

## Assessment of Effect of Port Site and Intraperitoneal Instillation of Bupivacaine in Reduction of Post-Operative Pain After Laparoscopic Cholecystectomy

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### Abstract

**Aim:** Effective postoperative pain control is an essential component for care of surgical patients. Inadequate pain control may result in increased morbidity or mortality. Analgesic effects of periportal infiltration of local anesthetics, infiltration of periportal parietal peritoneum, intraperitoneal spraying at subdiaphragmatic space and subhepatic space covering the area of hepatoduodenal ligament have been reported. The present controlled study aimed at assessing the effect of port site injection and intraperitoneal instillation of bupivacaine in reduction of post-operative pain after laparoscopic cholecystectomy.

**Methods:** The present study was conducted among a group of 180 patients diagnosed to have symptomatic cholelithiasis and who underwent elective laparoscopic cholecystectomy under general anesthesia. In group 1, pre-incisional local infiltration of 20ml 0.5% bupivacaine at the port sites; and in group 2, local infiltration of 20ml 0.5% bupivacaine at the port sites with intraperitoneal installation. In group 3, no local infiltration was done and treated as control group. Pain assessment is based on a Universal Pain Assessment Tool. The analysis of our study was performed one-way ANOVA & Post HOC test (Scheffe's HSD) & Chi square tests as and when indicated.

**Results:** Mean pain scores at 30 minutes were significantly lower in groups 1 & 2 compared to control group; but however, the values were not significantly different when compared to each other. Similarly, the mean pain scores at 4<sup>th</sup>, 8<sup>th</sup>, 16<sup>th</sup> and 24<sup>th</sup> hours for the preincisional and preclosure groups, didn't signify any inter-group advantage. Therefore, bupivacaine provides a substantial reduction of pain intensity up to 24 hours postoperatively; and was found to be statistically significant. However, timing of anesthesia was found to be statistically insignificant in terms of preclosure vs pre incisional of the port sites.

**Conclusion:** *Instillation of bupivacaine at the port sites in laparoscopic cholecystectomy irrespective of the timing of instillation is an ineffective method of achieving pain control in the post-operative period as long as 24 hours after surgery. There was no statistically significant reduction of post-operative pain between the pre-incisional and pre-closure groups.*

## Keywords

Bupivacaine; Cholecystectomy; Pain scores

## Introduction

In this modern era of minimally invasive surgery, the approach of a surgeon is focused more and more towards making the postoperative period as comfortable as possible for the patient. Laparoscopy is an excellent means to minimize the trauma and agony of the patient following surgery, however there still remains some challenge to minimize the post-operative pain in the patients. A recent randomized controlled trial has shown that there may be more intense pain and greater analgesic requirement in the immediate post-operative period after laparoscopic surgery than open laparotomy [1]. Conventional laparoscopic cholecystectomy involves a 10-mm incision on the umbilicus, a 5 or 10 mm incision in the epigastric or subxiphoid region, and one or two 5 mm incisions in the right upper quadrant [2].

Postoperative pain, requiring injectable analgesics is one of the hurdles in performing laparoscopic cholecystectomy as a day care procedure. Pain reaches at maximum level within 6 hours of the procedure and then gradually decreases over a couple of days, it varies considerably among patients [3,4]. The international association for the study of pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage”[5]. Effective postoperative pain control is an essential component for care of surgical patients. Inadequate pain control may result in increased morbidity or mortality [6]. Intraperitoneal instillation of local anesthetics is one of the simple, yet effective, techniques for providing pain relief during the early postoperative period after laparoscopic procedures. It was found that the response to intraperitoneal local anesthetics is mediated by local peritoneal effects rather by systemic absorption [7].

Analgesic effects of periportal infiltration of local anesthetics, infiltration of periportal parietal peritoneum, intraperitoneal spraying at sub diaphragmatic space and subhepatic space covering the area of hepatoduodenal ligament have been reported [8]. In one of the study it is demonstrate that local anesthetic instillation (bupivacaine) at the end of laparoscopy prevents postoperative pain and dramatically decreases the need for morphine. This technique improves patient comfort, shortens the stay in the postoperative care unit and decrease nursing care in the ward [9]. When administrated before surgery, infiltration of local anesthetics can decrease analgesic requirement during surgery as well as reduce the need for opioid containing analgesic postoperatively [10]. The present controlled study aimed at assessing the effect of port site injection and intraperitoneal instillation of bupivacaine in reduction of post-operative pain after laparoscopic cholecystectomy.

## Patients and Methods

The present study was conducted from April 2017 to March 2018 on a group of 180 patients diagnosed to have symptomatic cholelithiasis and who underwent elective laparoscopic cholecystectomy under General Anesthesia in Department of Surgery at Maharaja Agrasen Medical College, Agroha, Hisar. The diagnosis of cholelithiasis was made on the basis of clinical examination and ultrasonography. The study was a randomized controlled in which patients were randomly allocated into 3 groups of 60 patients (groups 1, 2 and 3) each. Patients with conversion of laparoscopic cholecystectomy into open cholecystectomy were excluded from the study.

The whole procedure and risks involved were fully explained to the patient and well informed and written consent in vernacular language was taken. In group 1, pre-incisional local infiltration of 20ml 0.5% bupivacaine at the port sites with intraperitoneal installation of 10ml 0.25% bupivacaine was done throughout all the layers of the abdominal wall (till peritoneum). In group 2, local infiltration of 20ml 0.5% bupivacaine at the port sites with intraperitoneal installation of 10ml 0.25% bupivacaine was done after the completion of surgical procedure, and just before the closure of skin. Bupivacaine instillation in both groups 1 and 2 was allocated according to the diameter of the trocar; 7 ml for 10 mm port and 3 ml for 5 mm port and 10ml intraperitoneal over liver site. In group 3, no local infiltration was done and was treated as control group. Pain assessment will be based on a Universal Pain Assessment Tool. The Universal Pain Assessment Tool used was a 10 cm 10-point scale.

Universal pain assessment tool (UPAT) is a combination of three different pain assessment scales viz. visual analogue scale (VAS), Wong Baker Facial Grimace Scale (WBFGS), and Activity Tolerance Scale (ATS). Universal pain assessment tool is translated into 10 languages and its aim is to describe completely the individual's pain experience. The combination of NRS, verbal description, association between pain and facial expression and individual threshold of pain makes this instrument usable in all age groups.

Pain assessment was based on a Universal Pain Assessment Tool. Score 0-No Pain

Score 1-2-Mild Pain

Score 3-6- Moderate Pain

Score 7-10-Severe Pain

## Results

The analysis of our study was performed using statistical analysis tools, initially crosstabs procedure was performed followed by one-way ANOVA and Post HOC test (Scheffe's HSD) and Chi square tests as and when indicated (Table 1).

**Table 1:**Gender Distribution amongst three groups.

Gender	Group 1 Pre-incisional	Group 2 (Pre-closure)	Group 3 (Controls)
Male	12 (20%)	07(11%)	14 (23%)
Female	48 (80%)	53 (89%)	46 (77%)

A total of 18% patients were males and 82% were females. Gender distribution was fairly equal in all the three groups with a higher incidence of female patients in each group (table 1). The age range of patients enrolled in the study was between 19-80, mean age being 43.25 years. There was no age-related statistical variation.  $F=0.828$ ,  $p=0.440$  (Not Significant) (Table 2).

**Table 2:** Age wise distribution of patients.

Group	N	Range	Age (years) Mean $\pm$ SD	ANOVA*	Comparison	P Value*
Group 1	60	19 – 80	44.58 $\pm$ 11.42	F=0.828; P=0.440; NS	Group 1 vs 2	0.565 <sup>NS</sup>
Group 2	60	22-75	43.01 $\pm$ 13.56		Group 1 vs 3	0.985 <sup>NS</sup>
Group 3	60	22-70	42.15 $\pm$ 16.36		Group 2 vs 3	0.462 <sup>NS</sup>

$p > 0.05$ ; Not significant; \*  $p < 0.05$ ; Significant

**Table 3:** Mean UPAT Scores at various time intervals.

Time	Group 1 Mean $\pm$ SD	Group 2 Mean $\pm$ SD	Group 3 Mean $\pm$ SD	Gp 1 vs 2(p value)	Gp 1 vs 3(p value)	Gp 2 vs 3 (p value)
Baseline (0 Hrs)	4.03 $\pm$ 1.02	4.16 $\pm$ 1.06	6.96 $\pm$ 1.26	0.445	<0.001**	<0.001**
30 Mins	4.10 $\pm$ 1.06	4.13 $\pm$ 0.86	7.16 $\pm$ 1.24	0.072	<0.001**	<0.001**
4 hrs	4.11 $\pm$ 1.05	4.05 $\pm$ 0.94	7.18 $\pm$ 0.86	0.927	<0.001**	<0.001**
8 hrs	4.40 $\pm$ 0.98	4.21 $\pm$ 1.18	7.10 $\pm$ 0.96	0.489	<0.001**	<0.001**
16 hrs	3.58 $\pm$ 1.16	3.78 $\pm$ 0.96	5.66 $\pm$ 1.24	0.603	<0.001**	<0.001**
24 hrs	3.43 $\pm$ 0.90	3.55 $\pm$ 1.08	4.36 $\pm$ 1.18	1	<0.001**	<0.001**

\*\* $p < 0.001$ ; Highly significant

**Graph 1:** Mean pain scores using UPAT scale at specific time intervals.

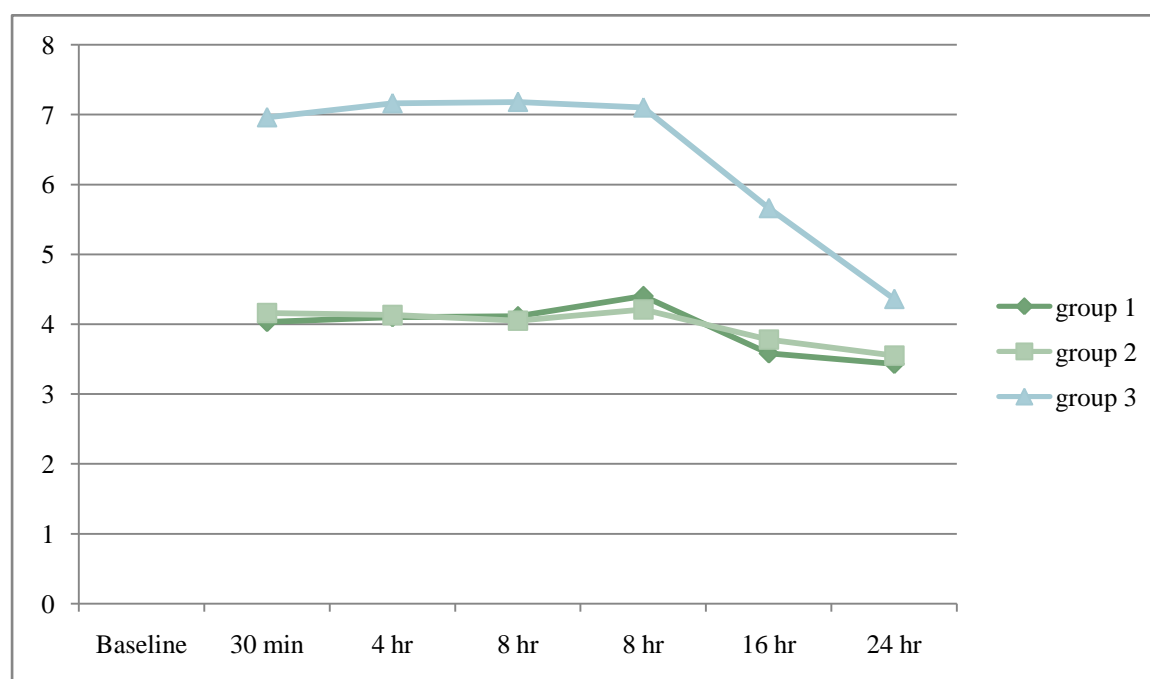


Table 3 and Graph 1 show mean pain scores using UPAT scale at specific time intervals. Repeated measure ANOVA and post hoc tests showed that the overall difference in mean pain scores on UPAT scales measured at different time intervals was significant between the group that did not receive bupivacaine (group 1) and those that received (groups 1 and 2) with a p value of 0.00. Repeated measure ANOVA mean pain scores measured at 0 hours alone were highly significant when groups 1 and 2 were compared with the control group ( $p < 0.001$ ). However, there was no statistically significant difference in the mean pain score in between the pre incisional and pre closure Group ( $p = 4.55$ ). Mean pain scores at 30 minutes were significantly lower in groups 1 and 2 compared to group C but however the values were not significantly different when compared to each other. Similarly, the mean pain scores at 4<sup>th</sup>, 8<sup>th</sup>, 16<sup>th</sup> and 24<sup>th</sup> hours for the pre-incisional and pre-closure group, does not signify any inter-group advantage. Bupivacaine provided a substantial reduction of pain intensity upto 24 hours postoperatively; and was found to be statistically significant. However, timing of anesthesia was found to be statistically insignificant in terms of pre-closure vis pre-incisional of the port sites.

## Discussion

Laparoscopic cholecystectomy is considered as gold standard approach to symptomatic cholelithiasis. Laparoscopy is associated with less pain than laparotomy but it is not pain free. Patients undergoing laparoscopic cholecystectomy suffer considerable pain on the day of surgery, frequently requiring analgesics [11]. Controversy exists about the principal source of pain after laparoscopic procedure. Some clinicians maintain that placement of trocars through the abdominal wall is the primary source; whereas others believe that most pain arises from

intraoperative dissection and insufflation of CO<sub>2</sub> resulting in distension of abdominal wall and prolonged elevation of diaphragm [12].

The mean age of patients involved in our study was 43.25 years and this is comparable to an analytical review of 1208 cases by Daradkesh in which the mean age was reported to be 47.2 years. In our study, out of 180 patients, 18% were males, and 82% were females and is comparable with study done by Daradkeh. In his study male population was 23.3% and female population was 76.7% [13]. In multiple randomized studies, it has been evaluated that size of port is associated with intensity of pain; the smaller the port size lesser will be the intensity of pain. Golder et al. [14] failed to show any difference in analgesic effect by replacing one epigastric 10mm port with one 5mm port. On the other hand, Bisgaard et al. showed significant reduction in overall pain for the first three postoperative hours in patients randomized to micro laparoscopic cholecystectomy (three 2mm trocars and one 10 mm trocars) than in traditional laparoscopic cholecystectomy group (two 5mm trocars and two 10mm trocars). In a study by Bresdola et al. [15] two port technique reduce overall pain during the first 24 hours as compared to traditional four port technique, but one third of patients required conversion to traditional four port laparoscopic cholecystectomy because of technical problem with two ports technique.

Kum et al. [16] randomized patients of laparoscopic cholecystectomy with trocars placed according to French or American technique. There was no difference in intensity of pain and shoulder tip pain between two groups, but pain was predominantly in epigastric region in American group, whereas in the French group pain was predominantly localized mid abdominally. Wallace et al. [17] randomized patients undergoing laparoscopic cholecystectomy to 15mm Hg or 7.5mm Hg insufflation pressure and found less pain in the low-pressure group throughout the first postoperative week.

Nasajiyan et al. [18] in a double-blind trial studied the use of low pressure gas as compared to standard pressure gas to create pneumoperitoneum. He found that there is no significant reduction in pain both the group. Frequency of shoulder pain in low pressure group was reduced. Low pressure gas was associated with reduction of surgeon visibility and subsequently more prolonged surgery duration. Aitola et al. [19] randomized patients to N<sub>2</sub>O or CO<sub>2</sub> Pneumoperitoneum and found significantly less pain up to 24 hours in the N<sub>2</sub>O pneumoperitoneum group than in patients given CO<sub>2</sub> insufflation. The mechanism underlying the pain provoking effects of CO<sub>2</sub> (or analgesic effect of N<sub>2</sub>O) is unknown.

Trocar and port site instillation have been a widely studied topic in pain reduction after laparoscopic cholecystectomy. Studies carried out by Johnson et al., Ke et al., Saff et al., Ure et al., Deans et al. and Maier et al. compared bupivacaine with saline; procedures included were diagnostic and operative gynecological laparoscopy, cholecystectomy, and hernia repair [20-25]. The local anesthetic was infiltrated subcutaneously, subfascially, or preperitoneally, or into all layers of the abdominal wall, including the cutaneous tissues, muscle and parietal peritoneum. The concentrations used were between 0.125% and 0.5%, and volumes between 5 and 60 ml with a mean dose of 76± mg. infiltration of port sites was performed

preoperatively at sites two. Only the study by Johnson et al. showed significant degree of pain control with local anesthetics.

In all these trials no effect on supplemental analgesic consumption was observed. No obvious relationship was apparent between application site, dose of the local anesthetic, and degree of obtained pain relief. Data from results of incisional local anesthetics did not provide evidence for any important effect of port site infiltration, either in the qualitative or in the quantitative analysis. Again, no clear difference and relationships were observed in dose and application sites between positive and negative trials. However, in a recent trial of a large-dose, somato-visceral, local anesthetic block after laparoscopic cholecystectomy, incisional pain, not intraabdominal or shoulder pain, was reduced and incisional pain dominated in the control group [26]. In open abdominal procedures, local anesthetics injected at incision site are good for small procedures, such as inguinal hernia repair. In conclusion, there is still no evidence for any major effect of port-site infiltration with local anesthetics. Cook and Lambert compared effect of post site infiltration plus tubal application of bupivacaine without any other analgesia and found no effect on pain outcome measures [27]. On the other hand, three studies comparing infiltration plus intraperitoneal instillation of bupivacaine, mesosalpinx infiltration plus intraperitoneal instillation of lidocaine, or port-site infiltration plus mesosalpinx infiltration and intraperitoneal instillation of ropivacaine with placebo and found significantly reduced pain scores and analgesic consumption up to 4 hours postoperatively or >24 hours after surgery [28-30]. Raetzell et al. concluded that the administration of bupivacaine up to a dose of 125 mg intraperitoneally after laparoscopic cholecystectomy fails to provide significant analgesic benefit. In their study they found significant side effects on pulmonary function and oxygen saturation so they did not recommend intraperitoneal local anesthetics for pain therapy after laparoscopy [31].

Loizides S et al.[32]concluded that serious adverse events were rare in studies undergoing elective laparoscopic cholecystectomy. However, the clinical importance of this reduction in pain is likely to be small. Such trials should include important clinical outcomes such as quality of life and time to return to work in their assessment.

We observed a significant reduction in overall pain scores in the study groups 1 and 2 for up to 24 hours, which is consistent with a previous randomized control trial done by Alexander DJ et al. [33]in which post-operative pain scores were significantly lower in group receiving periportal and peritoneal bupivacaine for pain relief after laparoscopic cholecystectomy, as compared to controls. Hasaniya et al. [34]studied the effect of pre-incisional bupivacaine instillation and concluded that the mean pain scores were lower as compared to controls at 4<sup>th</sup> and 24<sup>th</sup> hour postoperatively. Conflicting results have been reported by Ke, et al.stating that the popular practice of infiltrating bupivacaine at time of incision closure does not offer any benefit in the control of pain after laparoscopy.

## Conclusion

Instillation of bupivacaine at the port sites in laparoscopic cholecystectomy irrespective of the timing of instillation is an effective method of achieving pain control in the post-operative period as long as 24 hours after surgery. Mean pain scores at 0 hrs, 30 mins, 4hrs, 6hrs, 12hrs and 24 hrs postoperatively were significantly lower in the pre incisional and pre closure groups as compared to the control group, which received no local anesthesia at the port sites. There was no statistically significant reduction of post-operative pain between the pre incisional and pre closure group.

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