EFFICACY OF PORT-SITE AND INTRAPERITONEAL APPLICATION OF BUPIVACAINE IN REDUCING EARLY POST-LAPAROSCOPIC CHOLECYSTECTOMY PAIN

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ABSTRACT

Objectives: The aim of this study was to assess the analgesic efficacy of Bupivacaine application at port-site and intraperitoneal infiltration in patients with laparoscopic cholecystectomy.

Study Design: Randomized Controlled Clinical Trial.

Place and Duration: The study was conducted at Rehman Medical Institute (RMI) Peshawar, Pakistan from June 2009 to June 2012.

Materials and Methods: Patients who underwent elective laparoscopic cholecystectomy during the study period were included in the study. Eighty patients were randomized into two groups, study group and control group. The study group received 40 ml of 0.25% bupivacaine intraoperatively as intraperitoneal infiltration and local infiltration at the port sites. Pain assessment was done using visual analogue pain score (VAS) of 0-10 at fixed intervals during the first 24 hours post surgery.

Results: The mean VAS score in the study group was less as compared to the control group throughout the 24 hours assessment period, however this difference was statistically significant (p<0.001) only during the first three assessments at 1 hour, 4 hours and 8 hours post surgery. The analgesia requirement was also significantly (p<0.001) decreased in the study group.

Conclusion: Port site and intraperitoneal application of local anesthetic bupivacaine significantly reduced pain during the first 8 hours post surgery and total analgesia requirement was also significantly reduced. It is a simple and easily applicable technique which increases patient comfort and can be safely used to decrease post operative pain in patients undergoing laparoscopic cholecystectomy.

Keywords: Bupivacaine, Cholecystectomy, Laparoscopic.

INTRODUCTION

Cholecystectomy is one of the most common abdominal surgical procedures and is most commonly performed laparoscopically in developed countries[1]. Almost 90 percent of the cholecystectomies performed in the United States are performed laparoscopically[2]. Laparoscopic cholecystectomy, now considered as the gold standard for treating gallstone disease, has resulted in reduced postoperative pain, decreased length of hospital stay and early recovery to functional status (3-6). Although significant reduction in postoperative pain has occurred with the advent of laparoscopic cholecystectomy, it still remains a major problem in the first few days post surgery. Proper management of postoperative pain results in early mobilization, decreased hospital stay and increased patient satisfaction.

One of the mechanisms of preemptive analgesia is the administration of local anesthetics at surgical incision sites. Many trials have been conducted to assess the analgesic efficacy of intraperitoneal or incisional local anesthetic (mainly bupivacaine) infiltration. These trials have reached conflicting conclusions regarding the analgesic efficacy of intraperitoneal or incisional local anesthetic infiltration. Some studies have shown that this does not result in a significant decrease in postoperative pain or analgesic requirement[7-8] while other studies have concluded that local anesthetic administration increases patient comfort and decreases postoperative analgesic requirement[9-12]. Some studies have concluded that intraperitoneal administration of local anesthetic is more effective as compared to wound site infiltration[9] while other studies have reached the opposite conclusion[10]. |The present study was conducted to assess the

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analgesic efficacy of Bupivacaine application at port-site and intraperitoneal infiltration.

MATERIALS AND METHODS

These randomized controlled clinical trial were conducted at the surgery dept of Rehman Medical Institute (RMI). RMI is a private tertiary care teaching hospital situated in Peshawar, Khyber Pakhtunkhwa Pakistan. Patients who underwent elective laparoscopic cholecystectomy from June 2009 to June 2012 were included in the study. Patients with a history of allergy to local anesthetics or Non-steroidal anti-inflammatory drugs (NSAIDS), those with contraindications to the use of NSAIDS, chronic pain disorders, or those who were already taking pain medications for other reasons were excluded from the study. Patients with choledocholithiasis, placement of drain intra-operatively and previous history of abdominal surgery were also excluded. Informed written consent was taken from all the patients and the study was approved by hospital ethics committee.

A total of 84 patients were included in the study. They were randomized into two groups, the study group and control group of 42 patients each using random numbers table. All the patients received the similar type of standardized anesthetic regimen. The study group received 40 ml of 0.25% bupivacaine intraoperatively as intraperitoneal infiltration and local infiltration at the port sites. Intraperitoneal infiltration was done under both hemi-diaphragms and in the gallbladder bed.

Pain intensity was assessed using visual analogue scale (VAS) of 0-10. This was explained to all the patients pre-operatively. Pain was assessed at 1, 4, 8, 12, 16 and 24 hours post surgery. Shifting of patient from recovery room to ward was considered as zero hours. All

Table-1: Demographic variables and duration of procedure of patients who underwent Laparoscopic Cholecystectomy (n=40 control group, n=40 study group).

Variable		Control group	Study group	*p*- value
Age in years	Mean	47.00	48.55	0.581
	Std. Deviation	14.124	10.610	
	Std. Error Mean	2.233	1.678	
Gender	Male	6 (15%)	7 (17.5%)	0.762
	Female	34(85%)	33 (82.5%)	
Residence	Pakistan	13 (32.5%)	12 (30%)	0.809
	Afghanistan	27 (67.5%)	28 (70%)	
Co-morbids (DM, HTN)	Yes	2 (5%)	2 (5%)	1.00
	No	38 (95%)	38 (95%)	
Pre-op Diagnosis	Cholelithiasis only	37 (92.5%)	37 (92.5%)	1.00
	cholecystitis	3 (7.5%)	3 (7.5%)	
Duration of procedure (in minutes)	Mean	53.15	54.83	0.319
	Std. Deviation	8.043	6.846	
	Std. Error Mean	1.272	1.082	

Table-2: Post-op Analgesia requirement following laparoscopic cholecystectomy (n=40 control group, n=40 study group).

		Control group	Study group	*p*- value
Rescue Analgesia required	Yes	40 (100%)	26 (65%)	<0.001
	No	0	14 (35%)	
Number of injections required	0	0	14 (35%)	<0.001
	1	0	8 (20%)	
	2	30 (75%)	17 (42.5%)	
	3	10 (25%)	1 (2.5%)	

the patients had received injection diclofenac 50 mg intramuscular thrice daily for the first 24 hours post surgery. All the patients were allowed to receive analgesic medications as needed and the requirement of these medications were recorded. Ketorolac 30 mg intramuscular was used as a rescue analgesic.

Postoperative analgesia requirement was assessed in both groups and there was statistically significant difference in the requirement of analgesia demanded by the patients. In the control group all the patients required analgesia. Most of them (75%) required 2 injections of Ketorolac. In the study group only 65% of the patients required analgesia. (Table-2).

Table-3: VAS pain score during the first 24 hours post-op period among patients with Laparoscopic Cholecystectomy (n=40 control group, n=40 study group).

VAS Pain score		Control group	Study group	Kruskal Wallis test *p*-value
Pain score at 1 hours	Mean	5.33	3.75	<0.001
	Std. deviation	1.526	1.193	
Pain score at 4 hours	Mean	5.20	3.13	<0.001
	Std. deviation	1.924	1.202	
Pain score at 8 hours	Mean	4.65	3.10	<0.001
	Std. deviation	1.902	1.128	
Pain score at 12 hours	Mean	3.33	2.90	0.077
	Std. deviation	0.829	1.215	
Pain score at 16 hours	Mean	3.13	2.80	0.112
	Std. deviation	0.723	0.911	
Pain score at 24 hours	Mean	2.38	2.10	0.202
	Std. deviation	0.925	0.709	

The data was collected by a medical officer using a structured proforma. Patients, surgeons, medical officer collecting the data and the nursing staff were blinded to the randomization.

Data were analyzed using SPSS version 17. Descriptive statistics were used to describe the results. Chi-square test was performed for nominal variables and Kruskal Wallis test (non parametric test) for non-normally distributed data. Differences were considered statistically significant at a *p*-value <0.05.

RESULTS

Of the selected patients four dropped out from the study. Data analysis was done for the remaining 80 patients, 40 control group and 40 in the study group. Of these 67 (83.8%) were females. Their mean age (SD) at the time of presentation was 47.78 (12.43) years with range from 24 years to 80 years. Both control group and study group were similar and there was no statistically significant difference in the demographic variables and duration of procedure (Table-1).

The VAS pain score was assessed at 1, 4, 8, 12, 16 and 24 hours postoperatively. The mean scores across all these intervals was lower in the study group as compared to the control group and this difference was statistically significant during the first 8 hours post surgery (Table-3). Although the mean VAS pain score after 12 hours were less in the study group as compared to control group, it was not statistically significant. There were no extra complications observed with the use of Bupivacaine in the study group during the hospital stay.

DISCUSSION

One of the main findings of our study was that abdominal pain was significantly reduced in patients who had received bupivacaine. This was statistically significant in the early postoperative period and though the mean pain score was less in the latter half of the day, these were not statistically significant. Previous studies on this subject have reached conflicting conclusions. A study conducted in Israel

demonstrated that intraperitoneal application of bupivacaine did not alleviate pain after laparoscopic cholecystectomy. They also concluded that though there was less analgesia requirement in the study group but it did not reach statistical significance[7]. Similar findings were also reported in another study conducted in Thailand[8]. The results of our study are consistant with other studies which have shown a significant analgesic effect of bupivacaine local application[9-12].

In this study we did not assess the incisional or visceral pain and rather overall patient discomfort/pain was assessed. Pain score at the specified intervals, either visceral or somatic was assessed. There are studies which have tried to find out the effects of local anesthetic application on either somatic/incisional pain or visceral pain separately or both combined. One such study conducted in India showed that 0.5% bupivacaine effectively controlled the visceral pain however the port site application was not effective. There sample of patients only consisted of patients with cholecystitis[9]. Another study in Denmark had reported the opposite effects of another local anesthetic ropivacaine. They concluded that ropivacaine reduced the overall pain the first two hours and incisional pain for the first three postoperative hours ($p < 0.01$) but had no apparent effects on intraabdominal or shoulder pain. Their study also showed that overall narcotic analgesia requirement was significantly reduced in the first 3 hours post surgery[13]. Similar findings were reported in a study conducted in Korea which showed that only incisional pain was significantly reduced during the first three post-operative hours either with combination of intraperitoneal and incisional infiltration of bupivacaine or incisional application alone. The combination of intraperitoneal and incisional infiltration of bupivacaine did not reduce visceral pain more than after incisional application alone. They recommended incisional application of local anesthetic alone[14].

Although the anesthetic effect was expected to wear off in the latter half of the study period, no increase in pain score was noted after 8 hours. In the control group the mean pain score was more as compared to that in the study group throught the assessment period. The difference in the mean pain scores was statistically significant only during the first three assessments at 1 hour, 4 hours and 8 hours post surgery. This shows that the local anesthetic mainly increases patient comfort and decreases pain during the first 8 hours post surgery.

In our study the rescue analgesic requirement was significantly less in the study group as compared to the control group. Another study conducted in Pakistan[15] had also reported similar findings. In their study the mean pain score (statistically not significant) and analgesic requirement (statistically significant) was less in the study group as compared to control group. Similar findings of statistically significant less analgesic requirement have also been reported in other studies[13,16].

CONCLUSION

Our study showed that port site and intraperitoneal application of local anesthetic bupivacaine significantly reduced pain during the first 8 hours post surgery and total analgesia requirement was also significantly reduced.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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