A Clinical Study about the Efficacy of Epidural Ropivacaine 0.75% and Bupivacaine 0.5% in Lower Abdominal and Lower Limb Surgeries

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Abstract: <u>Background</u>: A prospective randomized clinical study was conducted to study the efficacy of ropivacaine and bupivacaine epidurally for lower abdominal and lower limb surgeries. <u>Methods</u>: 100 patients aged between 18 to 70 years were randomized into two groups. n = 50 in each group. Group A received 20ml of 0.75% Ropivacaine and Group B 20ml of 0.5% Bupivacaine. epidural anesthesia procedure was standardized. onset of sensory and motor blockade, statistical comparison of onset of sensory and motor blockade, Degree of motor blockade, Bromage scale was compared between the two groups. <u>Results</u>: Onset and regression of sensory blockade with ropivacaine & bupivacaine. This was not clinically significant with p value of 0.9188. onset of motor blockade in bupivacaine group was faster with a p value of 0.0001 which was statistically significant. Degree of motor blockade was denser in group B than group R. Hemodynamic changes at various time intervals were similar in both groups B and R. <u>Conclusion</u>: Hence This study concludes that the onset of sensory blockade was similar in both. onset of motor blockade was delayed in Ropivacaine. The degree of motor blockade was much denser in Bupivacaine. Cardiovascular stability was observed more with Ropivacaine.

Keywords: epidural bupivacaine & ropivacaine, lower abdominal, lower limb surgeries.

1. Introduction

- Regional anaesthesia has come to occupy an important part in clinical anaesthesiology today. As with other fields, regional anaesthesia too has undergone major developments both in techniques and drug availability.
- Epidural anesthesia is a technique for perioperative pain management with multiple applications in anesthesiology. It is useful as a primary anesthetic, but most commonly, it is used as a pain management adjuvant.
- It can be a single shot or a continuous infusion for long term pain relief which holds advantage over spinal anaesthesia as the latter is only a single shot technique.
- Aside from the benefit of potentially providing excellent analgesia, its use reduces the exposure to other anesthetics and analgesics and opioids, decreasing side effects.
- It has also shown to decrease cortisol levels, expedite the return of bowel function, decrease the incidence of pulmonary embolism and deep vein thrombosis in the postoperative period, and shorten lengths of in hospital stay. [1] [2] [3]. The incidence of postoperative respiratory problems and chest infections is reduced.
- Historically Bupivacaine was used clinically as it had a long duration of action. Subsequently it was found that propyl derivatives of pipecoloxylidide were less toxic than butyl derivatives (Bupivacaine).
- The recognition of acute life threatening cardiotoxicity of bupivacaine [4, 5] led to the search for a local anaesthetic agent comparable with bupivacaine but with lower cardiotoxicity resulting in development of a relatively new amide, ropivacaine, registered for use in 1996, [4] but introduced in India only in 2009. Ropivacaine is a long - acting local 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 profiles. Cardiotoxicity of Ropivacaine is less than Bupivacaine as it causes lesser depression of cardiac contractility [6].

• The present clinical study was designed to audit the efficacy of 0.75% Ropivacaine as compared to 0.5% Bupivacaine given epidurally for abdominal and lower limb surgeries.

Aims & Objectives

- a) A clinical study about the efficacy of Epidural Ropivacaine 0.75% and Bupivacaine 0.5% in lower abdominal and lower limb surgeries.
- b) To compare the efficacy between Epidural Ropivacaine (0.75%) and epidural 0.5% Bupivacaine in lower abdominal and limb surgeries in terms of:
 - Onset & level of Sensory and motor blockade.
 - Degree of Motor Blockade.
 - Recovery with reference to sensory and motor blockade
 - Complications/ side effects if any.

2. Materials and Methods

- Study Design: Prospective randomized control trial
- Study Place: NRI INSTITUTE OF MEDICAL SCIENCES, SANGIVALASA, VISAKHAPATNAM
- Study Sample: 100 patients
- **Study Duration:** The study was undertaken between may 2022 may 2023.

a) Inclusion Criteria: a) ASA grade I and II patients.

b) Patients aged between 18 to 70 years.

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c) Patients from whom consent was obtained.

Exclusion Criteria

- a) Patient refusal.
- b) Patients with infection at the puncture site.
- c) Patients with known allergy to local anaesthetic drug
- d) ASA grade III and IV patients.
- e) Patients with coagulation disorder.
- f) Pregnant patients.
- g) Patients with severe anaemia, hypovolemia, septicaemia.
- h) Patients with neurological deficits, spine deformity, history of hepatic or renal failure & seizures.

On the previous day of surgery all patients underwent routine pre operative assessment. Then the patients were randomly allocated into two groups (group R and group B). Clearance from the ethical committee was obtained before performing this study.

Drugs received by two groups are:

- Group R: 50 patients received 20ml of 0.75% Ropivacaine.
- Group B: 50 patients received 20ml of 0.5% Bupivacaine.



Loss of resistance method Epidural catheter insertion

- Anaesthesia machine was checked, pipeline and emergency oxygen supply kept ready. Working laryngoscope with medium and large size blades, endotracheal tube of appropriate size, oropharyngeal airways and working suction apparatus were kept ready. Emergency drugs and general anaesthesia drugs were kept ready.
- Before shifting the patient to operation theatre, IV access was obtained in the forearm with 18 gauge cannula and IV infusion started with Ringer Lactate.
- Continuous monitoring of Non invasive blood pressure (NIBP), heart rate (HR), electrocardiography (ECG) and oxygen saturation (SpO2) was done. Under aseptic precautions, epidural analgesia was performed in sitting position using 18 G Tuohy needle at L2 - L3 interspace after confirming epidural space with loss of resistance technique. The study solution of 20 ml of either 0.75% Ropivacaine or 0.5% Bupivacaine was administered and above - mentioned vitals were recorded every 5 minutes for the first hour and every 15 minutes till the end of surgery.
- Measured variables were time for onset of block at T8, maximum block height, total duration of analgesia, time to request for analgesia, time of onset of motor block, degree of motor block, total duration of block, quality of anaesthesia, and analgesic supplements given if any.
- Time to motor block was assessed every minute until maximum Bromage scale was achieved (1; no motor block, 2; partial motor block, 3; complete motor block of lower limbs) then every 60 minutes until the return of normal motor function.

3. Results

• Statistical analysis done with Statistical Package for Social Services (SPSS version 18). Quantitative data was

analysed by using the student's 't test'. Chi – Square test was used for analysing the quantitative data. A p value of less than 0.05 was seen as significant statistically.

 Table 1: Onset of sensory blockade

Time in minutes	Group B (n=50)	Group R (n=50)
0 - 5	25	24
6-11	16	24
11-15	9	2

Table 2: Statistical comparison of onset of sensory blockade

	Group B	Group R
Mean	5.98	5.92
Standard deviation	3.24	2.59
Standard error of mean	0.46	0.37

Table 3: Onset of motor blockade

Time in minutes	Group B (n=50)	Group R (n=50)
0 - 5	34	12
6-10	16	27
11-15	0	9
16 - 20	0	2

 Table 4: Statistical comparison of onset of motor blockade

	Group B	Group R
Mean	4.96	8.84
Standard deviation	1.85	3.84
Standard error of mean	0.26	0.54

Table 5: Degree of motor blockade

Degree of motor blockade	Group B	Group R
1	0	16
2	12	27
3	38	7

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Table 6: Bromage scale		
Grade	Criteria	Degree of block
1	Free movement of leg and feet	Nil (0%)
2	Just able to flex knees with free movement of feet	Partial (33%)
3	Unable to flex knees, but with free movement of feet	Almost complete (66%)

4. Discussion

- Onset of sensory blockade was maximum between 0 to 5 minutes in 50% of the patients in group B and 48% of the patients in group R. This was not clinically significant with p value of 0.9188 according to unpaired 't test'. Confidence interval was between 1.23 to 1.11.
- The onset of motor blockade was maximum between 0 to 5 minutes in 68% of patients in group B and the onset of motor blockade was maximum between 6 to 10 minutes in 54% of the patients in group R. This was statistically significant with p value of 0.0001 according to unpaired 't test'. Confidence interval was between 2.68 to 5.08.
- Degree of motor blockade was denser in group B (Bromage Grade 3) in 76% of the study group and less dense in group R (Bromage 2) in 54% of the study group.

Hemodynamic changes including mean heart rate, mean systolic blood pressure and mean diastolic blood pressure at various time intervals were similar in both groups B and R.

 Table 7: Complications in terms of occurrence of

 hypotension was less in Group R when compared to Group

 B and occurrence of bradycardia was nil in Group R when

 compared to Group B. This accounts for the less cardiotoxic

 effect of Ropivacaine when co6mpared to Bupivacaine.

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Complications	Group R	Group B
Hypotension	13	33
Bradycardia	Nil	6
Shivering	11	16
Nausea	Nil	5
Vomiting	4	4

5. Conclusion

- This study concludes that the onset of sensory blockade was similar between both Bupivacaine and Ropivacaine.
- The onset of motor blockade was delayed in Ropivacaine when compared with Bupivacaine. The degree of motor blockade was much denser in Bupivacaine when compared with Ropivacaine.
- Hemodynamic changes were similar in both Bupivacaine and Ropivacaine. Cardiovascular stability was observed more with Ropivacaine than Bupivacaine.

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