



Ropivacaine Versus Levobupivacaine in Combined Spinal Epidural Anaesthesia in Patients Scheduled for Lower Limb Surgeries

¹Dr. Bandi Sirisha

Postgraduate, Department of Anaesthesia, Katuri Medical College, Guntur, Dr. YSR University of Health Sciences, Andhra Pradesh, India

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Corresponding Author: Dr. Bandi Sirisha, Postgraduate, Department of Anaesthesia, Katuri Medical College, Guntur, Dr. YSR University of Health Sciences, Andhra Pradesh, India

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ABSTRACT

Background

Combined spinal and epidural anaesthesia (CSE) is a regional anaesthesia technique with the benefits of both spinal anaesthesia and epidural anaesthesia along with postoperative analgesia. Levobupivacaine, the S enantiomer of bupivacaine, shows more safety and efficacy compared to bupivacaine. Ropivacaine is claimed to produce less motor block in equianalgesic doses compared to levobupivacaine.

Aim

To compare the efficacy of ropivacaine with levobupivacaine in combined spinal epidural anaesthesia for patients scheduled for lower limb surgeries.

Methods

This comparative interventional study was conducted at a tertiary care centre among 100 patients who were scheduled for various lower limb surgeries under combined spinal epidural anaesthesia. The study was done from March 2022 to August 2022. Patients were randomized into groups R and L, each group containing 50 patients. Patients with a Body mass index above 35kg/m², pregnant and lactating women, allergies to study medications were excluded from the study. Age, gender, ASA grade, duration of surgery, onset of sensory, motor blocks, duration of sensory, motor blocks were compared between two groups.

Results

Most of the patients belonged to the age group 41-50 years. There is no significant difference in gender or

ASA grade between two groups. Duration of sensory block was more in ropivacaine group. 21 patients reached sensory block T10 in levobupivacaine group in 10min. Time for reaching maximum sensory block is less in ropivacaine group. Pain was less significantly in ropivacaine group at various intervals.

Conclusion

Levobupivacaine and Ropivacaine were effective for combined spinal epidural anaesthesia in patients scheduled for lower limb surgeries. As per the study results, ropivacaine is more effective compared to levobupivacaine when used as local anaesthetics in CSE.

Keywords

Combined spinal-epidural anaesthesia, Comparative study, Efficacy, Levobupivacaine, lower limb surgeries, ropivacaine.

INTRODUCTION

Combined spinal and epidural anaesthesia (CSE) is a regional anaesthesia technique with the benefits of both spinal anaesthesia and epidural anaesthesia with postoperative analgesia. The spinal part provides quick onset of a predictable block. The epidural catheter provides a long-lasting painkilling effect that can be titrated for getting the desired effect. It has the advantage of the accuracy of the subarachnoid block and flexibility provided by an epidural catheter.¹ Combined spinal epidural, single segment, needle through needle technique is recently gaining popularity in modern anaesthesia practice.^{2,3}

Advantages of CSE

- 1) Requirement of a low dose of local anaesthetic for quicker termination of the spinal anaesthesia.
- 2) Less incidence of nausea and hypotension
- 3) Effective post-operative pain relief.
- 4) Catheter can be left for 72 hours if needed.

- 5) Relatively rapid onset of anaesthesia

Indications of CSE

- 1) Caesarean sections
- 2) Hysterectomy
- 3) Prostate gland removal
- 4) Orthopaedic surgeries like hip replacement surgery, knee surgery, femur fracture in elderly patients
- 5) External cephalic version of breech presentation etc.

In the UK, the National Institute for Health and Care Excellence commends CSE for women who require rapid onset of analgesia in labour.⁴

The onset of analgesia is rapid with CSE compared with epidural analgesia.⁵

Complications of CSE⁶

- Failure of spinal component
- Failure of epidural component
- Misplacing of epidural catheter
- Damage to epidural catheter or spinal needle
- Paresthesia, subdural hematoma, cauda equina syndrome, post dural headache, abscess, bacterial meningitis and aseptic meningitis may occur rarely.
- Short-acting spinal anaesthesia with a reduced dose of local anaesthetic may help patients mobilize earlier and prevent complications linked to delayed motor blockade like urinary retention, Discomfort due to immobilization.⁷

Concerns of CSE⁸

Spinal needle may be too short

Failure to enter dura

Divergence from midline etc.

Levobupivacaine, the S enantiomer of bupivacaine, shows more safety and efficacy compared to bupivacaine. The most commonly used local

anaesthetic for traditional combined spinal-epidural anaesthesia is levobupivacaine. It is safer than bupivacaine and is less toxic to the central nervous system and heart. Ropivacaine is claimed to have various clinical and pharmacokinetic advantages over bupivacaine. Previously many studies were performed using local anaesthetics added to opioids in parturient patients.^{9,10,11} But still the results are inconclusive. Hence the current study was undertaken.

OBJECTIVE

To compare efficacy of ropivacaine with levobupivacaine in combined spinal epidural anaesthesia for patients scheduled for lower limb surgeries.

MATERIALS AND METHODS

Source of data: This comparative interventional randomized study was done on patients scheduled for various lower limb surgeries, at tertiary care center named Katuri medical college, college Andhra Pradesh, from March 2022 to August 2022.

Inclusion Criteria

- Patients aged above 18 years
- Both males and females
- Patients scheduled for elective lower limb surgeries under combined spinal epidural anaesthesia.
- Patients with ASA grade I and II
- Patients who provided informed consent to participate in the study.

Exclusion Criteria

- Pregnant and lactating women
- Patients with BMI ≥ 35 Kg/m².
- Patients with severe renal, cardiac and liver disorders that interrupt data collection.
- Patients with allergies to study medications.
- Patients with incomplete data
- Patients with infection at the site of injection
- Patients with spinal abnormalities.

Sampling: The convenience method was used to select study population.

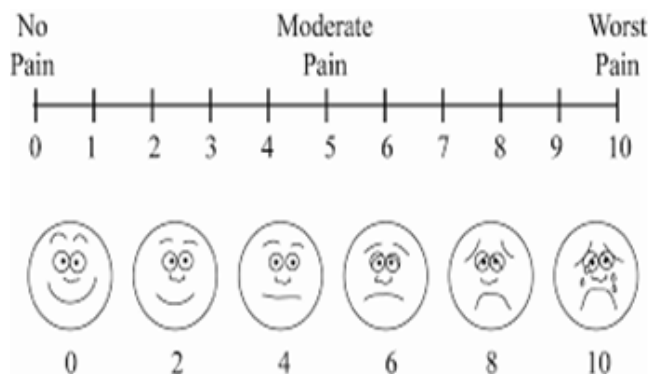
Sample Size Calculation

As per the previous study,¹² the analgesic duration achieved by levobupivacaine is 20% more than ropivacaine with a standard deviation of 25 min. At 95% confidence intervals, taking 5% error, the minimum sample size came to be 49 in each group. Hence, we included 50 patients in each group.

Parameters Assessed

- Age
- Gender
- ASA grade
- Onset of sensory block
- Time for grade IV motor blockade.
- Level of sensory block
- Time for 2 segment regression.
- Pain assessment using visual analogue scale (VAS).

Figure 1 Shows VAS score¹³



METHODOLOGY

100 patients were divided into two groups. Group R included 50 patients who were given ropivacaine. Group L included 50 patients who were given levobupivacaine. After taking informed consent from each subject, pre-tested proforma was used to collect the data. Data on demographic features, detailed medical history, clinical examinations and relevant investigations were collected.

TECHNIQUE

Separate needle technique is used in our study, though the needle-through needle technique is most commonly used. This technique uses two separate needles to perform spinal and epidural components of CSE. Both needles can be inserted at same vertebral inter space or at two separate interspaces. Again, the spinal and epidural components of the CSE can be performed in either order. But needle through needle technique carries high chance of failure rates.

Groups: Patients in Group L received 3 ml of 0.5%

heavy levobupivacaine.

Patients in Group R received 3 mL of 0.75% heavy Ropivacaine.

All the study drugs were prepared in identical volumes (3 ml) in a similar syringe used in the patients' management.

STATISTICAL ANALYSIS

Data analysis was done using Epi Info software version 7.2.5. The results were expressed as mean ± S.D, percentages, and numerical parameters were compared using students t-test between patients of two groups. Caetegorical parameters were compared using chi square test.

P value < 0.05 was considered significant.

ETHICAL CONSIDERATIONS

Informed consent form was taken from every subject who participated in the study.

RESULTS

DEMOGRAPHY

Age: Most of the patients were aged 41 to 50 years old.

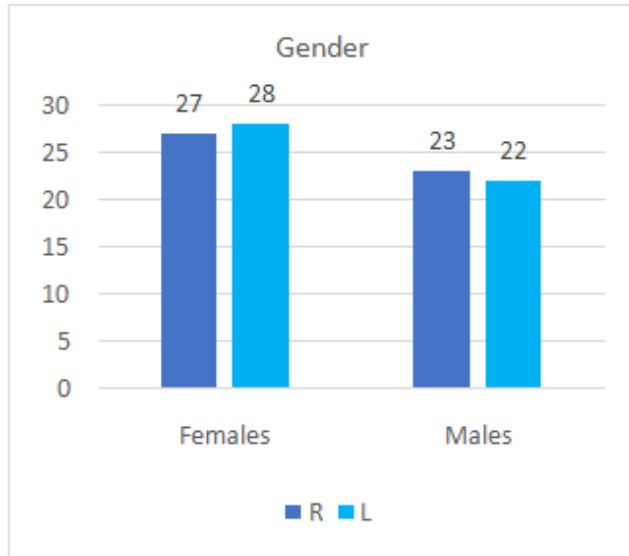
		AGE					Total
		18-30	31-40	41-50	51-60	61-70	
Group	L	6	5	18	15	6	50
	R	9	4	19	13	5	50

Table 1: Illustrates age distribution of patients in both groups.

Gender

There is no significant difference in gender between two groups (p=0.8).

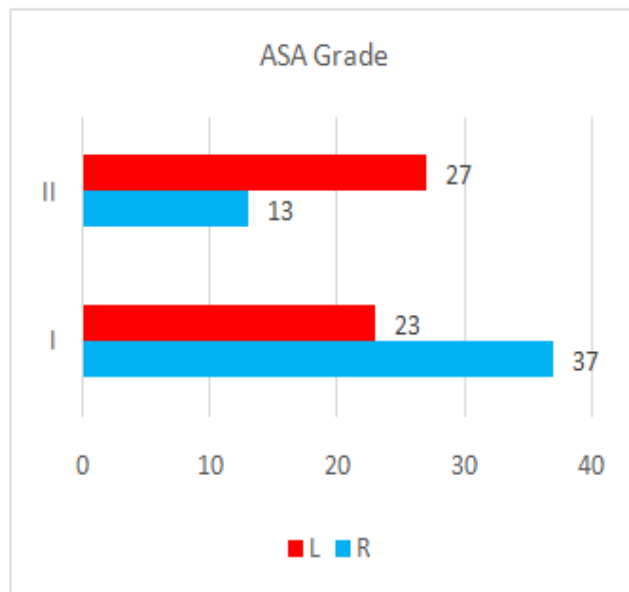
Graph 1 Gender distribution of patients



ASA Grade

Most of the patients belonged to ASA grade I.

Graph 2 ASA grade among patients.



Mean Duration of Sensory Block

There is significant difference in the mean duration of sensory block between two groups. It was earlier in Ropivacaine group.

Table 2: Shows duration of sensory block

DRUG	Mean	Std. Deviation
R	190.4	9.6
L	166.5	10.2

Sensory Block in Both Groups

21 patients reached sensory block T10 in levobupivacaine group in 10min.

Table 3 shows sensory block in both groups

	DRUG		Total	
	R (no of patients)	L (no of patients)		
SB 5MINS	Level			
	T8	1	1	2
	T10	18	21	39
	T12	24	28	52
	L1	3	0	3
	L2	4	0	4
Total		50	50	100

Time for Reaching Maximum Sensory Block

The time taken to reach maximum sensory block is 17.04 min in levobupivacaine group and 10.1 min in the ropivacaine group. It was earlier in ropivacaine group.

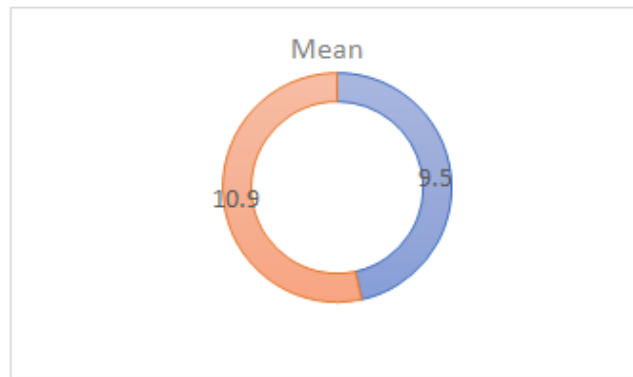
Table 4: shows the mean time for the maximum sensory block

DRUG	Meantime	SD
L	17.04	1.99
R	10.1	2.12
P value	0.0001	

Grade IV Motor Block

There is significant difference in grade IV motor block between the two groups (p=0.0001) Ropivacaine takes more time for grade IV motor block compared to levobupivacaine.

Graph 3 shows grade IV motor block (blue: levobupivacaine)



VAS Scores

There is significant difference in VAS score between two groups at various intervals. It was less in ropivacaine group compared to levobupivacaine group.

DRUG	L	R	
	Mean	Mean	P value
post op	0	0	0
30mins	1	0	.000
60mins	1.74	0	.000
90mins	2.36	0.08	.000
120mins	1.2	0.26	.000
300mins	1.94	2.5	.000

DISCUSSION

In the current study, we compared levobupivacaine with ropivacaine for combined spinal epidural anaesthesia (CSE). Most of the patients belonged to the age group 41-50 years. There is no significant difference in gender or ASA grade between two groups. The duration of sensory block was more in ropivacaine group. 21 patients reached sensory block T10 in levobupivacaine group in 10min. Time for reaching maximum sensory block is less in ropivacaine group. Pain was less significantly in ropivacaine group at various intervals.

The study by **Lee, Ying Y¹⁴ et al** was done on seventy-five patients scheduled for lower limb surgery under combined spinal-epidural anesthesia. Patients were randomized to receive intrathecal bupivacaine, levobupivacaine, or ropivacaine. The study concluded that median effective doses were 5.50 mg for bupivacaine and 8.41 mg for ropivacaine. This study suggests that Ropivacaine is less potent compared to Bupivacaine in intrathecal anaesthesia for lower limb surgery, in contrast to our study findings.

The study by **Ph. E. Gautier, et al.**¹⁵ was done to evaluate intrathecal ropivacaine for ambulatory surgery on 150 patients with ASA physical status 1 scheduled for knee arthroscopy. Patients received 8 mg of bupivacaine; 8 mg ropivacaine, 10 mg ropivacaine, 12 mg ropivacaine and 14 mg ropivacaine. The level and duration of sensory anaesthesia, Results showed that the Intrathecal ropivacaine 10 mg produced shorter sensory anesthesia and motor blockade compared to bupivacaine 8mg. The quality of intraoperative analgesia was mild in the 10-mg ropivacaine group. Ropivacaine 12 mg produced sensory and motor block almost equal to bupivacaine 8 mg. The study concluded that the intrathecal Ropivacaine 12 mg is almost equal to bupivacaine 8 mg and ropivacaine offers no major benefit compared with bupivacaine.

The study by **Sidharth Bhasin et al.**¹⁶ was done to compare the efficacy of bupivacaine with two concentrations of Ropivacaine (R1 and R2) on patients who undergone joint replacement surgeries. Patients were classified into three groups depending on the concentration of drug used. Daily average visual analogue pain scores on days 1 and 2 were found to be significantly higher in Group R1. There was more requirement of rescue analgesia in Group R1 on day 1. Postoperative hospital stay was more in Group R1. Hypotension and delayed motor block were more in Bupivacaine group. The study concluded that Ropivacaine 0.2% and bupivacaine 0.125% were having equally efficacy but ropivacaine had a better safety profile.

CONCLUSION

From our study, it was proved that Levobupivacaine and Ropivacaine were effective for combined spinal epidural anaesthesia in patients scheduled for lower

limb surgeries. As per the study results, ropivacaine is more effective compared to levobupivacaine when used as local anaesthetics in CSE.

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