COMPARISON OF 0.5% ROPIVACAINE WITH FENTANYL AND 0.5% BUPIVACAINE WITH FENTANYL FOR EPIDURAL ANAESTHESIA IN PATIENTS UNDERGOING LOWER ABDOMINAL AND LOWER EXTREMITY SURGERIES

Sreelakshmi Vangali[1], Sridevi Boddu[2], Seshaphani Udayagiri[3], Madusudhan Reddy Katha[4], Malleswari Rachamalla[5], Nagaraju Thalikota[6]

[1]Assistant Professor, Department of Anaesthesiology, Santhiram General Hospital and Medical College, Andhra Pradesh.
[2]Associate Professor, Department of Anaesthesiology, Santhiram General Hospital and Medical College, Andhra Pradesh.
[3]Professor and HOD, Department of Anaesthesiology, Santhiram General Hospital and Medical College, Andhra Pradesh.
[4]Professor, Department of Anaesthesiology, Santhiram General Hospital and Medical College, Andhra Pradesh.
[5]Associate Professor, Department of Anaesthesiology, Santhiram General Hospital and Medical College, Andhra Pradesh.
[6]Associate Professor, Department of Anaesthesiology, Santhiram General Hospital and Medical College, Andhra Pradesh.

ABSTRACT

BACKGROUND

Epidural anaesthesia with bupivacaine results in complete anaesthetic block of longer duration than ropivacaine. Fentanyl as an adjuvant may improve the quality of block of ropivacaine while maintaining its advantage of early motor recovery. In this study, we propose to compare the efficacy of epidural Ropivacaine-Fentanyl (RF) with Bupivacaine-Fentanyl (BF) for lower abdominal and lower extremity surgeries.

MATERIALS AND METHODS

60 patients were randomly allocated to receive either epidural 0.5% ropivacaine 20 mL plus 50 mcg fentanyl (group RF) or 0.5% bupivacaine 20 mL plus 50 mcg fentanyl (group BF). The onset, duration, spread of sensory and motor block, intensity of motor block, duration of analgesia, haemodynamic parameters and side effects were recorded. Statistical package for social sciences v20 software was used for statistical analysis.

RESULTS

The mean onset of sensory block to T10 dermatome was faster in group BF (8.6 ± 2.3 mins.) compared to group RF (11.5 ± 3.4 mins.). The time taken for maximum cephalad spread or time taken to reach highest sensory level and complete motor block was faster in group BF than group RF. Duration of analgesia (time for rescue analgesia) was comparable in both the groups (RF - 279.3 ± 37.3 mins. and BF - 288.5 ± 40 mins., not statistically significant). Two segment regression of sensory block was 151.7 ± 23.2 mins. in group RF and 142.8 ± 28.7 mins. in group BF, which is not statistically significant. The onset of grade I motor block was faster in group BF (8.43 ± 1.81 mins.) than group RF (14.03 ± 5.02 mins.). The mean duration of motor block was shorter in group RF 100.2 ± 26.9 mins. than group BF 147 ± 26.3 mins. The intensity of motor block achieved was more in group BF than group RF. The haemodynamic stability was better in group RF than group BF.

CONCLUSION

Epidural ropivacaine with fentanyl provided satisfactory block with better haemodynamic stability for major lower abdominal and lower extremity surgeries. It provided similar sensory block, but with a slower onset and motor block of slower onset, less intensity and shorter duration compared to bupivacaine with fentanyl, which is a desirable feature for early ambulation and shorter hospital stay.

KEYWORDS

Epidural Anaesthesia, Fentanyl, Ropivacaine 0.5%, Bupivacaine 0.5%, Lower Abdominal and Lower Extremity Surgeries.

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Corresponding Author:
Dr. Sreelakshmi Vangali,
W/o. Dr. P. Chakradhar,
House No. 4-819, Nandi Green Homes, Ramachandra Mission,
Kranthi Nagar, Nandyal-518502, Andhra Pradesh.
E-mail: srilu.puligunta@gmail.com
DOI: 10.18410/jebmh/2017/967

BACKGROUND

Regional anaesthesia is currently the most effective and convenient anaesthetic technique in patients undergoing lower body surgeries as it offers many advantages over GA. Epidural anaesthesia is preferred over spinal anaesthesia in major surgeries as it can be extended even into the postoperative period for better pain relief and allows early ambulation.

Lignocaine not only provides shorter duration of anaesthetic blockade, but can cause transient neurological symptoms and hence has been withdrawn from regional

anaesthesia in the recent past. However, bupivacaine produces profound motor blockade of longer duration and hence delays home discharge after surgery. In view of the wider application of regional anaesthetic procedures in modern anaesthesia practice, there is a need for local anaesthetic with desirable properties like longer duration of sensory blockade and shorter duration of motor block with better safety profile.

Ropivacaine, an amide local anaesthetic has been introduced recently and used successfully to provide epidural analgesia for patients in labour, cesarean delivery and postop analgesia. Intrathecally, it has been used for daycare procedures as it provides adequate sensory block with early motor recovery.[1,2]

Opioids are synergistic with local anaesthetics and intensify the sensory block without increasing sympathetic block while achieving satisfactory quality of epidural anaesthesia at a much lower dose of local anaesthetic.[3,4]

This prospective clinical study was conducted to compare the efficacy of ropivacaine with fentanyl versus bupivacaine with fentanyl in epidural anaesthesia for major lower abdominal and lower extremity surgeries.

MATERIALS AND METHODS

Source of Data- Sixty patients admitted in Santhiram General Hospital and Medical College, Nandyal, undergoing lower abdominal and lower extremity elective surgical procedure during 2015-16.

Inclusion Criteria

Patient belonging to ASA grade I and grade II patients between 18-60 years age; elective surgery for less than 3 hours duration.

Exclusion Criteria

Patient refusal; patient belonging to ASA grade III and grade IV; infection at the site of injection; coagulation abnormalities; hypersensitive to local anaesthetics or fentanyl; neurological or neuromuscular disease.

Preanaesthetic Examination and Preparation- Hospital Ethics Committee approved the protocol and ethical clearance certificate was obtained. Preanaesthetic checkup was done one day prior to the surgery. Patients were evaluated for any systemic disease and laboratory investigations recorded. Routine investigations like complete urine examination, complete blood picture, blood sugar, blood urea, serum creatinine, serum electrolytes, etc. ECG and chest x-ray in elderly patients and whenever indicated was undertaken to rule out the presence of systemic illness. The procedure of epidural block was explained to the patient and written informed consent was obtained. The patients were educated about the procedure of epidural analgesia, i.e. about the position, the technique, which is going to be performed, effects of the procedure and the parameters to be studied to gain the confidence and cooperation of the patients. All patients had intradermal sensitivity test, only those with normal response were included. Preparation of the patient included period of overnight fasting. Premedication was done with oral tablet alprazolam 0.25 mg and capsule omeprazole 20 mg.

Sixty patients were randomly allocated into two groups of thirty each by pre-decided randomisation schedule, group RF received epidural 20 mL of 0.5% ropivacaine plus fentanyl 50 mcg and group BF received 20 mL of bupivacaine 0.5% plus fentanyl 50 mcg epidurally.

Preparation of Operating Room- Anaesthesia machine/workstation was checked. Appropriate size endotracheal tube, working laryngoscopes, stylet and working suction apparatus were kept ready before the procedure. Emergency drug tray containing atropine, adrenaline, ephedrine, mephentermine, dopamine, hydrocortisone and antihistamines was kept ready.

On the day of surgery, preoperatively, pulse rate, blood pressure and respiratory rate were recorded in addition to height and weight of the patient. An IV access was secured with 18G IV cannula before the procedure and 500 mL of Ringer lactate was infused to preload the patient. The monitors connected to the patients included noninvasive BP, oxygen saturation using pulse oximeter and baseline PR, BP and SpO2 were recorded. Three lead ECG with standard lead II was used when necessary.

Epidural block was performed with the patient in sitting position under strict aseptic precautions. After infiltrating the skin with 2 cc of 1% lignocaine at L2-L3 or L3-L4 interspace, epidural block was given with 18G Tuohy needle using the standard midline approach. The epidural space was identified by "loss of resistance to air technique." 3 mL of local anaesthetic solution was injected as a test dose to rule out intrathecal infiltration. After waiting for three minutes, when subarachnoid injection was ruled out, 18G epidural catheter is threaded into the space, the Tuohy needle was withdrawn carefully so that 4 cm of the catheter was in the epidural space. The catheter was carefully taped over the back and patient was put in supine position. The remaining drug was injected carefully. 20 mL of test drug was administered over 2 mins. in increments after negative aspiration for blood and CSF. Time of completion of the injection of drug was recorded as 0 min. The height of block required was fixed uniformly as T6, though in most cases a lesser height was required. After epidural drug injection, data recording were performed during the first hour at 5, 10, 15, 30, 45 and 60 minutes and thereafter every half an hour upto three hours.

The following parameters were observed- Time of onset of sensory block at various dermatomal levels using pinprick, highest level of sensory block, time of onset of motor block, duration of analgesia, time to 2-segment regression of sensory block (duration of sensory block), duration of motor block, intensity of motor block, recording the blood pressure and pulse rate at various intervals, complications arising intraoperatively and postoperative complications up to 24 hours. The motor blockade was graded using the Bromage scale.

Grade 0- No paralysis (can fully flex the knees and feet).
Grade I- Inability to raise extended leg (able to move the feet only).

Grade II- Inability to flex knee (able to move the feet only).
Grade III- Inability to flex the ankle and digits (unable to move knees, feet).

Total duration of analgesia is taken as the time from the injection of drug to the first request for rescue analgesia.

Duration of sensory block is calculated with two dermatome regression from peak block height for each patient. Duration of motor block is calculated from onset of motor block to complete recovery from motor block. During surgery, all patients received oxygen (6 lit./min.) via Hudson mask. Any necessity of supplementation of anaesthesia was looked for in event of an inadequate block, patchy analgesia, etc. Episodes of changes in blood pressure more than 30% of baseline, pulse rate more than 20% of baseline were noted and treated with ephedrine IV and atropine 0.6 mg IV, respectively. Complications like nausea, vomiting, hypotension, bradycardia, dizziness, pruritus, convulsions, retention of urine, etc. were noted.

The intensity of pain was assessed using 10-point Visual Analogue Scale (VAS) where 0 indicated no pain, while 10 indicated unbearable distress. Quality of block was assessed using rating of comfort by the patients and additional medications received.

Excellent - No pain/discomfort.
Very good - Only mild discomfort, not requiring treatment.
Good - Pain/discomfort requiring further local anaesthetics.
Fair - Intravenous analgesic supplementation had to be given.
Poor - General anaesthetic had to be given.

Statistical Analysis- All the data was presented as mean ± standard deviation and number of patients. Statistical analysis was done using computer software package SPSS version for windows. The Student's t-test and Chi-square test were used to assess the statistical significance of the data as appropriate and a 'p' value <0.05 was considered significant.

RESULTS

The demographic data such as the ASA physical status, age, gender distribution, height and weight were comparable between the two groups (Table 1).

	Group RF	Group BF	P Value
No. of patients	30	30	
Male/female	18/12	16/14	
Age (years)	37.5 ± 10.15	38.2 ± 8.43	0.7724
Height (cm)	158.6 ± 6.42	159.6 ± 8.87	0.6306
Weight (kg)	58.8 ± 9.32	57.6 ± 7.50	0.5850

Table 1

Statistically not significant- p >0.05.

The various surgeries performed were appendicectomy, hernioplasty, hysterectomy, interlocking nailing of tibia and intramedullary nailing of femur. The average duration of surgery was comparable between the two groups. All patients were alert in operating room and able to respond to pinprick and motor block test.

The mean onset of sensory block to T10 dermatome was 11.50 ± 3.48 minutes in group RF and 8.6 ± 2.3 minutes in group BF, which was statistically significant (p=0.0003). The highest level of analgesia achieved was T4 in both group RF (5 out of 30) and group BF (5 out of 30), which was not statistically significant. The sensory level (maximal cephalad spread) was established after 21.4 ± 5.37 minutes in group RF and 15.6 ± 3.58 minutes in group BF, which was statistically significant (p <0.0001).

	Group RF	Group BF	P value	Significance (p<0.05)
Onset of sensory block (mins.)	11.5 ±3.48	8.6 ± 2.5	0.0003	S
Time for maximum cephalad spread	21.4 ± 5.37	15.6 ± 3.58	<0.0001	S
Duration of analgesia (mins.)	279.3 ± 37.3	288.5 ± 40.6	0.3661	NS
2-segment regression of sensory level in mins.	151.7 ± 23.2	142.8 ± 28.7	0.1948	NS
Onset of motor block (mins.)	14.03 ± 5.02	8.43 ± 1.81	<0.0001	S
Duration of motor block (mins.)	100.2 ± 26.9	147 ± 26.3	<0.0001	S

Table 2

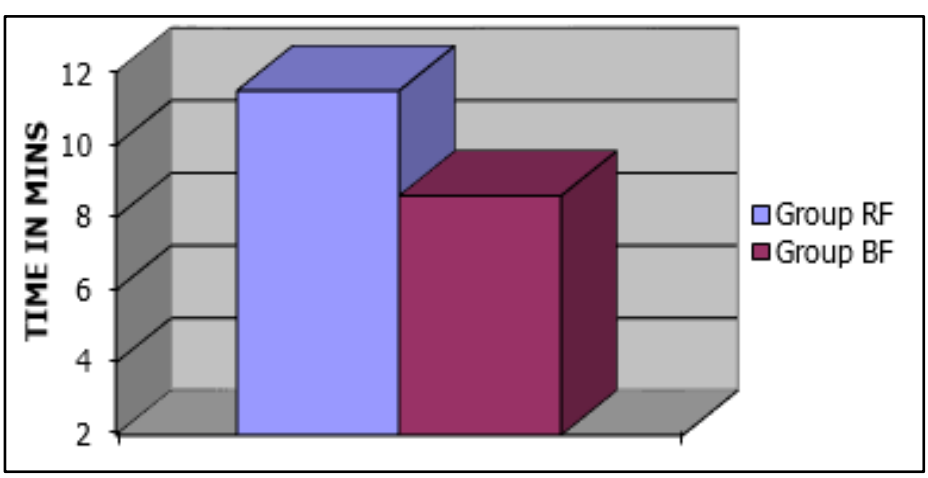

Figure 1. Mean Onset Time of Sensory Block

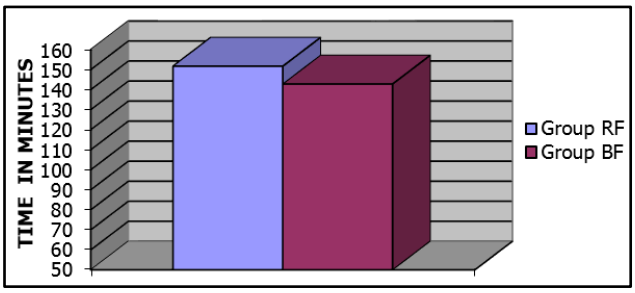

Figure 2. Two Segment Regression of Sensory Block

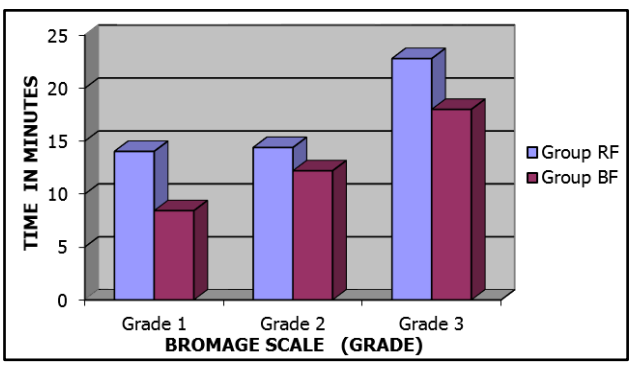

Figure 3. Onset of Motor Blockade

The mean duration of surgery lasted for 96.3 ± 31.9 mins. in group RF and 87.7 ± 41.0 mins. in group BF. The mean duration of analgesia was 279 ± 37.3 mins. in group RF compared to 288 ± 4.06 mins. in group BF p=0.3661, which was not statistically significant. Two-segment regression of the level of sensory block was 151.7 ± 23.2 minutes in group RF and 142.8 ± 28.7 mins. in group BF (p=0.1948), which was not statistically significant.

The onset of motor blockade was assessed using Bromage scale. In our study, the mean onset time was 14.03 ± 5.02 minutes (grade I), 14.4 ± 9.17 mins. (grade II), 22.85 ± 9.16 (grade III) for group RF; 8.43 ± 1.81 minutes (grade I), 12.2 ± 2.58 minutes (grade II) and 18 ± 7.64 minutes (grade III), respectively for group BF. 76.7% in group BF developed grade III motor block, while only 43.3% patients in group RF developed grade III motor block. The mean duration of motor block was 100.2 ± 26.9 minutes in group RF and 147 ± 26.3 minutes in group BF (P<0.0001).

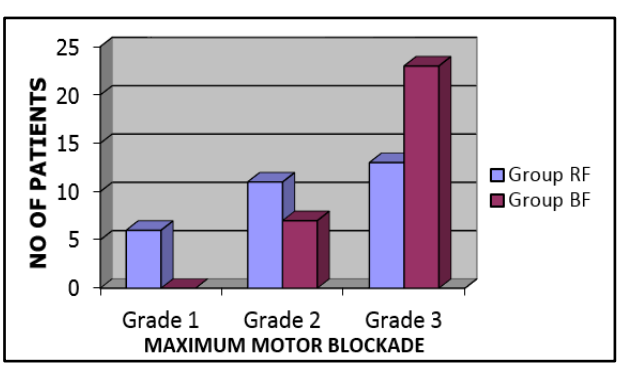

Figure 4. Maximum Motor Blockade

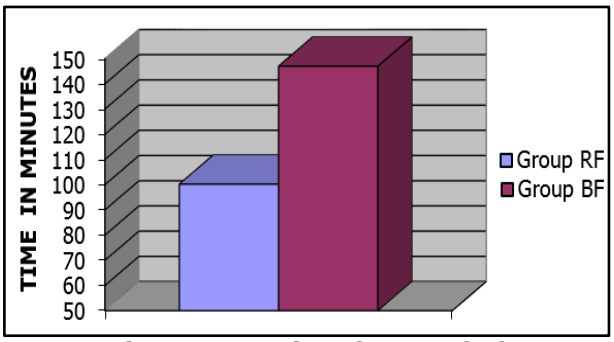

Figure 5. Duration of Motor Block

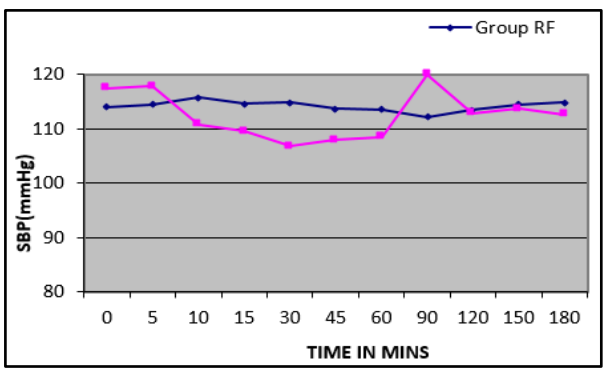

Figure 6. Changes in Systolic Blood Pressure

There was a statistically significant difference in systolic BP and diastolic BP measured at 30, 45 and 60 minutes intraoperatively. But, there was no significant difference in heart rate between the two groups. On comparison, it was seen that in group RF, the systolic and diastolic blood pressure was steady and regular, whereas in group BF, there was a sharp decline in blood pressure after 30 minutes of initiation of epidural anaesthesia.

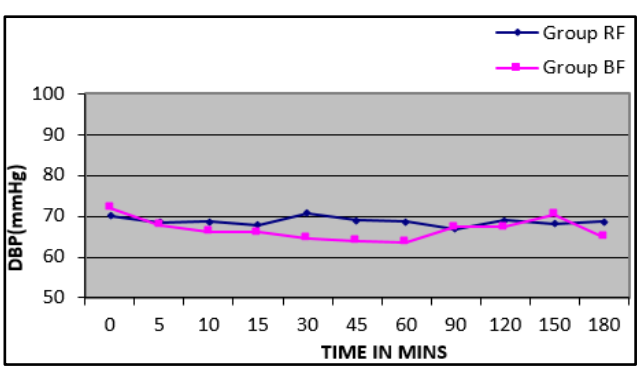

Figure 7. Changes in Diastolic Blood Pressure

Complications	Group RF		Group BF	
	No. of Patients	%	No. of Patients	%
Hypotension	1	3.3%	7	23.3%
Bradycardia	1	3.3%	4	13.3%
Nausea/vomiting	3	10%	3	10%
Pruritus	0		2	6.67%
Shivering	2	6.67%	2	6.67%

Table 3

The above table shows the complications in both the study groups. Group BF had more incidence of hypotension and bradycardia compared to group RF. Bradycardia was

treated with atropine 0.6 mg. Hypotension was treated with ephedrine IV, shivering was managed with warm fluids, oxygen and covering with blanket and verbal reassurance. Pruritus was mild and self-limiting. None of the study subjects developed respiratory depression or dizziness. Slightly more intravenous fluids were administered in group BF (1.82 ± 0.334 litres) compared to group RF (1.57 ± 0.173 litres), which was statistically significant (p=0.0006).

DISCUSSION

Epidural anaesthesia reduces perioperative physiologic responses to stress in addition to providing pain relief. Ropivacaine was identified in 1957, but not evaluated fully until 1988. Ropivacaine was registered for use in 1996,[1] but introduced in India only in 2009. When ropivacaine was first released, it was widely promoted as a potentially superior agent to bupivacaine because of lower toxicity profile and less motor blockade. Animal studies suggested that ropivacaine is less cardiotoxic than bupivacaine.[2] Ropivacaine produces fewer arrhythmias than bupivacaine and when given intravenously for the human volunteers, it was associated with less myocardial contractility and conductivity than bupivacaine.[5] In addition, early clinical studies in both obstetrics and non-obstetric patients showed both less intense and shorter lasting motor block with ropivacaine than with bupivacaine.[6,7,8]

In this study, both Ropivacaine-Fentanyl (RF) and Bupivacaine-Fentanyl (BF) produced effective epidural anaesthesia in patients undergoing lower abdominal and lower extremity surgeries.

In obstetric and non-obstetric patients, RF and BF in different concentrations and doses have been studied. Finucane et al[9] did a study to compare the effectiveness of 0.5% bupivacaine and 0.5% ropivacaine for epidural anaesthesia in abdominal hysterectomy surgeries. No significant differences were found between the two groups in duration of sensory block, but recovery from motor block was found to be more rapid in ropivacaine group.

In our study, patients who received 0.5% bupivacaine with fentanyl showed a faster onset of sensory block to T10 (8.6 ± 2.3 mins.) compared to ropivacaine with fentanyl group (11.5 ± 3.48 mins.) with significant 'p' value (0.0003), but the duration of analgesia and time to 2-segment regression were similar between the two groups. Brockway et al[7] in their study found that the onset time of analgesia/sensory block and duration of analgesia was similar in both ropivacaine and bupivacaine groups at equal concentrations, at all dermatomal levels, except at T10 level. In our study, we took the onset time for analgesia as the time taken to onset of sensory block at T10 dermatome. This might be the reason for the faster onset of sensory block in bupivacaine-fentanyl group compared to RF group in our study contrary to other studies.[10,6,8] Katz JA et al also found faster onset of sensory block and maximum cephalad spread with bupivacaine compared to ropivacaine.[11] The time for 2-segment regression of sensory level was longer (151.7 ± 23.2) for group RF compared to group BF (142.8 ± 28.7), but this was not statistically significant. The total duration of analgesia was also comparable between the two groups, group RF (279.3 ± 37.3) and group BF (288.5 ± 40.6). Several studies have demonstrated a longer duration of sensory block with bupivacaine than with ropivacaine.[10,12] But, our study confirmed the results of other workers that in equal doses and concentrations, the profile of sensory block is the same for ropivacaine and bupivacaine.[6-8]

The median maximum cephalad spread was T8 in both the groups. Our data also showed that the onset of motor blockade was faster with greater intensity and longer duration of block in BF group compared to RF group.[12,7,8] However, other studies by Brown DL et al, Griffin et al,[10,6,8] have found no difference in onset time of motor block between the two groups, while studies by Kerkkamp et al[12] showed a less intense motor block with a shorter duration in ropivacaine group with no difference in onset time. However, our study, confirmed the results of Brockway et al.[7]

The pain relief was assessed by using standardised Visual Analogue Score (VAS). Patients were asked to evaluate pain on VAS (VAS0 = no pain; VAS100 = worst possible pain). Wide variations in pain scores were seen throughout the study period. Quality of block was assessed by rating of comfort by the patients and there was no statistically significant difference between the two groups in contrary to other studies with ropivacaine and bupivacaine alone,[13,7] where 0.5% ropivacaine group had more unsatisfactory blocks. This might be due to the addition of 50 mcg of fentanyl epidurally to both the groups. Fentanyl as an adjuvant to local anaesthetic, in regional anaesthesia, reduces the need for supplementary intraoperative analgesics and prolongs the duration of postop analgesia without any effect on the quality of motor block.[3,4]

The intensity of hypotension and bradycardia are slightly more in group BF compared to that of group RF. Also, slightly more intravenous fluid was administered in group BF compared to that group RF (P<0.0006). This can be explained by the lesser myocardial depressant effects of ropivacaine compared to bupivacaine. Two patients in group RF complained of pruritus, but it was mild and self-limiting. There was statistically significant drop in the systolic blood pressure and diastolic blood pressure at 30, 45 and 60 minutes after injection of drugs in the bupivacaine-fentanyl group. There was no significant difference in the heart rate changes between the two groups.[12,14]

In our study, we used equal doses of ropivacaine and bupivacaine. There were no significant difference in the characteristics of sensory block (except for onset time and time of maximum cephalad spread), but motor block was of slower onset, less intensity and shorter duration. Our findings are explained by a greater degree of differential sensory-motor block and less lipophilic property of ropivacaine as suggested by early studies.[15]

No symptoms and signs of toxicity were seen in any of the study groups. The incidence of side effects like shivering, pruritus, nausea, vomiting, sedation, etc. were comparable in both the groups.[3,4]

CONCLUSION

Both Ropivacaine-Fentanyl (RF) and Bupivacaine-Fentanyl (BF) provides equal quality of sensory block for lower abdominal and lower extremity surgeries, but RF is associated with better haemodynamic stability and early recovery of motor power. Hence, RF maybe preferred over BF in daycare surgeries to facilitate early ambulation of patients in postop period and decrease the duration of hospital stay.

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