

## Comparison of post-operative pain with and without administration of local anesthetic intraperitoneally in laparoscopic cholecystectomy

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**Objectives:** To compare post-operative pain with and without administration of local anesthetic intraperitoneally in patients undergoing laparoscopic cholecystectomy.

**Methodology:** This randomized controlled trial was done in surgical unit of Fauji Foundation Hospital, Rawalpindi from July 2017 to Jan 2018. A total of 120 consecutive patients between age of 20 – 60 years of both gender and who were candidates of laparoscopic cholecystectomy were included in the study. They were equally allocated into two treatment groups by random assignment. Patients in group A (IP 0.5% Bupivacaine) underwent laparoscopic cholecystectomy with administration of 20 ml of 0.5% bupivacaine intraperitoneally. Group B (control) patients underwent laparoscopic cholecystectomy without administration of intraperitoneal local anesthetic.

Efficacy (VAS  $\leq 4$ ) in terms of reduced pain after instillation of local anesthetic intraperitoneally was measured at 8 hours after surgery.

**Results:** The mean age of both groups was  $46.80 \pm 7.12$  and  $49.40 \pm 6.19$  years, respectively. According to ASA classification I & II, 52 (86.7%) were in group A and 8 (13.3%) in group B. Effective pain control at 8 hours after surgery was achieved in 42 (70%) patients in group A as compared to 12 (20%) in group B ( $p = 0.001$ ).

**Conclusions:** Intraperitoneal administration of 0.5% Bupivacaine after laparoscopic cholecystectomy was found to be an effective option for post-operative pain management at 8 hours after surgery.

**Keywords:** Cholecystectomy, Laparoscopic injections, intraperitoneal, postoperative pain.

## INTRODUCTION

Cholecystectomy is the most commonly performed procedure on biliary tract and second most commonly performed surgical procedure.<sup>1</sup> Better pain management and reduced hospital stay has made laparoscopic cholecystectomy (LC) the gold standard procedure for symptomatic gall stones.<sup>2,3</sup> Despite the common belief, LC is still associated with a considerable post-operative pain. Compared with conventional open cholecystectomy where the pain is parietal in origin, pain arising after LC is multifactorial and mainly visceral in nature. Surgical incisions, CO<sub>2</sub> insufflation and raised pressure in abdominal cavity are some of the factors responsible for pain.<sup>4,5</sup>

Local anesthetics have good analgesic effects and are quite safe to use. Bupivacaine has a half-life of 2.7 – 3.5 hours, 100 mg of bupivacaine in a dose of 2.5 mg/kg of body weight can be given safely in a 70 kg person.<sup>6-9</sup> Controversies exist regarding the use of intraperitoneal local anesthetics. Some studies done in this regard showed a significant pain relief post operatively<sup>2</sup> but some showed little or no use of such agents.<sup>10-12</sup> The objective of this study was to assess the efficacy of bupivacaine in alleviating post-operative pain following LC.

## METHODOLOGY

After getting approval of Institutional Review Board (IRB) vide letter No. PF/NA/ADM-I, this randomized controlled trial was conducted in surgical department of Fauji Foundation Hospital, Rawalpindi from July 2017 to Jan 2018. A written informed consent was signed by all patients. WHO sample size calculator was used for sample size calculation by keeping significance level 5%, power of test 80%, anticipated proportions of two groups were, 25.8% and 77.4% respectively.<sup>2</sup> The sample size came out to be 120 patients divided into two groups ( $n = 60$  each). Respondents were selected through non-probability consecutive sampling technique.

Patients with age range 20 – 60 years, both genders and patients according to ASA I and ASA II undergoing LC were enrolled in the study. Those with acute cholecystitis, acute pancreatitis, previous history of abdominal surgery, with intraperitoneal biliary leakage and those allergic to local anesthetic were excluded from the study. They were randomly assigned into two groups, Bupivacaine (group-A) and Control (group-B) by the lottery method (Fig. 1).

Patients in group A underwent LC with administration of 20 ml of 0.5% bupivacaine intraperitoneally. Patients

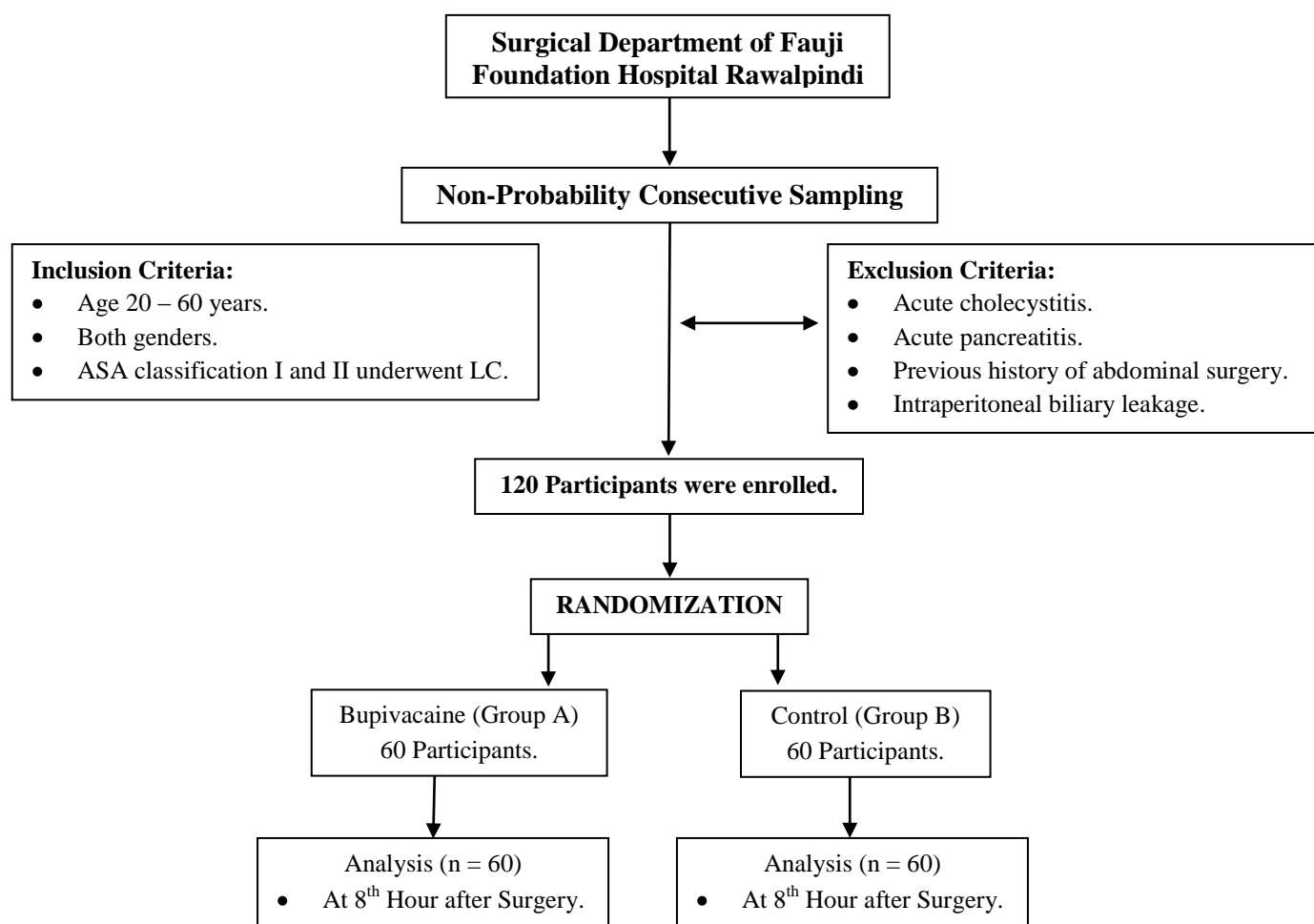


Fig. 1:

in group B underwent LC without administration of intraperitoneal local anesthetic. Both groups were operated upon by the same team of surgeons using four ports. Post-operative pain was assessed and recorded using visual analogue scale (VAS) at 8 hours postoperatively. A score  $\leq 4$  at 8 hours were considered as effectiveness. For post-operative pain 30 mg of ketorolac was given I/V and additional doses were given if required.

**Statistical Analysis:** SPSS version 20 was used for data analysis. For quantitative variables like age and post-operative pain at 8 hours means  $\pm$  SD were calculated. Kolmogorov–Smirnov and Shapiro–Wilk test was used for normality data between the groups. Chi square test of statistical significance was used to compare the effectiveness in both groups keeping  $p \leq 0.05$  as significant. Effectiveness in both groups was also

stratified among age, gender, BMI and ASA to see the modified effect. Post stratification chi-square test was applied.

## RESULTS

A total of 120 patients were evaluated for post-operative pain following laparoscopic cholecystectomy. The socio-demographic characteristics of patients were recorded Table 1.

In group A (IP 0.5% Bupivacaine), mean VAS 8 hours after surgery was  $3.63 \pm 1.76$  and in group B (control) mean VAS 8 hours after surgery was  $5.27 \pm 1.75$  (Table-2). Effective pain control (VAS  $\leq 4$ ) at 8 hours after surgery was achieved in 70.0% (n = 42/60) patients in group A as compared to 20% (n = 12/60) in group B (control) (Table-3).

**Table1: Socio-demographic details of patients (n = 120).**

Variables		Groups		Total
		Bupivacaine (n = 60)	Control (n = 60)	
Age (Mean)		46.80 ± 7.12	49.40 ± 6.19	
Gender (%)	Males	2 (3.3%)	6 (10%)	8 (6.7%)
	Females	58 (96.7%)	54 (90%)	112 (93.3%)
BMI (Kg/m <sup>2</sup> )	≤ 30 Kg/m <sup>2</sup>	48 (80%)	40 (66.7%)	88 (73.3%)
	≥ 30 Kg/m <sup>2</sup>	12 (20%)	20 (33.3%)	32 (26.7%)
ASA Classification	I	52 (86.7%)	52 (86.7%)	104 (86.7%)
	II	8 (13.3%)	8 (13.3%)	16 (13.3%)

**Table 2: Mean VAS 8 hours post-surgery and efficacy of treatment (n = 120).**

Bupivacaine Group	Control Group	$\chi^2$ -value	P-value
Mean ± SD	Mean ± SD		
3.63 ± 1.76	5.27 ± 1.75	120.0	0.001

**Table 3: Efficacy of treatment in both groups at 8 hours post-surgery (n = 120).**

Efficacy	Bupivacaine Group	Control Group	Total	$\chi^2$ -value	P-value
Absence of pain	42 (70.0%)	12 (20.0%)	54 (45.0%)	30.31	0.001
Presence of pain	18 (30.0%)	48 (80.0%)	66 (55.0%)		
Total	60 (100%)	60 (100%)	120 (100%)		

## DISCUSSION

Laparoscopic cholecystectomy is one of the most common surgeries with minimal tissue injury, rapid postoperative recovery, early mobilization, low postoperative complications, and shorter hospital stays. Our results showed demographic characteristics were similar in both groups ( $p \geq 0.05$ ) and effective pain control was achieved in 70% patients in group A as compared to 20% in group B (control) at 8 hours after surgery. The difference was found to be statistically significant ( $p = 0.001$ ).

Similar trends were found when our results were compared with the already published reports on the given subject. Garza et al also found a significant difference ( $p = 0.018$ ) in pain levels between both groups 6 hours postoperatively. Average analgesic requirement was also lower in the bupivacaine group.<sup>13</sup>

In double blind randomized controlled trial Khatri et al observed that intraperitoneal bupivacaine significantly reduces pain following LC. Mean intensity of pain on VAS over 10 hours was higher in placebo group compared to bupivacaine group. All patients in placebo group required analgesia within 6 hours after surgery and 68% in bupivacaine group required analgesia during the same post op period.<sup>14</sup>

Gupta et al divided patients into 3 groups as, Group 1 was control, Group 2 was assigned to receive portside infiltration of bupivacaine, while group 3 received combined port site and intraperitoneal instillation of bupivacaine. At 1<sup>st</sup>, 4<sup>th</sup> & 8<sup>th</sup> post-operative hour, minimum VAS score was in group 3. Patients in group 3 received a lower total amount of rescue analgesia and they also had the shortest hospital stay after LC, compared to the patients in the other groups.<sup>15</sup>

Shran et al reported VAS was significantly lower after bupivacaine and rescue analgesia was given when VAS was  $\geq 6$ .<sup>1</sup> Lin et al aimed to compare the efficacy of 50 mg 0.5% bupivacaine in patients undergoing LC for postoperative pain relief. The postoperative pain at intervals of 1, 2, 4, 8, 12, and 24 h showed that VAS pain scores were significantly lower in Bupivacaine group as compared to control group at 1, 2, and 4 hours after surgery with for all variables.<sup>16</sup>

Our sample size was relatively smaller and we did consecutive sampling due to time constraint for completion of study in the required time frame, which may result in introduction of bias. We recommend continuation of this project for gathering more patients to increase the sample size to a statistically significant figure. We also recommend random sampling to reduce the bias and to generalize our results to the population in question.

## CONCLUSION

Present study showed that intraperitoneal administration of 0.5% Bupivacaine was an effective treatment option for postoperative pain control at 8 hours after laparoscopic cholecystectomy.

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