

Comparison of Epidural Analgesia using 0.25% Bupivacaine and 0.2% Ropivacaine for the Management of Postoperative Pain in Gastrointestinal Surgeries

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Abstract:

Background: Epidural analgesia, especially thoracic epidural analgesia (TEA), has been used extensively for a wide variety of GI surgeries. The degree to which the GI tract is affected by regional anesthesia depends on the type and extent of the block. Epidural analgesia not only enhances post operative recovery, minimizes pain & faster mobilization of the patient but also decreases opioid requirements and reduces postoperative ileus.^[1] The favorable physiologic effects on the respiratory and cardiovascular systems by epidural analgesia may serve as yet another reason as to why epidural analgesia is a devoted part of ERAS protocols. Local anaesthetic drugs like bupivacaine & ropivacaine have widely been used in epidural anaesthesia in recent era.

Aims and Objectives: To compare the efficacy of analgesic effect of epidural 0.25% bupivacaine and 0.2% ropivacaine in patients who have undergone gastrointestinal surgeries in the postoperative period.

Methods: A total of 60 adult patients of either sex of ASA physical status I and II, aged 20-60 years, undergoing gastrointestinal surgeries were enrolled into the study. Patients were randomly divided into two groups of 30 each:

Group B-received 10 cc of 0.25% Bupivacaine as epidural dose & Group R-received 10 cc of 0.2% Ropivacaine as epidural dose in the postoperative period. Onset of pain relief, duration of analgesia & requirement of rescue analgesia using epidural bolus as top up doses were noted. Incidence of motor blockade, VAS scores, hemodynamic parameters & adverse events were also noted.

Result: Time of onset of sensory analgesia (Group B 12.12±2.10 in mins. vs. Group R 11.74±1.55 in mins. P value:0.55) and duration of sensory analgesia (Group B 175.55±23.18 in mins. vs. Group R 170.42±20.25 in mins. P value:0.61) were comparable between both the groups. Total epidural dose requirement (Group B 34.22±3.22 in ml vs. Group R 32.20±2.40 in ml P value: 0.18) and the mean number of epidural top-up doses(Group B 4.45±0.35 vs Group R 4.00±0.25 P value: 0.24) required for epidural analgesia in the first 12 h of postoperative period between Group B and Group R were comparable and statistically not significant. Six patients (20%) in Group B showed motor blockade of Bromage-I whereas no incidence of motor blockade was reported in Group R. Postoperative hemodynamic parameters and VAS scores were comparable between the two groups for the first 12 hours of postoperative period. The observed side effects included bradycardia, nausea and vomiting, and shivering were comparable between the two groups. However, incidence of hypotension was slightly higher in Group B compared to Group R (26.6% vs 13.3%).

Conclusion: 0.2% Ropivacaine as local anaesthetic is a suitable alternative drug to 0.25% Bupivacaine for epidural analgesia in patients who have undergone gastrointestinal surgical procedures in the postoperative period as it not only provides good quality analgesia but also enhances early mobilisation and postoperative recovery of the patients.

Keywords: Bupivacaine, Ropivacaine, Epidural analgesia.

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Introduction

Epidural block with deposition of local anesthetic within the epidural space results in blockade of the afferent and efferent sympathetic-mediated GI reflexes, but parasympathetic innervation is left intact. The effect of an imbalanced sympathetic and parasympathetic nervous system has been associated with improved GI blood flow and anastomotic mucosal perfusion. This controls pain and decreases the need for opioids. [4-8] The early postoperative period after GI surgery is characterized by a systemic stress response and catabolic activity. This effect, in conjunction with a lack of nutrition, results in postoperative weakness and muscle wasting. Epidural analgesia has been shown to decrease opioid requirements and reduce postoperative ileus. This, in turn, enhances enteral feeding [1]. Avoiding systemic opioids and the use of epidural analgesia helps to reduce the incidence of nausea and vomiting.

Bupivacaine & Ropivacaine are commonly used local anesthetic drugs in epidural anaesthesia. Ropivacaine is a long-acting regional anaesthetic that is structurally related to Bupivacaine. It is a pure S (-)-enantiomer, unlike Bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. [9]

Ropivacaine has a few properties that make it unique. Ropivacaine is less lipophilic compared to other local anaesthetics, such as bupivacaine, and is less likely to penetrate large myelinated motor fibers. It, therefore, selectively acts on the nociceptive A, B, and C fibers over the AB (motor) fibers. Ropivacaine is also manufactured as a pure S(-) enantiomer; the S(-) enantiomer has significantly less cardiotoxicity and neurotoxicity. [10,11]

Aim: To compare the onset & duration of analgesia of epidural 0.25% bupivacaine and 0.2% ropivacaine in patients who have undergone gastrointestinal surgeries in the postoperative period.

Materials and Methods

This is a prospective randomized double-blind study was conducted in the Department of Anaesthesia, over a period of 1 year. Present study was conducted amongst 60 American Society of Anaesthesiologist (ASA) status I-II patients of either sex in age group of 20-60 years coming to hospital for gastrointestinal surgeries.

Inclusion Criteria

1. Either gender patients in age group of 20-60 years.
2. Patients classified as ASA grade I-II.
3. Patients who gave consent to participate in study.

Exclusion Criteria

1. Patients with severe systemic disease, metabolic disorder, neurological, congenital or cardiovascular disease
2. Patients with coagulation disorders.
3. Local sepsis at site of epidural insertion.
4. Patients allergic to local anesthetics.
5. Patients' refusal for epidural anaesthesia.

Group B-received 10 cc of 0.25% Bupivacaine as epidural dose & Group R-received 10 cc of 0.2% Ropivacaine as epidural dose in the postoperative period.

Pre-anesthetic evaluation:

All patients were thoroughly examined and assessed pre-operatively for any cardiovascular, respiratory or any other systemic illness.

All the patients had the following investigations done.

- a. Haemoglobin percentage
- b. Urine examination for albumin and sugar
- c. Bleeding time and clotting time
- d. Blood sugar
- e. Blood urea
- f. Serum creatinine
- g. Serum electrolytes
- h. HIV and HBSAG

Chest X-ray and electrocardiogram were taken when required.

The patients were explained about the epidural technique with catheter in situ and its advantages and disadvantages. Grading of post operative pain was done using Visual analog Scale (VAS). The patient would be asked to quantify their pain using VAS pain scale, giving a score of 0 to 10, with 0 indicating no pain and 10 indicating the worst possible pain.

Written informed consent was obtained. All patients received premedication at 10p.m on the night before surgery with Tab. Alprazolam 0.25mg and Tab. Ranitidine 150mg and thereafter advised nil per oral.

Anaesthesia

On the day of surgery patients were shifted to the operating room, and multiparameter monitors were connected. The base line heart rate, SpO₂ and blood pressure (systolic, diastolic and MAP) were recorded. An 18G iv cannula was inserted and patients were put on Ringer lactate crystalloid infusion prior to surgery. The anaesthesia machine, airway equipment's and emergency drugs were kept ready.

Patients were positioned in right lateral decubitus posture. Observing sterile precautions T10-T11 space was identified. Skin was infiltrated with local

anaesthetic inj. 2% lignocaine 2ml. Epidural space was identified with an 18G Tuohy's needle, by using loss of resistance to air technique and a 19G epidural catheter was inserted about 5cms into the epidural space and secured in place. Throughout the procedure patient's vitals were monitored. A test dose of 3ml of 1.5% lignocaine with adrenaline (1:2,00,000) was given to rule out intravascular or intrathecal placement of the catheter. The patient was made to lie supine. Post the placement of epidural catheter general anaesthesia was performed to the patient. Inj Fentanyl 1mcg/kg and Glycopyrrolate 0.2 mg iv were given to all patient 5 minutes prior to the administration of induction agent. All the patients were preoxygenated with 100% oxygen for 5 minutes. All were induced with inj propofol 2-3mg/kg. Succinylcholine 1.5 mg/kg was given before intubation. After the airway was secured, anesthesia was maintained using oxygen and sevoflurane 1-2% and atracurium 0.5mg/kg intravenously. After the completion of surgery, the neuromuscular block was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.005mg/kg intravenously and patient was extubated subsequently. After extubation patients were randomly divided into two groups of 30 each:

Group B-received 10 cc 0.25% Bupivacaine as epidural dose & Group R-received 10cc 0.2% Ropivacaine as epidural dose in the postoperative period.

Fluid management: The patients were infused and maintained with crystalloids and colloids. Blood was transfused only when indicated.

The following observations were made in postoperative period:

1. Onset of sensory analgesia
2. Duration of sensory analgesia
3. VAS scores between the two groups.
4. BP monitoring (NIBP).
5. Heart rate (HR).
6. Total epidural dose requirement for 12 h post-operatively was noted.
7. Complications or side-effects if any.
8. Incidence of motor blockade after each epidural top-up bolus dose.

Onset of Sensory Analgesia

The onset of sensory analgesia was the time taken for the relief of pain with VAS score to become <4.

Duration of Sensory Analgesia

The time interval between onset of sensory analgesia (VAS score <4), till patient complained of pain (VAS score >5) when rescue epidural bolus was given as top up dose.

Incidence of Motor Blockade was noted if the patient developed modified Bromage scale grade 1 motor blockade after the completion of the injection of study drug. This was done using a modified Bromage score.

- Bromage 0: The patient can move the hip, knee, and ankle.
- Bromage 1: The patient is unable to move the hip but able to move the knee and ankle.
- Bromage 2: The patient is unable to move hip and knee but able to move the ankle.
- Bromage 3: The patient is unable to move hip, knee, and ankle.

During postoperative period, NIBP, HR, RR, and SpO₂ were recorded after activating epidural anaesthesia.

In the post-operative period, when the patients first complained of pain, intensity of pain was assessed using VAS scale. When the VAS score was >5, 8cc of the study drug i.e., either 0.25% Bupivacaine or 0.2% Ropivacaine was given as epidural bolus as top up dose intermittently up to 12 hrs in the postoperative period.

The intensity of pain and pain relief was assessed using VAS at 15 mins., 30 mins. followed by every hourly at 1 hr., 2hrs. up to 12 hrs postoperatively.

VAS consisted of a 10 cm line, marked at 1 cm each on which the patient makes a mark on the line that represents the intensity of pain he/she was experiencing. Mark "0" represents no pain and mark "10" represents worst possible pain. The numbers marked by the patient was taken as units of pain intensity.

Bradycardia was defined as fall of HR by 20% from the basal HR.

Hypotension was defined as a fall of systolic BP by 20% from basal systolic BP.

Statistical Analysis

After completion of the study, the results were compiled and statistically analysed using Chi Square test for non-parametric data and ANOVA for parametric data. Post HOC students paired t test was applied wherever indicated using SSPS 22.0 software. We have used means and standard deviations to represent the average and typical spread of values of variables and median to represent various scores. p value of less than 0.05 was considered significant and less than 0.001 as highly significant.

Results

Study of 60 patients was completed successfully.

Table 1: Comparison of demographic data and baseline parameters between the two groups [mean \pm SD]:

Parameters	Group B	Group R	p value
Age (in years)	45.21 \pm 11.20	46.28 \pm 41.25	0.77
Weight(kgs)	65.34 \pm 8.89	64.72 \pm 7.20	0.54
Sex	Male (n)	20	0.90
	Female (n)	10	
Baseline HR (in bpm)	75.24 \pm 5.12	77.25 \pm 7.75	0.38
Mean SBP (mmHg)	130 \pm 12.5	127 \pm 12.8	0.20
Mean DBP (mmHg)	80 \pm 5.8	79 \pm 7.9	0.12

The demographic data and baseline parameters were comparable between both the groups.

Table 2: Comparison of postoperative analgesia between the two groups [mean \pm SD]:

Parameters	Group B	Group R	P value
Time of onset of sensory analgesia in mins.	12.12 \pm 2.10	11.74 \pm 1.55	0.55
Duration of sensory analgesia in mins.	175.55 \pm 23.18	170.42 \pm 20.25	0.61

Time of onset of sensory analgesia (Group B 12.12 \pm 2.10 in mins. Vs. Group R 11.74 \pm 1.55 in mins.) and Duration of sensory analgesia (Group B 175.55 \pm 23.18 in mins. Vs. Group R 170.42 \pm 20.25 in mins.) were comparable between both the groups.

Table 3: Comparison of total number and volume of epidural bolus doses (top-up) between the two groups for the first 12 hours in postoperative period [mean \pm SD]:

Parameters	Group B	Group R	P value
Total number of epidural bolus doses	4.45 \pm 0.35	4.00 \pm 0.25	0.24
Total Volume of Epidural Drug(mL)	34.22 \pm 3.22	32.20 \pm 2.40	0.18

Total epidural dose requirement and the mean number of epidural top-ups required for epidural analgesia for the first 12 hrs. in the postoperative period between Group B and Group R were comparable and statistically not significant.

Table 4: Comparison of mean VAS scores between the two groups for the first 12 hours in the postoperative period [mean \pm SD]:

Time	Group B	Group R	P value
15 mins	2.35 \pm 0.30	2.65 \pm 0.50	0.45
30 mins	1.95 \pm 0.40	1.85 \pm 0.24	0.72
1 st hour	1.45 \pm 0.21	1.23 \pm 0.15	0.66
2 nd hour	2.25 \pm 0.55	1.95 \pm 0.35	0.54
3 rd hour	1.82 \pm 0.42	1.65 \pm 0.15	0.89
4 th hour	1.55 \pm 0.35	1.38 \pm 0.65	0.66
5 th hour	1.65 \pm 0.34	1.45 \pm 0.65	0.54
6 th hour	1.45 \pm 0.25	1.25 \pm 0.50	0.35
8 th hour	1.10 \pm 0.15	0.95 \pm 0.12	0.24
10 th hour	0.9 \pm 0.10	0.85 \pm 0.12	0.90
12 th hour	1.10 \pm 0.3	1.12 \pm 0.10	0.95

VAS scores for the first 12 hours in the postoperative period were comparable between both the groups and statistically not significant.

Table 5: Comparison of Hemodynamic parameters of the two groups postoperatively for the first 12 hours in the postoperative period [mean \pm SD]:

	Group B	Group R	P value
Mean HR (beats/min)	85 \pm 7.38	82 \pm 6.55	0.35
Mean SBP (mmHg)	134 \pm 10.4	132 \pm 12.5	0.65
Mean DBP (mmHg)	81 \pm 7.5	80 \pm 7.4	0.25
Mean MAP(mmHg)	95 \pm 4.12	92 \pm 65	0.35

Hemodynamic parameters of the two groups postoperatively for the first 12 hours were comparable and statistically not significant.

Table 6: Comparison of incidence of motor blockade between the two groups:

	Group B	Group R	P value
Present	6	0	<0.05
Absent	24	30	

Six patients (20%) in Group B showed motor blockade whereas no incidence of motor blockade was reported in Group R. The motor blockade here corresponded to Bromage-I.

Table 7: Comparison of side effects between the two groups:

Parameters	Group B		Group R		p value
	No.	%	No.	%	
Bradycardia	2	6.6%	1	3.3%	0.65
Hypotension	8	26.6%	4	13.3%	
Nausea & Vomiting	2	6.6%	2	6.6%	
Shivering	2	6.6%	2	6.6%	

The observed side effects included bradycardia, nausea and vomiting, and shivering were comparable between the two groups. However, incidence of hypotension was slightly higher in Group B compared to Group R (26.6% vs 13.3%). (Table 7).

Discussion

Visceral pain blocks are usually associated with somatosensory pain controls using central neuraxial regional anaesthesia techniques, such as epidural analgesia. With respect to pain management, thoracic epidural analgesia is a highly effective means of pain control for patients who have undergone laparotomy based gastrointestinal surgeries.

In clinical studies comparing potencies of ropivacaine and bupivacaine administered for epidural block the anesthetic profiles of the drugs were almost identical. [12]

In this study we compared the efficacy of analgesic effect of epidural 0.25% bupivacaine and 0.2% ropivacaine in patients who have undergone gastrointestinal surgeries in the postoperative period.

Time of onset of sensory analgesia (Group B 12.12±2.10 in mins. vs Group R 11.74±1.55 in mins. P value: 0.55) was comparable between both the groups. This observation was similar to studies done by McCrae *et al.* [13] and Brockway *et al.* [14] who compared different concentrations of ropivacaine and bupivacaine administered extradurally. Fernandez *et al* compared 0.0625% bupivacaine with 0.1% ropivacaine with fentanyl. There was no significant difference between two groups with respect to onset of pain relief. [15]

Duration of sensory analgesia (Group B 175.55±23.18 in mins vs. Group R 170.42±20.25 in mins P value: 0.61) was comparable and statistically not significant between the two groups. Korula *et al.* [16] compared the clinical efficacy of the equipotent doses of ropivacaine 0.75% and bupivacaine 0.125% for epidural anaesthesia and ropivacaine 0.2% and bupivacaine 0.125% for postoperative analgesia in patients undergoing bilateral mesh hernioplasty where it was found that the sensory blockade achieved in both the groups were similar which was similar to our study. Our

results can also be compared to the study done by Brockway *et al.*[14] which showed comparable duration of epidural analgesia when used at equal concentration and dosage.

Total epidural dose requirement (Group B 34.22±3.22 in ml vs Group R 32.20±2.40 in ml P value: 0.18) and the mean number of epidural top-ups(Group B 4.45±0.35 vs Group R 4.00±0.25 P value: 0.24) required for epidural analgesia for the first 12 h in the postoperative period between Group B and Group R were comparable and statistically not significant. Our study was comparable to study done by Meister *et al* who compared 0.125% bupivacaine and 0.125% ropivacaine with fentanyl. [17]

Six patients (20%) in Group B showed motor blockade of Bromage-1 whereas no incidence of motor blockade was reported in Group R which were similar to studies done by Muldoon *et al.* [18] and Korula *et al* [16]. This is probably because Ropivacaine being less lipophilic than Bupivacaine penetrates less into myelin sheaths of large A fibers (Aβ) that transmit motor impulses.

Postoperative hemodynamic parameters and VAS scores were comparable between the two groups for the first 12 hours of postoperative period.. Side effects included bradycardia, nausea and vomiting, and shivering were comparable between the two groups. However incidence of hypotension was slightly higher in Group B compared to Group R(26.6% vs 13.3%).

Conclusion

To conclude, both 0.25% Bupivacaine and 0.2 % Ropivacaine provided good quality postoperative analgesia in patients who have undergone gastrointestinal surgical procedures with comparable sensory blockade parameters & requirement of postoperative epidural bolus doses as top ups. Both the groups had similar mean VAS scores and comparable hemodynamic parameters postoperatively. However, Ropivacaine group didn't show incidence of motor blockade whereas six patients (20%) in Bupivacaine group showed motor blockade of Bromage-1. Henceforth we conclude Ropivacaine is a good alternative local anaesthetic to Bupivacaine that can be used for

epidural analgesia in patients who have undergone gastrointestinal surgical procedures in the postoperative period as it not only provides good quality analgesia to patients but also doesn't affect the motor function thereby helping in early ambulation and postoperative recovery of the patients.

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