	71.8	72.3	0.46
45 min	72.8	72.4	0.81
60 min	73.2	72.4	0.19

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120min	72.3	72.1	0.21

There was slight decrease in MAP at 10 and 15min in group B

Table 6: Mean MAP in both group

Intervals	Mean MAP B	Mean MAP R	P value
Baseline	94.5	109	0.14
5 min	102	103	0.61
10 min	98	109	**0.02**
15 min	98	105	0.045
30 min	104	109	0.21
45 min	91	105	0.81
60 min	104	107	0.18
120min	104	108	0.91

There was no decline in SPO2 in both groups- no significant difference

Table 7: SPO2 in both groups

Intervals	Mean SPO2 B	Mean SPO2 R	P value
Baseline	99.1	99.4	0.21
5 min	99.1	99.1	1
10 min	99	99	1
15 min	98.7	98.3	0.23
30 min	99.2	99.4	0.41
45 min	99	99.1	0.89
60 min	99.3	99.3	0.71
120min	99.5	99.5	0.2

DISCUSSION

Bupivacaine HCL (1-butyl-2', 6' pipecoloxylidide hydrochloride) is a long acting amide local anaesthetic. Due to its long-acting amide local anaesthetic properties, bupivacaine has been a commonly utilised medication in epidural anaesthesia. It is commercially available as a racemic combination with equal amounts of the S (-) and R (+) isomers. Despite being widely used, it has numerous of negative side effects, which includes undesired motor blockage, CNS, and cardiotoxicity.[5]

Ropivacaine is a new, long-lasting amide local anaesthetic that is structurally related to Bupivacaine and Mepivacaine's class of aminoamides.[6] Ropivacaine works by blocking the sodium and potassium ion channels in the dorsal horn of the spinal cord, which prevents the formation of action potentials. The spinal cord's calcium ion channel blockage limits nociceptive afferent neurons' ability to transmit electrical signals, producing the potent analgesic effect associated with centrally administered local anaesthetics.[7]

In present study, there was no significant difference between two groups in the time of onset of sensory block, time of onset of Motor block & two segment regression. There was a significant difference between two groups in duration of motor block (more in B group) & duration of analgesia (more in R group). Finucane *et al.*,[8] identified that the time of onset of sensory block was less in patients who received 0.75% ropivacaine compared to 0.5% bupivacaine.

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Brockway *et al.*,[9] identified that motor block caused by ropivacaine was gradual in onset. There was no significant difference in pulse rate and MAP in their study, which was in contrast to our study, where we found that ropivacaine is more hemodynamically stable. Concepcion[10] *identified that average* time for 2 segment regression was 164 ± 22 min in 0.75% ropivacaine group.

Brown *et al.*,[11] & Cekmen *et al.*,[12] found that the duration of motor block was more in 0.5% bupivacaine group compared to ropivacaine, which is in contrast to our study findings. Zaric *et al.*,[13] identified that motor block with 0.75% ropivacaine was almost similar and comparable to 0.5% bupivacaine. Various studies didn't demonstrate the difference in onset of sensory block between ropivacaine and bupivacaine.[14-17]

Dense motor block is desired during surgery, and a less intense motor block is needed for obstetric or for PO epidural analgesia. To produce more persistent anaesthesia and motor block, greater concentrations of 0.75% and 1% ropivacaine was produced. Raising the concentration of ropivacaine was not shown to alter the speed of onset of block but equal volume can provide profound motor block and increased duration of sensory block.[18]

We assessed the safety and efficacy of bupivacaine and ropivacaine among patients scheduled for lower limb and abdominal surgeries. The information obtained from this study would be handover to all stakeholders, which may significantly improve clinical outcomes and prevent complications. Limitations of our study were small sample size (n=60), indicating that the study sample was small, and the primary limitation was the interpretation of results. The study was done on patients aged 18-60 years of age only.

CONCLUSION

There was no difference in the onset of sensory and motor blocks between patients of bupivacaine and ropivacaine groups. But duration of motor block was more in Bupivacaine group and duration of analgesia were more in Ropivacaine group patients. This implies that Ropivacaine has more efficacy compared to Bupivacaine. We highly recommend the usage of Ropivacaine for epidural anaesthesia in patients undergoing lower abdominal and extremity surgeries.

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