EFFECTS OF PORT SITE BUPIVACAINE INFILTRATION TO REDUCE POST OPERATIVE PAIN IN LAPAROSCOPIC CHOLECYSTECTOMY: A DOUBLE BLIND RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Laparoscopic cholecystectomy has become the treatment of choice for symptomatic gall stone disease. But post operative pain may prolong hospital stay and increase morbidity. The aim of the study was to find out the effect of port site infiltration of Bupivacaine in reducing post operative pain following routine laparoscopic cholecystectomy. **Materials and methods:** This is a double blind randomized controlled trial conducted in the Department of Surgery, Chittagong Medical College Hospital, Bangladesh. A total 200 patients underwent routine laparoscopic cholecystectomy were enrolled in the study. All patients are assigned in two groups- control group (Infiltration of 20 ml normal saline at port site) and Bupivacaine group (20 ml Bupivacaine at port site). Both groups are followed at 4 hrs, 12 hrs and 24 hrs after operation to assess the intensity of pain by using Visual Analogue Pain Scale (VAS). Time regarding the first analgesic request by the patients, total dose of analgesic, days of return to normal day to day activities and normal works were also recorded. **Results:** The mean age of control group and Bupivacaine group were 41.64 and 37.54 years respectively. At 4hrs post operative mean pain score were 6.76 and 5.62 respectively (p value 0.015). At 12 hrs mean pain score were 4.4 and 3.88 respectively (p value 0.001). At 24hrs pain score were 2.66 and 2.08 respectively (p value 0.002). Mean time of first analgesic required were 4.8hrs and 7hrs respectively (p value 0.000). Mean duration of hospital stay were 2.26 days and 2.22 days respectively (p value 0.371). Total dose of analgesic required were 12 and 9 between the groups respectively (p value 0.000). Mean time of return to normal day to days activities were 3.98 days and 2.98 days respectively (p value 0.000). Return to normal work after 6.98 days and 6.46 days respectively between the groups (p value 0.008) that is statistically significant. **Conclusion :** Infiltration of Bupivacaine at port site at post operative period of laparoscopic cholecystectomy patients significantly reduces pain than control group. It helps patients for early mobilization, early return to normal activities and works. Thus it reduces overall cost and morbidity of symptomatic cholelithiasis patients.

Key words

Visual Analogue Pain Scale (VAS); Laparoscopic cholecystectomy; Port site Bupivacaine infiltration.

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Introduction

Laparoscopic surgery is a minimally invasive technique and causes reduced surgical trauma as compared to open procedure[1, 2]. Laparoscopic cholecystectomy has become the treatment of choice for gall stone disease since 1987[3]. It results in less postoperative pain and reduced analgesic consumption as compared with open cholecystectomy[4]. Pain following laparoscopic procedure is multifactorial. Several attempts have

been made to differentiate various pain qualities and localization [5-12]. But there was difficulty in making such isolation [12-13]. Post operative pain after laparoscopic cholecystectomy remains an issue. Pain can prolong hospital stay and lead to increased morbidity. The most frequent complaint after elective laparoscopic cholecystectomy is early postoperative pain[14]. The pain of highest intensity is experienced during the first postoperative hours and usually wanes over the subsequent 2-3 days[14,15]. Effective management of post operative pain will results in early recovery reduces the requirement of total doses of analgesic, early discharge from hospital and early return to normal day to activities as well as early return to normal work. Thus this will reduce the total cost related to the operation and total working days lost. The current study will investigate whether port site infiltration of Bupivacaine is effective or not in reducing post operative pain following routine cholecystectomy. The onset of action of Bupivacaine Hydrochloride is rapid and long lasting. The duration of anesthesia is significantly longer with Bupivacaine Hydrochloride than with any other commonly used local anesthetic.

Materials and methods

This is a hospital based double blind randomized controlled trial conducted in the General Surgery Department of Chittagong Medical College Hospital, Bangladesh from January 2009 to December 2009. The study was approved by the Institutional Review Board and by the Ethical Review Committee of Chittagong Medical College. Informed written consent were taken by the patients. All aspect of confidentiality were preserved. A total of 200 patients underwent elective laparoscopic cholecystectomy during the study period and meeting inclusion and exclusion criteria were included in the study. Inclusion criteria was patients with symptomatic gall stone disease underwent laparoscopic cholecystectomy. Exclusion criteria were planned open cholecystectomy, intraoperative conversion, open trocher insertion and allergy to Bupivacaine. All the patients included in the study were counted with a serial number and were randomly divided into two groups – control group (n=100) and Bupivacaine group (n=100). Lottery method was followed for the first case of the study and it was in control group. The rest 99 cases of the control group were selected by using random number table. The rest of the patients were labeled as Bupivacaine group. All the patients of both control group (n=100) and Bupivacaine group (n=100) underwent laparoscopic cholecystectomy under general anaesthesisia with standard protocol followed in Chittagong Medical College Hospital. The patients of control group received a total of 20ml normal saline at their port sites and the patients of Bupivacaine group received a total of 20 ml 0.5% Bupivacaine at their port sites. The lottery for the first case, selection of serial number of the patients using random number table and supply of either normal saline or Bupivacaine were done by a third person. As a result the researcher and the patient remained blind about who was in control group and who was in Bupivacaine group. Patients pain score were determined at 4, 12 and 24 hours of operation. Patients with a pain score (VAS) of 5 and above received 50mg diclofenac sodium in suppository form (From same manufacturer). Data is processed and analyzed by computer based software Statistical Package for Social Science (SPSS) version 17.0. Data is expressed as mean ±SD. Confidence level was fixed at 95% and p value of 0.05 or less was considered significant.

Results

Table I : Distribution of the respondents by age

Age of the Respondent	Control group	Bupivacaine group	Total
≤ 20	2 (2.0%)	4 (4.0%)	6 (3.0%)
20 – 30	10 (10.0%)	30 (30.0%)	40 (20.0%)
30 – 40	42 (42.0%)	32 (32.0%)	74 (37.0%)
40 – 50	28 (28.0%)	16 (16.0%)	44 (22.0%)
> 50	18 (18.0%)	18 (18.0%)	36 (18.0%)
Total	100 (100.0%)	100 (100.0%)	200 (100.0%)
Mean ± SD	41.64 ± 11.36	37.54 ± 11.67	39.59 ± 11.64

Table II : Distribution of the respondents by sex

Sex	Control	Bupivacaine	Total
Male	30 (30.0%)	28 (28.0%)	58 (29.0%)
Female	70 (70.0%)	72 (72.0%)	142 (71.0%)
Total	100 (100.0%)	100 (100.0%)	200 (100.0%)

Table III : Distribution of the respondent by Visual Analogue Pain Score (VAS) at 4 hrs, 12 hrs, 24 hrs

Duration of follow up.	Bupivacciue group Mean ± SD	Control group Mean ± SD	Significance
4 hrs	5.62 ± 1.28	6.74 ± 1.37	p = 0.015
12 hrs	3.88 ± 0.93	4.5 ± 1.11	p = 1.11
24 hrs	2.08 ± 0.66	2.66 ± 0.94	p = 0.002

Table IV : Distribution of the respondent on the basis of analgesic required

Analgesic required	Bupivacaine group Mean ± SD	Control group Mean ± SD	Significant
1st analgesic required (Hrs)	7.0 ± 1.24	4.8 ± 0.68	p = 0.000
Total dose of analgesic required.	9.0 ± 0.83	12.0 ± 1.42	p = 0.000

Table V : Distribution of the respondents on the basis of total hospital stay, beginning of normal activities and return to normal work

Duration in days	Bupivacaine group Mean ± SD	Control group Mean ± SD	Significance
Total hospital stay	2.22 ± 0.62	2.26 ± 0.78	p = 0.371
Beginning of normal activity	2.98 ± 0.82	3.98 ± 0.82	p = 0.000
Return to normal work	6.46 ± 0.97	6.98 ± 0.82	p = 0.08

Table I shows that the highest proportion of the respondents (n=74) are in the age group of 30-40 years (Control-42, Bupivacaine-32) The mean age of the control group and the Bupivacaine group were 41, 64 years and 37,54 years respectively.

Table II shows that more than 70% of the respondents were female. Female predominated both in control (70%) and Bupivacaine (72%) groups. Male constituted ≤ 30% in both the groups.

Table III shows distribution of the respondents by Visual Analogue Pain Score (VAS) at 4 hours, 12 hours & 24 hours of operation. The mean pain score at 4 hours is 6.76 and 5.62 for control group and Bupivacaine group respectively (p value 0.015).

At 12 hours mean pain score is control group and Bupivacaine group were 4.5 and 3.88 respectively (p value 1.11). At 24 hours mean pain score are 2.66 and 2.08 for control group and Bupivacaine group respectively (p value 0.002).

Table IV shows mean time for first dose of analgesic required following laparoscopic cholecystectomy both by the control and the bubivacaine group. The mean time for first analgesic requirement was 4.8 hours and 7.0 hours for control and Bupivacaine group respectively (p value 0.000). It also shows distribution of the respondents by total doses of analgesic required before complete disappearance of pain. The mean doses required for the control group and the Bupivacaine group was 12 and 9 respectively (p value 0.000).

Table V shows distribution of the respondents by duration of hospital stay, beginning of normal activity, return to normal work. Total days of hospital stay between control group and Bupivacaine group were 2.26 and 2.22 days respectively (p value 0.371). Beginning of normal activity between control group and Bupivacaine group were 3.98 and 2.98 days respectively (p value 0.000). Return to normal work between control group and Bupivacaine group were 6.98 and 6.46 days respectively (p value 0.08).

Discussion

Pain remains a major complaint in the early post operative period following laparoscopic cholecystectomy but it is less intense and short lasting in comparison to open cholecystectomy [10,16]. Post operative pain control is directed to early mobilization, recovery, discharge and return to work. Thus the shorter the duration of post operative pain the lesser the loss of working days and productivity. This study was undertaken to find out the effect of Bupivacaine in post operative pain following laparoscopic choolecy-stectomy. Both group of patients were followed up at 4 hours, 12 hours and 24 hours of operation for post operative pain using visual analogue pain score. Data were also collected for pain score at the end of 4 hours of operation for control group and Bupivacaine group were 6.76 (± 1.37) and 5.62 (± 1.28) respectively (p value – 0.015), at the end of 12 hours 4.5 (± 1.11) and 3.88 (± 0.93)

respectively (p value – 0.001). at the end of 24 hours of operation 2.66 (± 0.94) and 2.08 (± 0.66) respectively (p value-0.002).

Pasqulucci et al observed significant pain reduction in Bupivacaine group up to 21 hours following laparoscopic cholecystectomy using same concentration (20ml of 0.5% Bupivacaine) and volume of Bupivacaine at port sites[16]. This result is similar to the result of our study. On the other hand Chundrigar T. Hedges AR. et al noted pain relief only up to 2 hours following operation[17]. This was probably due to use of lower concentration of Bupivacaine (0.25%) by them as compared to our study.

The mean (± SD) time required for the first dose analgesic following operation was 4.8 hours (±0.68) for the control group and 7.0 hours (± 1.24) for the Bupivacaine group [p value 0.000]. Total doses (Mean ± SD) of analgesic required for control group was 12.00 ± 1.42 and 9.00 ± 0.83 for the Bupivacaine group before complete disappearance of post operative [p value 0.000]. Other studies also reported lower analgesic consumption in local anesthetic group using meperidine or ketorolac in the post operative period[17,18].

The respondents of the control group returned of their normal day to day activities on about fourth day after operation but the Bupivacaine group on about third day after operation 2.98 (±0.82) day [p value-0.000]. There was also statistical significant difference between the groups regarding their return to normal work following operation.

Thus the findings of the study revealed that infiltration of local anesthetic agent (Bupivacaine) after surgery through the port site had pain of reduced intensity at 4 hours, 12 hours and 24 hours of operation than who were not infiltrated. The study also showed that patients who received local anesthetics at the port sites had longer delay time required for the need of first dose of analgesic, total doses of analgesics required before complete disappearance of post operative pain and time required for return to normal day to day activities and usual work. The mean (± SD) requiring the first dose of analgesic, shorter duration of post operative pain requiring analgesic, lower doses of analgesic required in the post operative period. Shorter time to return to their normal day to day activities and usual work than who did not receive. These findings can be explained by the fact that pain intensity was less among patients who received local anaesthetic Bupivacaine at the post operative period.

Limitation

It is a single center studies with small number of sample. Multi center study with large number of sample is recommended.

Conclusion

Post operative pain remains an issue following laparoscopic cholecystectomy. Pain can increase morbidity, over all operative cost and economic loss as pain can delay in mobility of the patient, increased analgesic consumption and delay in return to normal activities and work. Infiltration of local anesthetic agent Bupivacaine in recommended dose has been found and effective method of management of post operative pain following laparoscopic cholecystectomy. This reduces the post operative pain and helps patients in early mobilization and early return to normal activities and work. Thus it reduces overall treatment cost of symptomatic gall stone disease.

Disclosure

All the authors declare no completing interest.

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