**ORIGINAL RESEARCH PAPER** 

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# COMPARISON OF INTRAPERITONEAL INSTILLATION OF BUPIVACAINE VERSUS ROPIVACAINE FOR POSTOPERATIVE ANALGESIA IN LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND STUDY

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# ABSTRACT

**BACKGROUND AND AIMS:** Laparoscopic operative procedures have revolutionized surgery with many advantages: a smaller and more cosmetic incision, reduced blood loss, reduced postoperative stay and pain, which cut down on hospital cost. Although, there are clear benefits compared with open surgery, post-operative pain after laparoscopic cholecystectomy remains an issue. The Aimed of our study was to compare the efficacy of intraperitoneal instillation of bupivacaine and ropivacaine for postoperative pain relief in patients undergoing laparoscopic cholecystectomy.

**METHOD:** After approval from institutional ethical committee this randomized double blind study was carried out in the department of the Anaesthesiology. 92 patients aged 20-70 years, ASA status I & II and within 50-80 kg weight, scheduled for laparoscopic cholecystectomy were randomly divided into two groups with 46 patients in each group. Group(A) patients received 0.5% bupivacaine in a dose of 2 mg/kg and Group(B) patients received 0.75% ropivacaine in a dose of 2 mg/kg, both drugs diluted in normal saline to make a solution of 50 ml. The Drug solution was instilled intraperitoneally through the infra-umbilical trocar at the end of surgery in Trendelenburg's position to facilitate the dispersion of the drug solution in the subhepatic region. NIBP, HR, SPO2, VAS, VRS (verbal rating scale) and rescue analgesia were recorded immediately postoperatively and then regularly every hour for the next 12 hours.

**RESULT:** The age and sex distribution of both groups were similar. The pulse rate, systolic & diastolic blood pressure were comparatively lower in Group (B than in Group (A). The VAS score was significantly (p < 0.05) lower in ropivacaine group (B) from postoperative 4th, 5th and 7hr to 12th hr. Rescue analgesia was given when VAS was >40. VRS score was significantly lower in Group(B) immediate postoperative period, 1th and then from 3hrs to 12 hours showing longer duration of analgesia in this group. The rescue analgesic requirement was also less in Group (B). total analgesic consumption was significantly lower in ropivacaine group ( $89.52\pm30.12$ ) compare to bupivacaine group ( $107.14\pm41.06$ ) respectively P=0.047.

**CONCLUSION:** We conclude that the instillation of local anesthetic solution intraperitoneally was an easy, non-invasive and effective method of postoperative pain relief in laparoscopic cholecystectomy. Ropivacaine provided analgesia for longer duration as compared to bupivacaine.

# **KEYWORDS**

Laparoscopic Cholecystectomy; Intraperitoneal; Local Anesthetic; Bupivacaine; Ropivacaine

# INTRODUCTION

Cholecystectomy is a commonly done procedure world over. Laparoscopic surgery has been established as a gold standard for performing cholecystectomy over past few years.<sup>1,2</sup> Laparoscopic operative procedures have revolutionized surgery with many advantages: a smaller and more cosmetic incision, reduced blood loss, reduced postoperative stay and pain, which cut down on hospital cost.<sup>3</sup> Although, there are clear benefits compared with open surgery, post-operative pain after laparoscopic cholecystectomy remains an issue<sup>4</sup>.

There are many factors which contribute for pain after laparoscopic cholecystectomy<sup>1</sup>. These factors include-stretching of parietal peritoneum from intraperitoneal insufflations of gas, traumatic traction of nerves irritation of diaphragm by carbon dioxide, release of inflammatory mediators, dissection of gall bladder and tissue damage due to incision.

Various methods like use of NSAIDS, intraperitoneal local anest hetics, heated gas, low pressure gas, nitric oxide pneumoperitoneum intraperitoneal saline have been used to reduce pain after laparoscopic cholecystectomy<sup>5</sup>.

The Aimed of our study was to compare the efficacy of intraperitoneal instillation of bupivacaine versus ropivacaine for postoperative pain relief.

## METHODOLOGY

A prospective randomized double-blind study was conducted in general Surgery OT, Department of Anesthesia, SMS medical college Jaipur with Due permission from the institutional ethical committee (Approval No 405/MC/EC/2019) and research review board and after taking written informed consent from the patients. In this study, a total of 92 patients aged between 20-70 years, ASA status I & II and within 50-80 kg weight, scheduled for laparoscopic cholecystectomy were taken. Patients were randomly divided into two groups by using

computer generated random number table. Two study groups were made and 46 patients in each group. Group A patients received 0.5% bupivacaine in a dose of 2 mg/kg and Group B patients received 0.75% ropivacaine in a dose of 2 mg/kg, both drugs diluted in normal saline to make a solution of 50 ml. On arrival of patients in the operation theatre, weight, fasting status, consent and PAC was checked. Baseline parameter (Spo<sub>2</sub> heart rate, blood pressure) were recorded. All patients received the same anesthetic technique. The Drug solution was instilled intra-peritoneally through the infra-umbilical trocar at the end of surgery by surgeon. Trendelenburg position was used to facilitate dispersion of drug solution in sub hepatic region. Non-invasive blood pressure, heart rate and peripheral oxygen saturation were recorded immediate postoperatively and then regularly every hour till next 12 hours. The verbal rating pain scale (VRS) and Visual Analogue scale (VAS) was used for postoperative pain assessment. The pain intensity was measured every hour immediate postoperatively to till next 12 hours. When the score according to VAS was > 40 a bolus dose of injection diclofenac aqueous (75 mg) intravenous was administered as a rescue analgesic and then additional dose of analgesic was given as when required. Number of doses of rescue analgesic received by the patients were recorded.

## RESULTS

The following results were obtained during the study and the data was analyzed using statistical software Microsoft excel and SPSS 22 for windows. Both the groups, the bupivacaine group (group A) and the ropivacaine group (group B) were comparable and statically nonsignificant with regards to the demographic profile i.e. age, weight and sex as well as the duration of surgery (table1).

## Table 1: Demographic profile

	Group A, n (%)		Group B, n (%)		P value
	Mean	SD	Mean	SD	
Age (Years)	41.85	10.15	41.26	9.80	0.778
Weight (Kg)	57.04	4.77	56.28	5.07	0.460
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Height (cm)	160.39	5.94	159.87	5.85	0.672		
Duration of surgery(min)	42.89	2.36	42.43	2.05	0.324		
Sex							
Male	12 (26.09)		14 (30.43)				
Female	34 (7	73.91)	32 (69.57)				

The mean systolic blood pressure in two groups at different intervals which showed that they were statistically significant (p<0.05) from immediate postoperatively to 1th hour in group B as compared to group A. Afterwards they were comparable and statistically non-significant. And the mean diastolic blood pressure in two groups at different intervals which showed that they were statistically significant (p<0.05) at immediate postoperatively hour in group B as compared to group A. Afterwards they were comparable and statistically non-significant. Figure 1 shows the comparable and statistically non-significant (p<0.05) from immediate postoperatively hour in group B as compared to groups at different intervals which showed that they were statistically non-significant (p<0.05) from immediate postoperatively to 9th hour in group B as compared to group A. Afterwards they were comparable and statistically non-significant. heart rate was comparable and statistically non-significant (p<0.05) from immediate postoperatively to 9th hour in group B as compared to group A. Afterwards they were comparable and statistically non-significant. heart rate was comparatively lower in group B than in group A in postoperative period.

Figure 1: Mean heart rate (per minute) in the two groups at different interval of time(hours).



Figure 2 shows that there is a significant difference in VAS scores in group A and group B in 4th, 5th, 7th, 8th, 9th, 10th, 11th, 12th postoperative hour and VAS scores are higher in group A as compare to group B. Figure 3 shows that there is a significant difference in VRS scores in group A and group B in immediate postoperative, 1st, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 11th, 12th, postoperative hour and VRS scores are higher in group A as compare to group B. This difference is due to the lower VRS score in Group B.

### Figure 2: Mean VAS scores in two groups at different interval.



### Figure 3: Mean VRS scores in two groups at different Interval.



Table 2 shows that number of patients required analgesia in group A higher as compared to group B. No patient required analgesia in group B after 7th hour but group A patients required analgesia up to 9th hour.

Rescue analgesia was given when VAS score was > 40.

### Table 2: Number of patients requiring rescue analgesics.

	Group A (N=46)		Group B (N=46)		P value	
	Yes	No	Yes	No		
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Immediate Post	1	45	0	46	1.00 (NS)
operatively					
1st postoperative	5	41	2	44	0.414 (NS)
hour					
2nd postoperative	16	30	15	31	1.00 (NS)
hour					
3rd postoperative	21	25	13	33	0.131 (NS)
hour					
4th postoperative	3	43	2	44	1.00 (NS)
hour					
5th postoperative	4	42	1	45	0.358 (NS)
hour					Ì, Î
6th postoperative	1	45	2	44	1.00 (NS)
hour					, ,
7th postoperative	1	45	1	45	0.475 (NS)
hour					, í
8th postoperative	1	45	0	46	1.00 (NS)
hour					, ,
9th postoperative	7	39	0	46	0.018 (S)
hour					、 <i>、 、 、</i>
10thpostoperative	0	46	0	46	-
hour					
11thpostoperative	0	46	0	46	-
hour				-	
12thpostoperative	0	46	0	46	-
hour				-	
Total doses of	60		36		
rescue Analgesia					
required					

Figure 2 shows that time to first analgesic requirement is lower in group (A) as compared to group (B) and statistically non-significant. The time required for rescue analgesia was less in bupivacaine group than with ropivacaine, which means Group B has longer action for relief of pain. Figure 3 shows that the total analgesic dose consumption is higher in group (A) as compare to group (B) and the difference is statistically significant.

# Figure 2: Mean time to first analgesic requirement (±SD) (in min).



Figure 3: Mean analgesic dose consumption (in mg) in the two groups.



#### DISCUSSION

Our study was done to evaluate the analgesic efficacy of intra peritoneal infiltration of local anesthetic in laparoscopic cholecys tectomy patients. The primary aim was to compare the analgesic efficacy of intra peritoneal bupivacaine with of ropivacaine. In the present study, a total of 92 patients were taken. Two study groups were made each consisting of 46 patients. Patients receiving a solution of

0.5% Bupivacaine in a dose 2 mg/kg diluted with normal saline to a total volume of 50 ml were placed in group A. Patients receiving a solution of 0.75% Ropivacaine in a dose 2 mg/kg diluted with normal saline to a total volume of 50 ml were placed in group B.

Both groups were almost similar for age, sex, physical parameters and duration of surgery. Table 1 showed mean age in group A and B were 41.85±10.15, 41.26±9.80 respectively for two groups and showed that cholecystectomy incidence was more in females than in males in the two groups but statistical comparison between two groups was non-significant. So, M:F ratio in two groups was 12:34, 14:36 in groups A and B respectively. Table 1 also showed mean height and weight in the two groups were statistically insignificant and mean duration of surgery (min.) was 42.89±2.36, 42.43±2.05 in groups A and B respectively and statically non-significant.

Figure 1 showed that heart rates were comparatively lower in group B than in Group A. The results were comparable and the difference was found to be significant in the two groups at immediate postoperatively,1st, 2nd, 3rd, 4th, 5th,6th, 7th, 8th, and 9th hours. In a similar study conducted by Sharan R et al<sup>6</sup> also found the heart rate was lower in the ropivacaine group, with statistically significant difference at 2nd,4th, 6th, and 8th hours. Blood pressure (systolic, diastolic, and mean) were comparable and statistically insignificant in both the study groups. In a similar study done by Meena RK et al blood pressures (systolic, diastolic, and mean) were comparable and statistically insignificant in both the study groups, the reason being the rescue analgesia given on demand whenever VAS scores reached 40.<sup>10</sup> Studies done by Gupta et al, Tae Han Kim et al, Goldstein et al also found the same findings.

In Our study Figure 2 & 3 showed that the mean VAS score readings were lower in Group B in comparison to Group A and were statistically significant at 4th, 5th, and then from 7th to 12th hours and the mean VRS score readings were lower in Group B in comparison to Group A and were statistically significant at immediate postoperative, 1st, and then from 3rd to 12th hour in both the groups. Similarly, Meena RK et al<sup>10</sup>. in their study compared bupivacaine and ropivacaine and found that mean VAS score was lower in both the groups with significant difference between the VAS score from the 5th postoperative h to 12th h except in the 6th h and VRS score was lower in both the groups with significant difference between the VRS score in immediate postoperative period, 1st h, 3rd h, and then from 7th h to 12th h. The results were also supported by Khurana et al11. In our study, the number of patients requiring rescue analgesia was lower in group B in comparison to group A. Time to first analgesic requirement was compared in both group and was found to be lower in group A. The total analgesic dose consumption was also higher in this group. The differences in time to first analgesic requirement was statistically nonsignificant and total analgesic consumption was statistically significant (p<0.05). This implies that the analgesia provided by ropivacaine is of longer duration and denser than bupivacaine. In a study conducted by Sharan R et al<sup>6</sup>. time to first analgesic requirement was found lower in ropivacaine group in compared to bupivacaine group.

Complication were found in less than 13% of the patient in both the Groups were comparable and difference was statistically nonsignificant Post-operative nausea and vomiting were seen in five patients in Group A and four patients in Group B. Bradycardia was observed in one patient in Group A and hypotension was observed in two patients in Group A. In Group B no bradycardia and hypotension was observed. There was no respiratory depression in any of the group.

## CONCLUSION

This study concludes that that intraperitoneal instillation of local anesthetic during a laparoscopic cholecystectomy was a noninvasive, rapid safe and simple analgesic technique which reduces total amount of rescue analgesia consumption during the first 12h. Bupivacaine and ropivacaine both are effective in decreasing post-operative pain in laparoscopic cholecystectomy patients. In particular, the ropivacaine group had better result. Analgesia provided by ropivacaine was of longer duration as compared to bupivacaine.

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