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Original Article

Comparative Evaluation of Ropivacaine (0.5%) and Levobupivacaine (0.5%) in Segmental Spinal Anesthesia for Patients Undergoing Laparoscopic Cholecystectomy: A Randomized and Clinical Trial

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Abstract

Introduction: Unadulterated S-enantiomers of bupivacaine include ropivacaine and levobupivacaine. These are the two amide local anesthetics that were just recently introduced and have a reduced likelihood of cardiotoxicity compared to racemic bupivacaine.

Purpose: The present study was conducted to compare equipotent doses of ropivacaine and levobupivacaine with the addition of fentanyl for the intraoperative characteristics and recovery profile of these drugs for patients undergoing elective laparoscopic cholecystectomy under segmental spinal anesthesia.

Methods: This randomized, prospective, double-blind, and single-center study comprised included 150 participants. They were allocated randomly into two Groups I and II receiving 0.5% hyperbaric Levobupivacaine and 0.5% hyperbaric Ropivacaine, respectively. Both the groups were compared with regard to characteristics of sensory block, motor block, hemodynamic parameters, and side effects.

Results: In our study, duration of sensory block and motor block is significantly more in Group I than Group II ($P < 0.05$), with mean duration of motor block in Group I was 194.12 min, while it was 98.33 min in Group II and mean duration of sensory block in Group I was 140 min, while it was 84 min in Group II was found to be highly significant ($P < 0.0001$). Both the sensory and motor blocks have a more rapid recovery with ropivacaine (0.5%) compared to levobupivacaine (0.5%). The study of hemodynamic parameters of the patients showed that the parameters such as heart rate, systolic, and mean arterial pressures were less variable in Group II during measurement at various intervals. Group II had more hemodynamic stability than Group I confirming the higher safety profile.

Conclusion: This study suggests that ropivacaine (0.5%) is suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage.

Key words: Bupivacaine, Cardiotoxicity, Fentanyl, Laparoscopic cholecystectomy levobupivacaine, Ropivacaine

INTRODUCTION

The standard method for doing a laparoscopic cholecystectomy (LC) using pneumoperitoneum is under general anesthesia. Several LCs have been successfully performed using spinal anesthesia techniques, in part because of the development of surgical and anesthetic techniques.[1-3] In comparison to general anesthesia, spinal anesthesia is less invasive and has lower rates of morbidity and mortality. Under spinal anesthesia, the individual undergoing surgery is awake, there are no airway devices, there is less postoperative pain, and nausea and vomiting are not present.[3] Uniform and complete muscular relaxation, a cognizant patient, cost-effectiveness, a relatively uncomplicated recovery, a pain-free early postoperative phase, and protection from potential general anesthesia

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problems are some of the benefits of spinal anesthesia over general anesthesia.[4,5]

Unadulterated S-enantiomers of bupivacaine include ropivacaine and levobupivacaine. These are the two amide local anesthetics that were just recently introduced and have a reduced likelihood of cardiotoxicity compared to racemic bupivacaine. The aforementioned drugs allow for a more rapid restoration of motor function due to their capacity to block sensory nerves more severely than motor nerves, which makes them potentially valuable anesthetic agents.[6,7]

With the potential to provide post-operative analgesia as well as better anesthesia quality, adjuvants such as opioids have been delivered concurrently with local anesthetics. Fentanyl has been found to considerably lengthen the duration of the sensory and motor block and improve VAS scores in brachial plexus blocks when used with local anesthetics.[8,9]

In this background, we designed a study to compare equipotent doses of ropivacaine and levobupivacaine with the addition of fentanyl for the intraoperative characteristics and recovery profile of these drugs for patients undergoing elective LC under segmental spinal anesthesia.

MATERIALS AND METHODS

This study was initiated after receiving approval from the institutional ethical review committee. Our study adhered to the principles mentioned in the Declaration of Helsinki. This randomized, prospective, double-blind, and single-center study comprised 150 American Society of Anesthesiologists (ASA) physical status I and II patients, aged 18–65 years, who had undergone elective LC under subarachnoid block at our institute during the time period of the study. Patients who were willing to participate and gave written informed consent, ASA 1 and 2 patients between 18 and 65 years old, with a BMI <30 kg/m^2 and having normal coagulation status, were included in the study. Patients not giving written informed consent, of ASA Status 3 and 4, age <18 or >65 years, BMI >30 kg/m^2, with evidence of severe cardiovascular, renal, hematologic, or hepatic disease, preexisting neurological or psychiatric illness, chronic pain syndrome, or a past history of alcohol or drug abuse, were excluded from the research study. After comprehensive pre-anesthetic check-up, patients were included in the study if they met the required inclusion criteria. All the relevant details of the participants were taken and noted down on a pre-designed, pre-structured proforma for the study. Participants were then allocated randomly into two groups (Group I and Group II) with the help of a computerized random number list. Depending on the group under which participants fell, the interventional modality was applied to the study participants. Participants falling under Group I received 2 mL (0.5% hyperbaric Levobupivacaine) and 25 μg (0.5 mL) fentanyl, while patients in Group II were given 2 mL (0.5% hyperbaric Ropivacaine) and 25 μg (0.5 mL) fentanyl. Patients who were included in the trial were kept fasting for 6 h (minimum 6 h) before surgery. Tablets of alprax 0.25 mg, pantoprazole 40 mg on the night before surgery, On the morning of the surgery, each patient received pre-loading with Ringer lactate (10–15 mL/kg over 30 min) and premedication (Ondansetron 0.1 mg/kg and Ranitidine Hydrochloride 150 mg intravenously). Then, the patients were shifted to the operating theater for all routine monitoring: Non-invasive blood pressure, pulse oximetry, end-tidal carbon dioxide, and electrocardiogram. Inj. Midazolam 0.03 mg/kg IV was given to the patient just before the start of the procedure to ease anxiety and apprehension. The sealed and coded envelopes containing details of the drug combinations to be used were kept in the operating room. Any one envelope was opened by a nursing assistant who was not a part of the study any further. Then, according to the random number list generated for randomization, respective drug combinations were prepared for each patient and marked with a coded label by the anesthesiologist who was not a part of the study, and it was handed over to the anesthesiologist performing the segmental spinal block in a blinded manner. Neither the principal anesthesiologist performing the block nor the patient were aware of the nature of the study solution.

Group I and Group II received 2 mL of 0.5% hyperbaric levobupivacaine and 2 mL of 0.5% hyperbaric ropivacaine added to 0.5 mL of 25 μg fentanyl, respectively.

In the sitting position, either of the drugs was aseptically administered through a 25G Quincke needle between T9-T10/T10-T11 interspace. As soon as the subarachnoid block was performed, patients were placed in a supine position.

Sensory block was graded according to the Gromley and Hill test using a pin protruding through a guard every 2 min until no sensation was achieved at T8 level. Motor block was graded according to the Modified Bromage Scale (0–3), where 0 = no motor block (full flexion of hip, knee, and ankle), 1 = ability to move knees and feet, inability to flex hip, 2 = ability to move feet only, inability to flex hip or knee, and 3 = full motor block, respectively.

The onset time of sensory block was assessed by referring to the interval between spinal puncture and the maximal pinprick score. The onset time of motor block was assessed by evaluating the time interval between puncture and the maximal definitive Bromage score. The offset time was

considered a corresponding return to normal sensitivity and motility. The spread of anesthesia was referring to the upper dermatome with any grade of sensory impairment. Any side effects such as nausea, vomiting, pain, shivering, sedation, hypotension, bradycardia, and respiratory discomfort were noted and treated with the appropriate drug if required.

The surgical procedure was started within 30 min of the spinal puncture. The time interval for anesthesia parameters was checked every 2 min until 30 min to note the onset and maximum degree of block. Vital parameters were recorded at 5, 10, 15, 30, and 60 min, and then every 15 min till surgery ended, then every hour postoperatively until motility and sensitivity returned to basal condition.

Using a test for two proportions at a 95% confidence interval (CI) and 80% power, the sample size was estimated. In pilot research completed before the current investigation, the effectiveness of levobupivacaine was reported to be 90% and 60% in the ropivacaine group, respectively. Considering α = 1% at 95% CI and 95% power, p1 of 0.9 and p2 of 0.6, and a 1:1 ratio, we obtained a sample size of 71 in each group, amounting to a total minimum sample size of 141. Accounting for 5% lost to follow-up and rounding off to the nearest whole number, a final sample size of 150 was taken.

The statistical analysis was carried out utilizing IBM's Statistical Package for the Social Sciences version 23 (IBM, USA). The data were initially analyzed and coded using MS Excel Office version 2021. The Shapiro-Wilk and Kolmogorov–Smirnov tests were used to evaluate if the data were normally distributed. For categorical data, frequency and proportions were used in the descriptive analysis, whereas mean and standard deviation were used for continuous variables. The Fisher's exact test and the Chi-square test were applied when needed to evaluate if the categorical variables were showing any association. The Student's t test was used to see whether the continuous variable means differed significantly across the groups.

RESULTS

The mean ± SD of mean age in Groups I and II was 50.59 ± 11.68 and 49.43 ± 9.58, respectively. There was no significant difference between the two groups in terms of mean weight (t = 6.363, $P = 0.750$), although the mean age was higher in Group I. In Group I, 20 were male and 50 were female among the study participants. In Group II, males were 30 and females were 40 of the study population. The demographic data in both groups were comparable.

In our study, the onset of sensory block in the T10 segment was 3.5 min in Group I and 5 min in Group II ($P = 0.989$), which was insignificant. The median maximum sensory block at dermatome level is in Group I levobupivacaine T4 (T2-T8), in Group II ropivacaine T4 (T2-T10) with ($P = 0.512$), which is insignificant. The time to the maximum sensory block was reached in 25 min in Group I, 20 min in Group II ($P = 0.241$). Duration to T10 sensory block was set at 140 min in Group I and 84 min in Group II ($P = 0.0135$), which was found to be significant. The onset of sensory block regression was 265 min in Group I and 220 min in Group II ($P = 0.0058$), which was significant in both groups.

Bromage Scale 3 was seen in Group I in 67 patients (95.7%) and in Group II in 48 patients (68.5%) ($P = 0.0053$), which was significant in both groups. The time to max. motor block (min.) was 5 min in Group I and 10 min in Group II ($P = 0.0484$), which was significant in both groups. Motor block regression of 178 min in Group I and 90 min in Group II was found to be highly significant ($P < 0.0001$). The duration of motor blocks was 194.12 min in Group I and 98.33 min in Group II, which was found to be highly significant ($P < 0.0001$).

Per-abdominal pain was slightly higher in Group I, with 3 (4.29%) members experiencing it and 2 (2.86%) study participants in Group II. Post-operative shoulder tip pain was felt by 5 (7.14%) participants in Group I and 7 (10%) in Group II. Itching was seen in 2 (2.86%) members in Group I and 3 (4.29%) in Group II. Nausea and vomiting were seen in 2 (2.86%) members and 1 (1.43%) in Group II. A respiratory rate <12/min. was seen in only 1 (1.43%) member belonging to Group I. Hypotension was present in 22 (7.14%) in Group I and 29 (4.29%) in Group II.

The mean HR for Group I was 131 ± 4.07 and 133 ± 2.10 at 5-min interval. The fall in HR continued to increase throughout the follow-up until 30 min, when it reached its nadir at 126 ± 3.02 bpm and 128 ± 2.10 in Group II, thus showing a mean fall of 5 bpm. At 120 min, the mean HR was 130 ± 1.05 in Group I and 132 ± 3.42, thus showing a mean change of only 0.63 ± 3.28 bpm. Statistically, at all the time intervals except 120 min, the difference was significantly insignificant ($P > 0.05$).

At 5 min., mean arterial pressure (MAP) was 131 ± 4.07 mmHg in Group I as compared to 133 ± 2.01 mmHg in Group II. Statistically, this difference was insignificant ($P > 0.05$). At 60 min, the mean MAP was 130 ± 1.05 mmHg in Group I and 132 ± 3.42 mmHg in Group II. The decrease in MAP showed a declining trend to reach its nadir at 30 min, when the mean MAP was 126 ± 3.02 in Group I, thus showing a mean decrease of 5 mmHg and 128 ± 2.10 in Group II, thus showing a

Table 1: Demographic data in studied cases

Parameters	Group I (n)	Group II (n)	*P*-value
Mean age (in years)	50.59±11.68	49.43±9.58	0.850 (NS)
Sex			
Male	20	30	0.980 (NS)
Female	50	40	0.670 (NS)
ASA grade			
I	40	40	0.780 (NS)
II	30	30	0.900 (NS)
Mean weight (in kg.)	72.45±5.35	70.75±4.08	0.750 (NS)
Height (in cm.)	165±4.85	162±5.62	0.650 (NS)

Data presented as mean±standard deviation or Number: *P<0.05 was considered significant

Table 2: Parameters for sensory block

Parameters	Group I	Group II	*P*-value
Onset to T10 (min.)	3.5 (2–14)	5 (2–10)	0.989(NS)
Median max. block (dermatome)	T4 (T2–T8)	T4 (T2–T10)	0.512(NS)
Time to maximum sensory block (min.)	25 (10–30)	20 (2–25)	0.241(NS)
Duration to T10 (min.)	140 (50–200)	84 (45–120)	0.0135(S)
Sensory block regression (min.)	265 (170–390)	220 (170–350)	0.0058(S)

Table 3: Parameters for motor block

Parameters	Group I	Group II	*P*-value
Bromage scale (grade 3)	67 (95.7%)	48 (68.5%)	0.0053(S)
Time to max. motor block (min.)	5 (2–20)	10 (5–20)	0.0484(S)
Motor block regression (min.)	178 (90–210)	90 (60–120)	<0.0001(S)
Duration of motor blocks (min.)	194.12 (120–250)	98.33 (70–150)	<0.0001(S)

Data presented as mean±standard deviation or Number: *P<0.05 was considered significant

Table 4: Side effects

Side effects	Group I (n=70)		Group II (n=70)	
	n	%	*n*	%
Per abdominal pain	3	4.29	2	2.86
Post-operative shoulder pain	5	7.14	7	10.00
Itching	2	2.86	3	4.29
Nausea/Vomiting	2	2.86	1	1.43
Respiratory Rate <12/min.	1	1.43	0	0.00
Hypotension	5	7.14	3	4.29

Table 5: Heart rate in study participants during surgery

Time interval	Groups (Mean±SD)		t-value	*P*-value
	Group I	Group II		
05 min	131±4.07	133±2.10	−3.573	0.189 (NS)
10 min	129±3.86	131±2.01	−1.750	0.270 (NS)
15 min	127±2.02	129±3.02	−2.44	0.267 (NS)
30 min	126±3.02	128±2.10	−4.185	0.190 (NS)
60 min	130±1.05	132±3.42	1.187	0.510 (NS)

Data presented as mean±standard deviation or Number: *P<0.05 was considered significant

Table 6: Mean arterial pressure in study participants during surgery

Time interval	Groups (Mean±SD)		t-value	*P*-value
	Group I (n)	Group II (n)		
05 min	131±4.07	133±2.10	−3.573	0.986 (NS)
10 min	129±3.86	131±2.01	−1.750	0.810 (NS)
15 min	127±2.02	129±3.02	−2.44	0.252 (NS)
30 min	126±3.02	128±2.10	−4.185	0.451 (NS)
60 min	130±1.05	132±3.42	1.187	0.074 (NS)

Data presented as mean±standard deviation or Number: *P<0.05 was considered significant

mean decrease of 5 mmHg. At 60 min, the mean MAP was 130 ± 1.05mmHg in Group I as compared to 132 ± 3.42 mmHg in Group II. Statistically, the mean change in MAP was statistically insignificant at all the follow-up intervals (P > 0.05) [Figures 1-3] [Tables 1-6].

DISCUSSION

In our study, the onset of sensory block in the T10 segment was 3.5 min in Group I and 5 min in Group II (P = 0.989), the difference was statistically insignificant. Median maximum sensory block at dermatome level was observed in Group I with levobupivacaine T4 (T2-T8) and in Group II with ropivacaine T4 (T2-T10) (P = 0.512); here too, the statistical difference was insignificant. The time to the maximum sensory block was reached in 25 min in Group I and 20 min in Group II (P = 0.241). The duration to the T10 sensory block was set at 140 min in Group I and 84 min in Group II (P = 0.0135), and the difference was found to be statistically significant. The onset of sensory block regression was 265 min in Group I and 220 min in Group II (P = 0.0058), which was significant in both groups. Our study is in line with the results reported by Kopacz *et al*.[10]

In our study, the duration of sensory block and motor block was significantly greater in Group I than Group II (P < 0.05), with the mean duration of motor block in Group I being 194.12 min, while it was 98.33 min in Group II, and the mean duration of sensory block in Group I being 140 min, while it was 84 min in Group II, which was found to be highly significant (P < 0.0001). This could be explained by the greater vasoconstrictor property of levobupivacaine, as studied by Rachel and Foster.[11]

Breebaart *et al*. compared 10 mg levobupivacaine and 15 mg ropivacaine for our patients' knee arthroscopy and found the same results: the ropivacaine group moved

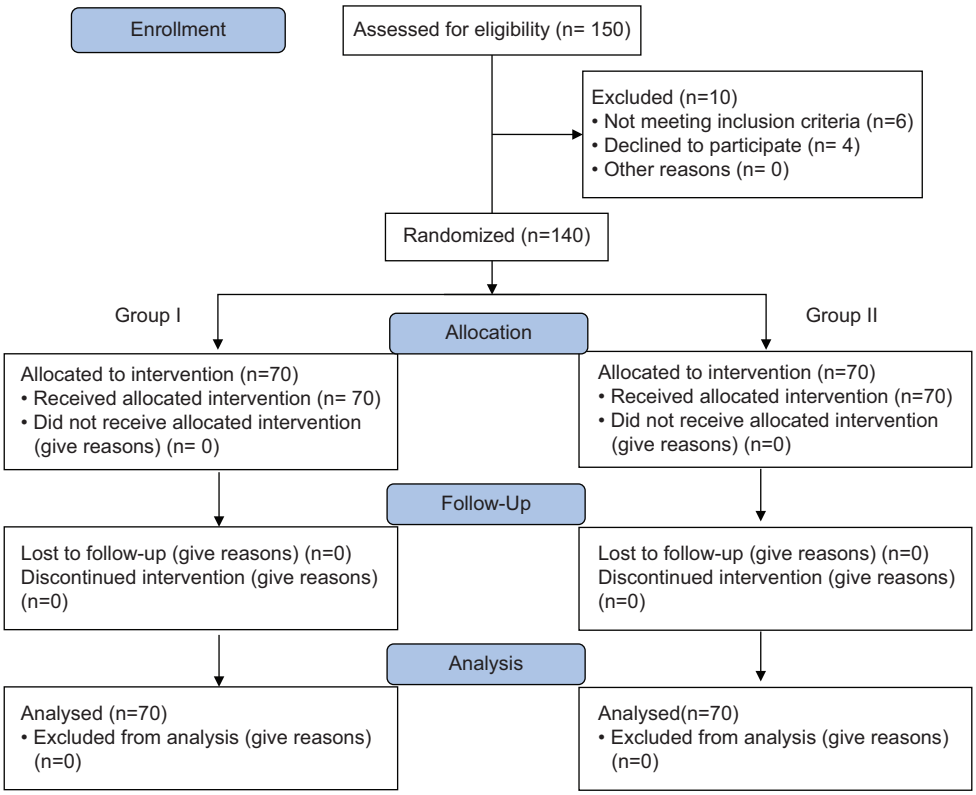

Figure 1: CONSORT flow diagram

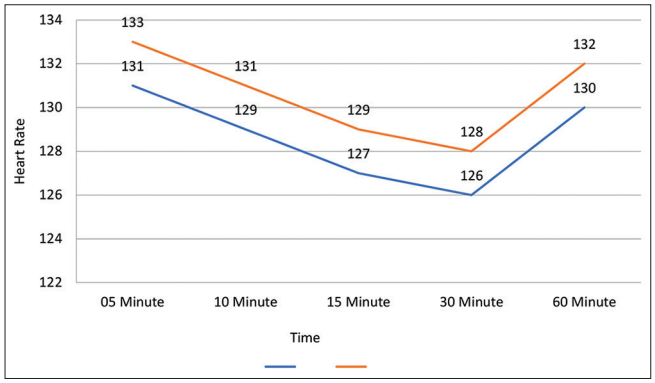

Figure 2: Heart rate in study participants during surgery

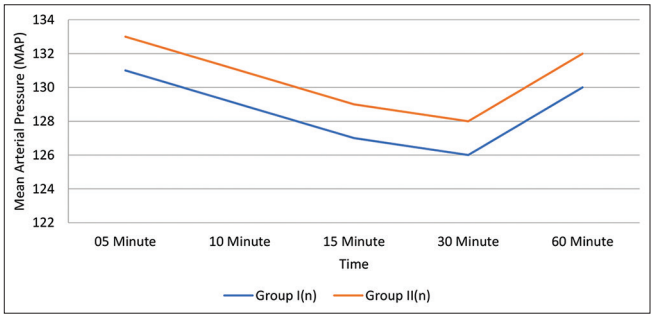

Figure 3: Mean arterial pressure in study participants during surgery

early and the need for post-operative analgesia was less in levobupivacaine, but they discharged home late. Ropivacaine presented a shorter duration of sensory and motor block than bupivacaine and levobupivacaine ($P < 0.05$).[12]

In our study, bromage scale 3 was seen in Group I in 67 patients (95.7%) and in Group II in 48 patients (68.5%) ($P = 0.0053$), which was significant in both groups. Time to maximum block (min.) was 5 min in Group I and 10 min in Group II ($P = 0.0484$). The motor block regression of 178 min and 90 min in Group II was found to be highly significant ($P < 0.0001$). The duration of motor blocks was 194.12 min in Group I and 98.33 min in Group II, which was found to be highly significant ($P < 0.0001$). Ropivacaine (Group II) had a shorter duration of motor block than levobupivacaine (Group I). Thus, the study suggests that levobupivacaine and ropivacaine provide satisfactory sensory anesthesia with minimal motor blockade at a concentration of 0.5%.

With regard to the side effects seen in our study, Jindal and Gupta,[13] Athar *et al*.,[14] Mehta *et al*.,[15] and Luck *et al*.[16] support our findings. While Jain *et al*.[17] found hypotension more frequently in the levobupivacaine group than the ropivacaine group, Singh *et al*. (2017)[18] found bradycardia more frequently in the ropivacaine group.

The study of differences in hemodynamic parameters among the patients showed that parameters such as heart

rate, systolic, and MAP s were less variable in Group II during measurement at various intervals. Group II had more hemodynamic stability than Group I, confirming the higher safety profile and lower incidence of hypotension in Group II. These findings were similar to those of the studies conducted by Barişkaner *et al*.,[19] and Udelsmann *et al*.[20]

CONCLUSION

Segmental blockade provided by thoracic spinal anesthesia has the advantage of limiting sympathectomy to fewer segments with less vasodilatation than lumbar spinal anesthesia and thus fewer hemodynamic changes, which were achieved by both drugs.

Both groups showed minimal hemodynamic variability. This is considered an advantage of thoracic spinal anesthesia. Because of the proximity of the drug deposition site to the target site, thoracic spinal anesthesia requires a lower drug dose to achieve the desired effect.

Hyperbaric ropivacaine (0.5%) produces a segmental spinal block that has sensory block onset characteristics similar to those of equivalent doses of hyperbaric levobupivacaine (0.5%) but with a less intense motor block. Both the sensory and motor blocks are also subject to a more rapid recovery with ropivacaine (0.5%) compared with levobupivacaine (0.5%). This suggests that ropivacaine (0.5%) is suitable for short procedures where a rapid return of ambulatory function is desirable, such as in the day-case setting, where its recovery profile could confer a distinct clinical advantage.

This study has provided preliminary evidence that segmental spinal anesthesia can be an effective anesthetic technique for routine laparoscopic surgery with minimal side effects.

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