COMPARISON OF ROPIVACAINE 0.75% AND BUPIVACAINE 0.5% FOR EPIDURAL ANAESTHESIA IN ELECTIVE LOWER LIMB AND LOWER ABDOMINAL SURGERIES

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ABSTRACT

BACKGROUND

Different local anaesthetics are used for epidural anaesthesia, most popular in India being lidocaine and bupivacaine. Bupivacaine is a longacting amide local anaesthetic, which is widely used for many years. However, it is associated with a number of side effects like Central Nervous System (CNS) toxicity and cardiotoxicity. Ropivacaine has been introduced recently in India and has been developed as a possible alternative to bupivacaine. It has a lower lipophilicity than bupivacaine and hence associated with a decreased potential for CNS and cardiotoxicity.

The aim of the study is to compare the time of onset of sensory and motor block, duration of sensory and motor blockade and also the haemodynamic changes produced by bupivacaine 0.5% and ropivacaine 0.75% for epidural in elective lower limb and lower abdominal surgeries.

MATERIALS AND METHODS

60 patients aged 18-55 yrs. scheduled for elective lower limb and lower abdominal surgeries belonging to ASA class I and II were given epidural anaesthesia using 15 mL of 0.5% bupivacaine (group B) and 15 mL of 0.75% ropivacaine (group R). Assessment of the sensory and motor blockade was done at intervals till maximum level achieved. Measurements of blood pressure, heart rate and arterial oxygen saturation were obtained at various time intervals. The total duration of the sensory blockade and motor blockade were also noted.

RESULTS

Our results showed no significant difference between the groups regarding sensory and motor onset time and time to attain and maximum level of sensory block. Our results also showed a significant difference in the intensity of motor blockade and the time to attain the maximum motor blockade, the total duration of analgesia and duration of motor blockade.

CONCLUSION

Hence, it is concluded that epidural ropivacaine 0.75% produces a more intense as well as prolonged motor blockade and prolonged sensory blockade than 0.5% bupivacaine. Epidural ropivacaine 0.75% can be a safe and effect alternative to bupivacaine 0.5% in lower limb and lower abdominal surgeries.

KEYWORDS

Epidural Anaesthesia; Ropivacaine 0.75%; Bupivacaine 0.5%; Lower Limb Surgeries; Lower Abdominal Surgeries; Sensory Blockade; Motor Blockade.

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BACKGROUND

Regional anaesthesia has the potential to provide excellent operating conditions and prolonged postoperative pain relief.[1] The epidural blockade is becoming one of the most useful and versatile procedures in modern anaesthesiology. It is more versatile than spinal anaesthesia giving the clinician the opportunity to-

1. Provide effective surgical anaesthesia and can meet the extended duration of surgical needs.
2. Provide prolonged postoperative analgesia.
3. Reduces the incidence of haemodynamic changes as a result of the sympathetic blockade as it produces segmental anaesthesia, unlike subarachnoid block anaesthesia.

Different local anaesthetics are used for epidural anaesthesia,[2] most popular in India being lidocaine and bupivacaine. Though long acting, the drawback of bupivacaine has increased incidence of fatal cardiac toxicity after accidental intravascular injection, because of narrow Cardiovascular Collapse/Central Nervous System toxicity (CC/CNS).[3] For this reason, there has been a search for

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alternative drugs with desirable blocking properties of bupivacaine, but with a greater margin of safety.

Ropivacaine is the newer long-acting amide local anaesthetic with all the advantages of bupivacaine, but with less cardiotoxicity.[4]

It has been found that lipid solubility of ropivacaine is 2.8 compared to 30 for bupivacaine.[5] Hence, it appears that ropivacaine may not produce an effective motor blockade in epidural anaesthesia. Reduced lipophilicity is also associated with decreased potential for CNS and cardiotoxicity.

Since, there is a controversy regarding the effectiveness of ropivacaine as a local anaesthetic for epidural anaesthesia and also ropivacaine being recently introduced in India as a local anaesthetic, it is felt that there is a need for a study to compare the most dependent and trusted epidural local anaesthetic bupivacaine with recently introduced ropivacaine.

The development of concept of Minimum Local Anaesthetic Concentration (MLAC) has suggested that ropivacaine is 40% less potent than bupivacaine with respect to sensory and motor block.[6]

Hence, it would be ideal to compare 0.5% bupivacaine with 0.75% ropivacaine as the equipotent concentration for epidural anaesthesia in lower limb and lower abdominal surgeries.

Hence, this study was undertaken to compare the effectiveness of 0.75% ropivacaine and 0.5% bupivacaine as local anaesthetics for epidural anaesthesia in elective lower limb and lower abdominal surgeries.

MATERIALS AND METHODS

A prospective randomised double-blind study entitled "Comparison of ropivacaine 0.75% and bupivacaine 0.5% for epidural anaesthesia in elective lower limb and lower abdominal surgeries" was undertaken in Santhiram Medical College and General Hospital, Nandyal, during the period between June 2016 and January 2017.

After obtaining institutional ethical committee approval and written informed consent, 60 patients belonging to ASA physical status I and II, aged between 18-55 years, belonging to either sex, undergoing elective lower limb and lower abdominal surgical procedures were selected for the study.

Exclusion Criteria

1. Patients belonging to ASA class III, IV and V.
2. Patients posted for emergency surgeries.
3. Pregnant patients.
4. Patients having raised ICP, severe hypovolaemia, bleeding coagulopathy and local infection.

All patients were of average Indian height and weight.

After a detailed preanaesthetic examination, an informed valid written consent was taken.

Patients were randomised into two groups, group 'R' (ropivacaine group) and group 'B' (bupivacaine group) by computer-generated random numbers after taking statistician's advice.

Group R (n=30) received 15 mL of 0.75% ropivacaine epidurally.

Group B (n=30) received 15 mL of 0.5% bupivacaine epidurally.

Premedication with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg was given orally the night before surgery. Patients were asked to maintain nil per oral status for at least 6 hrs.

In the operation theatre, baseline blood pressure and pulse rate were recorded. An 18G IV cannula was inserted and all patients were preloaded with 500 mL of Ringer lactate 30 mins. prior to the epidural procedure and premedicated with Inj. Midazolam 1 mg IV before the epidural block.

With the patients in sitting position under aseptic precautions, epidural space was identified by loss of resistance technique using 18G Tuohy needle via the midline approach at either L3-L4 or L2-L3 interspinous space.

An epidural catheter was threaded and fixed at 3 cms inside the epidural space. After negative aspiration for blood, 3 mL of lignocaine with 1:2,00,000 adrenaline test dose was administered to exclude intrathecal and intravascular placement of the needle. Then, after 3 mins., the study drug was injected incrementally over 2 mins.

The study drugs were prepared and given by another anaesthesiologist who is not involved in the study. Thus, the observer as well as the patients were blinded for the study drugs.

The following parameters were observed and recorded. Sensory blockade was assessed by pinprick method using a 27G hypodermic needle and onset of sensory block (time from epidural injection to loss of pinprick sensation at L1 level on the dependent side).

Highest dermatomal level blocked was assessed by pinprick method and was taken as the highest level of sensory blockade.

Time for maximum sensory blockade is defined as the time from the completion of injection of the study drug to the maximum sensory blockade attained and duration of analgesia is taken from the time of injection till the patient complains of pain at the site of surgery.

Degree of motor block was assessed using Modified Bromage scale[7] and graded as-

0- No motor paralysis.
1- Inability to raise extended leg, but can flex the knee.
2- Inability to flex knee, but can flex the ankle.
3- Inability to flex the ankle, but can move the toes.
4- Inability to move toes (total paralysis).

Time for the onset of motor block (time from epidural injection from the time Bromage grade 0 changed to grade 1) and time for maximum motor blockade (time from the completion of injection of study drug to the maximum motor blockade attained) were noted.

Duration of motor block was taken from the time of injection till the patient attains complete motor recovery (Bromage 0).

Measurements of blood pressure, heart rate, respiratory rate and oxygen saturation were obtained at 0, 2, 5, 10 mins. after epidural anaesthesia and every 10 mins. thereafter.

Patients were monitored for intraoperative events like hypotension, bradycardia, nausea and vomiting and followed up for 24 hrs. for any postoperative complications.

Bradycardia was treated with atropine 0.5 mg IV and hypotension with IV fluids and if needed mephentermine 3 mg (IV) given in increments.

The results of the study were statistically analysed between the two groups.

Statistical analysis was done using SPSS version 13.0.

The inferential statistics (test of significance) was done using Student's unpaired t-test, two-way repeated measure ANOVA and Chi-square test.

P-value is the probability rate at 0.05 level of significance for corresponding degree of freedom.

P >0.05 is not significant.

P <0.05 is significant.

P <0.01 is highly significant.

RESULTS

The patients in both groups were compared in respect to age, weight and height and it was found that there is no statistically significant difference with respect to age, weight, height and sex distribution (P>0.05). There is also no statistically significant difference with respect to the type of surgical procedure and mean duration of surgery between the two groups (p>0.05).

The onset, maximum level and duration of sensory and motor blockade and haemodynamic parameters were studied.

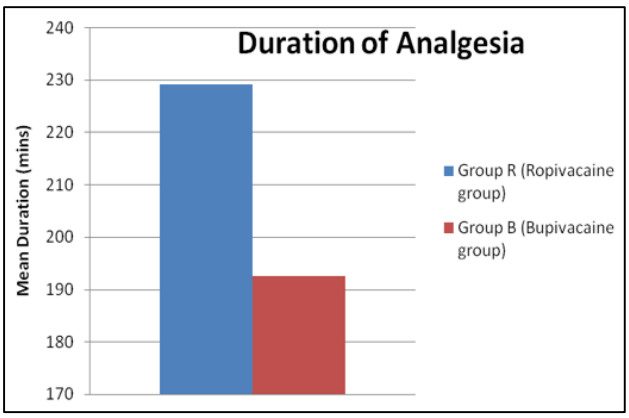
The following tables show the results obtained in the present study.

	Group R	Group B	P-value
Age (yrs.)	33.10 ± 8.34	34.47 ± 8.18	0.52 (NS)
Weigtht (kg)	60.83 ± 4.73	63.17 ± 6.80	0.13 (NS)
Height (cms)	168.10 ± 9.56	169.77 ± 6.92	0.44 (NS)
Sex (M/F)	25/5	26/4	0.48 (NS)
Duration of surgery (mins.)	98.17 ± 28.12	91.50 ± 23.09	0.32 (NS)

Table 1. Demographic Profile and Duration of Surgery in the Two Groups

	Group R	Group B	P-value
Sensory onset (mins.)	1.80 ± 1.42	1.63 ± 1.27	0.63
Max sensory level	T4 (4)	T4 (3)	0.3
Time for max sensory level (mins.)	23.87 ± 10.22	21.43 ± 7.39	0.29
Duration of analgesia (mins.)	229.0 ± 49.98	192.60 ± 29.83	0.001

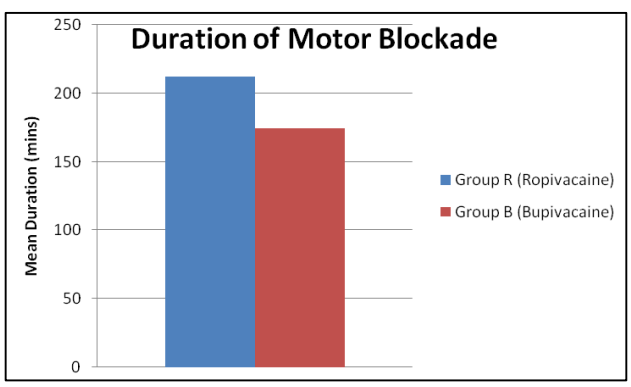
Table 2. Sensory Block



Graph 1. Duration of Analgesia

	Group R	Group B	P-value
Motor onset (mins.)	6.20 ± 3.83	5.47 ± 2.57	0.39
Max motor block	13 (Br 4)	4 (Br 4)	0.001
Time for max motor block (mins.)	31.80 ± 14.51	22.03 ± 9.29	0.002
Duration of motor block (mins.)	212.50 ± 55.95	174.40 ± 29.81	0.001

Table 3. Motor Block



Graph 2. Duration of Motor Blockade

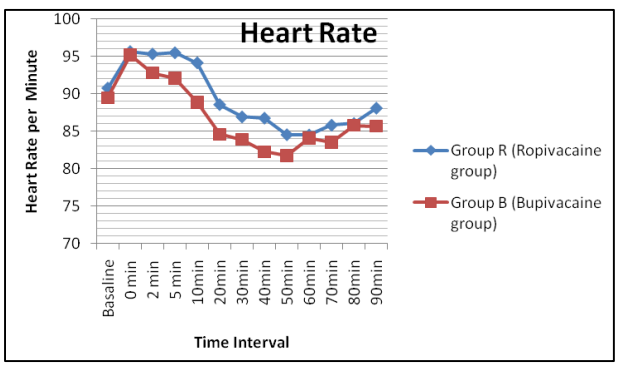
There was no statistically significant difference in the onset of sensory and motor block, maximum sensory level and the time taken to attain the same in both the groups.

13 patients in group R had grade 4 motor blockade compared with 4 patients in group B, which is statistically highly significant. The time taken to attain the maximum motor blockade was 31.80 ± 14.51 in group R and 22.03 ± 9.29 in group B. This is statistically highly significant.

The duration of motor blockade and analgesia in group R was 212.50 ± 55.95 and 229.0 ± 49.98, respectively, whereas the duration of motor block and analgesia in group B was 174.40 ± 29.8 and 192.60 ± 29.83, respectively. This is again statistically highly significant.

	Group R (ropivacaine group)	Group B (bupivacaine group)	p-value
Basal HR	90.77 ± 15.57	89.47 ± 15.35	0.746
HR - 0 min.	95.63 ± 13.29	95.20 ± 13.69	0.902
HR - 2 mins.	95.30 ± 11.90	92.80 ± 15.07	0.479
HR - 5 mins.	95.47 ± 12.80	92.07 ± 12.48	0.302
HR - 10 mins.	94.13 ± 13.88	88.83 ± 13.19	0.135
HR - 20 mins.	88.57 ± 10.55	84.57 ± 11.46	0.165
HR - 30 mins.	86.93 ± 13.35	83.87 ± 11.69	0.349
HR - 40 mins.	86.77 ± 12.47	82.23 ± 9.95	0.125
HR - 50 mins.	84.57 ± 13.34	81.70 ± 9.56	0.342
HR - 60 mins.	84.53 ± 12.26	84.07 ± 10.08	0.874
HR - 70 mins.	85.83 ± 12.82	83.52 ± 8.45	0.413
HR - 80 mins.	86.06 ± 14.06	85.76 ± 11.08	0.927
HR - 90 mins.	88.10 ± 13.74	85.66 ± 10.95	0.450

Table 4. Mean Heart Rate (BPM) at Various Time Intervels

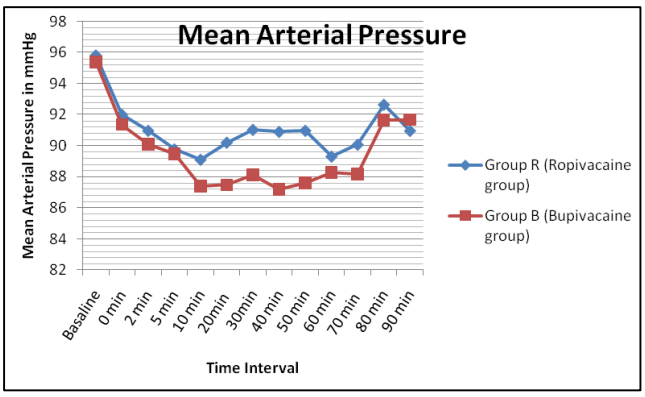


Graph 3. HR - Heart Rate/Min.

There is no statistically significant difference in the mean heart rate between groups at various intervels. None of the patients in both the groups developed bradycardia.

	Group R	Group B	p-value
	(Ropivacaine group)	(Bupivacaine group)	
Basal MAP	95.83 ± 10.71	95.40 ± 11.91	0.884
MAP-0 mins.	92.00 ± 13.51	91.37 ± 9.66	0.836
MAP - 2 mins.	90.97 ± 11.46	90.10 ± 10.72	0.762
MAP - 5 mins.	89.77 ± 10.51	89.50 ± 14.07	0.933
MAP - 10 mins.	89.10 ± 11.23	87.43 ± 9.90	0.544
MAP - 20 mins.	90.20 ± 13.38	87.50 ± 9.81	0.376
MAP - 30 mins.	91.03 ± 11.45	88.13 ± 10.04	0.301
MAP - 40 mins.	90.90 ± 12.68	87.20 ± 9.77	0.211
MAP - 50 mins.	90.97 ± 12.74	87.63 ± 8.64	0.24
MAP - 60 mins.	89.30 ± 11.96	88.31 ± 10.79	0.738
MAP - 70 mins.	90.07 ± 9.62	88.20 ± 10.92	0.484
MAP - 80 mins.	92.65 ± 11.37	91.67 ± 11.39	0.74
MAP - 90 mins.	90.96 ± 11.32	91.68 ± 10.92	0.803

Table 5. Mean MAP at Various Time Intervels in mmHg



Graph 4. MAP - Mean Arterial Pressure in mmHg

There is no statistically significant difference in mean arterial pressure between both the groups. 7 patients in group R and 4 patients in group B developed hypotension, which was treated with intravenous fluids and Inj. Mephenteramine.

3 patients in group R and 5 patients in group B required additional analgesics. No patients in either group had nausea and vomiting.

DISCUSSION

Epidural anaesthesia is a widely practiced regional anaesthesia technique for many lower limb and lower abdominal surgeries. Advantages of epidural over spinal anaesthesia is decreased frequency of hypotension, no limitation on duration of surgery and effective postoperative analgesia.

Bupivacaine is an excellent drug for epidural anaesthesia, but its major disadvantage is its cardiotoxicity when used in high volumes required for epidural block.

Ropivacaine (LEA-103) is a new longacting amino-amide local anaesthetic agent similar in structure to bupivacaine. Ropivacaine is prepared as the S-isomer rather than a racaemic mixture such as bupivacaine. Systemic toxicity of the S-isomer is less than that of racaemic preparations. Pharmacologic studies in isolated nerves and intact animals have indicated that ropivacaine possesses an anaesthetic profile similar to that of bupivacaine, but with less potential for cardiotoxicity than bupivacaine.[4]

The present study included 60 patients of ASA I and II, physical status aged between 18 to 55 years, undergoing various elective lower limb and lower abdominal surgeries were grouped randomly into either bupivacaine (B) group or ropivacaine (R) group of 30 each. 15 mL of the study drug was injected into the epidural catheter and various parameters were studied.

The hypothesis that was made before the study was that ropivacaine will produce less intense and shorter duration of motor blockade than bupivacaine as ropivacaine being less potent due to its lesser lipid solubility (2.8) compared to bupivacaine (30).

The development of Minimal Local Anaesthetic Concentration (MLAC) has suggested that ropivacaine is approximately 40% less potent than bupivacaine with

respect to sensory block and motor block and as such 0.5% bupivacaine will be equipotent with 0.75% ropivacaine.

Casati et al[8] in their study reported that patients receiving 0.5% ropivacaine more frequently had an inadequate motor blockade during surgery than those receiving bupivacaine 0.5%.

We also conducted a pilot study in 10 patients using ropivacaine 0.5% for epidural anaesthesia. Many of the patients had inadequate sensory and motor blockade. Hence, in our study, 0.75% ropivacaine was selected instead of 0.5% ropivacaine to be compared with 0.5% bupivacaine.

Demographic data comparing age, sex, weight, height and duration of surgery shows no statistically significant difference among both the groups.

Sensory Blockade

In our study, the mean time for onset of sensory block is 1.80 ± 1.42 mins. in group R and 1.63 ± 1.27 mins. in group B. There was no statistically significant difference in the onset of sensory blockade between the groups.

The studies conducted by Brockway et al[9] and David L Brown et al,[7] Jaffery A Katz et al[10] comparing bupivacaine and ropivacaine for epidural anaesthesia did not find any statistically significant difference in the onset of sensory block, which compares with our study.

In our study, the maximum level of sensory blockade was T4 (n=4) in group R and also in group B (n=3).

In the studies conducted by Thompson GE et al[11] and Wolff AP et al,[12] also the maximum level of sensory blockade achieved was T4 with 0.75% ropivacaine, which compares with our study.

In the studies conducted by Wolff et al,[12] Jaffery A Katz et al[10] and Bannister J et al,[13] the maximum level of sensory blockade with 0.5% bupivacaine was also T4, which again compares with our study.

The meantime for maximum sensory level in our study is 23.87 ± 10.22 mins. in ropivacaine group vs. 21.43 ± 7.39 mins. in bupivacaine group, which was statistically insignificant.

Our study agrees with the studies conducted by Jaffery A Katz et al,[10] Bannister J et al[13] and Dusanka Zaric et al,[14] where there was no statistically significant difference in the time taken for maximum sensory blockade between ropivacaine and bupivacaine.

Duration of analgesia in our study is longer with ropivacaine group compared with bupivacaine group. It is 229.0 ± 49.98 mins. with ropivacaine 0.75% vs. 192.60 ± 29.83 mins. with bupivacaine, which was statistically highly significant.

Our study concurs with the study conducted by J. Bannister et al[13] who observed the mean duration of analgesia to be 360 mins. with ropivacaine 0.75% and 300 mins. with bupivacaine 0.5%, which is highly significant.

The greater duration of analgesia with ropivacaine compared with bupivacaine could be due to higher concentration of ropivacaine used (0.75%). Many authors[13,12] have also found the reason for longer duration of analgesia to be due to the higher concentration of ropivacaine used.

Three patients in ropivacaine group required supplemental analgesics intraoperatively as they had inadequate block, whereas 5 patients in bupivacaine group required supplemental analgesics, which was statistically insignificant.

Motor Blockade

The onset of motor blockade was 6.20 ± 3.83 mins. in group R and 5.47 ± 2.57 mins. in group B, which is statistically insignificant.

In our study, motor blockade is checked by using modified Bromage scale and onset was taken as soon as the patient developed grade I motor blockade.

In a study conducted by Brockway MS et al,[9] the onset of motor block was 26 ± 25 mins. with ropivacaine 0.75% and 16 ± 9 mins. with bupivacaine 0.5%, which is statistically not significant as our study.

In our study, ropivacaine 0.75% produces more intense motor blockade than bupivacaine 0.5%. In ropivacaine group, number of patients with grade 4 motor blockade were 13 compared with only 4 patients in bupivacaine group, which is statistically highly significant.

The probable reason for more intense motor blockade with 0.75% ropivacaine compared with 0.5% bupivacaine is due to increased concentration of ropivacaine used. The same is felt by Brockway MS et al[9] that there was a tendency towards more intense motor block with increased concentration of the drug.

The maximum motor blockade attained with 0.5% bupivacaine in the studies conducted by Carpenter RL et al[15] and David L Brown et al[7] was 1 ± 1, Christelis N et al[6] is 2. Our study compares with the study conducted by Christelis N et al[6] as more number of patients had grade 2 motor blockade with bupivacaine 0.5%.

The mean time for maximum motor blockade in group R is 31.80 ± 14.51 and 22.03 ± 9.29 mins. in group B, which is statistically significant. This could possibly be due to more number of patients with maximum motor blockade of grade 2 in group B compared to grade 4 in group R. The time taken to attain grade 2 blockade will be shorter than to attain grade 4.

In the study conducted by Jaffery A Katz et al,[10] the time for maximum motor block with 0.75% ropivacaine was 47 ± 29 mins. and with 0.5% bupivacaine was 32 ± 17 mins., which concurs with our study.

Duration of motor blockade with ropivacaine 0.75% (212.50 ± 55.95 mins.) is more prolonged than with bupivacaine 0.5% (174.40 ± 29.81 mins.), which is statistically highly significant.

In the study conducted by Christelis J et al,[6] the mean duration of motor blockade was 237 ± 84 mins. in ropivacaine group and 144 ± 76 mins. in bupivacaine + fentanyl group. Our study concurs with this study.

The duration of motor blockade is more prolonged with ropivacaine 0.75% probably due to a 50% increase in the dose of ropivacaine compared to bupivacaine 0.5%. The

duration of motor block with 0.75% ropivacaine was 199 ± 15.4 mins. in the study conducted by Dusanka Zaric et al[14] 190 mins. in the study conducted by Brockway et al,[9] which compares with our study.

The duration of motor block with 0.5% bupivacaine in the study conducted by Brockway et al[9] was 194 mins., which corresponds with our study.

Haemodynamic Changes

There is no statistically significant difference in the heart rate between the two groups at various time intervals. No patients in either group developed significant bradycardia. The above result is consistent with the study conducted by Hans EM et al[16] wherein there was no statistically significant difference in the heart rate with bupivacaine 0.5%.

There was no statistically significant difference in SBP, DBP, MAP monitored at various intervals between the two groups as there was no statistically significant difference in the level of sensory block in both the groups.

However, 7 patients in group R and 4 patients in group B developed hypotension, which was treated with intravenous fluids and Inj. Mephentermine. Similar findings were also presented in the studies conducted by Wolff AP et al,[12] Christelis J et al[6] where more number of patients with 0.75% ropivacaine developed hypotension.

In the studies conducted by Brockway et al,[9] David L Brown et al[7] and Christelis J et al[6] no statistical significant difference was found in SBP, DBP, MAP in both the groups, which compares with our study.

Our study found no changes in the respiratory rates between the two groups, which corroborated with the other studies conducted by Brockway MS et al,[9] Katz et al,[10] Brown DL et al,[7] Finucane BT et al[5] and Wolff AP.[12]

In ropivacaine group, 7 patients had hypotension, no one had nausea and vomiting. In bupivacaine group, 4 patients had hypotension, no one had nausea and vomiting indicating no significant difference between the two groups with regard to these side effects.

Brockway MS et al[9] found similar number of side effects in each group, the commonest being backache (23%) followed by nausea (14%) and vomiting (2%).

CONCLUSION

From the present study, it can be concluded that epidural ropivacaine 0.75% produces a more intense as well as prolonged motor blockade and prolonged sensory blockade than 0.5% bupivacaine. Epidural ropivacaine 0.75% can be a safe and effective alternative to bupivacaine 0.5% in lower limb and lower abdominal surgeries.

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