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Original Research Article

Comparative Study to Evaluate the Efficacy of Hyperbaric Levobupivacaine with Buprenorphine versus Hyperbaric Bupivacaine with Buprenorphine in Spinal Anestheisa for Lower Abdominal Surgeries

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Conflict of interest: Nil

Abstract:

Background: Spinal anesthesia is crucial for lower abdominal surgeries, offering reliable anesthesia and pain management. This study compares the efficacy of two intrathecal anesthesia combinations, hyperbaric levobupivacaine with buprenorphine and hyperbaric bupivacaine with buprenorphine, for lower abdominal surgeries.

Methods: A double-blind, randomized controlled study included 160 ASA 1 and 2 patients aged 18-75. They were assigned to Group L (hyperbaric levobupivacaine + buprenorphine) or Group B (hyperbaric bupivacaine + buprenorphine). Parameters evaluated included onset time of sensory block, onset time of motor blockade, time to peak sensory and motor levels, and duration of analgesia.

Results: In the study, significant differences were observed in various outcome measures between Group B and Group L. Group L demonstrated significantly higher mean scores for onset motor time (2.55 vs. 3.11, $p < 0.001$), onset sensory time (3.27 vs. 3.95, $p < 0.001$), highest sensory time (6.29 vs. 7.32, $p < 0.001$), and complete motor time (11.57 vs. 16.88, $p < 0.001$) compared to Group B. However, no significant differences were found in the regression of sensory ($p = 0.844$), total sensory ($p = 0.790$), or total motor ($p = 0.799$) between the two groups. These results suggest that Group L exhibited superior performance in several motor and sensory domains.

Conclusion: Group Bupivacaine+buprenorphine exhibited superior anesthesia characteristics in lower abdominal surgeries. However, additional research is required to confirm its effectiveness in diverse clinical scenarios, highlighting the importance of personalized anesthetic choices.

Keywords: spinal anesthesia, lower abdominal surgeries, bupivacaine, levobupivacaine, buprenorphine, anesthesia efficacy.

Introduction

In the realm of modern medicine, the quest for refining and optimizing medical practices continually drives progress. Spinal anesthesia has emerged as a cornerstone technique for various lower abdominal surgeries due to its multifaceted advantages. It ensures reliable and effective anesthesia, fostering patient satisfaction and surgical success. The cost-effectiveness of this method benefits both patients and healthcare providers, making it a preferred choice in many clinical settings. Furthermore, spinal anesthesia's unique ability to induce muscle relaxation contributes to decreased intraoperative complications, thereby improving surgical conditions and facilitating the precision of surgical procedures. [1]

Postoperative pain management is a paramount concern, particularly in lower abdominal surgeries. Spinal anesthesia, known for its prolonged analgesic effects, offers patients extended pain relief, reducing the reliance on additional pain medications and promoting faster recovery.

Our study explores the comparative efficacy of two vital combinations: hyperbaric levobupivacaine with buprenorphine versus hyperbaric bupivacaine with buprenorphine. By conducting this research, we aim to provide invaluable insights into the

advantages and disadvantages of each combination. This knowledge will empower clinicians to make informed decisions when selecting the most suitable anesthesia technique for lower abdominal surgeries.

In addition to evaluating the relative benefits of these combinations, our research also investigates their hemodynamic effects, sensory and motor block characteristics, and the duration of postoperative analgesia.

Our findings will not only guide clinical practice but also inspire further optimization of anesthesia techniques. As medical science continues to advance, opportunities for refinement and innovation in anesthesia practice will abound. We hope that our research will serve as a catalyst for ongoing advancements in this field, ultimately benefiting surgical patients and healthcare systems on a global scale.

Material and Method

Double blind, randomized controlled study was conducted in Department of Anesthesiology, Pacific Institute of Medical Sciences, Umarda, Udaipur, Rajasthan with due permission from the institutional ethical committee and written informed consent between September 2022 to May 2023.

Sample size- Total 160 patients undergoing elective lower abdominal surgery was selected. Patients were randomized into two groups of 80 each. At α error 0.5 and power 80%, assuming the difference in mean to be detected 0.5 with SD 1.05 as per seed article.

Scales Used- Visual Analogue Scale (VAS) [2], Numerical rating scale [3], Modified Bromage Scale [4]

Inclusion Criteria-

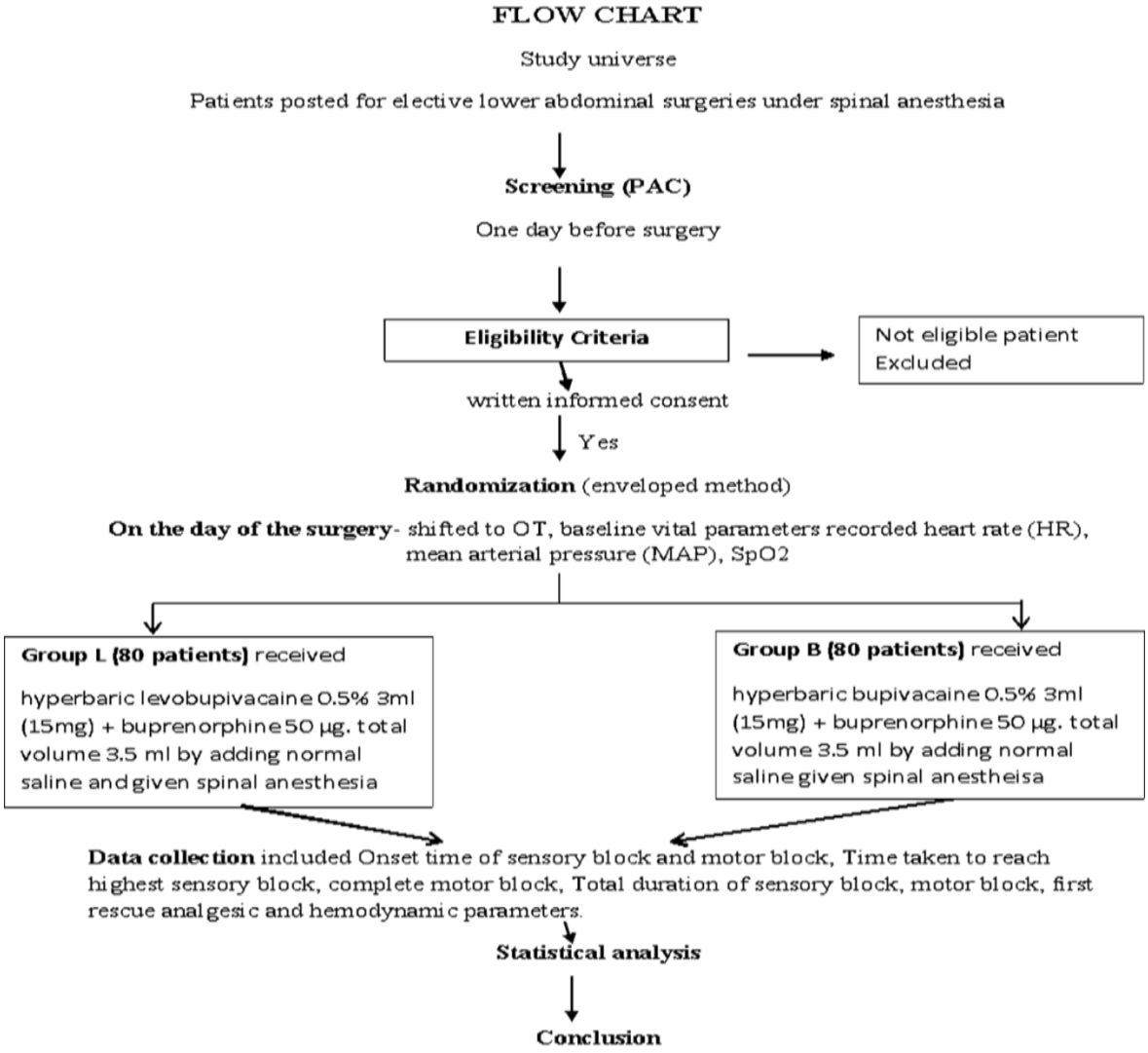
ASA physical status 1 and 2, Either sex, posted for elective lower abdominal surgery, Aged between 18 to 75 years, Weight between 40 to 80 kgs, Height >/= 150cms

Exclusion Criteria- Uncooperative patients or patient's refusal and all contraindications of spinal anesthesia

Method:

One day before surgery, a detailed pre anesthetic evaluation was done including clinical history, general and systemic examination, routine biochemical investigations, chest X ray and electrocardiography. The procedure of spinal anesthesia and Numerical Rating Scale (NRS) was explained to the patients to determine the level of analgesia in the postoperative period. It was carried out on a straight with a 0–10 cm line (no pain at all - maximum pain imaginable). was explained to the patient and written informed consent obtained. Patient was kept nil per orally from 12 midnight prior to the day of surgery. On the day of surgery, after identifying the patient, IV access was obtained with 18G/20G IV cannula and the patient was preloaded with Ringer Lactate solution at the rate of 15ml/hr. After shifting to OT, monitors were attached. Monitoring of vital parameters like heart rate (HR), noninvasive arterial blood pressure (NIBP), SpO2 and ECG were done. Baseline readings was recorded. Patient was made to sit and rest their forearms on their thighs so they can maintain a stable and comfortable position. The patient's back was cleaned with Povidone Iodine swab radially outwards from the proposed injection site. It will be allowed to rest on the skin for 2 min and then the back was cleaned with spirit and allowed to dry. Patient's back was draped with a sterile hole sheet and then spinal anesthesia was administered at L3-L4 interspace using 25 G Quincke's spinal needle. The study drug was injected into the subarachnoid space according to the group, after noting the clear free flow of CSF with the operation table kept flat. Patient was made to lie supine immediately. Group L received hyperbaric levobupivacaine 0.5% 3ml (15mg) + buprenorphine 50 µg. Group B received hyperbaric bupivacaine 0.5% 3ml (15mg) + buprenorphine 50 µg. The total volume will be made 3.5 ml by adding appropriate volume of normal saline and given intrathecally. Sensory block was assessed by loss of sensation to pinprick in the midline with an 18 G blunt needle from below upwards. It was performed every 2 min for first 10 min and then at an interval of 5 min until no change in level occurred. Onset time of sensory block (when patient does not feel pinprick at T10 level), time taken for highest level of sensory block achieved, time to maximum sensory block, and total duration of sensory block (regression to S1 dermatome) was noted. Motor blockade was assessed according to a modified Bromage scale. These tests was performed every 2 min for up to 10 min after spinal anesthesia. Onset time of motor block (grade 1), time to maximum motor block (grade 3), and total duration of motor block (from the time of intrathecal administration of the drug to motor recovery to Bromage 0 were noted. The surgical procedure was start 10 min after initiation of spinal anesthesia. If the level of analgesia was inadequate, switched to general anesthesia. The hemodynamic variables and SpO2 was recorded before spinal anesthesia and thereafter every 5 min for first 30 minutes and thereafter every 15 minutes until the end of the procedure. A decrease >25% from baseline, or to <60 mm Hg, in mean arterial pressure, was defined as hypotension and treated with mephentermine bolus 6 mg; a HR <50 bpm was defined as bradycardia and treated with 0.6 mg of atropine; and a decrease in SpO2 to <93% was defined as hypoxia and treated with supplemental oxygen using a face mask. In postoperative unit, patients was monitored for hemodynamic

parameters every 1 hour until the sensory and motor variables were back to normal. The patients was asked to assess their level of pain according to the VAS every 15 min for 120 min, then half hourly for 180 min, hourly for 12 h, and thereafter every 3 h till 24 h of surgery in both groups. Rescue analgesia in the form of injection tramadol hydrochloride (2 mg/kg) IV was supplemented on complaining of pain (NRS >3) in both groups. Total duration of analgesia was considered from the time of subarachnoid administration of the drug to the time at which patient demanded first dose of rescue analgesia. Patients was monitored for any side effects or complications such as hypotension, bradycardia, nausea, vomiting, sedation, urinary retention, pruritus, headache, backache, and neurological changes for 24 h.



[Table / Fig – 1]: consort flow diagram

Statistical Analysis

To determine sample size, Cohen's tables were used. According to these tables, a medium-sized effect for analysis of variance (ANOVA) was 0.25. A sample size calculation of two groups was needed. A total sample size of 180 patients was needed. Therefore, 180 patients were taken. Patient characteristic data were compared using independent sample t-test. Physiological data were averaged and compared by ANOVA test. Correlation coefficient and regression analysis were used in outcomes. Paired t-test and Mann-Whitney U test were used for statistical analysis. The p-value>0.05 is considered not significant, p-value<0.05 as significant and p-value <0.001 as highly significant.

Result

In this comprehensive study, we conducted an in-depth analysis of various motor and sensory parameters in two distinct groups, Group B and Group L. The findings unveiled striking disparities in several critical aspects of motor and sensory functions.

Demographic Data

Head	Details		Group	
			Group B	Group L
AGE	N		80.00	80.00
	Mean		46.40	46.03
	Std. Deviation		16.60	16.44
	t Stat			0.14
	P Value			0.89
ASA Grade	Grade I	Number of Cases	46.00	43.00
		Percentage	55.62%	53.75%
	Grade II	Number of Cases	43.00	37.00
		Percentage	44.37%	45.75%
	Total	Number of Cases	89.00	80.00
		Percentage	100%	100%
	Chi Square			0.10
	P Value			0.75
Sex Distribution	Male	Number of Cases	44.00	43.00
		Percentage	55.00%	53.75%
	Female	Number of Cases	36.00	37.00
		Percentage	45.00%	46.25%
	Total	Number of Cases	80.00	80.00
		Percentage	100%	100%
	Chi Square			0.00
	P Value			1.00

[Table / Fig – 2]: Demographic data of patients

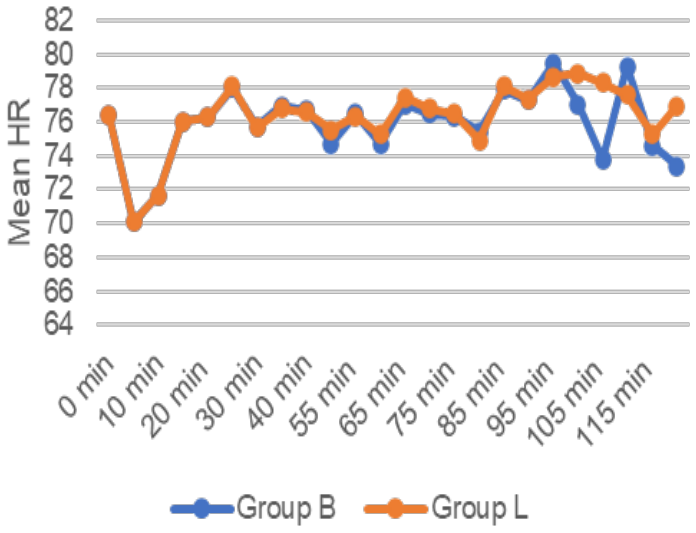
The data in Table reveals that the mean age of patients in groups B and L was 46.40 ± 16.60 years, and 46.03 ± 16.44 years, respectively. According to statistical analysis, there was no discernible variation in the mean ages of the two groups. Not Significant (P = 0.89). The number of patients in group B were comparable in Group L patients.

The above Table showing the distribution of patients according to ASA physical status grade. Out of total patient's in Group B 46 (55.62%) of patients belongs to ASA grade I and 43 (44.37%) of patients belong to ASA grade II. In Group L 43 (53.75%) of patients were of ASA grade 1 and 45.75 (45.75%) were of ASA grade II. Thus Prevalence of ASA Grade I and ASA grade II were comparable in both Group B and Group L.

The above-mentioned Table demonstrates that 44 patients (55 %) were male and 36 (45%) were female in Group B and 43 patients (53.75%) were male and 37 (46.25 %) were female in Group L. In both groups male patients were Comparable to female patients.

Hemodynamic Parameters

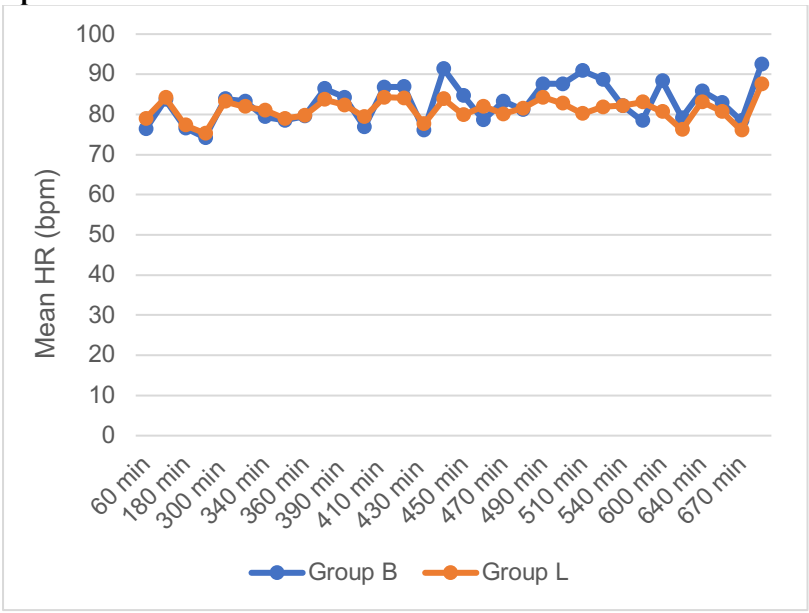
Heart Rate – Intraop



[Table/Fig – 3]: comparison of intraop mean heart rate of the study group at various time intervals

The mean Heart rate was recorded every 5 min for first 15 min and then every 10 min till end of surgery. There were no significant differences in heart rate between Group B and Group L at all time intervals (0 min to 120 min).

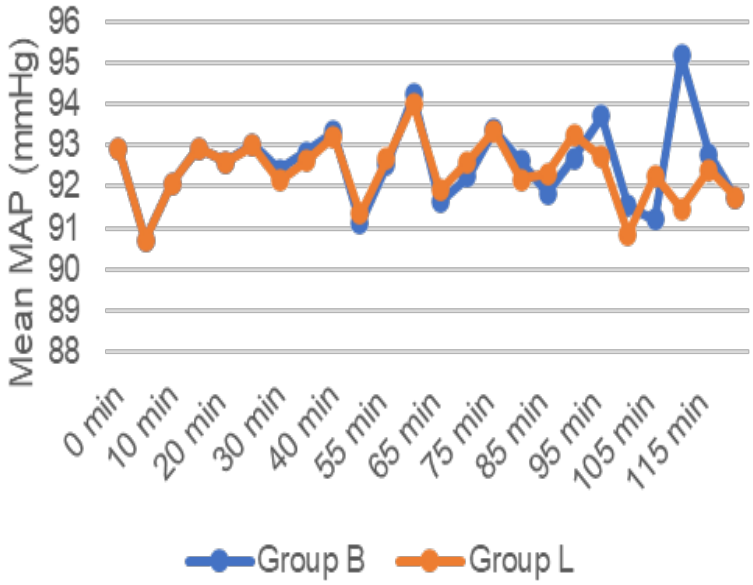
Heart Rate – Postop



[Table / Fig – 4]: comparison of Postop mean heart rate of the study group at various time intervals (n=160)

The mean heart rate was recordered hourly in the post operative period till sensory and motor variables back to normal. There were no significant differences in heart rate between Group B and Group L for most of the time intervals. However, at 660 min and 720 min, there were significant differences in heart rate at various time intervals between Group B and Group L ($p<0.05$).

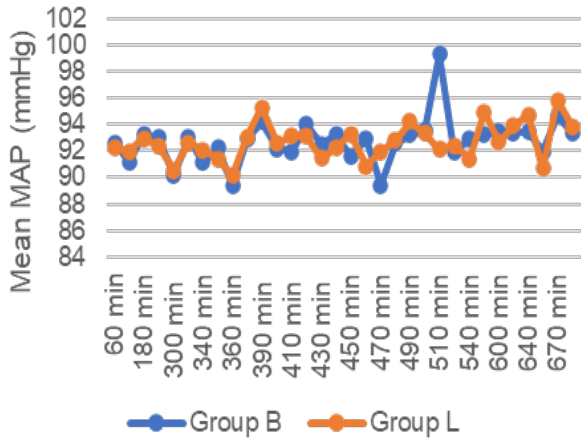
Mean Arterial Pressure (MAP)- Intraop



[Table / Fig – 5]: Comparison of intraop mean arterial pressure of the study group at various time intervals

The mean Arterial pressure was recorded every 5 min for first 15 min and then every 10 min till end of surgery. There were no significant differences in systolic blood pressure between Group B and Group L for most of the time intervals.

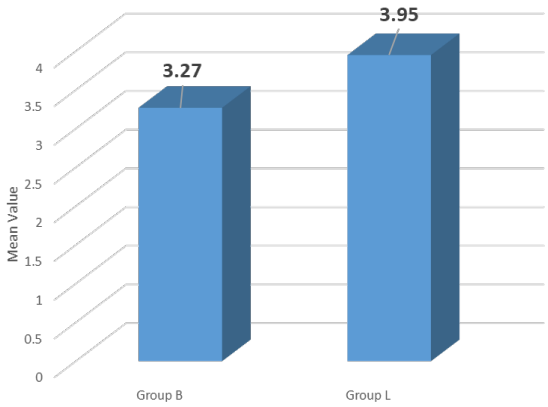
Mean Arterial Pressure (MAP)- Postop



[Table/Fig – 6]: comparison of postop mean arterial pressure of the study groups at various time intervals

The mean arterial pressure was recordered hourly in the post operative period till sensory and motor variables back to normal There were no significant differences in systolic blood pressure between Group B and Group L for most of the time intervals.

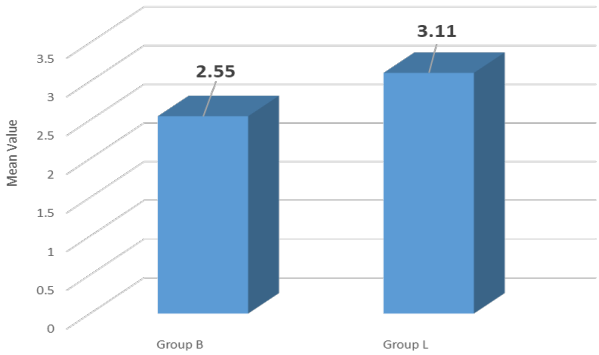
Onset Time of Sensory Block



[Table/Fig – 7]: Comparison of onset time of sensory block of the study groups

The time of onset of sensory block was calculated when sensory block was achieved at the level L5. There was a significant difference in the mean onset sensory scores between Group B (3.27± 0.95) and Group L (3.95±0.88). The results indicate that Group B has faster onset sensory block time compared to Group L.

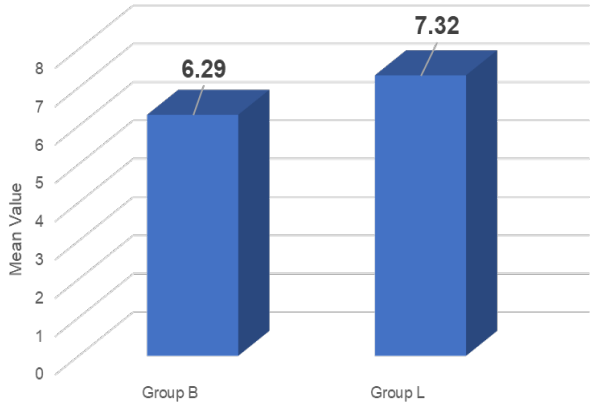
Onset Time of Motor Block



[Table/Fig – 8]: Comparison of onset time of motor block of the study groups

The onset of motor block is defined as time to reach Bromage score 1 was achieved by all patients in both groups. There was a significant difference in the mean onset motor scores between Group B (2.55± 0.95) and Group L (3.11±0.86). The results indicate that Group B has faster onset motor block time compared to Group L.

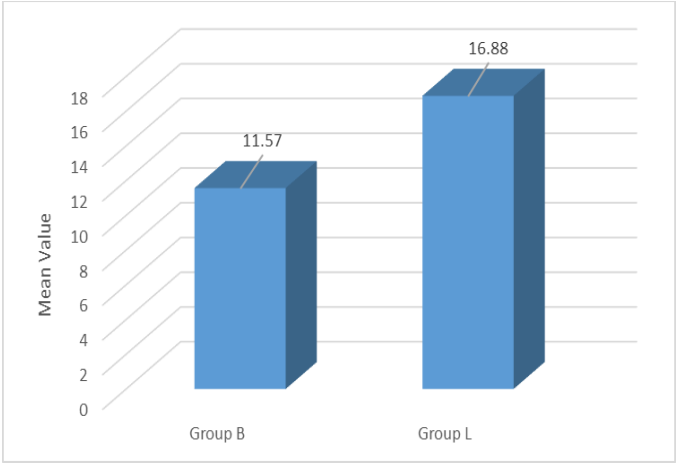
Highest Sensory Block



[Table/Fig – 9]: Comparison of highest sensory block time of the study groups

The highest sensory block level achieved was T5 in both Group B and Group L. There was a significant difference in the mean highest sensory scores between Group B (6.29± 1.06) and Group L (7.32± 0.87). The results indicate that Group B attained faster highest sensory block compared to Group L.

Complete Motor Block



[Table/Fig – 10]: Comparison of complete motor block time of the study groups

The onset of motor block is defined as time to reach Bromage score 3 was achieved by all patients in both groups. There was a significant difference in the complete onset motor block scores between Group B (11.57± 1.71) and Group L (16.88± 3.12). The results indicate that Group B has faster complete motor block time compared to Group L.

In this study, conducted to investigate the effects of combining intrathecal buprenorphine with hyperbaric bupivacaine and levobupivacaine in spinal anesthesia, we aimed to shed light on several critical parameters that influence the efficacy and outcomes of this anesthesia technique. Spinal anesthesia is a commonly employed method for lower abdominal surgeries, and understanding the nuances of these combinations can have significant clinical implications.

Our objective was to comprehensively evaluate and compare various aspects, including the onset time of sensory block, onset time of motor blockade, time taken to reach peak sensory and motor levels, and the total duration of analgesia when employing these distinct combinations.

To achieve this, we obtained ethical committee approval and enrolled 160 patients falling under ASA 1 and 2 categories, aged between 18 and 75, who were scheduled for elective lower abdominal surgeries. These patients were randomly assigned to one of two groups: Group L, which received 3ml of 0.5% hyperbaric Levobupivacaine with

buprenorphine 50µg, and Group B, which received 3ml of 0.5% hyperbaric bupivacaine with buprenorphine 50ug. We meticulously assessed anesthesia quality, block characteristics, analgesia duration, mobilization time, and potential side effects to draw meaningful comparisons.

Ture Pushpavathi et al, in 2019 also conducted a Comparative evaluation of anesthetic efficacy and hemodynamic effects of a combination of isobaric bupivacaine with buprenorphine vs. isobaric levobupivacaine with buprenorphine for spinal anesthesia and found that there was no noteworthy disparity in sensory block and motor block between the two groups [5]. But our study showed significant difference in onset of sensory and motor block as Group B exhibited faster onset of motor and sensory block.

Ajay singh et al, in 2018 conducted a comparative study of Intrathecal isobaric levobupivacaine versus hyperbaric bupivacaine for inguinal hernia surgery. They found levobupivacaine exhibited a shorter duration of sensory and motor block in contrast to bupivacaine proving them beneficial for facilitating earlier patient mobilization in daycare surgeries [6]. In our study both total duration of motor and sensory block was longer and similar. It could be due to additional adjuvant buprenorphine which increased their efficacy.

Archana Shivashankar et al, in 2016 conducted an in-depth comparative study to assess the efficacy of two distinct approaches for spinal anesthesia during caesarean sections: premixed injections of hyperbaric bupivacaine and buprenorphine versus sequential injections of the same substances their study highlighted that when buprenorphine was mixed with hyperbaric bupivacaine a higher level of sensory blockade achieved through the premixed approach. Similarly in our study, adding adjuvant in both groups showed similar higher level of sensory block [7].

in our study population, Group Bupivacaine+buprenorphine demonstrated a faster onset of motor and sensory block, as well as a more rapid achievement of peak sensory block and a more complete motor blockade.

Conclusion

In conclusion, Group Bupivacaine+buprenorphine displayed superior anesthesia characteristics 8.

compared to Levobupivacaine+buprenorphine in lower abdominal surgeries. This combination may be preferable for rapid and thorough anesthesia, but further research is required to validate its effectiveness in different clinical contexts. This study underscores the importance of personalized anesthetic choices, benefiting both practitioners and researchers

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