

Comparison of use of Bupivacaine and Normal Saline in Liver Bed & Ports after Laparoscopic Cholecystectomy in Postoperative Pain Reduction

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Abstract:

Background: Laparoscopic cholecystectomy results in less post operative pain than open cholecystectomy. However post operative pain remains an issue following the procedure which can prolong hospital stay and lead to increased morbidity.

Objectives: Effective management of post operative pain will thus help to mobilize the patients earlier, reduce the requirement for post operative analgesic; early hospital discharge, return to normal activities & normal work. This will help to reduce the total cost related to the operation and total working days lost.

Methods: In this randomized controlled trial a total of 100 patients undergoing routine laparoscopic cholecystectomy were enrolled in this study during March 2015 to May 2016 in Pabna Medical College Hospital. The patients were randomly assigned in control group and bupivacaine group. Patients of the bupivacaine group received local anesthetic agent bupivacaine at their port sites which was infiltrated in the skin, subcutaneous tissue, fascia, and liver bed at the end of the surgery. The control group received normal saline in the same manner. All the patients were followed up to assess the intensity of post operative pain using visual analogue pain scale at 4 hours, 12 hours and 24 hours of operation as well as at the time of discharge from the hospital and at one week after the operation. Data regarding the first analgesic request by the patient after surgery, total doses of analgesic consumed in the post operative period and return to normal day to day activities and the normal work were also collected.

Results: Data were analyzed using SPSS Statistics 17.0 and revealed that patients receiving bupivacaine infiltration at their port sites and liver bed following the surgery had lower pain scores at the times of assessment than those who received normal saline at their port sites. The patients of the bupivacaine group also took longer time for first request for analgesic after surgery and required less doses of analgesic.

Conclusion: Infiltration of bupivacaine at port site and liver bed following laparoscopic cholecystectomy is an effective method of managing post operative pain. This also lowers the doses of analgesic required, thus laparoscopic cholecystectomy can be considered as a fast-track surgery.

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Introduction

Laparoscopic cholecystectomy has become a standard technique for gall bladder surgery of symptomatic cholelithiasis and is now considered to be the gold standard treatment. The introduction of laparoscopic technique to general surgery has dramatically changed our view to the post operative course of patients after cholecystectomy. Laparoscopic cholecystectomy has proven to reduce the post operative pain significantly and allow a short hospital stay and recovery period which is reflected in patient's earlier return to normal life and work activities.^{1,2} In most of the centre patients are discharged home on the first post operative day. However, as experience expands further, few series have recently shown that the operation is safe and feasible even as an outpatient procedure in properly selected patients.^{3,4}

Thus, pain relief and patient comfort during the early post operative period becomes increasingly important, as the need for analgesic may delay discharge. Pain on the day of surgery is typically a diffuse abdominal pain, a more so to the right upper quadrant and right shoulder tip. The cause of this pain is thought to be related to abdominal muscle distension during laparoscopic procedure, irritating effects of residual carbon dioxide in the abdominal cavity and prolonged elevation of diaphragm by pneumoperitoneum.⁵

Decrease in post operative pain after infiltration of bupivacaine into the operative wound has been observed among patients who undergo herniorrhaphy and gynecological procedures.^{6,7} Post operative catheter infusion of bupivacaine into the sub costal incision during open cholecystectomy has shown to decrease atelectasis and reduce narcotic usage.⁸ Continuous post operative infusion of bupivacaine into the abdominal wound has reduced both post operative pain and narcotic requirements.^{9,10}

Bupivacaine is widely used, have a good safety profile. It provides the benefit of anesthesia without the systemic effects that may result from use of enterally and perenterally administered drugs.¹⁰

Bupivacaine has a half-life of 2.5 to 3.5 hours and has been reported to provide pain control for an average of 6 hours¹². The margin of safety of the bupivacaine need for anesthesia is wide. At the upper limit of 2.5 mg of bupivacaine per kilogram body weight, 100 mg of the drug can be used safely in a patient with a lean body mass of 40 kgs.¹¹

Controversy exists about the principle source of pain after laparoscopic procedures. Some clinicians believe that the placement of trocars through the abdominal wall is the primary source. Whereas other believes that most pain arises from intraperitoneal dissection.^{12,13} Variable analgesic effects of periportal infiltration of bupivacaine, intraperitoneal spraying above the gall bladder, instillation into the sub diaphragmatic space and into the sub hepatic space covering the area of hepato-duodenal ligament has been reported. Some of them failed to show any benefit.¹⁴

Several studies have described pain according to the presumed mechanism, visceral pain, which can theoretically be blocked by intraperitoneal infiltration and parietal pain, which can be blocked by port site infiltration.¹⁵

Our study is designed to evaluate the effect of combined liver bed and port site infiltration of bupivacaine in comparison to effect of application of normal saline for pain relief following laparoscopic cholecystectomy.

Results

This randomized control trial was conducted to determine the role of port site bupivacaine in reducing post operative pain following laparoscopic cholecystectomy. The results of the 100 respondents are tabulated below.

Table I. Distribution of the Respondents by Time of First Analgesic required

Time of First Analgesic(in hrs after operation)	Control	Bupivacaine	Total
≤4.00	15(30.0%)	0(0%)	15(15.0%)
4.00 - 6.00	35(70.0%)	18(36.0%)	53(53.0%)
6.00 - 8.00	0(0%)	22(44.0%)	22(22.0%)
>8.00	0(0%)	10(20.0%)	10(10.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean ± SD	4.8 ± 0.68	7.0 ± 1.24	5.9 ± 1.49

p value: 0.000

Table II. Distribution of the Respondents by Duration of Hospital Stay

Duration of hospital stay following operation	Control	Bupivacaine	Total
< 2	35(70.0%)	36(72.0%)	71(71.0%)
2 - 3	11(22.0%)	13(26.0%)	24(24.0%)
>4	4(8.0%)	1(2.0%)	5(5.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean $\pm$ SD	2.26 $\pm$ 0.78	2.22 $\pm$ 0.62	2.24 $\pm$ 0.70
p value - 0.371			

Table III. Distribution of the Respondents by Visual Analogue Pain Score at 4 hrs of Operation

Visual Analogue Pain Score at 4 hrs	Control	Bupivacaine	Total
≤ 5.0	7(14.0%)	18(36.0%)	25(25.0%)
5.0 - 7.0	22(44.0%)	23(46.0%)	45(45.0%)
7.0 - 9.0	19(38.0%)	9(18.0%)	28(28.0%)
>9.0	2(4.0%)	0(.0%)	2(2.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean $\pm$ SD	6.76 $\pm$ 1.37	5.62 $\pm$ 1.28	6.19 $\pm$ 1.44

Table IV. Distribution of the Respondents by Visual Analogue Pain Score at 12 hrs of Operation.

Visual Analogue Pain Score at 12 hrs	Control	Bupivacaine	Total
≤ 2.5	0(0%)	4(8.0%)	4(4.0%)
2.5 - 4.0	18(36.0%)	26(52.0%)	44(44.0%)
4.0 - 5.5	21(42.0%)	20(40.0%)	41(41.0%)
>5.5	11(22.0%)	0(.0%)	11(11.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean $\pm$ SD	4.5 $\pm$ 1.11	3.88 $\pm$ 0.93	4.19 $\pm$ 1.07

Table V. Distribution of the Respondents by Visual Analogue Pain Score at 24 hrs of Operation

Visual Analogue Pain Score of at 24 hrs	Control	Bupivacaine	Total
≤ 2.0	17(34.0%)	26 (52.0%)	43(43.0%)
2.0 - 3.0	16 (32.0%)	22(44.0%)	38(38.0%)
3.0 - 4.0	15(30.0%)	2(4.0%)	17(17.0%)
>4.0	2(4.0%)	0 (0%)	2(2.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean $\pm$ SD	2.66 $\pm$ 0.94	2.08 $\pm$ 0.66	2.37 $\pm$ 0.86

Table VI. Distribution of the Respondents by Visual Analogue Pain Score at Discharge

Visual Analogue Pain Score at Discharge	Control	Bupivacaine	Total
≤ 1.0	10(20.0%)	17(34.0%)	27(27.0%)
1.0 - 1.5	12(24.0%)	17(34.0%)	29(29.0%)
1.5 - 2.0	12(24.0%)	16(32.0%)	28(28.0%)
>2.0	16(32.0%)	0(0%)	16(16.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean ± SD	1.70 ± 0.54	1.30 ± 0.38	1.50 ± 0.51

Table VII. Distribution of the Respondents by Visual Analogue Pain Score at 1 week of Operation

Visual Analogue Score at 1 week	Control	Bupivacaine	Total
≤0.3	0(0%)	10(20.0%)	10(10.0%)
0.4 - 0.5	15(30.0%)	20(40.0%)	35(35.0%)
0.6 - 0.7	14(28.0%)	20 (40.0%)	34(34.0%)
≥0.8	21(42.0%)	0(0%)	21.0%
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean ± SD	0.69 ± 0.20	0.50 ± 0.14	0.60 ± 0.20

Table VIII. Distribution of the Respondents by Total doses of analgesic required

Total doses of analgesic required	Control	Bupivacaine	Total
≤8	0(0%)	17(34.0%)	17(17.0%)
9-10	10(20.0%)	33(66.0%)	43(43.0%)
11 - 12	20(40.0%)	0(.0%)	20(20.0%)
>13	20(40.0%)	0(0%)	20(20.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean ± SD	12.00 ± 1.42	9.00 ± 0.83	10.50 ± 1.90

Table IX. Distribution of the Respondents by Day on which post operative pain in the Respondent was completely gone

Day on which post operative pain was completely gone	Control	Bupivacaine	Total
≤4	0(0%)	17(34.0%)	17(17.0%)
4 - 5	17(34.0%)	17(34.0%)	34(34.0%)
5 - 6	16(32.0%)	16(32.0%)	32(32.0%)
>6	17(34.0%)	0(0%)	17(17.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean ± SD	6.00 ± 0.83	4.98 ± 0.82	5.49 ± 0.97

Table X. Distribution of the Respondents by Day on which the Respondent returned to normal activity

Day on which the Respondent returned to normal activity	Control	Bupivacaine	Total
≤2	0(0%)	17(34.0%)	17(17.0%)
2 - 3	17(34.0%)	17(34.0%)	34(34.0%)
3 - 4	17(34.0%)	16(32.0%)	33(33.0%)
>4	16(32.0%)	0(0%)	16(16.0%)
Total	50(100.0%)	50(100.0%)	100(100.0%)
Mean ± SD	3.98 ± 0.82	2.98 ± 0.82	3.48 ± 0.96

Discussion

Although Minimal Invasive Surgery is characterized by reduced pain, it is not painless. Patients undergoing laparoscopic cholecystectomy suffer considerable pain on the day of surgery frequently requiring narcotic analgesics. 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.

Controversy exists about the principal source of pain after laparoscopic procedure. Some clinicians maintain that placement of trocars through the abdominal wall is the primary source; whereas others believe that most pain arises from intraperitoneal dissection and insufflations of CO₂ resulting in distension of abdominal wall and prolonged elevation of diaphragm.

Early pain after laparoscopic cholecystectomy is a complex process and includes different pain components secondary to different pain mechanisms, such as surgical trauma to the abdominal wall, intra-abdominal trauma secondary to the gall bladder removal, abdominal distention, pneumoperitoneum using carbon dioxide etc. Optimally, therefore pain should be treated multimodally.¹⁶ We therefore studied the effect of combined somato-visceral (intraperitoneal and port site) instillation of local anesthesia for analgesia after laparoscopic cholecystectomy.

This study was undertaken to find out the effect of bupivacaine in post operative pain following laparoscopic cholecystectomy. The study under consideration involved two groups of patients undergoing elective laparoscopic cholecystectomy but one group received local anesthetic agent bupivacaine

at their port sites after operation (the bupivacaine group) but the other group did not (the control group). All the patients were followed up at 4 hours, 12 hours, 24 hours, discharge and at the end of one week of operation for post operative pain using visual analogue pain score. Data were also collected for time required for the need of first dose of analgesic, total duration of pain requiring analgesia, 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) 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], at discharge 1.70 (±0.54) and 1.30 (±0.38) respectively [p value-0.000] and, at the end one week of operation were 0.69 (±0.20) and 0.50 (±0.14) respectively [p value-0.000]. The mean (± SD) time required for the first dose analgesic following operation was 4.8 (±0.68) for the control group and 7.0 (±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 pain [p value-0.000]. The day on which the post operative pain was completely disappeared were 6.00(±0.83) for the control group and 4.98(±0.82) for the control group [p value-0.000]. The respondents of the control group returned to their normal day to day activities on 3.98 (±0.82) but the bupivacaine group on 2.98(±0.82) [p value-0.000]. The mean (± SD) post operative day when the respondents returned to their usual activity and work were 6.98(±0.82) for control group and 6.46 (±0.97) for the

bupivacaine group [p value-0.008]. The average duration of hospital stay for control group was 2.26 (± 0.78) days and for bupivacaine group was 2.22 (± 0.62) days [p value-0.371].

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, 24 hours and even at the time of discharge and at the end of one week of operation than who were not infiltrated. The study also showed that patients who received local anesthetics at the port sites had longer delay 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 anesthesia at the end of surgery than among those who did not. The study showed no statistically significant difference between the two groups in term of duration of hospital though the average duration of hospital stay was higher in the control group than the bupivacaine group.

In our study, over all pain (incisional & visceral) is reduced. In previous randomized control trial studies where, incisional local anesthetics were used for analgesia Alexander et al¹⁷ and Sarac et al¹⁸ found reduction in the intensity of pain and opioid requirement whereas Ure et al²¹ did not found pain to be reduced, when local anesthetics were infiltrated into the abdominal wall. This difference may be due to study in different ethnic group. Out of 10 Randomized placebo-controlled studies to check the effectiveness of intraperitoneal local anesthetics, five reported reduced overall pain after intraperitoneal instillation of local anesthetics in patient undergoing laparoscopic cholecystectomy. Our study showed modest overall analgesic effect whereas there was a statistically significant difference during the first 6 hours. Cuniffe et al¹⁵ showed a significant decrease in shoulder tip pain after intraperitoneal bupivacaine out of 8 RCT that was reviewed. Our present study did not show any significant reduction in shoulder tip pain and it was consistent with the findings of Chundrigar et al and Szem et al.^{11, 20}

Bisgaard et al¹⁹ examined the effect of combined multiregional incisional and intra-

peritoneal local anesthetic blockade in a RCT. Our study showed a significant difference in pain intensity in the early postoperative period.

Bisgaard et al showed a significant reduction in overall pain and narcotic requirements, however there was no significant effect on shoulder tip pain found in our present study.¹⁹

We found a large variation in pain scores at each of the assessment times. Aside from individual difference in pain perception, several other patient and technical factors may have affected the scores. Despite the large variation in the pain scores, we did detect differences in mean pain scores between the bupivacaine and control group during the 6 hours and 12 hours postoperative assessment but only Mean scores at 6 hours and 12 hours was found to be statistically significant.

As the efficacy of the local anesthetic suspended for the period of 6-8 hours, we expected effect of the local anesthetic to wear off after the period, there was no increase in the pain score at the 3rd pain assessment at 24 hours postoperatively in the patients who received bupivacaine.

For the control group pain scores peaked immediately and was maximum during the first 6-8 hours after the surgical procedure and thereafter declined to the level comparable to that for the bupivacaine group by the third assessment at 24 hours postoperatively.

We did find an appreciable difference in total narcotic requirement between the control and bupivacaine group and this was consistent with the findings that of Bisgaard et al¹⁹ in a randomized control study. If laparoscopic cholecystectomy is to be a routine ambulatory surgical procedure, the pain experienced by the patients during early postoperative period must be addressed.

Our study showed that Infiltration of bupivacaine into the port site and intraperitoneal instillation diminishes the peak of pain occurring during the first 6 hours after the surgical procedure and significantly reduces the need for narcotic analgesics. In open abdominal procedures, incisional local anesthetics are most promising after small procedures, such as hernia repair. However, in a recent trial of a large - dose, somato- visceral, local anesthetic block after laparoscopic cholecystectomy, incisional pain not intra abdominal or shoulder pain, was reduced and incisional pain dominated in the control group were obtained.

Any reduction in such pain is relevant, particularly if it is statistically significant, whether the lower pain score translated into increased patients comfort and compliance is questionable. However, at whatever level they functioned they did so more comfortably.

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