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Comparison of efficacy of intrathecal hyperbaric ropivacaine and hyperbaric bupivacaine in terms of enhanced recovery after surgery (ERAS) for ACL reconstructions

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ABSTRACT

Background: Bupivacaine is the drug of choice in spinal anaesthesia (SA), while Ropivacaine with its comparatively shorter duration of motor block allows early mobilization post ACL reconstruction surgery which is a crucial factor in Early Recovery after Surgery.

Materials and Methods: In this randomized double-blind comparative study of a total of 60 patients irrespective of gender undergoing ACL reconstruction surgery were studied. After Administration of SA to group R (2.5ml of 0.75% Heavy Ropivacaine) & group B (2.5ml of 0.5% Bupivacaine) both were compared for their post-operative effects with Bromage score, Aldrete score & Visual Analogue Score.

Result: The time required for complete regression of motor blockade in group R (144.5±26.1 mins) < group B (181±21.3mins) which allowed for early mobilization which over all provides better and faster recovery.

Conclusion: Hyperbaric Ropivacaine when compared to Bupivacaine promises better results in terms of early ambulation and intraoperative hemodynamic stability promoting ERAS in patients undergoing ACL reconstruction surgeries. Promoting ERAS policy will reduce the duration of hospital stay, thereby improving the cost-effectiveness of health services.

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1. Introduction

The subarachnoid block for ACL reconstruction surgeries is the anaesthetic modality of choice since long.¹ There are various new local anaesthetic (LA) molecules which provide better cardiovascular stability, optimum surgical anaesthesia and rapid recovery after anaesthesia.

ERAS is the current advancement and practice in field of anaesthesia. The ERAS protocol is evidenced based guidelines which were earlier used for colorectal surgeries in the early 21st century.² These guidelines are now being applied for different surgeries in order to promote early mobilisation leading to early discharge.

Ropivacaine is a newer LA molecule which is frequently preferred in day care short duration procedures. It has been proved in many clinical studies that Ropivacaine is less cardio and neurotoxic as compared to Bupivacaine.³ Ropivacaine has low lipid solubility and is believed to affect predominantly sensory nerves than motor nerves. This suggests that Ropivacaine can be a preferable choice for surgeries, potentially facilitating early post-operative mobilization due to its sensorimotor dissociation which is a crucial component in the ERAS protocol.⁴

We designed this study to compare the recovery parameters of ropivacaine with bupivacaine and the feasibility of use of these drugs in ERAS protocol for patients undergoing ACL reconstruction surgeries. The primary objective of this study was to compare the time of

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complete motor regression and the secondary objective were to compare the time of first rescue analgesic demand, time of first ambulation, intraoperative hemodynamic parameters and complications if any in the patients undergoing ACL reconstruction surgeries.

2. Materials and Methods

We conducted this hospital based prospective, randomized, double blind comparative study in complete accordance with the guidelines of Helsinki from August 2022 up to August 2023 in the time period of 1 year after obtaining the institutional ethical approval.

We included patients of either sex in the age group of 20 to 60 Years belonging to ASA physical status I, II and III undergoing ACL Reconstruction Surgeries and who consented to participate in the study.

Patients allergic to the local anaesthetic drug, Infection at the site of lumbar puncture, coexisting coagulopathy or any neurological condition were excluded from the study. A total 60 patients were randomly allotted to two equal groups. A minimum of 28 patients were required in each group to achieve a significance level of 95% and power of 80%. Hence, we included 30 patients in each group to consider any dropouts.

Group R received 2.5ml of 0.75% Hyperbaric Ropivacaine with 25mcg Fentanyl and Group B received 2.5ml of 0.5% Hyperbaric Bupivacaine with 25mcg Fentanyl.

After explaining the procedure and confirming the NBM hours, the patients were shifted in the operation theatre. An Intravenous access was taken with 20 Gauge cannula. Standard monitors like Pulse oximeter, Noninvasive Blood pressure and ECG were attached and the baseline parameters were noted. All the patients were premedicated with Inj. Ondansetron 4mg intravenously.

A sub arachnoid block was given by a blinded anesthesiologist to the patients in sitting position at the level of L3-L4 with the help of 26 Gauge Quincke spinal needle along with the drug depending upon the assigned group of the patient and then the patient was made supine.

The Intraoperative parameters like Heart Rate, Mean Arterial Blood pressure, Systolic and Diastolic Blood pressure were noted at 0, 5, 10, 15, 20, 25, 30, 60 and 90 mins following block. The patients were observed for intraoperative hypotension that is fall in Blood pressure by less than 20% than the baseline which was treated with Inj. Mephentermine 6mg Bolus Intravenously and Bradycardia that is Heart rate less than 50 beats per min which was treated with Inj Atropine 0.6mg Intravenously.

The patients were shifted to Postoperative Care Unit and observed for 2 hours postoperatively. Later shifted to orthopedic wards and observed until 24 hrs. They were assessed for postoperative mobilization according to the Bromage Score, for ambulation according to the Modified

Aldrete score and pain according to the Visual Analogue Score.

A rescue analgesia in the form of Inj. Paracetamol 1gm was given intravenously for a VAS of 4 or more.

Statistical analysis: Sample size was calculated based on the previous study done by Ramesh Koppal et al⁵ and by using OpenEpi version 3. Considering the significant level of probability at 5% ($P < 0.05$) and assuming 20% difference in the duration of motor blockade with intrathecal Hyperbaric Ropivacaine and Hyperbaric Bupivacaine. 28 patients were required in each group to achieve 80% power at the 10% significance level to detect the true difference among the two groups. We took 4 patients more in the sample size to avoid error due to drop-outs. Results were analysed using SPSS version 20 and expressed as mean \pm standard deviation. The comparison among 2 groups was done using unpaired T test. Appropriate univariate and bivariate analysis was carried out using Students t test for the continuous variable (age) and Chi square test for the categorical variables. The data was considered significant if p value ≤ 0.05 and highly significant if p value ≤ 0.001 .

3. Results

The results were noted and expressed in a tabulated format for comparison of both the groups.

Demographic chart: The demographics were statistically comparable in both the groups with respect to Age, Weight, ASA grading, Height and Gender and the P value was non-significant. (Table 1)

In our study, we noted that the postoperative mobilization and ambulation which was assessed by the Bromage Score (Table 2) and Modified Aldrete score (Table 3) respectively was achieved earlier by Group R than by Group B.

The postoperative pain assessed according to the Visual Analogue score (Table 4) was more in Group R than in group B however the p value was insignificant.

The number of steps walked was assessed after 24 hours for each patient in both the groups. The average number of steps walked in Group R (12.64) was more than the average number of steps walked by patients in Group B(8.54).(Figure 1)

The hemodynamic parameters like the Heart rate, Systolic and Diastolic blood pressure and the Mean Arterial pressure were more near the baseline in group R than group B.(Figure 2)

4. Discussion

We conducted this study to compare the outcomes of ropivacaine and bupivacaine with respect to ERAS when used in subarachnoid block for ACL reconstruction surgeries. Not many studies have been conducted to compare this aspect of the drugs.

Table 1: Demographic profile

| | Group R Mean±SD | Group B MEAN±SD | P Value |
|------------|-----------------|-----------------|------------|
| Age | 51.26 ± 5.81 | 51.03 ± 6.14 | P=0.88(NS) |
| Weight | 73.73 ± 5.54 | 74.63 ± 5.73 | P=0.61(NS) |
| ASA I/II | 14/16 | 12/18 | P=0.74(NS) |
| Height | 158.62±8.61 | 162.07±7.52 | P=0.94(NS) |
| Gender M/F | 18/12 | 16/14 | P=0.52(NS) |

Table 2: Post operative Bromage score in Group B and Group R

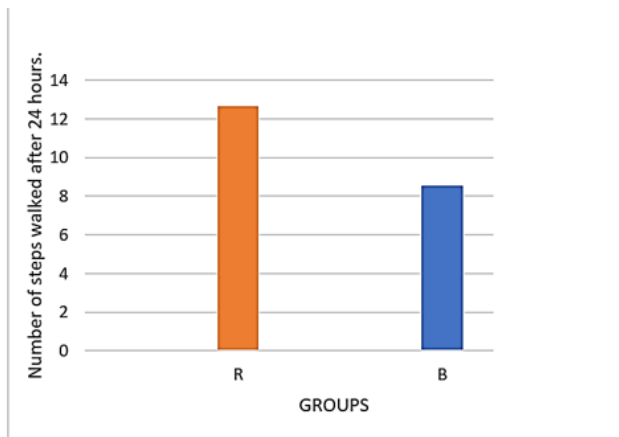
| Bromage Score | Group R Mean±SD | Group B Mean±SD | P Value |
|--------------------------------|-----------------|-----------------|------------------------------|
| Score II Almost Complete Block | 58.4± 6.04 | 86.1± 7.9 | P<0.05 |
| Score III Partial block | 98.5± 14.6 | 136.2± 12.3 | P<0.05 |
| Score IV None 0 | 144± 26.5 | 181± 21.3 | P<0.001 (highly significant) |

Table 3: Post operative Modified Aldrete score in Group B and Group R

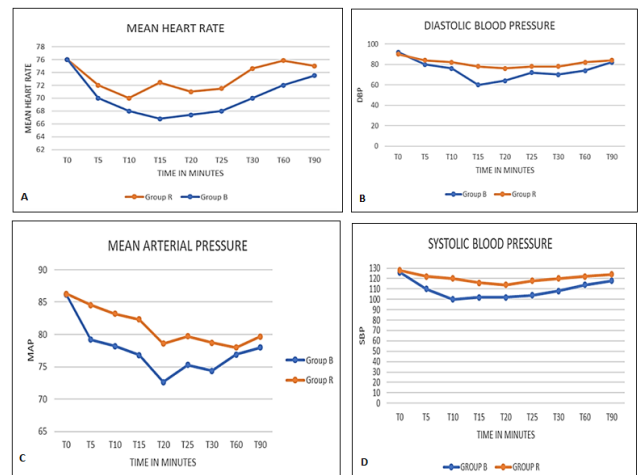
| | Group R Mean±SD | Group B Mean±SD | P value |
|--|-----------------|-----------------|-----------------------|
| Modified Aldrete Score of 10 Achieved In Minutes | 189.4 ± 10.33 | 256.9 ± 7.56 | P <0.05 (Significant) |

Table 4: Post operative VAS score in Group B and Group R

| Time | Group R Mean±SD | Group B Mean±SD | P Value |
|----------|-----------------|-----------------|------------|
| 30 mins | 0.7+/-0.595 | 0.6+/-0.420 | P=0.52(NS) |
| 60 mins | 1.56+/-0.504 | 1.4+/-0.498 | P=0.23(NS) |
| 9 mins | 2.93+/-0.639 | 2.6+/-0.723 | P=0.10(NS) |
| 6 hours | 2.93+/-0.639 | 4.0+/-0.742 | P=0.45(NS) |
| 12 hours | 5.03+/-0.764 | 4.0+/-0.742 | P=0.37(NS) |

**Figure 1:** Post operative number of steps walked in Group R and Group B

Minimally invasive surgeries with early recovery after surgery promoting day care hospitalization is the most catered requirement in the present scenario. Orthopedic surgeries are often movement limiting and require long resting periods. With advancements in surgical techniques, surgical duration as well as tissue handling has been reduced which in turn reduces the need for long term immobilization. The acute postoperative pain and delayed

**Figure 2:** Intra operative Hemodynamic changes in Group R & Group B

recovery of motor power remains the limiting factor for early mobilization. So, we utilized the motor sparing property of ropivacaine to facilitate the early ambulation after minimally invasive surgery like ACL reconstruction.

In our study Group R exhibited early regression of complete motor blockade as assessed by Bromage Score with Hyperbaric Ropivacaine & Fentanyl (144.5±26.1

min) as compared to Hyperbaric Bupivacaine & Fentanyl (181 ± 21.3 mins) which resulted in early ambulation promoting of ERAS.

U Srivastava et al had similar observation using bromage score to compare 15mg of 0.5% hyperbaric ropivacaine and 11mg of 0.5% Hyperbaric Bupivacaine for caesarean section.⁶ Further Ramesh Koppal et al noted significant difference in time required for regression of motor block between 2.5ml Ropivacaine with Fentanyl (154.5 ± 20.1 min) and 2.5ml Bupivacaine with Fentanyl (196.0 ± 24.2 min) for perineal surgeries.⁵

While Khan et al showed that the application of ERAS can significantly reduce LOS and incidence of complications.⁷

Hailey Hampton conducted a study to analyze the application of ERAS protocols in ACL cases and concluded that after ERAS protocol application the patients were more comfortable and pain-free and could be ambulated earlier with hastened recovery.⁸

R. Ramlogan et al in their study compared local anesthetic infiltration with peripheral nerve blocks and reported that the longer pain-free period and better control of the operated limb facilitated early mobilization and better patient satisfaction.^{9,10}

Lee et al studied a dose response curve of ropivacaine in lower limb surgeries and concluded that a comparative lower dose (ED₉₅ of 11.4 mg) to be effective in lower limb surgeries lasting for about 50 mins.¹¹ This supports the hypothesis of our study where early motor recovery is the objective. Thus, lower dose of Ropivacaine can provide optimum anesthesia to surgeries lasting for 1 to 1.5 hours with similar pain relief to bupivacaine and early initiation of motor movements, enhancing the quality of post operative recovery.

Vanja Contino et al compared Ropivacaine with bupivacaine in patients undergoing total hip arthroplasty and concluded that the patients receiving ropivacaine had superior ambulation time and distance and were shifted out of post anesthesia care unit earlier.¹² Authors strongly recommended use of Ropivacaine in day care surgeries. These findings are concurrent with ours and we authors also recommend use of 0.75% Ropivacaine to facilitate early ambulation in day care orthopedic practice.

Ph. E. Gautier conducted a study comparing different doses of Ropivacaine with that of bupivacaine but the study highlighted only upon post spinal transient neurological deficits, which were lesser with ropivacaine when compared with bupivacaine.¹³ These authors claimed that ropivacaine was less potent than bupivacaine as it caused lesser motor impairment than bupivacaine. In contrast though we agree with Gautier et al in terms that ropivacaine causes lesser motor impairment we do not agree to the conclusion of ropivacaine being inferior in terms of potency. In our study Ropivacaine provided comparable analgesia whilst early motor recovery which we suggest is beneficial for the

ERAS.

Gohil et al also compared 0.75% ropivacaine with 0.5% Bupivacaine and concluded them to be comparable and alternative options with early motor recovery using ropivacaine.¹⁴ We too elicited similar results from our study.

Stienstra R et al reviewed ropivacaine and highlighted an important aspect that ropivacaine in 50% higher concentration than bupivacaine is less cardio toxic.¹⁵ The use of ropivacaine can thus be useful in grade 3 and 4 cases where early post-operative ambulation is the cornerstone of hastened recovery.

Neha P et al in a study used ropivacaine 0.2% in adductor canal block for post-operative pain relief, utilising the same motor sparing property of ropivacaine whilst providing sufficient pain relief in ACL reconstruction surgeries.¹⁰ In our study we have used a higher concentration of ropivacaine and used it in subarachnoid block as a sole anaesthesia. In our study we also studied the regression of motor block and number of steps walked after 24 hours.

We authors admit certain limitation of our study. Pain being a subjective parameter the individual pain threshold may not be constant and the variation is not considered. Secondly all the patients were not treated by the same physiotherapist so the variability in number of steps walked may also add to some bias.

5. Conclusion

Hyperbaric Ropivacaine when compared to Hyperbaric Bupivacaine promises better results in terms of early ambulation and intraoperative hemodynamic stability promoting ERAS in patients undergoing ACL reconstruction surgeries. Promoting ERAS policy will reduce the duration of hospital stay, thereby improving the cost-effectiveness of health services.

6. Consent for Publication

Written informed consent taken.

7. Availability of Data and Material

Not applicable.

8. Source of Funding

No fundings.

9. Conflict of Interests

The authors declare that they have no conflict of interests.

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