

COMPARATIVE STUDY BETWEEN EPIDURAL ROPIVACAINE V/S BUPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN PATIENTS UNDERGOING UNILATERAL TOTAL HIP REPLACEMENT SURGERY-A PROSPECTIVE RANDOMIZED DOUBLE BLIND STUDY

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Abstract

Background: Total hip replacement (THR) is the most common joint replacement procedure that aims to relieve joint pain, increase mobility and improve the quality of life of the patients with chronic degenerative disease of hip joint and patients with proximal femoral fracture. **Objective:** To compare the efficacy of a standard, commonly used analgesic concentration of epidural bupivacaine (0.125%) versus ropivacaine (0.125%), in terms of patient pain scores, requirement of rescue analgesia, related complications, and duration of PO hospital stay. **Materials and Methods:** The current study was conducted in the department of Anesthesiology, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi during the time period from December 2018 to December 2019. **Results:** The results of our study indicate that for patients who are scheduled for hip surgery, both bupivacaine and ropivacaine epidural analgesia are effective in controlling postoperative pain but ropivacaine has several crucial advantages. There was no significant difference in mean age, sex, height, weight, or ASA class distribution between patients in this study. The surgeries were performed and the duration of surgery were comparable between them. **Conclusion:** Continuous epidural block with ropivacaine provides better hemodynamic stability in terms of heart rate, diastolic blood pressure and mean arterial pressure. Epidural block with ropivacaine reduces the duration of hospital stay as there is early mobilization is possible and, analgesia which is as good and sustained as bupivacaine analgesia.

INTRODUCTION

Total hip replacement (THR) is the most common joint replacement procedure that aims to relieve joint pain, increase mobility and improve the quality of life of the patients with chronic degenerative disease of hip joint and patients with proximal femoral fracture.

Anaesthesia and post-operative analgesia for THR is a challenge, as the age of the Patients presenting for THR varies, and 60% of the procedures are performed on patients above 65 years of age.^[1] It is therefore important to choose an effective intra-operative anaesthetic and analgesic regimen with minimal side-effects to allow timely mobility, optimal functional recovery and decrease postoperative morbidity and mortality.^[2]

Epidural analgesia has become a standard of care for such surgeries and is utilized by multiple modes of delivery including bolus injection, continuous injection, or patient-controlled infusion.^[3] Bupivacaine has been used successfully for many years for this purpose, in concentrations ranging from 0.0625% to 0.25%.^[4,5] Cardiac system and central nervous system (CNS) adverse effects related to bupivacaine have led to development of relatively safer drugs such as ropivacaine and levobupivacaine.^[5] Although bupivacaine is still a popular drug in various centers, use of epidural ropivacaine has now increased significantly as it seems to have benefits other than just good pain relief, in terms of a better safety profile.^[5-9] There is very little literature on comparisons between these two drugs, although a

recent study has compared these two drugs for epidural anesthesia and PO analgesia in lower limb surgeries.^[10] Similar studies analyzing PO pain relief profile of the two drugs have shown results in favor of use of ropivacaine.^[7,8]

Postoperative pain control can be achieved by a variety of techniques, such as intravenous Patient Control Analgesia (PCA), epidural analgesia, and lumbar paravertebral block. Intravenous PCA is inefficient in controlling pain during mobilization.^[3]

The aim of the present study was to compare the efficacy of a standard, commonly used analgesic concentration of epidural bupivacaine (0.125%) versus ropivacaine (0.125%), in terms of patient pain scores, requirement of rescue analgesia, related complications, and duration of PO hospital stay.

MATERIALS AND METHODS

The current study was conducted in the department of Anesthesiology, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi during the time period from December 2018 to December 2019. The study was conducted after Institutional Ethical Committee clearance and written & informed consent from patients.

Study Population

The study was conducted on patients scheduled for elective total hip replacement under spinal anaesthesia. Patients were included in the study under the following criteria.

Inclusion Criteria

1. Age group between 50-70 years.
2. Patients belonging to American society of Anesthesiologists physical status 1 and 2.
3. Patients undergoing unilateral total hip replacement surgery.
4. Hemodynamically stable.

Exclusion Criteria

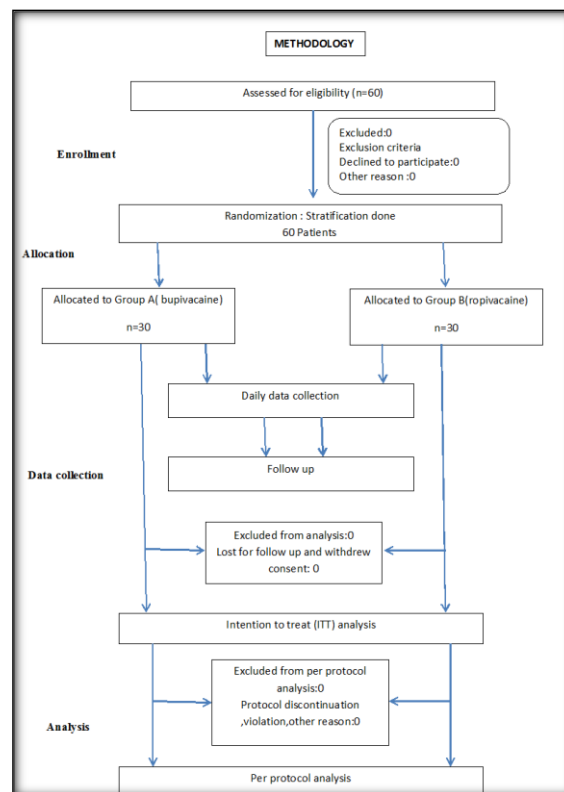
1. Patient refusal.
2. Vertebrae deformity.
3. Patient having allergy to amide group of local anaesthetic agent, opioids and nonsteroidal anti-inflammatory drugs.
4. Infection at the puncture site of proposed block.
5. Patients with deranged coagulation and bleeding parameters (INR > 1.5).
6. Patient on chronic analgesic/anticoagulant therapy.
7. Presence with cognitive or communicative impairment.

60 adult patients who fulfil the inclusion criteria were randomly assigned into two groups:

Group A: Post operatively patients were given with continuous infusion of 5ml/hr (0.125%) bupivacaine + 2mcg/ml Fentanyl (preservative free) via lumbar Epidural catheter.

Group B: Post operatively patients were given with continuous infusion of 5ml/hr (0.125%) ropivacaine + 2mcg/ml Fentanyl (preservative free) via lumbar Epidural catheter.

The patients were instructed on the use of a 1-10 visual analogue scale (VAS) for pain scores (where 0-no pain and 10-worst pain imaginable) at the preoperative visit.



Study Subjects Evaluation

It included preanaesthetic checkup, clinical examination and investigations which included complete blood counts (CBC), fasting blood sugar (FBS), liver function test (LFT), renal function test (RFT), electrocardiogram (for patients over 40 years of age), chest x-ray. Pre-anesthetic check-up done 1 day before surgery.

Statistical analysis of data:

The statistical analysis of data was done by using software SPSS for windows version (23.0). Chi-square test was used for categorical variables. For comparing two groups of mean student's t-test and for more than two groups one way analysis of variance (ANOVA) test was used. P-value < 0.05 is considered as statistically significant.

RESULTS

A total of 60 patients were assessed for eligibility and were enrolled and randomized to two groups of 30 each

Table 1: Distribution according to Age, Sex and ASA-P Status

Group	Age in years				Sex		ASA-P Status	
	≤50	51-55	56-60	>60	Female	Male	1	2
A	4(13.3%)	14(46.7%)	10(33.3%)	2(6.7%)	16(53.3%)	14(46.7%)	14(46.7%)	16(53.3%)
B	2(6.7%)	16(53.3%)	8(26.7%)	4(13.3%)	17(56.7%)	13(43.3%)	13(43.3%)	17(56.7%)

Age group of the study population was 50 to 70 years. The mean age of the study population in group A was 54.68years. The mean age of the population in group B was 55.43years. By applying independent samples 't' test, the p value was found to be 0.639 which was statistically insignificant and hence both the groups were comparable.

The groups were comparable in respect to gender distribution (p=0.795) and ASA-physical status (p=0.795).



Figure 1: Blood parameters

There were no significant difference in Hb, TLC, LFT, RFT and RBS distribution between the two groups.

Table 2: Intra-op variables

Group	N	Mean	Std. Deviation	t value	df	p value	95% Confidence Interval of the Difference	
							Lower	Upper
Blood loss (ml)	Group A	30	771.33	-1.380	58	0.173	-64.540	11.874
	Group B	30	797.67					
Urine Output (ml)	Group A	30	116.33	-.164	58	0.870	-8.790	7.456
	Group B	30	117.00					
IVF(ml)	Group A	30	1376.67	.978	58	0.332	-37.665	109.665
	Group B	30	1340.67					

The average blood loss in group A is 771ml and group B 797ml, average urine output are 116 and 117 in group A and B respectively and requirement of intraoperative fluids is about 1376 in group A and 1340 in group B.

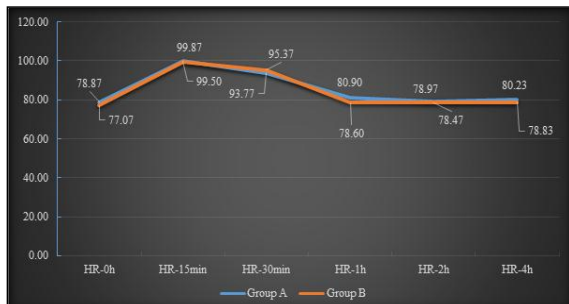


Figure 2: Heart rate in Post Anaesthesia Care Unit

Mean heart rate at 0hr, 15min, 30min, 1hr, 2hr, 4hr following drug administration are 78, 99, 93, 80, 78, 80 in group A. 77, 99, 95, 78, 78, 78 in group B respectively. As changes are comparable, but not statistically significant.

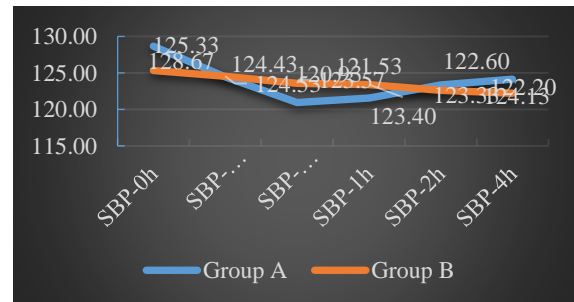


Figure 3: Diastolic blood pressure in Post Anaesthesia Care Unit

There is decrease in systolic blood pressure in group A at 15min, 30min from baseline when compared to group B, but it is not statistically significant.

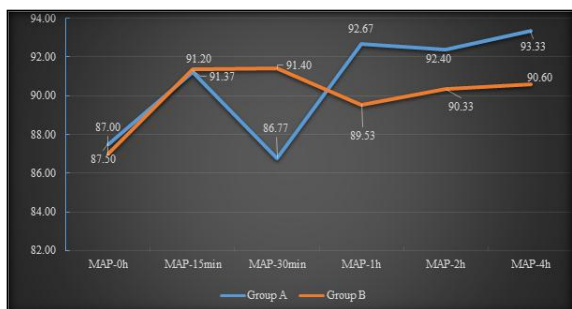


Figure 4: Mean arterial pressure in Post Anaesthesia Care Unit

There is a statistical significant fall in mean arterial pressure at 30min,1hr and 4hrs from base line in group A compared to group B.

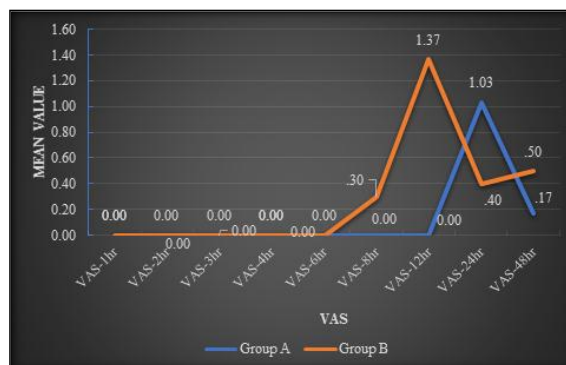


Figure 5: VAS score

Till 12hrs patients does not complained of pain in both the group.at 12hr group B has VAS-score of >4 and required rescue analgesia,which is statistically significant.

Table 3: Need of rescue analgesia

Group	Rescue analgesics	
	No	Yes
A	25(83.3%)	5(16.7%)
B	22(73.3%)	8(26.7%)

*p=0.347

Out of 30 patients in group A only 5patients(16.7%) needed rescue analgesic which is comparable with group B(8 patients-26%).

Table 4: Duration of hospital stay

	Group	N	Mean	Std. Deviation	t	df	p value	95% Confidence Interval of the Difference	
								Lower	Upper
Hospital Stay	Group A	30	7.50	1.167	3.841	58	.000	.495	1.572
	Group B	30	6.47	.900					

Mean duration of hospital stay in group A is 7.50days when compared to 6.47days in group B,which is stastistically significant(p=0.000).

DISCUSSION

Total hip replacement has been a major advancement in the treatment of chronic arthritis of hip and provides pain relief and increase mobility. Total hip replacement involves the prosthesis replacement of femoral and acetabular component of hip joint.

Inadequate analgesia may limit early mobilization, impede the physical therapy and delay the discharge.^[11]

The results of our study indicate that for patients who are scheduled for hip surgery, both bupivacaine and ropivacaine epidural analgesia are effective in controlling postoperative pain but ropivacaine has several crucial advantages.

There was no significant difference in mean age, sex, height, weight, or ASA class distribution between patients in this study. The surgeries were performed and the duration of surgery were comparable between them. We measured the VAS at 1,2,3, 4,6, 8, 12,24 and 48 hour postoperatively. We found that both drugs were effective in controlling postoperative pain and did not differ

clinically significant, reflecting good postoperative pain control in both groups. The results of our study are consistent with those of ofsonal Goyal et al [12] who did not observe any significant difference in analgesia by VAS score over 24 hours, except for peaked VAS score at 6hr post operative.

In Bhasin, et al.^[13] requirement of rescue analgesia on day1 was significantly higher in ropivacaine Group . Requirements in Groups R2 and B were lower but comparable. Sawhney et al.brought out that 0.2% ropivacaine had the least rescue analgesia requirement compared to other groups.^[14] Khanna et al. in their study reported significantly higher rescue drug requirements in 0.1% ropivacaine-only group.^[15] although they compared it with 0.0625% bupivacaine with fentanyl. No significant difference was found in the requirement of rescue analgesia between all three groups on day 2, which suggests that epidural analgesia is perhaps most effective in the first 24 h PO.^[16] whereas in our study pain relief were comparable in both the groups and rescue analgesia were supplemented with inj.paracetamol 1gm IV and first analgesic requirement was earlier in group

B between 12-16 hours versus 16-18 hours in group A.

In Bhasin, et al.^[13] bupivacaine group had significantly higher number of days of PO hospital stay compared to ropivacaine group, which were comparable. There is not much literature regarding analysis of number of days of PO stay, but general consensus is that use of ropivacaine leads to faster recovery and shorter PO period in the hospital.^[16,17] Indirect evidence of this fact is also elicited by the low incidence of adverse effects such as delayed or prolonged motor block (which might delay ambulation) with bupivacaine as compared to ropivacaine.^[17] But in our study we found Mean duration of hospital stay in group A is 7.50 days when compared to 6.47 days in group B.

CONCLUSION

Continuous epidural block with ropivacaine provides better hemodynamic stability in terms of heart rate, diastolic blood pressure and mean arterial pressure. Mean heart rate at 0hr, 15min, 30min, 1hr, 2hr, 4hr following drug administration are 78, 99, 93, 80, 78, 80 in epidural bupivacaine group and 70, 99, 95, 78, 78, 78 in epidural ropivacaine group respectively with no statistical significance. There is a statistical significant fall in diastolic blood pressure (DBP) and mean arterial pressure (MAP) at 30min, 1hr, 2hr and 4hrs from base line in epidural bupivacaine group compared to epidural ropivacaine group.

In terms VAS score till 12hrs patients did not complain of pain in both the group, at 12hr epidural ropivacaine group has VAS-score of >4, and 26.7% required rescue analgesia when compared to epidural group (16.7%).

Epidural block with ropivacaine reduces the duration of hospital stay as there is early mobilization is possible and, analgesia which is as good and sustained as bupivacaine analgesia.

Henceforth Continuous lumbar epidural block with 0.125% ropivacaine is an alternative to continuous epidural block with 0.125% bupivacaine in the intraoperative and post-operative management of total hip replacement.

Further larger studies are required.

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