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Port-site infiltration of bupivacaine in reduction of postoperative pain after laparoscopic cholecystectomy

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Abstract
Background: Port site pain remains prevalent complaint of early postoperative period after laparoscopic cholecystectomy.
Objectives: to see the analgesic efficacy of port-site infiltration of bupivacaine in laparoscopic cholecystectomy.
Methodology: This randomized controlled clinical trial was conducted in the Department of Surgery, Sylhet MAG Osmani Medical College Hospital, Sylhet from September 2017 to March 2018. Sixty patients underwent laparoscopic cholecystectomy were randomized into experimental group and control group by odd and even number respectively. Infiltration of 0.5% bupivacaine was at port sites subcutaneously in experimental group and none in control group. Postoperative pain intensity was measured using Numeric Rating Scale (NRS) at 6, 12, 24 and 48 hours.
Results: Pain score was lesser in experimental group compared to control group at 6, 12, 24 and 48 hours ($p< 0.001$). The amount of opioid analgesic needed (p=0.006) and hospital stay (p=0.048) were significantly lesser in experimental group. Less frequent nausea/vomiting (p=0.034) and bladder dysfunction (p=0.012) were in experimental group.
Conclusion: Port-site infiltration of bupivacaine is effective in reduction of postoperative pain in laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy, port-site bupivacaine, analgesia, NRS score

Introduction
Laparoscopic technique has become the gold standard for cholecystectomy in the past decade. Most patients are being discharged on the same day as surgery or on the first postoperative day [1, 2]. Although pain after laparoscopic cholecystectomy is less intense than after open cholecystectomy, some patients still experience considerable discomfort and pain during the first 24 to 72 postoperative hours [3]. The effective analgesic treatment after laparoscopic cholecystectomy has remained a clinical challenge [4]. In 17–41% of the patients, pain is the main reason for staying overnight in the hospital on the day of surgery [5, 6], and pain is the dominating complaint and the primary reason for prolonged convalescence after laparoscopic cholecystectomy [4, 5, 7]. Moreover, it has been hypothesized that intense acute pain after laparoscopic cholecystectomy may predict development of chronic pain (*e.g*, postlaparoscopic cholecystectomy syndrome) [8]. This prospective study was designed to evaluate the efficacy of port-site infiltration of bupivacaine on postoperative pain relief within the first 48 hours after laparoscopic cholecystectomy. The origin of pain after laparoscopic procedures is multifactorial. The pain may arise from the incisional trauma at port sites, the distention and chemical irritation of the peritoneum, the diaphragmatic stretching with phrenic nerve neuropraxia, and from direct tissue injury [9]. Therefore overall pain in laparoscopic cholecystectomy is a conglomerate of three different and clinically separate components: incisional pain (somatic pain), visceral pain (deep intraabdominal pain), and shoulder pain (presumably referred visceral pain) [6].
Several interventions have been investigated to reduce pain after laparoscopic cholecystectomy [10-15]. Variable analgesic effects of periportal infiltration of local anesthetics [10-12], infiltration of the periportal parietal peritoneum [13], intraperitoneal spraying above the gall bladder [14], instillation into the subdiaphragmatic space [15], and into the subhepatic space covering the area

of the hepatoduodenal ligament have been reported [14, 16].
Local anesthetics act by producing a conduction blockade of neural impulses in the afferent nerve. Bupivacaine has a half-life of 2.5-3.5 hours and has been reported to have provided pain control for an average of 6 hours. The margin of safety of the Bupivacaine need for anesthesia is wide. At the upper limit of 2.5 mg of Bupivacaine/kg body weight, 100 mg of the drug can be used safely in a patient with lean body mass of 40kgs [14].
This study was designed to evaluate the efficacy of port site infiltration of bupivacaine in relief of pain following laparoscopic cholecystectomy.

Materials and Methods

This randomized controlled clinical trial was conducted from September 2017 to March 2018 at the Department of Surgery, Sylhet MAG Osmani Medical College Hospital, Sylhet. Sixty ultrasonographically proved gall stones cases, aged above 18 years with ASA Class 1 or 2 and underwent elective laparoscopic cholecystectomy were selected. The patients with previous upper abdominal surgery, with choledocholithiasis, requiring placement of a drain intraoperatively and conversion to open cholecystectomy were excluded.
They were randomly allocated into two groups of 30 patients in each. Randomization was done by odd and even number. Every odd number of patient allocated to the Bupivacaine group (experimental group); while the even number was allocated to the control group. During the preoperative visit, the Numeric Rating Scale (NRS) ranging from 0 (no pain) to 10 (worst pain) was explained to every patient. The patient was asked to put a cross on the 0–10 cm Numeric Rating Scale according to pain intensity. The whole procedure and risks involved were fully explained to the patient in vernacular language and well informed written consent was taken.
Laparoscopic cholecystectomies were performed with four ports; access to the peritoneal cavity was gained infraumbilically by using 10 mm incision via direct trocar insertion with CO_2 insufflations gas pressure around 12 mmHg. Gall bladder was extracted through the epigastric port.
After operation and before closing the wound 0.5% bupivacaine was infiltrated at port sites subcutaneously (6ml was infiltrated through the abdominal wall around each midline port site and 4ml administered in the similar fashion at the lateral port sites) in experimental group and none in control group. Patients of both group received a single dose injection pethidine (50mg) when they come round.
After the surgery, patients were taken to postoperative room. The time of arrival at the postoperative room was defined as zero (0) hour postoperatively. At the early postoperative period (up to 48 hours), pain intensity was measured using Numeric Rating Scale (NRS) at 6, 12, 24 and 48 hours following operation. Analgesic was given as per need of the patients. In patients with NRS score above 4, 60 mg of ketorolac was administered intravenously (i.v.), while in patients with NRS score above 7, 100 mg of tramadol was administered intramuscular (i.m.) as rescue analgesia treatment. Post-operative nausea and vomiting planned to be treated with ondansetron 4 mg i.v.
Data were entered and analyzed using SPSS version 22. For quantitative variables i.e. age, analgesic dose and length of postoperative hospital stay mean and standard deviation were calculated and comparison was done using Student t-test. For qualitative variables i.e. sex, ASA grading, nausea-vomiting and bladder dysfunction frequency and percentage were calculated and comparison was done using Shi-Square test or Fisher's Exact test. For pain score repeated measure mean and standard deviation were calculated and level of significance was calculated using repeated measure ANOVA. A p-value <0.05 was considered significant.

Results

The mean age of the patients of experiment group and control group were 46.3 ± 11.4 years and 45.8 ± 13.5 years respectively; difference was not significant (p=0.878).
Female preponderance was recorded in both group (73.3% versus 76.7%) and difference was not significant (p=0.232).
ASA grading I was most common in both groups (63.3% versus 66.7%) and difference was not significant (p=0.787).
Current smoker was almost similar in both groups (16.7% versus 10.0%; p=0.353).
Table-2 showed that pain score at 6 hours of operation was lesser in experiment group (2.7 ± 0.7) compared to control group (5.3 ± 1.3). The pain score at 12 hours increased to 5.1 and 6.0 respectively and decreased to 1.7 and 2.5 at 48 hours respectively. The pain at each interval of evaluation was comparatively lesser in experiment group compared to control group ($p< 0.001$).
The mean total amount of opoid analgesic needed (156.7 ± 36.5 mg versus 183.3 ± 35.6 mg; p=0.006) and postoperative hospital stay (2.1 ± 0.3 day versus 2.4 ± 0.5 day; p=0.048) were significantly lesser in experiment group compared to control group.
The patients of experienced less frequent nausea/vomiting (16.7%) compared to experiment group (33.3%) (p=0.034). Bladder dysfunction was also less frequent experiment group compared to control group (6.7% versus 16.7%; p=0.012).

Table 1: Baseline characteristics

Baseline characteristics	Study groups		p-value
	Experiment group (n=30)	Control group (n=30)	
Age			
≤30	3 (10.0%)	4 (13.3%)	
31-40	7 (23.3%)	9 (30.0%)	
41-50	9 (30.0%)	6 (20.0%)	*p=0.878
51-60	8 (26.7%)	7 (23.3%)	
>60	3 (10.0%)	4 (13.3%)	
Mean ± SD	46.7 ± 10.6	45.8 ±11.5	†p=0.744
Sex			
Male	8 (26.7%)	7 (23.3%)	‡p=0.232
Female	22 (73.3%)	23 (76.7%)	
ASA grading			
Grade I	19 (63.3%)	20 (66.7%)	‡p=0.787
Grade II	11 (36.7%)	10 (33.3%)	
Smoker			
Yes	5 (16.7%)	3 (10.0%)	*p=0.353
No	25 (83.3%)	27 (90.0%)	

*Fisher's Exact test, †Student t test and ‡Chi-Square test

Table 2: Showing distribution of the pain score by NRS scale at different time interval after operation

Time interval	Pain Score (mean ± SD)		p-value
	Experiment group (n=30)	Control group (n=30)	
At 6 hours	2.7 ± 0.7	5.3 ± 1.3	
At 12 hours	5.1 ± 0.7	6.0 ± 1.1	*$p<$ 0.001
At 24 hours	2.8 ± 0.9	3.7 ± 0.9	
At 48 hours	1.7 ± 0.6	2.5 ± 0.7	

*Repeated measure ANOVA

Table 3: Comparison of outcome between groups

Parameters	Outcome		p-value
	Experiment group (n=30)	Control group (n=30)	
Total amount of opioid analgesic needed (mg)	156.7 ± 36.5	183.3 ± 35.6	*p=0.006
Hospital stay (day)	2.1 ± 0.3	2.4 ± 0.5	*p=0.038
Nausea/ vomiting	5 (16.7%)	10 (33.3%)	†p=0.034
Bladder dysfunction	2 (6.7%)	5 (16.7%)	‡p=0.012

*Student t test, †Chi-Square test and ‡Fisher's Exact test

Discussion

The fact that acute pain after laparoscopic cholecystectomy is complex in nature and does not resemble pain after other laparoscopic procedures suggests that effective analgesic treatment should be multimodal [6, 17].

The use of regional local anesthetics in combination with general anesthesia, has been investigated in several interventional studies during laparoscopic cholecystectomy, thus variable anesthetic effects of periportal infiltration of local anesthetics, infiltration of the peri-portal parietal peritoneum, intraperitoneal spraying above the gallbladder, infiltration into the gallbladder bed parenchyma, instillation into the sub-diaphragmatic space and into the sub-hepatic space covering the area of the hepato-dudenal ligament have been reported.[18] In this study analgesic efficacy of port-site infiltration of bupivacaine in laparoscopic cholecystectomy was evaluated.

In this study the mean age of the patients of experimental group and control group were 46.3 ± 11.4 years and 45.8 ± 13.5 years respectively; difference was not significant between two groups (p=0.878) suggesting an age matched study.

In the present study female preponderance was recorded in both group (73.3% versus 76.7%) and difference was not significant (p=0.232) suggesting a sex matched study.

This study showed that pain score at 6 hours of operation was lesser in experimental group (2.7 ± 0.7) compared to control group (5.3 ± 1.3). The pain score at 12 hours increased to 5.1 and 6.0 respectively and decreased to 1.7 and 2.5 at 48 hours respectively. The pain score at each interval of evaluation was comparatively lesser in experimental group compared to control group ($p< 0.001$). Similar findings were observed in the study of Alexander *et al*. [13].

The mean total amount of opoid analgesic needed (156.7 ± 36.5 versus 183.3 ± 35.6; p=0.006) and discharged on day (2.1 ± 0.3 versus 2.4 ± 0.5; p=0.048) were significantly lesser in experimental group compared to control group. Alexander *et al*. [13] found both opiate and oral analgesic requirements were reduced in patients administered peritoneal injection, although this was not statistically significant.

The patients of experimental group experienced less frequent nausea/vomiting compared to control group (p=0.034). Bladder dysfunction was also less frequent experimental group compared to control group (p=0.012).

This study was not without limitations. The limitations were (1) single centre study and (2) small sample size.

Conclusion

Port-site infiltration of bupivacaine after laparoscopic cholecystectomy is effective and safe analgesic technique in reduction of pain and period of hospitalization. This is a simple analgesic technique and can be practiced routinely in all elective laparoscopic cholecystectomy. However further study involving multicentre and large sample is warranted.

Conflict of Interests

No conflict of interests exists for the authors.

Authors' Contribution

Dr. Md. Babul Akter contributed to study conception, design and acquisition of data; Dr. Jahir Ahmed contributed acquisition of data; Dr. Md. Tabibul Islam contributed to data interpretation, the statistical analyses and the writing of the manuscript; Dr. Md. Ashik Anwar Bahar, Dr. Kazi Zana Alam, Dr. Md. Mizanur Rahman, Dr. Golam Mowla, Dr. Ahmod Nasim Hassan and Dr. ASM Anwarul Kabir contributed to critical revision of the manuscript. All the authors finally contributed to the final approval of the version to be published.

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