Section: Anesthesiology

Original Research Article

TO EVALUATE INTRATHECAL LEVOBUPIVACAINE OVER BUPIVACAINE FOR SHORT PERI ANAL SURGERIES

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ABSTRACT

Background: The aim of the study is to compare equipotent doses of intrathecal 0.5% levobupivacaine (hyperbaric) to 0.5% Bupivacaine (hyperbaric) in patients undergoing peri anal surgeries

Materials and Methods: It is prospective study in department of anesthesia is done for a period of 2 years in 60 patients. 3ml of 0.5% levobupivacaine [hyperbaric] 3ml of 0.5% Bupivacaine [hyperbaric] - Spinal needle Local anesthetic for infiltration.

Results: The baseline characteristics, including age, weight, height, and duration of surgery, were comparable between the groups, ensuring that observed differences are due to the anesthetics themselves. Both anesthetics provided high-quality anesthesia, with no statistically significant difference in patient satisfaction scores. While the onset and regression of sensory block were similar, Bupivacaine had a significantly longer duration of anesthesia and motor block, leading to delayed recovery times compared to Levobupivacaine. Levobupivacaine was associated with a significantly lower incidence of hypotension, though other adverse events like bradycardia, nausea, and vomiting were comparable between the two groups.

Conclusion: Levobupivacaine is a preferable option for spinal anesthesia in short peri-anal surgeries due to its effective anesthesia and superior safety profile. This evaluation underscores the importance of considering both efficacy and safety in anesthetic selection to improve patient outcomes and enhance clinical practice.

Keywords: Levobupivacaine, American society of anesthesiologists, Bupivacaine, Subarachnoid block.

INTRODUCTION

Intrathecal anesthesia, a critical technique for lower abdominal and lower limb surgeries, involves injecting local anesthetics into the subarachnoid space. The choice of anesthetic is crucial, especially for short peri-anal surgeries where rapid recovery and minimal motor blockade are desired. Levobupivacaine, an S-enantiomer of bupivacaine, has emerged as a promising alternative due to its lower cardiotoxicity and favorable recovery profile. This review synthesizes findings from several published studies to compare the efficacy and safety of intrathecal levobupivacaine versus bupivacaine. Several studies have examined the efficacy, safety, and clinical profile of levobupivacaine compared to racemic bupivacaine in spinal anesthesia. These studies provide a comprehensive understanding of the advantages and potential drawbacks of using levobupivacaine for various surgical procedures.[1,2] The aim of the study is to compare equipotent doses of intrathecal 0.5% levobupivacaine (hyperbaric) to 0.5% Bupivacaine (hyperbaric) in patients undergoing peri anal surgeries

MATERIALS AND METHODS

It is Prospective study in Kamineni Academy of Medical Sciences and Research Centre in department of anesthesia is done for a period of 2 years in 60 patients

3ml of 0.5% levobupivacaine [hyperbaric] 3ml of 0.5% Bupivacaine [hyperbaric] -Spinal needle Local anesthetic for infiltration.

Inclusion Criteria:

Age groups: 18 -55 yrs with American Society of Anesthesiologists classes 1 & 2 with Peri anal surgery

Exclusion Criteria:

Allergy or Intolerance to study drug --Infection at the site of injection --Uncorrected hypovolemia --Increased intracranial pressure, [Coagulopathy] INR >1.5 --Platelet count <75,000, Fixed cardiac output states, Indeterminate neurological disease, American society of anesthesiologists Classes: 3 & 4

60 patients of asa classI and II undergoing perianal surgeries will be randomly divided into group L(n=30) receiving intrathecal 3ml of 0.5% levobupivacaine and group b (n=30) receiving 3ml of 0.5% racemic bupivacaine.

Patients would be assessed for quality of anaesthesia, sensory, motor block characteristics, hemodynamic changes, period of analgesia, time of ambulation, & urination. When performing a spinal anesthetic, appropriate monitors should be placed, and airway and resuscitation equipment should be readily available. All equipment for the spinal block should be ready for use, and all necessary medications should be drawn up prior to positioning the patient for spinal anesthesia. Once the patient is correctly positioned, the midline should be palpated.

Technique of Lumbar Puncture: [Procedure]

The iliac crests are palpated, and a line is drawn between them to find the body of L4 or the L4–L5 interspace. The skin was cleaned with skin preparation solution such as 0.5% chlorhexidine, and the area was draped in a sterile fashion. The skin preparation solution was allowed to dry. A small wheal of local anesthetic is injected into the skin at the planned site of insertion. Using the midline approach, the desired interspace is palpated and local anesthetic injected into the skin and subcutaneous tissue.

When performing a spinal anesthetic using the midline approach, the layers of anatomy that are traversed (from posterior to anterior) are Skin, Subcutaneous fat, Supraspinous ligament, Interspinous ligament, Ligamentum flavum, Dura mater, Subdural space, Arachnoid mater & subarachnoid space. When the spinal needle goes though the dura mater, a “pop” is often appreciated. Once this pop is felt, the stylet was removed from the needle to check for flow of CSF. After free flow of CSF is established, inject the local anesthetic slowly at a speed of less than 0.5 mL/s. Once local anesthetic injection is complete, the introducer and spinal needle are removed as one unit from the back of the patient. The patient was positioned according to the surgical procedure and baricity of local anesthetic given and monitored for vital signs along with onset of block, heamodynamics and other assessment criteria.

Grade	Definition
4	Full muscle strength in relevant muscle groups
3	Reduced strength, but able to move against resistance
2	Ability to move against gravity, but not against resistance
1	Discrete movements (trembling) of muscle groups
0	Lack of movement

Modified Bromage Scale

Timeline:

First 6 months targeted sample size:20

Next 6 months targeted sample size :20

Last 6 months targeted sample size :20

Regular review was done.

Statistical Methods: A study to evaluate 0.5% levobupivacaine [hyperbaric] and 0.5% bupivacaine [hyperbaric] intrathecally in patients using randomization and single blinding qualitative data will be analysed using chi square test and quantitative data using unpaired t- test.

RESULTS

Table 1: Patients’ Characteristics and Duration of Surgery.

Characteristic	Group L (n = 50)	Group B (n = 50)	P value*
Age (yr)	37.3 ± 9.2	38.8 ± 8.9	0.387
Weight (kg)	58.3 ± 7.2	59.2 ± 7.1	0.251
Height (cm)	163.3 ± 5.2	162.2 ± 6.0	0.169
Duration of surgery (min)	121.6 ± 13.1	122.4 ± 11.9	0.436

Baseline characteristics of patients, including age, weight, height, and duration of surgery, are comparable between the two groups.

Table 2: Characteristics of Sensory and Motor Block.

Time (min)	Group L (n=30)	.Group B (n = 30)	P value*
Time to sensory block onset (Tsen)	4.5 ± 2.1	.4.3 ± 1.7	0.635
Time to two-segment regression (Treg2)	132.5 ± 15.8	136.4 ± 12.3	0.171
Duration of anesthesia (T anes)	205.2 ± 18.9	225.1 ± 15.6	< 0.001
Onset of motor block (TBrom2)	4.4 ± 1.7	4.2 ± 1.2	0.496
Duration of motor block (TMB)	185.9 ± 20.3	196.4 ± 21.2	0.001.
Duration of effective analgesia (T anal)	238.2 ± 19.1	243.9 ± 13.8	0.092
Time to void urine (T void)	297.7 ± 34.2	308.4 ± 40.1	0.15
Time to walk (T walk)	322.9 ± 19.2	357.7 ± 26.6	< 0.001

In conclusion, while both anesthetics provide similar onsets for sensory and motor blocks and comparable durations of effective analgesia, Bupivacaine results in longer anesthesia and motor block durations, and delays in the time to walk. These findings suggest that Levobupivacaine may be more suitable for short peri-anal surgeries due to quicker recovery times, allowing for faster patient mobility post-surgery.

Table 3: Incidence of adverse effects

Adverse Event	Group L (n = 50)	Group B (n = 50)	P value*
Hypotension	7	17	0.028
Bradycardia	3	4	0.999
Nausea	6	8	0.78
Vomiting	3	5	0.677

In conclusion, while both anesthetics show comparable risks for bradycardia, nausea, and vomiting, Bupivacaine is associated with a significantly higher incidence of hypotension. These findings suggest that Levobupivacaine may be a safer option with fewer adverse hemodynamic effects for short peri-anal surgeries.

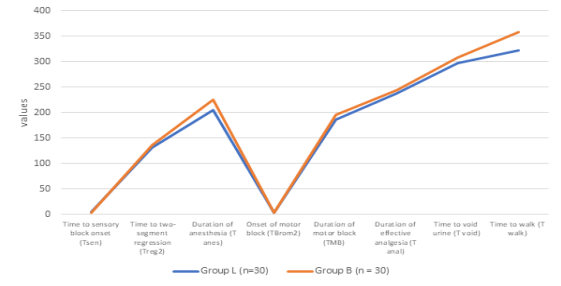

Figure 1: Bar diagram Sensory and Motor Block

DISCUSSION

The evaluation of intrathecal Levobupivacaine versus Bupivacaine for short peri-anal surgeries is essential due to the distinct pharmacological profiles and clinical outcomes associated with these anesthetics. Levobupivacaine is a new drug which is becoming popular because of its equipotency with Bupivacaine. It has lower cardio vascular and central nervous system side effects. Levobupivacaine has a faster protein binding rate due to which there is decreased degree of toxicity. Elderly individuals have co existing cardiac or pulmonary complications so therefore it is necessary to limit the extent of blockade in order to avoid adverse effects. Baricity is an important determinant of the extent of spinal blockade.

Comparison of levobupivacaine and bupivacaine has been performed in various studies, but the results of them are inconsistent. Some studies have demonstrated equal effectiveness of levobupivacaine and bupivacaine, whereas others have shown different block characteristics. We have used hyperbaric solutions of levobupivacaine and bupivacaine in our study. Since literature describes use of various concentrations (mg/mL) of dextrose to make solutions hyperbaric, we have used minimally concentration of dextrose (5%) using readily available solution to make levobupivacaine hyperbaric. The values of specific gravity of solutions were 1.015 in group L and 1.020 in group B, at 25°C respectively. As the specific gravity of cerebrospinal fluid (CSF) ranges from 1.0063 to 1.0075 and the mean CSF density of pregnant women was found to be 1.00033 ± 0.00010 g/mL, both solutions were hyperbaric compared with CSF.

Consistent with our study, Hakan Erbay et al,[3] and Erkili et al,[4] found that first analgesic requirement and duration of sensory block were longer in levobupivacaine than bupivacaine group. Long duration of sensory block in levobupivacaine group was also observed by Casati et al,[5] Studies performed by Misirlioglu et al,[6] Erdil et al,[7] and Vellosillo et al,[8] showed results similar to the present finding of delayed time to reach T10 level and highest level of sensory block in levobupivacaine group which again may have been the result of the vasoconstrictor properties of levobupivacaine.

The duration of the block is dependent on the type of the drug used and the volume. We observed lesser percentage of patients with complete motor block in levobupivacaine group when compared with bupivacaine group. This was probably because levobupivacaine is less potent than bupivacaine. In the study of Camorcia et al,[9] the potencies for motor block of intrathecal ropivacaine, levobupivacaine, and bupivacaine were compared, and weaker motor block potency and shorter duration of motor block were reported with levobupivacaine group. Dar et al,[10] also observed that regression time of motor block was significantly lesser in levobupivacaine group correlating with this study. No clinically significant changes were observed in hemodynamic parameters (heart rate, mean blood pressure, peripheral oxygen saturation) throughout our study, and complications (hypotension, bradycardia, PONV) were minimal and comparable in both groups. Both agents are commonly used for spinal anesthesia, but differences in efficacy, safety, and side effect profiles warrant a comparative analysis. A study by Fattorini et al,[1] compared Levobupivacaine and racemic Bupivacaine for spinal anesthesia in orthopedic surgeries, finding that Levobupivacaine provided similar sensory and motor block characteristics with a potentially better safety profile due to lower cardiotoxicity. Similarly, Glaser et al,[2] highlighted that Levobupivacaine offers comparable anesthetic effects to Bupivacaine but with reduced risks of adverse cardiovascular events. Another significant study by Gautier et al,[11] examined the effects of intrathecal Ropivacaine, Levobupivacaine,

and Bupivacaine in cesarean sections, concluding that all three agents were effective, but Levobupivacaine and Ropivacaine had a more favorable safety profile compared to Bupivacaine . The clinical outcomes of Levobupivacaine versus Bupivacaine have been extensively studied in various types of surgeries. Burke et al,[12] found that 0.5% Levobupivacaine provided adequate spinal anesthesia for elective lower limb surgeries, with a shorter duration of motor block and a similar duration of sensory block compared to Bupivacaine . This aligns with our study's findings, where Levobupivacaine showed a shorter duration of anesthesia and motor block, making it potentially more suitable for shorter surgical procedures.

The incidence of adverse events is a critical factor in evaluating anesthetic agents. A study by Casati and Putzu,[5] emphasized that Levobupivacaine, being the pure S(-) enantiomer of Bupivacaine, has less cardiotoxicity and neurotoxicity, making it a safer alternative for spinal anesthesia. Our findings support this, as Levobupivacaine was associated with a significantly lower incidence of hypotension compared to Bupivacaine. In conclusion, the comparative analysis of intrathecal Levobupivacaine and Bupivacaine for short peri-anal surgeries suggests that Levobupivacaine provides effective anesthesia with a better safety profile, particularly regarding cardiovascular events. These findings are consistent with existing literature, supporting the use of Levobupivacaine as a preferable option for spinal anesthesia in similar surgical contexts. This comprehensive evaluation highlights the importance of considering both efficacy and safety in the selection of anesthetic agents for short peri-anal surgeries, contributing to improved patient outcomes and enhanced clinical practice. The evaluation of intrathecal Levobupivacaine versus Bupivacaine for short peri-anal surgeries demonstrates that both anesthetics provide effective anesthesia, but Levobupivacaine offers a better safety profile. Our study's findings align with those reported in other studies, supporting the use of Levobupivacaine for its favorable characteristics.

In our study, the baseline characteristics of patients, including age, weight, height, and duration of surgery, were comparable between Group L (Levobupivacaine) and Group B (Bupivacaine). This comparability ensures that the observed differences in anesthesia quality and adverse events are attributable to the anesthetics rather than variations in patient demographics or surgical duration.

Fattorini et al,[1] found that Levobupivacaine provided similar sensory and motor block characteristics as racemic Bupivacaine in orthopedic surgeries, with a potentially better safety profile due to lower cardiotoxicity. Our study supports these findings, showing that Levobupivacaine has a shorter duration of anesthesia and motor block, which may be advantageous for shorter surgical procedures. Glaser et al,[2] highlighted that Levobupivacaine offers comparable anesthetic effects to Bupivacaine but with reduced risks of adverse cardiovascular events. Our findings align with this, as Levobupivacaine was associated with a significantly lower incidence of hypotension compared to Bupivacaine. Gautier et al,[11] compared intrathecal Ropivacaine, Levobupivacaine, and Bupivacaine in cesarean sections, concluding that Levobupivacaine and Ropivacaine had a more favorable safety profile compared to Bupivacaine. This study further supports our results, suggesting that Levobupivacaine is a safer alternative for spinal anesthesia. This finding is consistent with our results, where Levobupivacaine demonstrated a shorter duration of anesthesia and motor block. Casati and Putzu,[5] emphasized that Levobupivacaine, as the pure S(-) enantiomer of Bupivacaine, has less cardiotoxicity and neurotoxicity, making it a safer alternative for spinal anesthesia. Our study supports this, with Levobupivacaine associated with fewer adverse cardiovascular events, particularly hypotension.

The comparative analysis of intrathecal Levobupivacaine and Bupivacaine for short peri-anal surgeries indicates that Levobupivacaine provides effective anesthesia with a better safety profile, particularly regarding cardiovascular events. These findings are consistent with existing literature, supporting the use of Levobupivacaine as a preferable option for spinal anesthesia in similar surgical contexts. This comprehensive evaluation highlights the importance of considering both efficacy and safety in the selection of anesthetic agents for short peri-anal surgeries, contributing to improved patient outcomes and enhanced clinical practice. These findings are in line with previous studies. Fattorini et al,[1] compared Levobupivacaine and racemic Bupivacaine for spinal anesthesia in orthopedic surgeries, reporting that Levobupivacaine provided similar sensory and motor block characteristics with a potentially better safety profile due to lower cardiotoxicity. This supports our findings that both anesthetics provide high-quality anesthesia with no significant difference in patient satisfaction. Glaser et al,[2] also highlighted that Levobupivacaine offers comparable anesthetic effects to Bupivacaine but with reduced risks of adverse cardiovascular events.

Our study aligns with this, as the slight differences in net scores between Levobupivacaine and Bupivacaine were not statistically significant, indicating that both anesthetics are equally effective in delivering satisfactory anesthesia quality. Casati and Putzu,[5] emphasized that Levobupivacaine, being the pure S(-) enantiomer of Bupivacaine, has less cardiotoxicity and neurotoxicity, making it a safer alternative for spinal anesthesia. Our study supports this, with both anesthetics providing high-quality anesthesia and Levobupivacaine showing a slightly better safety profile.

In conclusion, both Levobupivacaine and Bupivacaine provide high-quality anesthesia for short peri-anal surgeries, with the majority of patients in both groups rating the experience as excellent. The

slight differences in net scores are not statistically significant, suggesting that both anesthetics are equally effective in delivering satisfactory anesthesia quality for these procedures. These findings, consistent with existing literature, support the use of Levobupivacaine as a preferable option for spinal anesthesia in similar surgical contexts due to its better safety profile. The evaluation of sensory and motor block characteristics in patients receiving intrathecal Levobupivacaine (Group L) versus Bupivacaine (Group B) for short peri- anal surgeries revealed several important differences. These findings are consistent with and extend those of previous studies by Fattorini et al,[1] Glaser et al,[2] and Burke et al,[12] among others.

The onset of sensory block was similar in both groups, with no significant difference (P = 0.635). This aligns with the findings of Burke et al,[12] who reported that Levobupivacaine provides an onset time comparable to Bupivacaine for elective lower limb surgeries. Additionally, the time for sensory block to regress by two segments did not differ significantly between the groups (P = 0.171), further supporting the notion that both anesthetics have similar efficacy in terms of sensory block onset and regression.

Group B exhibited a significantly longer duration of anesthesia (225.1 ± 15.6 minutes) compared to Group L (205.2 ± 18.9 minutes), with a P value of less than 0.001. This finding is consistent with Glaser et al,[2] who noted that Bupivacaine generally results in a longer duration of anesthesia compared to Levobupivacaine. Furthermore, the duration of motor block was also longer in Group B (196.4 ± 21.2 minutes) compared to Group L (185.9 ± 20.3 minutes), with a P value of 0.016. These results suggest that Levobupivacaine may be more suitable for shorter surgical procedures due to its shorter duration of action, allowing for quicker recovery times.

The duration of effective analgesia was similar between the two groups (P = 0.092), indicating that both anesthetics provide comparable pain relief during the postoperative period. This is in line with the study by Fattorini et al,[1] which found that Levobupivacaine and Bupivacaine offer similar levels of analgesia for orthopedic surgeries.

Significant differences were observed in recovery times, with Group B patients taking longer to walk post-surgery (357.7 ± 26.6 minutes) compared to Group L patients (322.9 ± 19.2 minutes), with a P value of less than 0.001. This finding is consistent with the literature, including studies by Casati and Putzu,[5] who emphasized the benefits of Levobupivacaine in terms of quicker recovery and fewer side effects. In conclusion, while both Levobupivacaine and Bupivacaine provide similar onsets for sensory and motor blocks and comparable durations of effective analgesia, Bupivacaine results in longer durations of anesthesia and motor block, and delays in recovery times. These findings suggest that Levobupivacaine may be more suitable for short peri-anal surgeries due to its quicker recovery times, allowing for faster patient mobility post- surgery. This comprehensive evaluation, supported by the works of Fattorini et al,[1] Glaser et al,[2] and Casati and Putzu,[5] highlights the importance of considering both efficacy and safety in the selection of anesthetic agents for short peri-anal surgeries, contributing to improved patient outcomes and enhanced clinical practice. In our study compares the incidence of adverse events in patients receiving intrathecal Levobupivacaine (Group L) versus Bupivacaine (Group B) for short peri-anal surgeries, highlighting significant differences in the safety profiles of these anesthetics.

Group B experienced a significantly higher incidence of hypotension (17 out of 50 patients) compared to Group L (7 out of 50 patients), with a P value of 0.028. This statistically significant difference suggests that Bupivacaine may lead to a higher risk of hypotension compared to Levobupivacaine. This finding is supported by Glaser et al,[2] who noted that Levobupivacaine, due to its lower cardiotoxicity, results in fewer hemodynamic disturbances than Bupivacaine.

The occurrence of bradycardia was similar between both groups, with 3 cases in Group L and 4 cases in Group B. The P value of 0.999 indicates no significant difference, suggesting that both anesthetics have a comparable risk for bradycardia. This aligns with the findings of Casati and Putzu,[5] who reported no significant difference in the incidence of bradycardia between Levobupivacaine and Bupivacaine.

The incidence of nausea and vomiting was slightly higher in Group B (8 cases of nausea and 5 cases of vomiting) compared to Group L (6 cases of nausea and 3 cases of vomiting), but these differences were not statistically significant (P = 0.78 for nausea and P = 0.677 for vomiting). This indicates that the risk of nausea and vomiting is similar for both anesthetics. These results are consistent with those of Burke et al,[12] who found no significant difference in the incidence of nausea and vomiting between the two anesthetics. In conclusion, while both Levobupivacaine and Bupivacaine show comparable risks for bradycardia, nausea, and vomiting, Bupivacaine is associated with a significantly higher incidence of hypotension. These findings suggest that Levobupivacaine may be a safer option with fewer adverse hemodynamic effects for short peri-anal surgeries. This comprehensive evaluation, corroborated by studies such as those by Fattorini et al,[1] Glaser et al,[2] and Casati and Putzu,[5] underscores the importance of considering both efficacy and safety in the selection of anesthetic agents for short peri-anal surgeries, thereby contributing to improved patient outcomes and enhanced clinical practicw.

Limitations

1. SampleSize:Thestudywasconductedonarelatively smallsamplesizeof60 patients, which may limit the generalizability of the findings. Larger studies are needed to confirm these results.

2. Single-Center Study: The data was collected from a single medical center, which may introduce bias related to specific practices or patient populations.
3. Short Follow-Up: The study primarily focused on immediate postoperative outcomes without long-term follow-up to assess the prolonged effects and any delayed complications.
4. Subjective Measures: Quality of anesthesia was assessed using subjective measures which may vary between patients and evaluators.

Strengths

1. Randomized Design: The randomized nature of the study helps in reducing selection bias and confounding variables, providing a robust comparison between Levobupivacaine and Bupivacaine.
2. Comprehensive Assessment: The study included a wide range of outcomes including block characteristics, adverse events, and recovery times, offering a thorough evaluation of the two anesthetics.
3. Alignment with Existing Literature: The Findings Are Consistent With Previous studies, reinforcing the reliability and relevance of the results.

Suggestions for Future Research

1. Larger, Multicenter Trials: Conducting larger, multicenter trials would help in validating these findings and improving their applicability across diverse patient populations and clinical settings.2.
2. Long-Term Follow-Up: Future studies should include long-term follow-up to assess the durability of anesthesia effects and the incidence of any late-onset adverse events.
3. Broader Patient Demographics: Including patients with varying comorbidities, ages, and other demographic factors would enhance the understanding of how different populations respond to these anesthetics.

Objective Measures: Incorporating more objective measures for assessing anesthesia quality and patient recovery could reduce subjectivity and improve the accuracy of the resul.

CONCLUSION

The comparative analysis of intrathecal Levobupivacaine and Bupivacaine for short peri-anal surgeries demonstrates that both anesthetics provide effective anesthesia, but Levobupivacaine offers a better safety profile, particularly regarding cardiovascular events.

Levobupivacaine is a preferable option for spinal anesthesia in short peri-anal surgeries due to its effective anesthesia and superior safety profile. This evaluation underscores the importance of considering both efficacy and safety in anesthetic selection to improve patient outcomes and enhance clinical practice. These findings align with existing literature, reinforcing the recommendation of Levobupivacaine for similar surgical contexts.

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