IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 14, Issue 9 Ver. VI (Sep. 2015), PP 37-43
www.iosrjournals.org

A Comparative Study of Post Operative Epidural Analgesia Between 0.125% Bupivacaine And 0.2% Ropivacaine in Lower Limb Surgeries.

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Abstract:
Background: *Epidural analgesia is used for many surgeries for effective pain relief post operatively in normal as well as high risk patients such as those with decreased cardiopulmonary reserve.*
Aim: *To compare the efficacy of two regional anaesthetic drugs in providing post operative analgesia and in maintaining hemodynamic stability.*
Setting and Design: *Randomized prospective cohort study*
Methods: *60 patients were randomly allocated to receive epidurally, continuous infusion of 0.2% ropivacaine (Group A), or continuous infusion of 0.125% bupivacaine (Group B) for 48 hours.*
Results: *HR(Heart rate), SBP(Systolic blood pressure), DBP(Diastolic blood pressure), VAS(Visual Analogue Scale), MBS(Modified Bromage Score), additional analgesic administration were observed in Group A (Ropivacaine) and Group B (Bupivacaine).No significant difference in HR, BP in both groups. Patients in group A having higher VAS score at 1 hour (p value- 0.0126), 12 hours (p value -0.0311) and 24 hours (p value- 0.042) after the commencement of epidural infusion. Additional analgesic requirement is higher in group A with statistically significant difference (p value – 0.0153) at 12 hours after starting the epidural infusion.*
Conclusion: *Both bupivacaine and ropivacaine are effective in providing epidural analgesia but bupivacaine being better in terms of analgesic efficacy.*
Key Words: *Epidural analgesia, Bupivacaine, Ropivacaine*

I. Introduction

Epidural local anaesthetics are widely used in the management of postoperative pain. It provides high quality analgesia with minimal adverse effects. Epidural analgesia also blunts the autonomic and somatic reflex responses to pain. Epidural analgesia needs comparatively small doses and low concentration of local anaesthetics (whiteside et al). It is used in thoracic, abdominal and lower limb surgeries successfully. This technique has gained popularity in labour analgesia as epidural local anaesthetics tend to reduce the pain and sympathetic response with out causing any motor deficits.

This study is performed to compare the effects and side effects of epidural ropivacaine to epidural bupivacaine for post operative analgesia following lower limb surgeries.

II. Aim Of The Study

- To compare the efficacy of continuous infusion of epidural ropivacaine and epidural bupivacaine for post operative analgesia.
- To study the effect of two drugs in maintaining the hemodynamic stability.

III. Materials And Methods

A prospective randomized controlled study was done as part of dissertation at GGH, Guntur Medical College, Guntur.

This study was conducted after obtaining approval from the institutional ethics committee. Informed consent was obtained from all the patients.

Study Groups:
Group-A : 0.2% Ropivacaine epidural infusion infused at 8ml/hr.
Number of patients: 30.
Group-B : 0.125% Bupivacaine epidural infusion infused at 8ml/hr.
Number of patients: 30.

Patient Selection Criteria:
Age : 20 – 60 yrs.
Sex : male/female.
ASA Risk : I / II.
Weight : 40-75kgs.
Height : 150-180cms.
Surgery : Elective lower limb surgeries.

Exclusion Criteria:
Patient refusal.
Infection at the site of injection.
Features of raised intra cranial tension.
ASA III / IV / V.
Presence of coagulopathies.
Allergy to local anaesthetics.
Spine abnormalities / history of any spine surgeries.
Emergency surgeries.
Duration of surgery prolonged beyond the dose of local anaesthetic given by spinal.

IV. Preparation Of Solutions:

25cc of 0.25% bupivacaine is mixed with 25cc of sterile water making a 0.125% bupivacaine solution. 50 cc of 0.2% ropivacaine is taken directly for infusion.

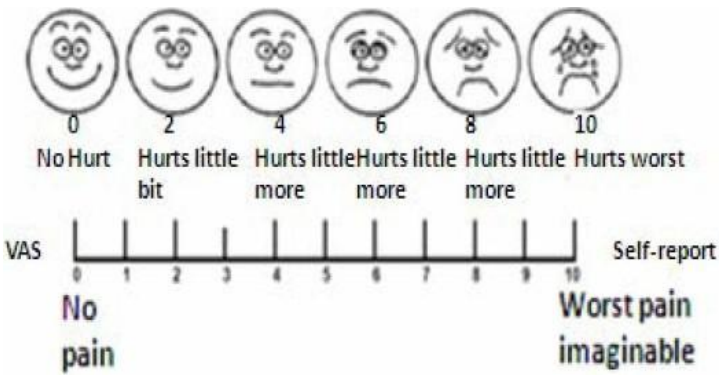
All 60 patients undergoing elective lower limb surgeries were visited by an anaesthesiologist, an evening prior to surgery. They were asked about general information viz. name, age, sex, weight. Preoperative general and systemic examination was done. Baseline investigations and any special investigation as per requirement were done.

These patients were randomly allocated into two groups -Group A and Group B based on computerized randomization chart. Each group has 30 patients. Patients were educated how to read a visual analogue scale.

On the day of surgery, after confirming the consent and adequate fasting, patients were shifted to operation theatre. Basic monitoring was done with ECG, pulse oximetry and non-invasive blood pressure.

Under aseptic precautions in sitting position an epidural cannula was inserted at the L_{2-3} lumbar epidural space using 16 gauge Tuohy's epidural needle. A test dose of 3ml 2% lignocaine with 15µgms of adrenaline was then injected. After confirming the position, catheter fixed such that 4-5cms of the catheter lies within the epidural space. Surgery was performed under spinal anaesthesia for lower limb surgeries. Spinal anaesthesia is achieved with 3.5cc of 0.5% bupivacaine at L_{3-4} space with 23G spinal needle, after placing epidural catheter. No additional analgesic was given intra operatively.

Post operatively patients were shifted to post-op ward with basic monitoring. An infusion pump of the corresponding drug was connected to the epidural catheter and infusion commenced at 8ml/hr immediately before patient complained of any pain due to residual analgesic effect of spinal anaesthesia .Pulse rate, blood pressure, pain score, motor blockade, additional analgesic requirement and side effects were monitored for 48hours post operatively. A ten point visual analogue scale was used to assess pain. Patients were educated pre-operatively to mark the points depending on the intensity of pain. In our study any score more than 3 is taken as the trigger to give supplementary analgesia. We gave injection tramadol 100mg IV boluses. Injection Ondansetron 0.15mg/kg intravenously was given every 8hours as prophylaxis for post operative nausea & vomiting.



Motor blockade was assessed in opposite lower limb using a six point Modified Bromage Score.
Modified Bromage score as used by Breen et al[2]

Statistical Tools

Score	Criteria
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

The information collected regarding all the selected cases were recorded in a master chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta.

Using this software range, frequencies, percentages, means, standard deviations, chi square and 'P' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

V. Results

Age distribution:

Persons aged 21 years to 60 years were included in the study. Ropivacaine group had an age of 40.2 $\pm$13.1 years and bupivacaine group 39.3 $\pm$12.6 years. There was no significant difference in the age composition of the two groups.

Sex distribution:

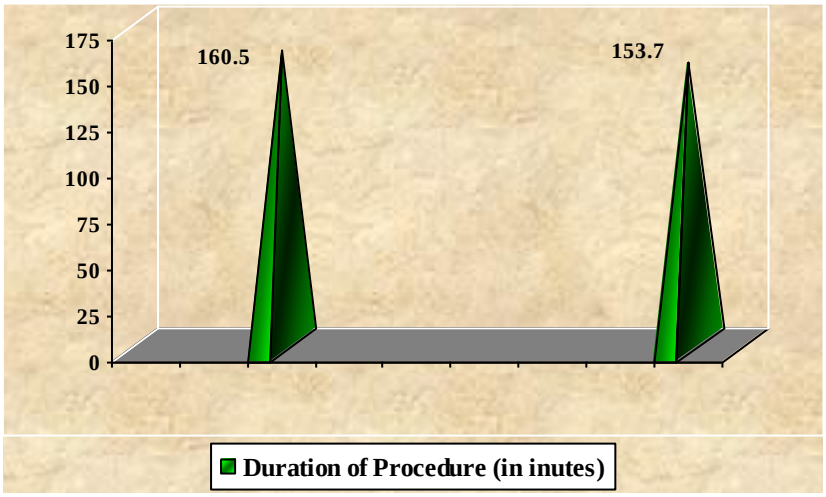
70% of the Ropivacaine and 76.7% of the Bupivacaine were males. There was no statistically significant difference in the sex composition of the two groups.

Physiological parameters

Mean height and weight of the ropivacaine group and bupivacaine group did not have any significant difference.

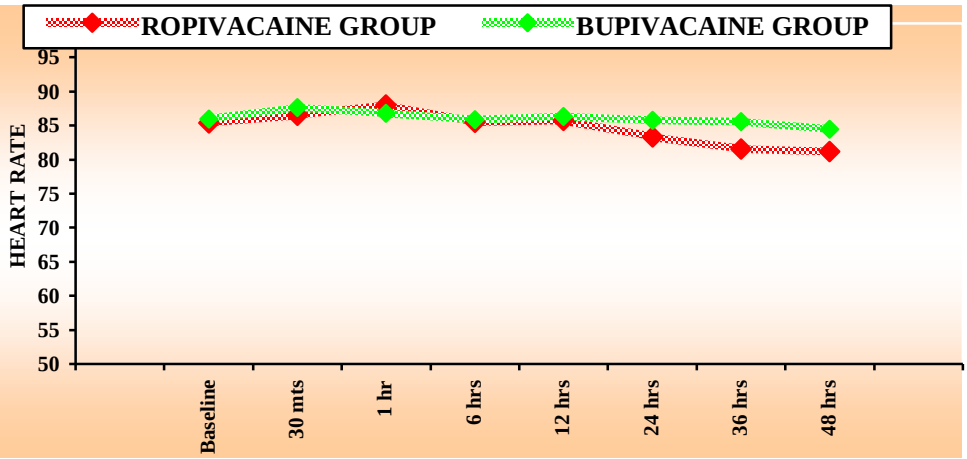
Duration of Procedure:

Duration of procedure for the ropivacaine group was 160.5 $\pm$40.7 minutes and for the bupivacaine group it was 153.7 $\pm$34.9 minutes. This difference was statistically not significant (p = 0.4771).



Changes in heart rate

Mean heart rate at various time intervals did not have any statistically significant difference.



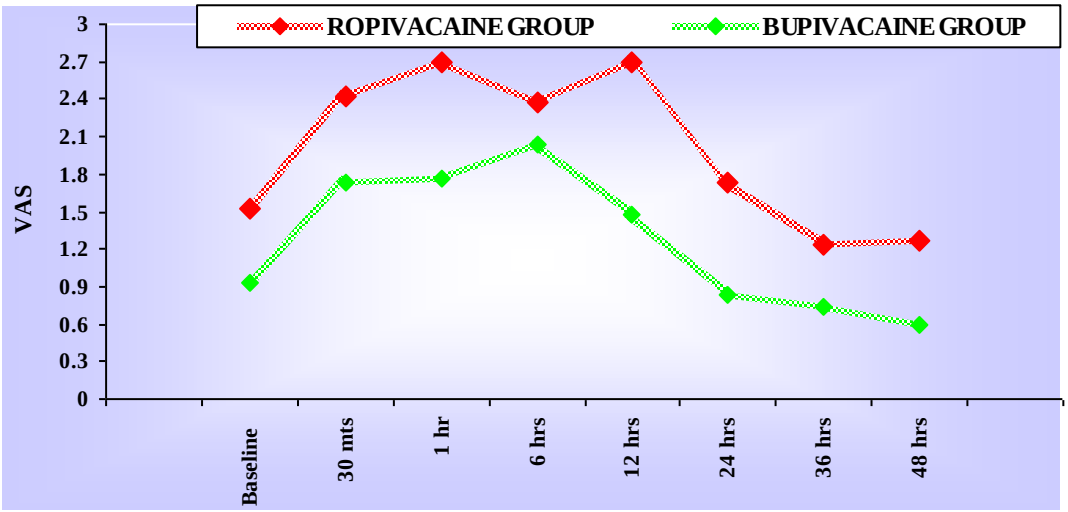
Changes in Systolic and diastolic B.P.

Systolic and diastolic blood pressure at various time intervals did not have any statistically significant difference.

Changes in Visual Analogue Scale:

VAS	Value (Mean + SD) for				'p'
	Ropivacaine Group		Bupivacaine Group		
	Mean	S.D.	Mean	S.D.	
Baseline	1.53	1.25	0.93	1.36	0.1018 Not significant
30 minutes	2.43	1.94	1.73	1.39	0. 1786 Not significant
1 hour	2.7	1.78	1.77	0.86	**0. 0126 Significant**
6 hours	2.37	1.5	2.03	1.03	0.1081 Not significant
12 hours	2.67	2.27	1.47	1.36	**0. 0311 Significant**
24 hours	1.73	1.93	0.83	1.39	**0. 042 Significant**
36 hours	1.23	1.41	0.73	1.08	0. 1422 Not significant
48 hours	1.27	1.46	0.6	1.04	0. 058Not significant

Pain experienced by the patients assessed by visual analogue scale showed significant difference with patients in group A having higher VAS score at 1 hour (p value- 0.0126), 12 hours (p value-0.0311) and 24 hours (p value- 0.042) after the commencement of epidural infusion



Changes in Modified Bromage Score:

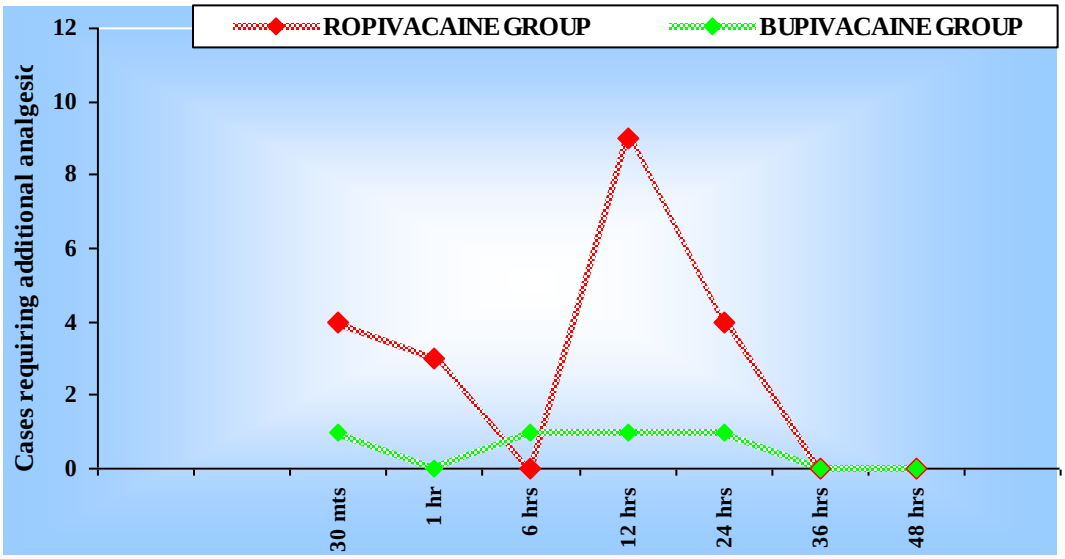
Modified Bromage Score value was uniformly 6 during the post operative period for both the groups.

Requirement of i.v tramadol as rescue Additional analgesic

No. of cases requiring additional analgesic at	Value (Mean ± SD) for				'p'
	Ropivacaine Group		Bupivacaine Group		
	No.	%	No.	%	
30 minutes	4	13.3	1	3.3	0.1766 Not significant
1 hour	3	10	-	-	0. 1186 Not significant
6 hours	-	-	1	3.3	0.5 Not significant
12 hours	9	30	1	3.3	**0.0153 Significant**
24 hours	4	13.3	1	3.3	0.1766 Not significant
36 hours	-	-	-	-	-
48 hours	-	-	-	-	-

It was showed that at 12 hours 9 patients in group A compared to 1 patient in group B had required i.v tramadol as rescue analgesics and were significant with a p value of 0.0153

Requirement Of Additional I.V Tramadol As Rescue Analgesic



Side Effects:

There were no side effects at all times in the post operative period in both the groups.

VI. Discussion

Today post-operative pain scores are lower by using multimodal analgesia and epidural analgesia. As is known insufficient pain therapy prolongs the hospital stay and raises mortality rates, epidural analgesics are commonly used for management of acute and chronic pain. It enables the use of lower doses of drugs and there by reduces the side-effects. Studies have shown that it can even be used in the presence of sepsis with no side-effects (kotze et al[3]).Epidural analgesia provides better post-operative pain relief than intravenous PCA (Jayr et al[4]).

Bupivacaine is the most common drug used for providing epidural analgesia. Early reports of severe cardiotoxicity following accidental injection of bupivacaine intravascularly have led to the search of newer local anesthetics. Ropivacaine and levo-bupivacaine which are S-enantiomers was introduced to reduce the cardiotoxic effects of bupivacaine.

Studies comparing these drugs show conflicting results. Also most studies are clouded by the addition of opioids and other adjunctives like clonidine (Forster et al[5]) (s.j singh[6]). In our study we compared ropivacaine with bupivacaine.

From the previous studies we found that age and sex affects the pain score of the patients post operatively. In our study we took patients in the age group of 20 –60yrs. The mean age group among the ropivacaine group is 40.3 and in bupivacaine group is 39.3 and this is not statistically significant. Percentages of male and female patients were 70% and 30% in ropivacaine and 76.7% and 23.3% in bupivacaine group with a 'p' value of 0.7703 which is not statistically significant.

Previous studies have shown that height and weight of the patients will affect the dose and spread of the local anaesthetics .Our study has patients with mean height of 164.9 ±7.2cms in group A and 165.9 ±6.4cms in group B and is statistically insignificant.

We did the study in elective lower limb orthopedic surgeries with the type of procedures being mostly intramedullary nailing, knee arthroscopy etc. Types of procedures in the two groups were comparable (table-5). Duration of procedure is 160.5 minutes in ropivacaine group compared to 153.7 minutes in bupivacaine group (table-6). These results are statistically insignificant

Studies by Muldoon et al[7] used 0.2% solutions of both drugs for comparing post operative analgesia. Jorgensen et al[8] used the same solutions at 8ml/hr. both the studies concluded that both are effective in providing analgesia but bupivacaine being a better analgesic than ropivacaine .motor blockade was found to be higher in bupivacaine group but it was statistically insignificant.

Kanai et al[9] did a study in patients undergoing lower limb surgeries using 0.125% bupivacaine, 0.2% ropivacaine and 0.1% ropivacaine as continuous infusion at 6ml/hr. They suggested 0.2% ropivacaine to be a better analgesic than 0.1% solution. We performed study with 0.125% bupivacaine and 0.2% ropivacaine epidural infusion infused at 8ml/hr

We monitored the hemodynamic status of the patients postoperatively. There were no significant variations in heart rate and blood pressure during the study. These results correlates with most of the studies as in none of the previous studies had reported any hemodynamic instability in the analgesic concentrations of these local anaesthetics.

Analgesic efficacies of the drugs were compared with visual analogue scale. From our clinical experience we took the cut off point for rescue analgesia to be 3 while using a 10 point VAS scale. In our study we found a mean VAS of 2.7 for ropivacaine group and 1.77 for bupivacaine group at one hour of starting the infusion with a p value of 0.0126 and at 12 hours the VAS score being 2.67 and 1.47 respectively with a p value of 0.0311, both being statistically significant. At 24 hours also statistically significant difference in VAS score of 1.93 and 1.39 was seen for ropivacaine and bupivacaine with a p value of 0.042. Our result showed that analgesic effect of 0.2% ropivacaine is less compared to 0.125% bupivacaine.

We gave injection Tramadol 100mg intravenously as rescue analgesic whenever the patients pain score raised above 3 without giving any additional local anaesthetic epidurally. We analyzed the requirement of additional rescue i.v analgesia and found that at 12 hours 9 patients in ropivacaine group compared to 1 patient in bupivacaine group has a required additional i.v analgesic and are significant with a p value of 0.0153. Although analgesic requirements were high as with the study of Heid etal[10] in ropivacaine group compared to bupivacaine group at other points of observation also, it is not found to be statistically significant. But Pasquele De Negri et al[11] found ropivacaine to better as bupivacaine group required more epidural top-ups than ropivacaine in their study in children.

We used Modified Bromage score to assess the level of motor blockade. From our study we found that there was no motor deficits in any group at any point of time.. Our finding agrees with the observations of Heid et al[10] and M Dresner et al[12] . Jorgensen et al[8] did a study with 0.2% of the local anaesthetics to find no significant motor blockade, which also matches with our results.

No side effects like hypotension, pruritis, urinary retention, or any features of local anaesthetic toxicity are detected during any point in our study.

The additive effect of residual analgesia of spinal anaesthesia at the end of surgery with the study drugs were not evaluated which is a limitation of the present study.

VII. Conclusion

Both bupivacaine and ropivacaine are effective in providing epidural analgesia but bupivacaine being better in terms of analgesic efficacy. No significant motor blockade is noted at analgesic concentrations of both drugs.

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