Role of intraperitoneal bupivacaine in laparoscopic cholecystectomy

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DOI: https://doi.org/10.33545/surgery.2020.v4.i1g.368

Abstract
Objective: To compare the mean pain score through Visual Analogue Scale in patients undergoing laparoscopic cholecystectomy with and without intraperitoneal bupivacaine.

Study design: Randomized controlled trial.

Place and duration of study: General surgery department, Dr. Baba Saheb Ambedkar Medical College and Hospital, New Delhi, India

Methodology: Total ninety eight patients were selected for the study. Patients were admitted through OPD. Two were exempted from the study. Both groups had 49 patients. Group A patients received 20 ml of 0.5% of intraperitoneal bupivacaine while Group B patients did not receive intraperitoneal bupivacaine. The anesthetic technique was standardized for the two groups. The degree of postoperative pain was assessed using Visual Analogue Scale at 4,8,12 and 24 hours after the surgery. The results were analyzed on SPSS version 18.

Results: The mean pain scores were lower in group A than in group B at rest. Consumption of analgesics was also lower in patients of group A(28%) while it was 71% in patients of group B. The incidence of abdominal pain was significantly lower in patients receiving intraperitoneal bupivacaine. Mean VAS pain scores from 4-24 hrs postoperatively of group A was 0.90± 0.51 with 95% confidence interval while in group B it was 0.96±0.90 with 95% confidence interval.

Conclusion: Instillation of 20 ml of 0.5% of intraperitoneal bupivacaine after removal of gall bladder in laparoscopic cholecystectomy offers good analgesia.

Keywords: Analgesia, bupivacaine, laparoscopic cholecystectomy, postoperative pain

Introduction
Laparoscopy has been in practice for more than eight years. Although the equipments are expensive, but due to less hospital stay and cosmetic results, laparoscopic cholecystectomy has gained popularity among public [1]. Administration of intraperitoneal local anesthetic (LA), either during or after surgery, is used by many surgeons as a method of reducing postoperative pain. This technique was first evaluated in patients undergoing gynecological laparoscopic surgery. Its application in laparoscopic cholecystectomy was initially examined in a randomized trial in 1993 [2].

Bupivacaine is a local anaesthetic and is used to control postoperative pain after laparoscopic procedures. In many studies 0.125% to 0.5% bupivacaine is used intraperitoneally [3] or in the wound 1 but with conflicting result. While in others, the use of intraperitoneal bupivacaine is found safe and effective. Technique for relieving postoperative pain control and is easy to perform in patients undergoing laparoscopic cholecystectomy [1, 4, 5, 6, 7, 8].

This study was conducted to see the efficacy of instillation of intraperitoneal bupivacaine after removal of gall bladder fossa for post operative pain relief after laparoscopic cholecystectomy and then to apply the same for the future laparoscopic cholecystectomies.

Methodology
The study was conducted in General surgery ward Dr. Baba Saheb Ambedkar Medical College and Hospital, New Delhi from March 2017 till June 2017 for a period of three months.

Sampling technique is non probability purposive. After the approval of local ethical committee 98 patients were picked up from the out patient department of Surgical Unit I (Ward 3) Dr. Baba Saheb Ambedkar Medical College and Hospital, New Delhi. Written and informed consent was taken from all patients.
The method of using VAS was explained to the patients pre-operatively. All the surgical procedures were performed by same surgical team headed by a consultant with at least 4 years post graduation experience. General anaesthesia was given to all the patients. Second generation cephalosporins (cefuroxime) 1.5 g was injected i.v. before the induction of anaesthesia. Laparoscopic cholecystectomy was completed with the standard four port technique and carbon dioxide pneumoperitoneum.

After removal of gall bladder from gall bladder fossa, 0.5% of 20 ml bupivacaine was instilled in the gall bladder fossa under direct laparoscopic control in group A patients while group B patients did not receive any such solution. Simultaneously, each patient was injected i.v. before the induction of anaesthesia. Local analgesics were also recorded. All the assessments were performed by a single observer (post graduate on duty) who was blinded to the group allocations. Data regarding mean pain score was collected through structured proforma. Data was analyzed at SPSS version 18.0. Baseline data (intensity of pain at rest) was found statistically non-significant. Weight (kgs) among two groups was found statistically non-significant (P=0.91).

In Group A mean weight was 54.96±7.81 kgs. It was 43.18±14.01, 49 patients did not receive any such solution.

After removal of gall bladder from gall bladder fossa, 0.5% of 20 ml bupivacaine was instilled in the gall bladder fossa under direct laparoscopic control in group A patients while group B patients did not receive any such solution. Simultaneously, each patient was injected i.v. before the induction of anaesthesia. Local analgesics were also recorded. All the assessments were performed by a single observer (post graduate on duty) who was blinded to the group allocations. Data regarding mean pain score was collected through structured proforma. Data was analyzed at SPSS version 18.0. Baseline data (intensity of pain at rest) was found statistically non-significant. Weight (kgs) among two groups was found statistically non-significant (P=0.91).

The consumption of analgesics were also recorded. The difference of analgesics was also recorded. All the assessments were performed by a single observer (post graduate on duty) who was blinded to the group allocations. Data regarding mean pain score was collected through structured proforma. Data was analyzed at SPSS version 18.0. Baseline data (intensity of pain at rest) was found statistically non-significant. Weight (kgs) among two groups was found statistically non-significant (P=0.91).

Among two groups showed less intensity of pain with time duration as compared to Group B. The results were concluded statistically significant with p-value less than 0.05 (P<0.05).

**Results**

A total of ninety eight patients planned for elective cholecystectomy were included in this study divided in two groups. All are adult males and females. The gender distribution among two groups showed non-significant difference. The difference of analgesics was also recorded. All the assessments were performed by a single observer (post graduate on duty) who was blinded to the group allocations. Data regarding mean pain score was collected through structured proforma. Data was analyzed at SPSS version 18.0. Baseline data (intensity of pain at rest) was found statistically non-significant. Weight (kgs) among two groups was found statistically non-significant (P=0.91).

ASA Status I were more frequent in both groups as compared to Status II. Status I were 29 (59.2%) whereas Status II were 20 (40.8%) in Group A. In Group B ASA Status I were 34 (69.4%) and Status II was 15 (30.6%). There is no statistical difference in frequency distribution of two groups in ASA status. (Fishers Exact Test=0.40, P=0.25). Visual Analogue Score (VAS) showed significant change, on the average at 4 hours, showed 12 hours and 24 hours between the two groups (P=0.001). Group A showed less intensity of pain with time duration as compared to Group B. Table: 1, 2, 3.

| Statistics | Group | n | Mean | SD | t-Value | p-Value |
|------------|-------|---|------|----|---------|---------|
| VAS’ at 4 hrs | Group A | 49 | 2.02 | 4.57 | 14.29 | 0.001** |
| VAS at 8 hrs | Group A | 49 | 1.22 | 3.31 | 15.31 | 0.001** |
| VAS at 12 hrs | Group A | 49 | 0.82 | 2.76 | 17.05 | 0.001** |
| VAS at 24 hrs | Group A | 49 | 0.33 | 2.37 | 13.97 | 0.001** |

*Visual Analogue Scale; **Highly significant; n.s: Non significant

### Table 2: Changes in Visual Analogue Scale in Two Groups with Duration - Group B

| Statistics | Group | n | Mean | SD | t-Value | p-Value |
|------------|-------|---|------|----|---------|---------|
| VAS’ at 4 hrs | Group A | 49 | 2.02 | 4.57 | 14.29 | 0.001** |
| VAS at 8 hrs | Group A | 49 | 1.22 | 3.31 | 15.31 | 0.001** |
| VAS at 12 hrs | Group A | 49 | 0.82 | 2.76 | 17.05 | 0.001** |
| VAS at 24 hrs | Group A | 49 | 0.33 | 2.37 | 13.97 | 0.001** |

*Visual Analogue Scale; **Highly significant; n.s: Non significant

**Discussion**

Although minimally invasive surgery is characterized by reduced pain, it is not pain less. Patients undergoing laparoscopic cholecystectomy suffered considerable pain on the day of surgery frequently requiring narcotic analgesics. Local infiltration of analgesia had been used successfully in combination with General anaesthesia or in combination with general anaesthesia for breast surgery, facial cosmetic operations and body contouring procedures.
In the early post operative period visceral pain accounts for the most of the pain experienced after laparoscopic cholecystectomy [9].

Local anesthetics induced anti nociception by acting on the nerve membranes. These analgesics interventions need to produce a sufficiently dense and long duration of blockade for them to block the transmission of noxious afferent information from the periphery to the spinal cord and brain [10]. There is little evidence with regard to which type of LA is most effective because limited data are available for drugs other than bupivacaine. Bupivacaine itself (or levobupivacaine) is an excellent choice for intraperitoneal LA because of its long duration of action [11].

The originality of this trial was the instillation of 0.5% of 20 ml bupivacaine intraperitoneally only after removal of gall bladder. We didn’t apply trocar site or inscissional local anesthetics because many studies did not support port site local anesthetic infiltration of wound [12,13].

Clinical studies of intraperitoneal bupivacaine had inconsistent results. Few authors have found a statistically significant difference with the use of local anesthetics [12, 8, 11, 14, 15, 16], others could not repeat these results [9, 17, 18]. Furthermore in a few studies that have found a statistically significant difference with the use of bupivacaine, the difference between the average pain scores was less than 1 in a scale of [10,14,16].

In our study, we found that the patients receiving 0.5% of 20 ml of bupivacaine intraperitoneally had decreased mean pain score at 24 hours post surgery and they have also decreased analgesics consumption. The mean dose of local anesthetic used in our study i.e bupivacaine was well tolerated and had no side effects.

To evaluate the nature of pain after LC, the control group, using no local anesthetics, was assessed. Although the median VAS pain scores were low in our study, incisional pain still dominated over visceral pain. These findings were confirmed by Ure et al., [19] but opposed by Joris et al., [9] who found that intraabdominal pain dominated. Interestingly, we found that the median visceral VAS pain scores of these studies and our results were similar. The median visceral VAS scores of these studies were usually below [3].

We thought these pain scores were within the tolerable range. Our low visceral VAS scores may, in part, explain the lack of demonstrable effects of the combined somato visceral or visceral regimen on the visceral pain.

Our findings were also in contradiction with those of Pasqualucci et al. [20] who found that an intra abdominal regimen (0.5% bupivacaine 20 mL) reduced postoperative pain and analgesic requirement if the treatment was administered before surgery.

Bisgaard et al. [21] and Ure et al [19] have suggested that parietal pain is the predominant cause of pain. By contrast, my data as well as others’ [9, 13] indicate that visceral pain is the main cause of pain. Bisgaard et al [21] recommended parietal infiltration rather than intraperitoneal injection.

Therefore, we believe that intraperitoneal instillation of 0.5% bupivacaine after the removal of gall bladder is recommended as its decreases the incidence of abdominal pain for the first 24 hours. Taking into consideration the present study, we concluded that the use of intraperitoneal 0.5% bupivacaine in the dosage mentioned above is safe and effective technique for controlling pain and easy to perform in patients undergoing laparoscopic cholecystectomy.

Conclusion

Visceral pain is prominent after laparoscopic cholecystectomy and can be effectively controlled by instillation of 0.5% of 20 ml of bupivacaine at the gall bladder fossa after removing gall bladder in laparoscopic cholecystectomy.

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