Effect of local anesthetic instillation intraperitoneally on post-op pain relief after laparoscopic cholecystectomy

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Abstract

Background: To determine the effect of local anesthetic intraperitonel instillation on post-op pain relief after laparoscopic cholecystectomy.

Methods: In this randomized controlled trial 64 patients, diagnosed as having gall-stones, were divided into 2 groups for laparoscopic cholecystectomy. In Group A Intraperitoneal irrigation of the diaphragmatic surface and gallbladder fossa was done with 0.5% bupivacaine, while in Group B no drug was used intraperitoneally.

Results: Out of 32 patients enrolled as bupivacaine group, 27 were female and 5 were male patients with average age of 46.12 years, whereas in control group, there were 28 female and 04 male patients in a total of 32 patients, and the avrage age was 45.36 years. Mean VAS scores in bupivacaine group at 8, 16 and 24 hrs were 3.875, 2.5625 and 0.75 respectively, while they were 6.50, 3.25 and 0.875 in controls at 8, 16 and 24hrs respectively. VAS scores tended to be higher in females. Need for post-op analgesia in 1st 8hrs & 1st 16hrs was more in the controls(87.50% & 56.25% respectively). The need for post-op analgesia at 24hrs after surgery was almost equal in both groups. Post-op pain relief in 1st 8hrs was better in the bupivacaine group i.e. 31.25% vs. 12.5%.

Conclusion: The early post-op VAS scores and pain intensity after 8hrs & 16hrs is decreased with the use of intra-peritoneal instillation of injection Bupivacaine, but in long term it offers no added benefit to the post-operative pain relief and does not decrease the need for analgesia post-operatively.

Keywords: Bupivacaine, Diaphragmatic surface, Gall bladder fossa, Post-operative pain relief, Laparoscopic Cholecystectomy.

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Introduction

Cholelithiasis is found in a large number of people though asymptomatic. Worldwide occurrence of gallstones varies from 6-20%.[1] Asymptomatic gallstone patients develop complications at an annual rate of 1-2%.[2] Laparoscopic cholecystectomy (LC) is nowadays established as a gold standard form of treatment of patients with cholilithiasis. It is feasible and safe with high patient satisfaction even with broad selection criteria. Improvements may be achieved in postoperative pain management.[3] Although the post-operative pain after LC is quite less as compared to open cholecystectomy (OC), but the recent studies have shown that patients may experience considerable post-operative pain after LC, the postoperative shoulder and visceral abdominal pain experienced by patients still causes preventable distress.[4] The various methods now being utilized with variable success in the post-operative pain management after laparoscopic surgery include agents like non-steroidal anti-inflammatory drugs (NSAIDS), infiltration of wound with local anesthetics (LA) and intermittent intra-muscular narcotics.[2] Intra-peritoneal irrigation of the diaphragmatic surface and gallbladder fossa using normal saline, bupivacaine, or lignocaine may effectively control visceral abdominal pain after LC.[4] The pain scores are lower in patients with intra-peritoneal instillation as compared to local instillation or oral analgesia. Additional rescue analgesic treatment was significantly lower in patients with intra-peritoneal instillation (35%) as compared with those with local/ no instillation (84%). The combination of pre-incisional local infiltration and intra-peritoneal instillation of levobupivacaine 0.25% shows an advantage for postoperative analgesia after laparoscopic cholecystectomy.[5]

Patients and Methods

This randomized controlled trial was conducted at the Surgery Department, M.L.B. Medical College, Jhansi,(U.P.), from July 2015 to February 2016. We selected 64 patients with gall bladder disease. Among these 64,55 were female & 9 were male. An informed consent was taken from all patients before enrolment in the study. These 64 patients diagnosed as having gall-stones were grouped into 2 (32 in each group) for

laparoscopic cholecystectomy. In Group A Intraperitoneal irrigation of the diaphragmatic surface and gallbladder fossa using 0.5% injection bupivacaine was done peri operatively after removal of gall bladder, while Group B did not receive any injection. Inclusion criteria constituted age below 20-60 yrs and all patients with cholilithiasis on ultrasound. Patients with history of upper abdominal surgery/ upper GI malignancy/ obstructive jaundice/ hepatobiliary pathology, bleeding diathesis/ Hepatitis B or C patient, hypersensitivity to the drug to be used in the procedure, using anticoagulants and known cardiac patients, were excluded. The patients were randomized into 2 groups through a computer generated list. Group A patients were instilled intraperitoneally using 20ml of 0.5% injection bupivacaine in diaphragmatic surface and gallbladder fossa just after laproscopic cholecystectomy and Group B patients (control) were not instilled with any injection. Immediately after surgery all patients were injected Tramadol Hydrochloride in a dose of 1 mg/kg body weight intramuscularly. Then assessed according to visual analogue scale for post-operative pain and need for post-operative analgesia 8 hourly for the first 24hours in the post anesthesia care unit. Injection Tramadol Hydrochloride (1 mg/kg) intramuscularly was given if analgesia was required on 8 hourly bases. Descriptive statistics were used to calculate mean and standard deviation for numerical variables i.e. age, VAS. Frequency and percentages were presented for categorical variables i.e. gender, post-op pain relief, need for post-op analgesia and intensity of pain. Chi-square test was used to compare pain relief in both groups. P-value of < 0.05 was taken as significant.

Results

VAS scores tend to be higher in controls in the initial 8 hrs & 16 hrs of surgery, while they were higher in bupivacaine group after 24 hrs. Mean VAS scores in bupivacaine group at 8, 16 & 24 hrs were 3.875, 2.5625 & 0.75 respectively, while they were 6.5, 3.25 & 0.875 in controls at 8, 16 & 24 hrs respectively. (Table 1)

Table 1: Comparison of mean vas between groups

Groups	VAS (8 hrs) Mean±SD	VAS (16 hrs) Mean±SD	VAS (24 hrs) Mean±SD
A(n=32)	3.875±0.8706	2.5625±1.0453	0.75±0.984
B(n=32)	6.5±1.437	3.25±1.218	0.875±1.008

Pain intensity was milder initially during 1st 8hrs & 16 hrs in bupivacaine group as compared to controls. (Table 2) In bupivacaine group 14 patients had mild pain, while 18 had moderate-severe pain after 1st 8hrs while in controls 5 patients had mild pain, while 27 had moderate-severe pain after 1st 8 hrs. Pain scores and intensity was higher in controls with no significant difference between both groups 24 hrs after surgery. 20 patients had no pain after 24 hrs in bupivacaine group, while 18 patients in controls had no pain after 24hrs. 12 patients in bupivacaine group and 14 patients in controls had mild-moderate pain 24hrs after surgery. VAS scores tend to be higher in females (mean VAS at 8, 16 and 24 hrs was 5.32, 2.98 and 0.67 respectively) as compared to males (mean VAS at 8, 16 and 24 hrs was 4.35, 2.5 and 0.45 respectively). Need for post-op analgesia in 1st 8hrs was more in the controls i.e. 87.5% (34 patients), while it was 56.25% in bupivacaine group (Table 3).

Table 2: Comparison of pain intensity

	Pain intensity			
Groups	**Grading**	**8 hrs**	**16 hrs**	**24 hrs**
A(n=32)	No Pain	0	1(3.125%)	20(62.5%)
	Mild	14(43.75%)	21(65.625%)	12(37.5%)
	Moderate	16(50%)	10(31.25%)	0
	Severe	2(6.25%)	0	0
B(n=32)	No Pain	0	0	18(56.25%)
	Mild	5(15.625%)	14(43.75%)	14(43.75%)
	Moderate	14(43.75%)	16(50%)	0
	Severe	13(40.625%)	2(6.25%)	0

Table 3: Need for additional post-op analgesia in both groups

Time after surgery	Groups	Yes	No
After 8 hours	A	18(56.25%)	14(43.75%)
	B	28(87.5%)	4(12.5%)
After 16 hours	A	10(31.25%)	22(68.75%)

	B	18(56.25%)	14(43.75%)
After 24 hours	A	0	32(100%)
	B	2(6.25%)	30(93.75%)

The need for post-op analgesia at 24hrs after surgery has slight difference in both groups. It was 0% in bupivacaine group vs. 6.5% in controls at 24hrs after surgery. (Table 3)

Need for additional post-op analgesia indirectly reflects the post-op pain relief at the corresponding time after surgery. In our study the post-op pain relief in 1st 8 hrs &16 hrs were better in the bupivacaine group i.e. 31.25% (bupivacaine group) vs. 12.5% (controls) & 68.75% (bupivacaine group) vs. 43.75%(controls) respectively, these differences were statistically significant with p-values of 0.005 & 0.043 respectively. The post-op pain relief at 24 hrs after surgery was almost equal in both groups, it is 100% in bupivacaine group vs. 93.75% in controls at 24hrs after surgery and this difference was not statistically significant with a p-value of 0.15. (Table 4)

Table 4: Post-op pain relief in both groups

Time after surgery	Groups	Poor	Good	Chi-square test
After 8 hours	**A**	56.25%	43.75%	7.7295
	B	87.50%	12.50%	
After 16 hours	**A**	31.25%	68.75%	4.0635
	B	56.25%	43.75%	
After 24 hours	**A**	0	100%	0.1508
	B	6.25%	93.75%	

Discussion

Since the evolution of laparoscopic cholecystectomy in 1980s, this procedure has replaced open cholecystectomy all over the world because of its less post-operative pain, early mobilization, and less post-operative hospital stay.[6] The technique of laparoscopic cholecystectomy which was difficult to learn in its evolving phase, had led the surgeons to put conditions like acute cholecystitis into contraindications while performing laparoscopic cholecystectomy in the past. As the technique flourished, surgeons started performing laparoscopic cholecystectomy in acute phase of cholecystitis as well.[7] Laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis. Although there are clear benefits compared with open surgery, postoperative pain after laparoscopic cholecystectomy remains an issue. Pain can prolong hospital stay and lead to increased morbidity, which is particularly important now that many centers are performing this operation as a day-case procedure. Evidence suggests that females have a lower pain threshold and a lower tolerance to painful stimuli.[9] A meta-analysis of 24 studies revealed there was a significant improvement in postoperative pain relief after instillation of intra-peritoneal LA.[10] Although statistically significant, this is slightly lower than the difference found in a meta-analysis published in 2000.[11] This previous review reported improved pain relief in 7 of 13 trials in favor of the treatment groups. However, they could not find a significant effect of intra-peritoneal LA on the total amount of analgesia delivered in the postoperative period. This might be explained by the fact that LA has its effects only over the initial few hours.[10] Need for additional post-op analgesia indirectly reflects the post-op pain relief at the corresponding time after surgery. According to our study the post-op pain relief in 1st 8 hrs &16 hrs were better in the bupivacaine group i.e. 31.25% (bupivacaine group) vs. 12.5% (controls) & 68.75% (bupivacaine group) vs. 43.75%(controls) respectively, these differences were statistically significant with p-values of 0.005 & 0.043 respectively. The post-op pain relief at 24 hrs after surgery was almost equal in both groups, it is 100% in bupivacaine group vs. 93.75% in controls at 24hrs after surgery and this difference was not statistically significant with a p-value of 0.15. Bisgaard *et al* applied a near-maximum dose of local anesthetic or placebo in a randomized trial.[12] Ropivacaine (or saline) was infiltrated into the port incisions and ropivacaine (or saline) at several sites intra-peritoneally. Both treatment groups were given NSAIDs and acetaminophen in fixed doses and opioids when needed. The local anesthetic regimen significantly reduced incisional pain during the first few hours postoperatively. No analgesic benefits on visceral pain or shoulder pain were found, but overall pain was significantly reduced during the first 2 postoperative hours and opioid requirements were decreased during the first 3 postoperative hours. The findings were later replicated in by Lee *et al* in a trial of low methodologic quality, stating that there were no analgesic differences between incisional *versus* intra-peritoneal local anesthetic regimens.[13] In a study by Rehan AG et al (2010) found that infiltration of 0.25% bupivacaine at port sites, under the right hemi diaphragm and gall bladder bed decreased the post-operative pain in first 24 hours. It also significantly reduced the analgesic requirements in the postoperative period in first 24 hours.[14] The results of the study by Bhardwaj et al (2002)demonstrated that intra-peritoneal instillation of bupivacaine with adrenaline produces lower VAS up to 8 hours postoperatively whereas it produces lower VRS

up to 4 hrs postoperatively. The postoperative analgesic requirements are also less but there is no difference in the shoulder pain between the two groups.[15] According to the above discussion, factors which may influence the intra-peritoneal analgesia are dose and concentration of local anesthesia, site of instillation (sub- diaphragmatic vs. sub-hepatic/ gall bladder fossa), timing of instillation (before vs. after surgery), pneumo-peritoneum (volume, pressure, temperature), volume of residual CO_2 (causing diaphragmatic irritation), spillage of blood and bile (may interfere with absorption), degree of non-visceral pain (e.g. from incision site) and post-operative analgesia regimen.

Conclusion

1. In early post-op VAS scores and pain intensity is decreased with the use of intra-peritoneal instillation of injection Bupivacaine, but in long term it offers no added benefit to the post-operative pain relief and does not decrease the need for analgesia post-operatively.
2. There is significant statistical difference between conventional intra-muscular post-op analgesia and instillation of injection Bupivacaine in diaphragmatic surface and gallbladder fossa on early pain relief and use of analgesia after laparoscopic cholecystectomy according to our study.

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