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Efficacy of Intraperitoneal Bupivacaine Instillation During Laparoscopic Cholecystectomy in Terms of Reduction in Post-Operative Shoulder Tip Pain & Need for Analgesia

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ABSTRACT

Pain after laparoscopic cholecystectomy (laparoscopic cholecystectomy e) is usually an acute pain. **Objective:** To compare frequency of post-operative shoulder tip pain & need for analgesia, with and without intraperitoneal bupivacaine instillation during laparoscopic cholecystectomy. **Settings:** Department of Surgery, Allied Hospital Faisalabad. **Duration:** From 14-07-2017 to 14-01-2018. **Study Design:** Randomized Controlled Trial. **Methodology:** A total of 190 cases undergoing laparoscopic cholecystectomy were randomly divided into two equal groups. Group A: laparoscopic cholecystectomy using intraperitoneal bupivacaine instillation. Group B: laparoscopic cholecystectomy without using intraperitoneal bupivacaine instillation. After surgery all patients were observed for post-operative pain and analgesic (NSAID or Opioid) requirement at 8 hours. **Results:** Out of 190 cases, mean age was calculated as 38.22±9.31 years in Group-A & 37.06±9.43 years in Group-B, 33.68% (n=32) in Group-A & 34.74% (n=33) in Group-B were male whereas 66.32% (n=63) in Group-A and 65.26% (n=62) in Group-B were females, comparison of frequency of post-operative pain and need for analgesia in both groups shows that 12.63% (n=12) in Group-A and 43.16% (n=41) in Group-B had postoperative pain and need for analgesia, p value was 0.000 showing a significant difference. **Conclusion:** Post-operative shoulder tip pain and need for analgesia was found significantly lower with intraperitoneal bupivacaine instillation during laparoscopic cholecystectomy when compared without it.

Keywords: Laparoscopic cholecystectomy, Post-operative shoulder tip pain, need for analgesia, intraperitoneal bupivacaine instillation.

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INTRODUCTION

Cholelithiasis is found in a large number of people, though asymptomatic may lead to different complications and morbidity. Worldwide occurrence of gallstones varies from 6-20%. Asymptomatic patients develop complications at an annual rate of 1-2%.[1] Lap. chole is the gold standard for cholelithiasis. Pain after surgery still is considerable and may prevent early discharge.[2] Patients of lap. chole experience less postoperative pain when compared with that of open cholecystectomy, but still patients have significant pain. According to location pain after lap. chole can be abdominal or shoulder pain. Abdominal pain may be visceral pain associated with tissue injury due to gallbladder dissection and the stretching of nerve endings in the peritoneal cavity; and parietal pain occurs at port site due to incisional trauma.[3] Shoulder pain is commonly found in patients of lap. chole with an incidence of 35%- 60% in the postoperative period. The proposed mechanism of shoulder pain includes phrenic nerve neurapraxia, stretching of the sub diaphragmatic fibers by pneumoperitoneum and referred pain from traumatized area. This results in lengthening of hospital stay, which is particularly of utmost importance since many centers are performing this operation as a day-case procedure.[4] Postoperative pain control is directed at early mobilization, recovery and discharge. Various methods have been proposed to control postoperative pain such as use of local anesthesia, preoperative administration of anti-inflammatory drugs, utilizing carbon dioxide (CO_2) at body temperature, applying intra-pleural morphine and the combined use of nonsteroidal anti-inflammatory drugs (NSAIDS) and opioids.[5] Aerosolized intraperitoneal local anesthetic (AILA)[6] and intraperitoneal bupivacaine instillation.[7]

The rationale of my study is to find out the efficacy of intraperitoneal bupivacaine instillation during lap. chole in terms of decreased post-operative shoulder tip pain and decreased analgesic requirement and if there will be statistically significant reduction in post-operative shoulder tip pain and need for analgesia post-operatively, then this technique can be used routinely in future for better results as it will help in reduced hospital stay and early discharge of patient.

Operational Definitions

1. Post-operative shoulder tip pain: It was assessed at 8 hours post-operatively by using Visual Analogue Pain Scale. VAS ≥4 at 8 hours was considered as pain

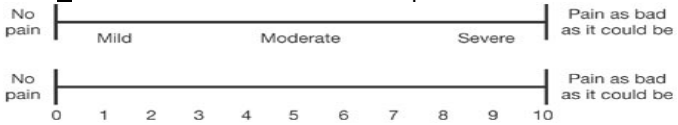

Figure 1: Visual Analogue Pain Scale

2. Need for analgesia: The number of patients requiring additional rescue analgesic treatment at 8 hours post operatively in accordance with visual analogue pain scale was recorded. VAS >4 was used to for analgesia requirement.

Hypothesis: Use of intraperitoneal bupivacaine instillation during lap. chole is better as compared to lap. chole without intraperitoneal bupivacaine instillation in terms of post-operative shoulder tip pain and need for analgesia.

METHODOLOGY

Study Design: Randomized Controlled Trial.

Settings: Department of Surgery, Allied Hospital/ Faisalabad Medical University, Faisalabad-Pakistan.

Duration: From 14-07-2017 to 14-01-2018.

Sample Technique: Non-probability consecutive sampling

Sample Size: By using WHO sample size calculator for 2 proportions. P1 = 30%1, P2 = 15%1, Power of study = 80%, Level of significance = 5%, Sample size = 190 [95 in each group]

Inclusion Criteria:

Patients with cholelithiasis on ultrasound

All patients of both genders with age between 20-60 years

Patients fit for general anesthesia. (ASA I, II)

Exclusion Criteria:

Patients with obstructive jaundice/ hepatobiliary pathology.

Known patients with hepatitis B or C.

Patients with hypersensitivity to drug to be used in the procedure.

Patients taking anticoagulant treatment or with deranged clotting profile i.e. INR> 1.5.

Patient with history of upper abdominal surgery / upper GI malignancy.

Data Collection Procedure: Permission was sought from Ethical Committee. Patients with diagnosis of cholelithiasis were collected from OPD of surgical department Allied Hospital Faisalabad. Written informed consent was taken from all the 190 patients undergoing lap. chole. The qualifying patients were informed of the risk and benefits of each procedure and asked to sign a detailed informed consent in their respective native language. They were randomly divided into two equal groups: Group A: lap. chole using intraperitoneal bupivacaine instillation. Group B: lap. chole without using intraperitoneal bupivacaine instillation. (Control). 95 patients were included in each group using a computer-generated random number. All patients were kept nil per oral from midnight. General anesthesia was given to all the patients. In group A, Patients were instilled with 20 ml of 0.5% intraperitoneal bupivacaine injection during lap. chole. In group B (CONTROL) patients were not instilled with any injection. After surgery all patients were observed for post-operative pain and analgesic (NSAID or Opioid) requirement at 8 hours. Post-operative pain was assessed using visual analogue scale (consisting of a 10cm-long horizontal line without graduation varying from “no pain at all” on the left side to “unbearable pain” on the right side) The number of patients requiring additional rescue analgesic treatment was recorded using visual analogue pain scale at 8 hours post operatively.

Data Analysis: All the collected information was analyzed by SPSS version 20. Mean and standard deviation was calculated for all quantitative variables like age, weight, height, BMI. Frequency and percentage was calculated for all qualitative variables like gender, ASA, need for analgesia and post-operative pain. Chi square test was applied to compare frequency of post-operative pain and need for analgesia in both groups. P value of ≤0.05 was considered as significant. Effect modifiers like age, ASA, BMI and gender were controlled by stratification and post stratification. Chi square test was applied. P value ≤0.05 was taken as significant.

RESULTS

A total of 190 cases enrolled to compare frequency of post-operative shoulder tip pain and need for analgesia, with and without intraperitoneal bupivacaine instillation during lap. chole. Age distribution of the patients was done, it shows that 58.95%(n=56) in Group-A and 62.11%(n=59) in Group-B were between 20-40 years of age whereas 41.05%(n=39) in Group-A and 37.89%(n=36) in Group-B were between 41-60 years of age, mean ± sd was calculated as 38.22±9.31 years in Group-A and 37.06±9.43 years in Group-B. (Table No. 1).

Table 1: Age distribution (n=190)

Age (in years)	Group A (n=95)		Group B (n=95)	
	No. of pts	%	No. of pts	%
20-40	56	58.95	59	62.11
41-60	39	41.05	36	37.89
Total	**95**	**100**	**95**	**100**
Mean±sd	**38.22±9.31**		**37.06±9.43**	

Gender distribution of the patients was done, it shows that 33.68% (n=32) in Group-A and 34.74% (n=33) in Group-B were male whereas 66.32% (n=63) in Group-A and 65.26% (n=62) in Group-B were females. Table 2

Table 2: Gender distribution (n=190)

Gender	Group A (n=95)		Group B (n=95)	
	No. of pts	%	No. of pts	%
Male	32	33.68	33	34.74
Female	63	66.32	62	65.26
Total	**95**	**100**	**95**	**100**

Mean BMI of the patients was done; it shows that 29.04±2.87 in Group-A and 29.17±2.78 in Group-B. Table 3

Table 3: Mean BMI of the patients (n=190)

BMI	Group A (n=95)		Group B (n=95)	
	Mean	SD	Mean	SD
	29.04	2.87	29.17	2.78

Status of ASA of the patients was done, it shows that 45.26% (n=43) in Group-A and 55.79% (n=53) in Group-B had ASA-I whereas 54.74% (n=52) in Group-A 44.21% (n=42) in Group-B had ASA-II. Table 4

Table 4: ASA status of the patients (n=190)

ASA	Group A (n=95)		Group B (n=95)	
	No. of pts	%	No. of pts	%
I	43	45.26	53	55.79
II	52	54.74	42	44.21
Total	**95**	**100**	**95**	**100**

Comparison of frequency of post-operative pain and need for analgesia in both groups shows that 12.63% (n=12) in Group-A and 43.16% (n=41) in Group-B had postoperative pain and need for analgesia whereas 87.37% (n=83) in Group-A and 56.84% (n=54) in Group-B had no postoperative pain and need for analgesia, p value was 0.000 showing a significant difference. Table 5

Table 5: Comparison of frequency of post-operative pain and need for analgesia in both groups(n=190)

Post-operative pain and need for analgesia	Group A (n=95)		Group B (n=95)	
	No. of pts	%	No. of pts	%
Yes	12	12.63	41	43.16
No	83	87.37	54	56.84
Total	**95**	**100**	**95**	**100**

P value=0.000

Effect modifiers like age, ASA, BMI and gender were controlled by stratification and post stratification. Chi square test was applied. P value $\leq$0.05 was taken as significant. Table 6-9

Table 6: Stratification for age with regards to comparison of frequency in both groups (n=190)

AGE	Group	Post-Operative Pain and Need for Analgesia		P value
		Yes	No	
20-40 Years	A	8	48	0.0009
	B	25	34	
41-60 Years	A	4	35	0.0008
	B	16	20	

Table 7: Stratification for gender with regards to comparison of frequency in both groups (n=190)

Gender	Group	Post-Operative Pain and Need for Analgesia		P value
		Yes	No	
Male	A	5	27	0.03
	B	13	20	
Female	A	7	56	0.000
	B	28	31	

Table 8: Stratification for ASA with regards to comparison of frequency in both groups (n=195)

ASA	Group	Post-Operative Pain and Need for Analgesia		P value
		Yes	No	
ASA-I	A	6	37	0.005
	B	21	32	
ASA-II	A	6	46	0.0001
	B	20	22	

Table 9: Stratification for BMI with regards to comparison of frequency in both groups (n=190)

BMI	Group	Post-Operative Pain and Need for Analgesia		P value
		Yes	No	
BMI < 30	A	9	52	0.0001
	B	29	32	
BMI ≥ 30	A	3	31	0.008
	B	12	22	

DISCUSSION

Laparoscopic cholecystectomy introduced by Phillipe Mouret in 1987 is now the gold standard for the treatment of gallstones disease. Pain after laparoscopic cholecystectomy is usually an acute pain, sharp in character that starts with the surgical trauma and ends with tissue healing. The origin of pain after laparoscopic cholecystectomy is multifactorial. Pain arising from incision sites is somatic pain, whereas pain from the gallbladder bed being mainly visceral in nature, and shoulder pain is mainly due to the residual CO2 irritating the diaphragm. It is, therefore, likely that combined methods of analgesia can best reduce postoperative pain. In this study, out of 190 cases, mean age was calculated as 38.22$\pm$9.31 years in Group-A and 37.06$\pm$9.43 years in Group-B, 33.68% (n=32) in Group-A and 34.74% (n=33) in Group-B were male whereas 66.32% (n=63) in Group-A and 65.26% (n=62) in Group-B were females, comparison of frequency of post-operative pain and need for analgesia in both groups shows that 12.63% (n=12) in Group-A and 43.16% (n=41) in Group-B had postoperative pain and need for analgesia, p value was 0.000 showing a significant difference. We compared our results with other studies where intraperitoneal local anesthetic significantly reduced the incidence of post-operative shoulder tip pain i.e. 11.8% (Treatment group) versus 57.9% (Control group), *P value* of 0.004 which is statistically significant.[6]The findings of our study are in agreement with this study, whereas another study, the incidence of right shoulder tip pain with intraperitoneal local anesthetic was 9%(Treatment group) versus 13%(control group), *p value* > 0.05 which is statistically not significant[4] does not correspond to our results. M. Upadya, S. H. Pushpavathi and others[76] compared the efficacy of intra-peritoneal administration of bupivacaine 0.5% and IV acetaminophen for postoperative analgesia in patients undergoing laparoscopic cholecystectomy and concluded that although local anesthetic infiltration and intra-peritoneal administration of 0.5% bupivacaine decreases the severity of incisional, visceral and shoulder pain in the early postoperative period, IV paracetamol provides sustained pain relief for 24 postoperative hours after elective laparoscopic cholecystectomy. Sami Hasson and others[8] evaluated the effect of bupivacaine instillation on pain relief in the early post-operative period following laparoscopic cholecystectomy and concluded that intra incisional infiltration with bupivacaine is a simple and feasible procedure which significantly reduces post-operative pain. By using IPLA it may be possible to modulate peritoneal and visceral signaling to the brain, thereby attenuating the metabolic impact of visceral surgery. There is a

blockade of free afferent nerve endings in the peritoneum. Systemic absorption of local anesthetic from the peritoneal cavity may also play a part in reduced nociception. The local anesthetics have anti-inflammatory actions and mechanisms of these effects may be prostaglandin antagonism, inhibition of leukocyte migration, and lysosomal enzyme release, all effects seen in vitro and animal studies. A pro inflammatory cytokine cascade in the peritoneal cavity, with direct action on the visceral afferents and the vagus as a major vehicle, is a feasible contributor to postoperative visceral pain perception and the "sickness response." By using IPLA it may be possible to modulate peritoneal and visceral signaling to the brain, thereby attenuating the metabolic impact of visceral surgery. Meta-analysis by Kahokehr revealed an overall reduction of pain, opioid analgesia use, need for rescue analgesia, postoperative cortisol, and glucose response.[9] Kahokehr et al. investigated the effects of intraoperative instillation and postoperative infusion of IPLA ropivacaine after colectomy improves early surgical recovery.[9] Considering the facts recorded in this study and supported with other studies, the hypothesis of this study that "use of intraperitoneal bupivacaine instillation during laparoscopic cholecystectomy is better as compared to laparoscopic cholecystectomy without intraperitoneal bupivacaine instillation in terms of post-operative shoulder tip pain and need for analgesia" is justified.

CONCLUSION

Post-operative shoulder tip pain and need for analgesia was found significantly lower with intraperitoneal bupivacaine instillation during laparoscopic cholecystectomy when compared without it.

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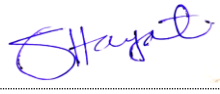
Dr. Saddaqat Hayat Senior Registrar, Surgery Allied Hospital, Faisalabad	Main Author, Principal Investigator	
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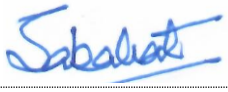
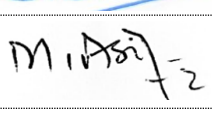
Dr. Sabahat Shaheen PGR, Surgery Allied Hospital, Faisalabad	References writing	
Dr. Muhammad Asif Post Graduate Resident, Surgical Unit-III Allied Hospital, Faisalabad	Proof Reading	
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