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PREINCISIONAL PERIportal AND INTRA PERITONEAL INFILTRATION OF LEVOBUPIVACAINE AND ROPIVACAINE IN LAPAROSCOPIC CHOLECYSTECTOMY: A COMPARATIVE STUDY

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ABSTRACT: AIM AND OBJECT: It is mandatory to minimize pain after laparoscopic surgeries; the aim of this study is to evaluate the effect of pre incisional periportal infiltration and intraperitoneal injection with Levobupivacaine as compared to Ropivacaine for hemodynamic stability and pain relief in laparoscopic surgeries. **METHOD AND MATERIAL:** The prospective randomized study includes 100 laparoscopic cholecystectomy coming under ASA grade I & II. Patients randomly allocated in two groups of 50 patients each. Two study groups received preincisional periportal and intraperitoneal infiltration with 0.125% leobupivacaine 20 ml and ropivacaine 20 ml respectively. Hemodynamic stability and post-operative analgesia was studied. **RESULT:** Requirement of Diclofenac Sodium was reduced in Levobupivacaine group, and was statistically significantly ($P < 0.05$) in post-operative period with better hemodynamic stability as compare to Ropivacaine group. **CONCLUSION:** Pre incisional periportal and intraperitoneal administration of Levobupivacaine demonstrated useful effect on post-operative pain relief after laparoscopic cholecystectomy especially in early 24 hrs period. **KEYWORDS:** Levobupivacaine, Ropivacaine; preincisional periportal infiltration and intraperitoneal injection.

INTRODUCTION: Laparoscopic Cholecystectomy (LC) has been the favored treatment for gallbladder lesions. A major benefit of laparoscopy in upper gastrointestinal surgery results from avoidance of an upper abdominal incision. LC has proven benefits of less pain^{1,2} and improved pulmonary function tests compared with small incision cholecystectomy. However, it is not completely painless. This pain is thought to be multifactorial in nature and severity, Causes of pain include visceral pain due to peritoneal irritation caused by entrapment of dissolved CO₂ in the abdomen (compartment syndrome), shoulder pain due to irritation of diaphragmatic peritoneum, incisional pain etc and various methods of analgesia have been introduced. Although opioids provide a powerful analgesia, but associated with many side effects. The aim is avoidance of opioids and includes nonsteroidal anti-inflammatory drugs (NSAIDs), intraperitoneal local anesthesia, local anesthetic infiltration of the wound, intraperitoneal saline, adequate removal of the insufflation gas, heated gas, low pressure gas, and nitrous oxide pneumoperitoneum. The combination of techniques that have parietal, diaphragmatic, and visceral components may reduce pain after laparoscopy.

Preincisional pereportal analgesia with long-acting local anesthesia theoretically achieves peripheral blockage of pain stimuli, which is more advantageous than treating pain after it occurs. It is postulated that this reduces postoperative pain and analgesic requirements.

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In this prospective, randomized trial, we chose ropivacaine and levobupivacaine, for periportal and intraperitoneal infiltration in LC. The purpose was to evaluate the analgesic effect and haemodynamic stability in patients of laparoscopic cholecystectomy.

MATERIALS AND METHODS: This prospective, randomized trial was designed included 100 laparoscopic cholecystectomies carried out by the same surgeon. It conforms to CONSORT guidelines for the reporting of clinical trials. Ethical approval by the scientific committee of our hospital was achieved as was written consent from the patients. Patients were randomly allocated into 2 groups. The randomization was conducted by sealed envelope on the patient's arrival at the theater until the planned number of equivalent groups was reached. An independent surgeon was responsible for the randomization as well as for the preparation of an unmarked syringe containing 20 mL of study drug. The operating surgeon, the staff, and the patients were blinded to this procedure.

Group (I) included 50 cases Ropivacaine (0.125%) was used, and in Group (II) which included 50 cases, Levobupivacaine (0.125%) was given.

The patients belonged to ASA II or I, according to the classification of the American Society of Anesthesiologists.

Patients with a previous upper abdominal operation or suspected bile duct stones by ultrasonography and liver function tests were excluded from laparoscopic cholecystectomy; Similar anesthetic and operative techniques were applied in all patients.

All patients received an intravenous injection of midazolam 2 mg and ondansetron 4 mg just before the anesthesia.

General anesthesia with an endotracheal tube was achieved by using fentanyl 3 to 5 µg/kg and propofol 2 to 3 mg/kg followed by vecuronium 0.1 mg/kg and Isoflurane for maintenance.

Pneumoperitoneum was through the infraumbilical region (Hasson open method) and insufflation of warmed carbon dioxide. This first trocar was used for the introduction of an optic direct view 0° for cholecystectomy.

Intraabdominal pressure was maintained at 12 mm Hg for cholecystectomy. Before the skin incision and trocar placement, local infiltration of the port sites with 10 mL study drug was performed.

Laparoscopic cholecystectomy was performed with the patient in a slight reverse Trendelenburg position with a 4-trocar technique. 10 ml of local anesthetic solution was sprinkled intraperitoneally at the end of surgery before closure of trocar site.

A drain was used and clamped for 1 hr. Antibiotic prophylaxis was attempted with 3 doses of a second-generation cephalosporin.

An independent nurse recorded the postoperative pain at the 3rd, 6th, 12th, and 24th hour after the operation according to patient's perception. The randomization was blind to both of them.

Postoperative nausea and shoulder pain were noted. The nausea was assessed by the patient's complaint and the need for the use of an antiemetic drug.

STATISTICAL ANALYSIS: Parametric data were compared between groups by analysis of variances (ANOVA) and post-hoc testing.

Statistical significance was assumed if $P < 0.05$. Nonparametric data were analyzed with chi-square tests between groups. The analysis was performed with the Statistical Package for the Social Sciences.

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RESULTS: The prospective, randomized, comparative study was conducted in the Department of Anesthesiology & Critical Care MGMC, Jaipur on 100 patients aged between 18-50 years posted for LC.

There were no clinical or statistically significant differences in the demographic profile of patients in either group.

Fig. 1

Fig. 2

Fig. 3

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Only 16% subjects in Group I did not required rescue analgesia at 30 minutes as compared to 92% subjects in Group II ($p < 0.001$).

Over 4 hour period all subjects in Group I required rescue analgesia while only 58% subjects in Group II required it ($p < 0.001$).

	Group 1 Mean $\pm$ SD	Group 2 Mean $\pm$ SD	P value
PRE OP	82.80 $\pm$ 16.67	78.66 $\pm$ 10.51	0.14
INTRA OP	99.04 $\pm$ 18.30	85.80 $\pm$ 10.99	<0.001
POST OP	98.64 $\pm$ 20.49	86.16 $\pm$ 12.43	<0.001

Table 1

Heart Rate was significantly higher in Group 1 as compared to Group 2 subjects in intra-operative and post-operative period.

Fig. 4

The change in heart rate in the intra-operative period of more than 10% was observed in 76% subjects of Group 1 as compared to 30% of subjects in Group 2.

Fig. 5

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The change of >10% in post-operative heart rate as compared to pre-operative value was observed in 76% subjects of Group 1 as compared to 48% of subjects in Group 2.

	Group 1 Mean $\pm$ SD	Group 2 Mean $\pm$ SD	value
PPRE OP	77.26 $\pm$ 9.26	75.01 $\pm$ 10.05	0.24
POST OP	86.68 $\pm$ 8.95	81.62 $\pm$ 11.32	0.01

Table 2

Blood Pressure was also more in Group 1 than Group 2 subjects during post-operative period.

Fig. 6

Difference in pre-operative and post-operative mean blood pressure was marginally significant among both the groups.

No episode of Postoperative nausea and shoulder pain was noted in either group.

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. Results of studies on this subject show some controversy.

Such differences in results could be due to many reasons, such as heterogeneity of patient populations, number of surgeons and lack of study power.

In this present study that compared the efficacy of preincisional periportal and intraperitoneal levobupivacaine infiltration in comparison to Ropivacaine on postoperative analgesia in patients undergoing laparoscopic cholecystectomy, we determined that levobupivacaine was more safe and effective in pain management.

Numerous studies have been performed on the effects of intraperitoneal local anaesthetics on postoperative analgesia. In these studies, different local anaesthetics in different volumes and

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concentrations have been used before and after the intervention. Although there are studies indicating that intra peritoneal local anaesthetics decrease postoperative abdominal pain and analgesic consumption, there are some studies suggesting that they are ineffective. However, several investigators reported that combination of somato-visceral local anaesthetic treatment decrease incisional and intraabdominal pain and shoulder pain after laparoscopic cholecystectomy. Although there are numerous studies on the use of different local anaesthetics in laparoscopic cholecystectomy, the number of studies on levobupivacaine use is few.

The timing of administration of local anesthetic is another point of controversy. Infiltration of anesthetic agent before incision is known as preemptive analgesia. Some studies showed that this type of analgesia is more effective in preventing afferent signals from reaching the spinal cord and thus more beneficial in reducing postoperative pain significantly compared with giving the local anesthetic at the completion of procedure.

Another group also reported that visual analog pain scores and consumption of analgesics were significantly lower in patients receiving intraperitoneal bupivacaine immediately after creation of pneumoperitoneum than at the end of surgery.

Liu et al³ conducted study on Local anesthesia with ropivacaine for patients undergoing laparoscopic cholecystectomy and found that infiltrating ropivacaine after surgery through the port site reduced pain intensity, the number of patients requiring postoperative analgesics, and hospital stay. Administering local anesthesia at the end of surgery offered a longer time delay to the need for analgesics, compared with patients who did not receive postoperative local anesthesia.

Louizos⁴ and colleagues reported that 20 mL of levobupivacaine application is effective in decreasing right shoulder pain

Sarac et al⁵ suggested that preemptive injection of Ropivacaine is not as effective as postoperative injection.

In our study, we found that infiltration with Levobupivacaine is safer and hemodynamically more stable than use of Ropivacaine. Use of rescue analgesia was lesser in Group I as well as less pain to patients.

Dath et al⁶. Compared bupivacaine with normal saline applied at the trocar incision site before closing the incision in patients undergoing laparoscopic cholecystectomy; they found that postoperative VAS values were significantly lower in patients receiving bupivacaine and recommended that local anaesthetic application at the trocar incision site should be standard after laparoscopic cholecystectomy.

Another study comparing incisional bupivacaine and normal saline applied before trocar placement in laparoscopic cholecystectomy interventions and found that postoperative pain, analgesia and antiemetic medication use were significantly lower in patients receiving local anaesthetics.

Lee and colleagues⁸, in their study where they compared preoperative and postoperative application of incisional and intraperitoneal bupivacaine (60 mL, 0.25%), found that pain was significantly lower in the preincisional infiltration group compared to that in postoperative incisional infiltration group, and preoperative and postoperative intraperitoneal infiltration groups, they recommended the preoperative application of local anaesthetics in the incisional region..

In our study, we found that infiltration with Levobupivacaine is safer and hemodynamically more stable than use of Ropivacaine. Use of rescue analgesia was lesser in Group I as well as less pain to patients.

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CONCLUSION: Levobupivacaine prolongs the post-operative analgesia requirement and provides hemodynamic stability when given in form of preincisional periportal infiltration and intra peritoneal injection in comparison to Ropivacaine.

No episode of Postoperative nausea and shoulder pain was noted in either group.

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