



**COMPARISON OF INTRAPERITONEAL AND PERIORTAL 0.5% LEVOBUPIVACAINE AND 0.5% ROPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN LAPAROSCOPIC CHOLECYSTECTOMY**

**Dr. Ashish Mathur**

Assistant professor, Department Of Anaesthesiology, G.R. Medical College, Gwalior, M.P.

**Dr. Kushal Jethani\***

Resident, Department Of Anaesthesiology, G.R. Medical College, Gwalior, M.P.  
\*Corresponding Author

**Dr. Bhanu Chaudhary**

Professor and Head department of anaesthesiology, G.R. Medical College, Gwalior, M.P.

**ABSTRACT**

**AIMS AND OBJECTIVES:** To evaluate and compare the efficacy of intraperitoneal and periportal 0.5% Levobupivacaine and 0.5% Ropivacaine for postoperative pain relief in laparoscopic cholecystectomy.

**MATERIAL AND METHOD:** 60 patients ASA grade I & II undergoing elective cholecystectomy. Patients were classified randomly into 2 groups (thirty patients in each group). Group R (n=30): 30 ml of 0.5% Ropivacaine hydrochloride, Group L (n=30): 30 ml of 0.5% Levobupivacaine hydrochloride. Randomization was done with the closed envelope technique. A 20 ml of test solution was instilled, by the operating surgeon, on the upper surface of liver and on right sub-diaphragmatic space, under the vision of camera, through the epigastric port with the help of 18 G Spinal needle. Patient was kept in Trendelenberg position for 5 minutes. At the end of procedure, intra-abdominal CO<sub>2</sub> was carefully vented out by the surgeon and 10 ml of the test solution was injected as skin infiltrate into all sites of incision. Postoperatively, patients were assessed for parietal pain and visceral pain using a 100 mm VAS scale at 30 min and at 1, 2, 3, 4, 6, 12 and 24 hours. Rescue analgesia consisted of an inj. Tramadol 100 mg intravenous (slow) if the VAS score was more than 50.

**RESULT:** Analysis revealed that there were no significant differences between the patients with respect to age, sex, weight, duration of surgery, HR and blood pressure. Duration of postoperative analgesia observed from the time of reversal to first demand of analgesia in the recovery room was more in group L compared to group R. The total analgesic consumption in 24 hours postoperatively, was more in Ropivacaine than in Levobupivacaine group.

**CONCLUSION:** There was significant prolongation of duration of postoperative analgesia in Levobupivacaine group as compared to Ropivacaine group. In terms of analgesic efficacy, Levobupivacaine appears to be superior to Ropivacaine.

**KEYWORDS :** Ropivacain , Levobupivacain , rescue analgesia

**INTRODUCTION:**

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or in terms of such damage."<sup>1</sup>

Definition of postoperative pain is "condition of tissue injury together with muscle spasm after surgery"<sup>2</sup>.

Visceral pain following laparoscopic surgery is perceived due to stretching of intraperitoneal cavity, peritoneal inflammation and irritation of phrenic nerve whereas pain in open procedures is mainly somatic in nature.

Levobupivacaine is an amino amide type of local anesthetics. The reduced toxicity of Levobupivacaine provides a wider safety margin in the daily clinical practice either as single shot or for continuous infusion, as well as for postoperative pain control<sup>3</sup>.

Ropivacaine a new long-acting amide local anaesthetic agent, is a pure S-enantiomer. It has shown to have higher CNS and cardiovascular safety compared with Bupivacaine. Ropivacaine is virtually identical to Bupivacaine in terms of onset, quality and duration of sensory block, but seems to produce less motor block<sup>4</sup>.

**MATERIAL AND METHODS:**

60 patients ASA grade I & II undergoing elective cholecystectomy. Patients were classified randomly into 2 groups (thirty patients in each group). Group R (n=30): 30 ml of 0.5% Ropivacaine hydrochloride, Group L (n=30): 30 ml of 0.5% Levobupivacaine hydrochloride. Randomization was done with the closed envelope technique. A 20 ml of test solution was instilled, by the operating surgeon, on the upper surface of liver and on right sub-diaphragmatic space, under the vision of camera, through the epigastric port with the help of 18 G Spinal needle. Patient was kept in Trendelenberg position for 5 minutes. At the end of procedure, intra-abdominal CO<sub>2</sub> was carefully vented out by the surgeon and 10 ml of the test solution was injected as skin infiltrate into all sites of

incision. Postoperatively, patients were assessed for parietal pain and visceral pain using a 100 mm VAS scale at 30 min and at 1, 2, 3, 4, 6, 12 and 24 hours.

Blood pressure and heart rate were assessed at 30 min, then at 1, 2, 3, 4, 6, 12 and 24 hours. Time to first rescue analgesia, sedation, nausea and vomiting, dizziness, backache and urinary retention were also assessed. Rescue analgesia consisted of an injection of tramadol 100 mg intravenous (slow) if the VAS score was more than 50.

The statistical analysis of this study was done by using Paired and Unpaired T test and using SPSS 20.0 version, where p value <0.05 was considered statistically significant and p value >0.05 was taken as statistically insignificant.

**RESULT AND ANALYSIS:**

**Table-1 Demographic Data in the two groups**

Variable	Group L (n=30)	Group R (n=30)	t-value	p-value
	Mean±SD	Mean±SD		
Age (yrs)	38.60 ± 13.94	41.3 ± 14.1	0.75	0.45
Weight (Kgs)	59.4 ± 8.49	60.7 ± 8.73	0.58	0.56

Table showing the demographic data, the mean (±SD) age of the patients in group L and R were (38.60 ± 13.94) and (41.3 ± 14.1) respectively and the mean (±SD) weight of the patients in group L and R were (59.4 ± 8.49) and (60.7 ± 8.73) respectively.

There was no statistically significant difference in age or weight of the patients among the two groups (p>0.05).

**Table-2 Sex (M: F) Distribution in two study groups**

S. NO.	Sex	Group L		Group R	
		(n)	(%)	(n)	(%)
1.	Male	5	16.6	9	30
2.	Female	25	83.4	21	70
3.	Total	30	100	30	100

The table shows that majority of patient in both the groups were females.

**Table-3 Duration of surgery (mins) in the two groups**

Variable	Group L (n=30)	Group R (n=30)	t-value	p-value
	Mean± SD	Mean± SD		
Duration of surgery (mins)	89.84 ± 13.48	90.5 ± 17.24	0.17	0.86

Table showing the mean (±SD) duration of surgery and the statistical comparison (t value and p value) of duration of surgery in the two groups.

There was no statistically significant difference in duration of surgery among the two groups (p>0.05).

**Table-4 Comparison of Perioperative pulse rate (Mean ± SD)**

Time		Group L	Group R
		Mean ± SD	Mean ± SD
<b>Preoperative</b>		86.67 ± 5.28	85.4 ± 4.95
<b>POST OPERATIVE</b>	30 min	90.47 ± 10.94	96 ± 5.92
	1hour	90.60 ± 9.05	95.2 ± 5.98
	2 hour	89.20 ± 8.49	93.3 ± 5.62
	3 hour	87.90 ± 7.38	90.3 ± 7.22
	4 hour	90.27 ± 8.16	89.7 ± 5.92
	6 hour	88.27 ± 7.76	87 ± 6.49
	12 hour	84.87 ± 6.36	87.1 ± 5.72
24 hour	84.84 ± 6.41	85.6 ± 5.24	

Table showing the pulse rate (Mean ± SD) of group L and group R at various time intervals.

**Table-5 Comparison of Peri-operative systolic blood pressure (Mean ± SD) in the two groups**

Time		Group L	Group R
		Mean ± SD	Mean ± SD
<b>Preoperative</b>		131.1 ± 9.78	132.1 ± 7.41
<b>POST OPERATIVE</b>	30 min	129.7 ± 8.89	140.3 ± 5.43
	1hour	127.5 ± 7.56	137.9 ± 4.85
	2 hour	129.5 ± 6.45	137.07 ± 4.12
	3 hour	129.9 ± 8.22	135.8 ± 4.27
	4 hour	129.9 ± 8.22	137.6 ± 4.60
	6 hour	128.6 ± 7.58	130.47 ± 8.08
	12 hour	130.33 ± 8.43	133.5 ± 9.3
	24 hour	129.93 ± 8.14	131.6 ± 10.77

Table showing the systolic blood pressure (Mean ± SD) of group L and group R at various time intervals

**Table-6 Comparison of Peri-operative diastolic blood pressure (Mean ± SD) in the two groups**

Time		Group L	Group R
		Mean ± SD	Mean ± SD
<b>PREOPERATIVE</b>		77.53 ± 9.82	79.8 ± 6.45
<b>POST OPERATIVE</b>	30 min	78.33 ± 7.31	85.4 ± 3.45
	1hour	78.1 ± 7.27	84.3 ± 2.56
	2 hour	77.6 ± 5.54	83.3 ± 2.8
	3 hour	78.1 ± 4.1	81.9 ± 2.62
	4 hour	78 ± 5.2	82.5 ± 3.6
	6 hour	78.7 ± 6.22	78.1 ± 6.59
	12 hour	77.1 ± 4.92	79 ± 5.25
	24 hour	78.7 ± 3.81	78.7 ± 5.59

Table showing the diastolic blood pressure (Mean ± SD) of group L and group R at various time intervals.

**Table-7 Mean (±SD) Time for First Rescue Analgesia in the two groups**

Variable	Group L (n=30)	Group R (n=30)
	Mean+ SD	Mean+ SD
<b>Time for First Rescue Analgesia (mins)</b>	225.83 ± 30.99	195.3 ± 33.09

Table showing the Mean (±SD) time for First Rescue Analgesia in the two groups.

Time for First Rescue Analgesia is greater in group L as compared to group R.

**Table-8 Statistical comparison (t value and p value) of Time for First Rescue Analgesia (mins) in the two groups**

Variable	Group L Vs. R	
	t value	p value
Time for first Rescue Analgesia (mins)	3.69	<0.05

Table showing the statistical comparison (t value and p value) of Time for First Rescue Analgesia (mins) in the two groups.

The time for First Rescue Analgesia was significantly greater in group L as compared to group R.(p<0.05)

**Table-9 Statistical comparison (t value and p value) of VAS score in the two groups at different postoperative time intervals**

Time		Group L	Group R	Group L vs R	
		Mean ± SD	Mean ± SD	t value	p value
<b>POST OPERATIVE</b>	30 min	4 ± 7.24	5 ± 8.61	0.49	0.62
	1hour	10 ± 7.88	11.67 ± 9.13	0.76	0.45
	2 hour	16.7 ± 4.79	33.34 ± 4.8	13.44	<0.05
	3 hour	31.7 ± 9.5	49.3 ± 12	6.30	<0.05
	4 hour	49.7 ± 8.09	31.3 ± 10.1	7.79	<0.05
	6 hour	30 ± 8.30	41 ± 9.9	4.66	<0.05
	12 hour	51.33 ± 8.604	50 ± 8.3	0.61	0.54
	24 hour	31 ± 8.84	40.7 ± 9.07	4.19	<0.05

Table showing Statistical comparison (t value and p value) of VAS score in the two groups at different postoperative time intervals.

Significant difference was found in the VAS score between the two groups at 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> and 6<sup>th</sup> hour.

**Table-10 Mean (±SD) VAS score in the two Groups**

Variable	Group L (n=30)	Group R (n=30)	Group L vs R	
	Mean ± SD	Mean ± SD	t value	p value
VAS score	28.04 ± 3.23	32.79 ± 3.92	5.12	<0.05

Table showing the Mean (±SD) of VAS score and the statistical comparison (t value and p value) of VAS score in the two groups.

Group L had a lower mean VAS score as compared to Group R which was statistically significant (p<0.05).

**Table-11 Statistical Analysis of total analgesic consumption in 24 hrs in the two groups**

Variable	Group L (n=30)	Group R (n=30)	Group L vs Group R	
	Mean+ SD	Mean+ SD	t value	p value
Total dose of Tramadol (mg)	330+46.6	383.3+37.9	4.87	<0.05

Table showing the Statistical Analysis of total analgesic consumption in 24 hours in both the groups.

The consumption of tramadol was significantly lesser in Group L when compared to Group R(p<0.05)

**Table-12 Comparison of Incidence of Complications in the two groups**

Complications	Group L (n=30)		Group R (n=30)	
	No.	%	No.	%
Nausea and vomiting	2	6.67%	3	10%
Hypotension	0	0	0	0
Bradycardia	0	0	0	0
Shivering	4	13.34%	2	6.67%
Dyspnoea	0	0	0	0
Chest pain	0	0	0	0
Dysarrhythmia	0	0	0	0

Table showing the incidence of complications in both the groups.

Nausea and vomiting was seen in 2 out of 30 (6.67%) patients of group L and was seen in 3 out of 30 (10%) patients belonging to group R.

Shivering was noted in 4 (13.34%) patients of group L; but only in 2 (6.67%) patients in group R.

No other complication was seen in any of the groups

### DISCUSSION

Adequate postoperative relief of pain after laparoscopy is an essential goal. Postoperative pain associated with laparoscopy is due to peritoneal stretching, diaphragmatic irritation, or, to a lesser extent, abdominal puncture. The receptors involved seem to be susceptible to blockade with a relatively low dose of local anesthetic.

### DEMOGRAPHIC DATA:

As shown in Table no.1 the mean ( $\pm$ SD) age (in yrs) of patients in group L and group R were ( $38.60 \pm 13.94$ ) and ( $41.3 \pm 14.1$ ) respectively. The mean ( $\pm$ SD) weight (in kgs) of the patients in group L and group R were ( $59.4 \pm 8.49$ ) and ( $60.7 \pm 8.73$ ) respectively.

There were no significant difference ( $p > 0.05$ ) among the group L and group R with respect to mean age and weight.

The majority of patients in both the groups were noted to be females (Table-2)

### DURATION OF SURGERY:

As shown in (Table no.3) the mean ( $\pm$ SD) duration of surgery of the patients in group L and R were ( $89.84 \pm 13.48$ ) and ( $90.5 \pm 17.24$ ) respectively.

There were no significant difference ( $p > 0.05$ ) among the study groups with respect to duration of surgery.

### HAEMODYNAMICS:

Perioperative pulse rate in group L and group R is shown in Table no.4. comparison of pulse rate, before and after the surgery, in group R revealed that there was a significant increase in postoperative pulse rate at various time intervals as compared to baseline values ( $p < 0.05$ ). While in group L the increase in postoperative pulse rate was not significant with that of baseline values ( $p > 0.05$ )

Similar changes were observed in other hemodynamic variables like Systolic Blood Pressure and Diastolic Blood Pressure in the two groups.

Levobupivacaine was hemodynamically more effective than Ropivacaine ( $p < 0.05$ ).

These results were in accordance with **Gupta P et al<sup>5</sup>** and **Narra G R et al<sup>6</sup>**.

### TIME FOR FIRST RESCUE ANALGESIA:

As shown in Table no.7, the mean ( $\pm$ SD) time for first rescue analgesia in group L was  $225.83 \pm 30.99$  mins and group R was 195.3

$\pm 33.09$  mins respectively.

On comparison and application of statistical analysis (Table no.8), there were significant prolongation of time for first rescue analgesia in group L as compared to group R ( $p < 0.05$ ).

The above findings were in accordance with **Gupta et al<sup>5</sup>** who concluded that patients of Ropivacaine group made their first request for analgesics earlier than the Levobupivacaine group.

Our study is also in accordance with **Johansson B et al<sup>7</sup>**, **Bindra T K et al<sup>8</sup>** and **Albuquerque et al<sup>9</sup>**.

### VASS SCORE:

In our study (Table 9), the mean VAS score at 30<sup>th</sup> min postoperatively was  $4 \pm 7.24$  in Group L and  $5 \pm 8.61$  in Group R and was comparable ( $P = 0.62$ ). The mean VAS score at 1<sup>st</sup> hr postoperatively increased to  $10 \pm 7.88$  in Group L and  $11.67 \pm 9.13$  in Group R and was comparable ( $P = 0.45$ ). In group L, the mean VAS score further increased with time, until when VAS score approached 50 and patients were given 1<sup>st</sup> dose of rescue analgesia at about 4<sup>th</sup> hr postoperatively. In group R too, the mean VAS score increased with time and approximated 50 at around 3<sup>rd</sup> hour postoperatively, and received their 1<sup>st</sup> dose of rescue analgesia. Later on, rescue analgesics were repeated whenever their VAS score increased more than 50.

On statistical comparison of average VAS score values of 24 hours observation period, significantly higher VAS scores were observed in group R when compared to group L ( $< 0.05$ ) (Table-10)

These findings were in accordance with study conducted by **Papagiaunopoulou P et al<sup>10</sup>** who compared the analgesic efficacy of Levobupivacaine (0.5%) with Ropivacaine (1%) and normal saline (0.9%) and inferred that Levobupivacaine group had significantly lower VAS scores compared to Ropivacaine group.

Our study is also in accordance with **Narra G R et al<sup>6</sup>**, **Cha S M et al<sup>11</sup>**, **Louizos A A et al<sup>12</sup>**, **Gogos G P et al<sup>13</sup>**, **Kim T H et al<sup>14</sup>**, **Pavlidis T E et al<sup>15</sup>**, **Bindra T K et al<sup>8</sup>**, **Albuquerque et al<sup>9</sup>** and **Shivhare P et al<sup>16</sup>**, **Alper I et al<sup>17</sup>**, **Karaman Y et al<sup>18</sup>**, **Ismail M T et al<sup>19</sup>**.

### TOTAL ANALGESIC CONSUMPTION IN 24 HOURS:

As shown in Table no.11, on statistical comparison of total analgesic consumption in 24 hrs in the two groups, patients in group L were found to require significantly lower dose of tramadol than that in group R ( $p < 0.05$ ).

These findings of our study were supported by a comparative study performed by **Gupta P et al<sup>5</sup>**, **Narra G R et al<sup>6</sup>** and **Papagiaunopoulou P et al<sup>10</sup>** as they declared that total analgesic consumption in 24 hrs was lower in levobupivacaine group than in ropivacaine group.

The study results are also supported by **Cha S M et al<sup>11</sup>**, **Louizos A A et al<sup>12</sup>**, **Kim T H et al<sup>14</sup>**, **Pavlidis T E et al<sup>15</sup>**, **Bindra T K et al<sup>8</sup>** and **Albuquerque et al<sup>9</sup>**, **Alper I et al<sup>17</sup>** and **Karaman Y et al<sup>18</sup>**.

### COMPLICATIONS:

As shown in Table no.12, patients in group L experienced shivering as the most common adverse effect and those in group R experienced nausea-vomiting as the most common adverse effect. Shivering was noted in 4 out of 30 (13.34%) patients of group L; but only in 2 out of 30 (6.67%) patients in group R. Nausea and vomiting was seen in 2 out of 30 (6.67%) patients of group L and in 3 out of 30 (10%) patients belonging to group R.

There were no any incidence of hypotension, bradycardia, dyspnea, chest pain or dysrhythmia.

### CONCLUSION

There was significant prolongation of duration of postoperative

analgesia in Levobupivacaine group as compared to Ropivacaine group. In terms of analgesic efficacy, Levobupivacaine appears to be superior to Ropivacaine. No significant adverse effect and haemodynamic instability is seen with both Levobupivacaine and Ropivacaine. Intraperitoneal instillation combined with periportal infiltration of local anaesthetic is a useful adjunct as part of a multimodal analgesic regimen to reduce the postoperative pain in laparoscopic cholecystectomy.

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