**Original** Article



# A Prospective Randomized Control Trial to Study the Role of Intraperitoneal Irrigation with Normal Saline in Reduction of Postoperative Pain in Patients Undergoing Laparoscopic Cholecystectomy

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#### Abstract

Aim: The study was performed to examine the effect of intraperitoneal irrigation with normal saline on postoperative abdominal and shoulder pain following laparoscopic cholecystectomy.
Methods: 60 patients with symptomatic gallstone disease undergoing laparoscopic cholecystectomy were randomized in two groups. In study group A (n=30 patients) 30ml/kg of 0.9% normal saline was instilled at the gallbladder bed, while no intervention was performed on control group B (n=30).
Results: Abdominal pain was worst during the first 24 hours after laparoscopic cholecystectomy. At 6, 12 and 24 hrs, group A exhibited significantly less abdominal pain than group B. Group A also experienced less shoulder tip pain during the first postoperative day as compared to the control group.
Conclusion: Intraperitoneal irrigation with normal saline is effective in reducing postoperative abdominal and shoulder tip pain following laparoscopic cholecystectomy.

Key words: Cholecystectomy, laparoscopy, pneumoperitoneum, pain

#### Introduction

Open cholecystectomy, which was introduced by Langenbuch, is still considered to be the gold standard for the treatment of symptomatic cholelithiasis [1]. However, in 1992, a National Institutes of Health (NIH) conference concluded that "laparoscopic cholecystectomy was the treatment of choice for cholelithiasis" [2]. Laparoscopic cholecystectomy (LC) has many advantages over open cholecystectomy. These include reduced pain, better cosmetic outcomes, shorter hospital stays and earlier recovery times [3], which is reflected by the patient's return to normal activities [4].

Because postoperative pain is unpredictable, there is a need for the systematic prevention of pain before a patient awakens Department of Surgery Government Medical College Rajindra Hospital Patiala, Punjab, India

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Corresponding author: Dr. Pankaj Dugg VPO Nussi, Jalandhar 144004, Punjab, India pankajdugg84@gmail.com from anaesthesia [5]. LC is not a painless procedure, but it is less painful than open cholecystectomy. According to research reports, "many patients experience considerable pain after laparoscopic cholecystectomy and improvement in the analgesic technique is desirable" [6]. Pain following LC is multi-factorial and is differentiated into three components - visceral, abdominal wall, and referred pain to the shoulder. Pain is worst during the first 24 hours, with visceral pain being worse than abdominal wall pain [7]. Thus, pain relief and patient comfort during the early postoperative period are important, as the need for analgesics may delay discharge [8].

Different treatments have been proposed to relieve postoperative pain following laparoscopy. These include NSAIDS/opioids, intraperitoneal local anaesthetics, port-site infiltration of local anaesthetics, instillation of intraperitoneal saline, removal of insufflation gas/gas drains, low pressure abdominal insufflations, acetazolamide administration and use of N2O in place of CO2 [9]. Subdiaphragmatic instillation of 25-30 ml/kg body weight of normal saline and its subsequent aspiration was shown to decrease visceral and shoulder tip pain due to the dilution of carbonic acid and the displacement of sub-phrenic CO2 [10].

The following study was conducted to analyze the effect of intraperitoneal irrigation with normal saline on postoperative abdominal and shoulder pain following laparoscopic cholecystectomy.

#### **Materials and Methods**

The study was conducted in a tertiary health care center from December 2011 to June 2012. The study was conducted after obtaining informed consent from the patients. The study was approved by an ethical review committee.

60 patients with symptomatic gallstone disease undergoing LC were randomized in two groups by distributing cards of two different colors (red – study group and blue – control group) equally among patients. Cards were picked up blindly by the senior resident and distributed to the patients. The inclusion criteria were: age between 16 and 70 years, symptomatic cholelithiasis, no evidence of common bile duct (CBD) stones and abdominal wall skin free from infection. Exclusion criteria were: hypersensitivity to bupivacaine hydrochloride, age below 16 or above 70 years, prior upper abdominal surgery, pregnancy and prolonged administration of NSAIDS or other analgesics.

The study group (n=30) was instilled with 25-30 ml/kg body weight of saline at 37°C at the gallbladder bed and subdiaphragmatic space at the end of surgery, while the control group (n=30) was not given any kind of instillation. All cases were performed by experienced laparoscopic surgeons. LC was performed with the patient in a slight reverse Trendelenburg position in accordance with the "American" variables in all the patients. A pneumoperitoneum was created with a pressure of 10-12 mm Hg.

In group A, a silicone catheter (epidural catheter) was inserted through the lateral trocar with the aid of a laproscope in such a manner that the tip of the catheter was placed in the bed of the gallbladder. Next, peritoneal saline irrigation with 25 to 30 ml/kg body weight of saline at 37°C was done in the gallbladder bed and under the right diaphgram. Fluid was suctioned out after deflation of the pneumoperitoneum. In group B, no instillation was done. Wound closure was performed with skin staplers in both groups. A drain was not used on any patient. Antibiotic prophylaxis was administered via three doses of a second-generation cephalosporin.

An independent nurse recorded the postoperative abdominal and shoulder tip pain (according to the patient's perception) at the 6th, 12th, 24th and 48th hour following the operation. The randomization was blind to both the nurse and patient. Pain assessment was based on a 0 to 10 visual analogue scale (VAS, 0: no pain, 10: the worst imaginable pain). Preoperatively, the nurse introduced patients to the concept of a VAS scale. If the VAS score was above 3, an intramuscular (IM) injection of 75 mg of diclofenac was applied. If pain was persistent, the diclofenac IM injection was repeated. Postoperative nausea was noted. The nausea was assessed by the patient's complaint and the need for the use of an antiemetic drug.

Parametric data were compared between groups by analysis of variances (ANOVA) and post-hoc testing. Non-parametric data were analyzed with the Mann-Whitney test and chi-square tests between groups. Statistical significance was assumed if p<0.05.

#### Results

There was no statistical difference found in the age, sex or duration of surgery between the two groups. LC was performed on five men and 25 women with a mean age of 42 years (range 26 to 70) in study group A and on three men and 27 women with a mean age of 42 years (range 24 to 60) in control group B (Table 1). The laparoscopic procedure was completed successfully in all cases without any intra-operative complications or need of conversion to an open operation. The mean duration of the operation was 50 minutes (range 35 to 65) in study group A and 40 minutes in group B. In our study, the average hospital stay was 1.7 days in group A and 1.57 days in group B; the difference was

Table 1. Patient demographics, duration of surgery and length of hospital stays.

	Group A	Group B
Age (mean years+/-SD)	42+/-10	41+/-10
Sex(M/F)	5/25	3/27
Duration of surgery (mean minutes+/-SD)	50+/-11	40+/-13
Hospital stay (mean days+/-SD)	1.7+/-0.65	1.57+/-0.62

**Table 2.** Case summaries. Comparison between the VAS score for visceral pain.

		6 hrs	12 hrs	24 hrs	48 hrs
Group A	Ν	30	30	30	30
	Mean	2.63	1.73	.53	.10
	Median	2.00	2.00	0.00	0.00
	Minimum	0	0	0	0
	Maximum	5	4	2	1
	Std. Deviation	1.159	1.202	.776	.305
Group B	Ν	30	30	30	30
	Mean	4.23	3.53	1.40	.30
	Median	5.00	4.00	1.00	0.00
	Minimum	0	0	0	0
	Maximum	7	7	4	1
	Std. Deviation	1.995	2.013	1.221	.466

Table 3. Case summaries. Comparison b/w the VAS score for shoulder tip pain.

		6 hrs	12 hrs	24 hrs	48 hrs
Group A	N	30	30	30	30
	Mean	.40	.53	.83	.17
	Median	0.00	0.00	0.00	0.00
	Minimum	0	0	0	0
	Maximum	3	3	3	2
	Std. Deviation	.894	1.042	1.206	.461
Group B	Ν	30	30	30	30
	Mean	1.27	1.00	.60	.27
	Median	1.50	1.00	0.00	0.00
	Minimum	0	0	0	0
	Maximum	4	3	3	2
	Std. Deviation	1.311	1.050	.894	.583



Figure 1. Comparison between the mean VAS score for visceral pain.



Figure 2. Comparison between the mean VAS score for shoulder tip pain.

found to be insignificant (Table 1).

VAS pain scores were compared between the groups using non-parametric tests (Mann-Whitney Test). Patients in group A experienced significantly less visceral pain compared to group B at 6 hrs, 12 hrs and 24 hrs. At 48 hours, both groups experienced pain of similar intensities (Table 2 and 4) (Figure 1). VAS pain scores for shoulder tip pain were compared between groups using non-parametric tests (Mann-Whitney test). Patients in group A experienced less shoulder tip pain at 6 hrs and 12 hrs postoperative as compared to

**Table 4.** Comparison between the groups for vas score for visceralpain and shoulder tip pain.

Time in	Visceral Pain	Shoulder Tip Pain		
Hours	Group A vs. B	Group A vs. B		
6 hr	< 0.001	0.006		
12 hr	< 0.001	0.046		
24 hr	0.003	0.643		
48 hr	0.055	0.479		

group B. At 24 hrs and 48 hrs, no significant difference in pain intensity was observed between group A and B (Table 3 and 4) (Figure 2).

At 6 hrs, 20% of the patients in group A and 63.33% of the patients in group B were given analgesic injections (p<0.0017). At 12 hrs, 3.33% of the patients in group A and 36.66% of the patients in group B were given analgesic injections (p<0.0025). At 24 hrs, 6.66% of the patients in both groups were given analgesic injections. At 48 hrs, none of the patients from either group were given analgesic injections (Table 5) (Figure 3).

## Discussion

Pain following laparoscopic surgery may cause more discomfort to the patient than the pain at the incision sites and it may persist for about three days [11]. In this study, normal saline irrigation reduced the incidence and intensity of upper abdominal and shoulder pain after laparoscopic surgery.

Our study demonstrates that intraperitoneal irrigation with normal saline reduces abdominal pain and

Table 5. Number patients requiring analgesics. Frequency of analgesic administration.

	Ν	6 hrs	12 hrs	24 hrs	48 hrs
Group A	30 (100%)	6 (20.0%)	1 (3.33%)	2 (6.66%)	0 (0%)
Group B	30 (100%)	19 (63.33%)	11 (36.66%)	2 (6.66%)	0 (0%)
P Value		< 0.0017	0.0025	1.000	



Figure 3. Frequency of analgesic administration.

shoulder tip pain significantly after LC. The VAS scores for abdominal pain in group A (normal saline group) were significantly less than that of group B (control) at 6 hours (p<.001), 12 hours (p<.001), 24 hours (p<.003) and 48 hours (p<0.055) (Table 4). The VAS scores for shoulder tip pain for group A were significantly less than that of group B at 6 hours (p<0.018) and 24 hours (<0.046) (Table 4). The administration of analgesics was also significantly less in group A than in group B at 6 hours (p<0.0017) and 12 hours (p<0.0025), whereas there were no significant differences at 24 hours and 48 hours (Table 5). The frequency of nausea in the early postoperative period in study group A was less, though not significantly so, than that of the control group.

Our study is in concordance with Tsimoyiannis et al. [10], who conducted two different trials with normal saline irrigation. In their first trial, they concluded that postoperative pain was reduced significantly in groups in which normal saline irrigation was performed using either normal saline left behind or suctioned or by using a sub-hepatic drain. In another trial, Tsimoyiannis et al. [10] randomized 300 patients to one of six groups of 50 patients each and concluded that postoperative pain after LC was significantly reduced by subdiaphragmatical intraperitoneal normal saline infusion.

Barczynski et al. [12] also concluded that in terms of lower postoperative pain and a better quality of life within the early recovery period, a low pressure pneumoperitoneum with saline wash is superior to a low pressure pneumoperitoneum alone. Our study is also supported by the work of Pappas et al. [13], who concluded that normal saline infusion at the end of the procedure is a safe and effective method for reducing pain after LC. There are no published studies that disagree with our finding that the use of normal saline reduces abdominal and shoulder tip pain following LC.

A pneumoperitoneum is most commonly achieved by carbon dioxide insufflation. Carbon dioxide readily dissolves in water and forms carbonic acid, which is then absorbed into the intravascular space. Upon contact with red blood cells, which contain carbonic anhydrase, carbonic acid is transformed into bicarbonate. The bicarbonate thus formed is converted back into carbon dioxide in the lungs and is expelled. Peritoneal irritation by carbonic acid, which is formed by reaction between CO2 and water and the creation of space between the liver and diaphragm by residual pneumoperitoneum, has been implicated in visceral and shoulder tip pain [14]. As a physiologic buffer system, normal saline facilitates the dissipation of carbon dioxide in the abdominal cavity, thus preventing diaphragmatic irritation and lessening postoperative upper abdominal and shoulder pain. Therefore, normal saline should be effective in reducing upper abdominal and shoulder pain.

The effect of normal saline is long lasting and continuous until it is absorbed. A safe amount of normal saline was used (1,000 ml) for irrigation of the peritoneal cavity. Problems with fluid shift are unlikely, as the estimated intraperitoneal absorption rate is approximately 30-60 ml/h [14].

The study demonstrated that intraperitoneal normal saline irrigation reduced the incidence and intensity of upper abdominal and shoulder pain at both early and late time points following LC.

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