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Original Research Article

Effect of intra-peritoneal instillation of bupivacaine in laparoscopic cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is a minimally invasive surgical procedure for removal of a diseased gall bladder. This technique essentially has replaced the open technique for routine cholecystectomies since the early 1990s. Laparoscopic cholecystectomy has become the gold standard for cholecystectomy in the past decade. Most patients are being discharged on the first or second post-operative day. The aim of the study was to evaluate effect of instillation of intra-peritoneal bupivacaine for pain relief in laparoscopic cholecystectomy. The primary outcome is to evaluate pain scores after this procedure.
Methods: It's an institutional based, observational and randomised control study was conducted in a patients undergoing laparocopic cholecystectomy with gall bladder disease in KPCMCH between 18-70 years of age. The study period was 12 months (from June 2021 to May 2022). 100 patients were included in this study.
Results: Our study showed that, less number of patients had right shoulder tip pain (in Numerical rating scale) and requirement of rescue analgesia in case compared to control group.
Conclusions: We concluded that instillation of intra-peritoneal bupivacaine reduces pain scores after difficult laparoscopic cholecystectomy.

Keywords: Bupivacaine, Irrigation, Laparoscopic cholecystectomy, Post-operative pain

INTRODUCTION

Laparoscopic cholecystectomy is a minimally invasive surgical procedure for removal of a diseased gall bladder.[1-3] This technique essentially has replaced the open technique for routine cholecystectomies since the early 1990s.

Laparoscopic cholecystectomy has become the gold standard for cholecystectomy in the past decade.[4] Most patients are being discharged on the first or second postoperative day. At times laparoscopic cholecystectomy becomes difficult. It takes longer time even with bile/stone spillage and occasionally it requires conversion to open cholecystectomy.[5] However pain, nausea and vomiting after difficult laparoscopic cholecystectomy may occur from visceral manipulation and may be severe enough to prevent early discharge from hospital. Systemic use of analgesics for post-operative pain relief has become a popular practice in many surgical procedures and in laparocopic procedures as well. But excessive use of analgesics especially opiods can again lead to nausea and vomiting.[6] Against this background, a clinical study is conducted to evaluate the efficacy of intra-peritoneal bupivacaine instillation in laparoscopic cholecystectomy patients to overcome post-operative pain, nausea, vomiting and reduced need of parenteral analgesics.[7,8]

METHODS

Study area

The study area was KPC Medical College and Hospital.

Inclusion criteria

All patients undergoing only laparoscopic cholecystectomy at KPCMCH between 18-70 years age group with preoperative scoring assessment of difficulty.

Study population

Patients undergoing laparocopic cholecystectomy with gall bladder disease in KPCMCH between 18-70 years of age.

Study period

The study period was 12 months (from June 2021 to May 2022).

Study design

It was institution based, observational; and randomised control study.

Sample size

100 patients with preoperative difficulty scoring.

Case and control group

100 patients following inclusion criteria are randomised into 2 groups based on simple randomisation sampling with the help of random number table so that each and every study subject get equal chance of being selected either in case or control group: (a) group 1 (case group)= 50 patients received intraperitoneal bupivacaine; group 2 (control group)= 50 patients not received intraperitoneal bupivacaine.

Exclusion criteria

Patients excluded were those who were below 18 years, above 70 years, undergoing easy laparoscopic cholecystectomy according to scoring system, not giving consent for study, the cases of LC conversion to open cholecystectomy due to equipment failure or any other unsurmountable operative difficulty, undergoing ancillary surgery (exploration of CBD, appendicectomy, other concomitant abdominal problems etc) along with laparoscopic cholecystectomy, and those declared unfit for pneumoperitoneum by anaesthesiologist due to comorbidities. All the cases of laparoscopic cholecystectomy, coming under inclusion criteria is included in this study. Then 100 patients were randomised into 2 groups.

Group A (50 patients) received intraperitoneal bupivacaine (10 ml of 0.5% bupivacaine instilled intra-peritoneally in hepatodiaphragmatic space, gall bladder fossa and hepatoduodenal ligament) and group B (50 patients) not (control group) after removal of gall bladder. Surgery was done using CO_2 pneumoperitoneum with 10-12 mmHg pressure and using standard two 10 mm and two 5 mm ports. The timing was noted from the first port site incision till the last ports closure. All the post-operative events of difficult laparoscopic cholecystectomy patients were recorded after till 24 hours of surgery and studied in terms of pain score (according to Numerical rating scale), nausea, vomiting, post-operative analgesic requirement, early ambulation and drainage output and they received standard postoperative care and follow up such as IV fluid, parenteral analgesics (NSAIDS or COX 2 inhibitors) or injection paracetamol, injection PPI for 24 hours and Parenteral Antibiotic upto discharge from hospital.[9-11]

Ethical consideration

Ethical committee approval was taken from the concerned authorities.

RESULTS

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. A total of 100 patients were randomly allocated into two equal groups: group 1 received 10 ml intraperitoneal bupivacaine instillation and group 2 received 10 ml normal saline instillation. Patients with failed technique (dropped out) owing to technical problems (4 in group 1 and 2 in group 2) did not complete the study. Therefore, 46 patients in group 1 and 48 patients in group 2 were included. There was no significant difference between the demographic data including age and weight (Table 1). There was no significant difference in HR mean value between both groups throughout the perioperative period. There was no significant difference in MAP between both groups throughout the perioperative period (Table 2 and 3). The NRS mean value in group 2 was 1.17±1.27, 2.09±1.59, 4.87±2.01, 0.91±1.41, 1.52±1.73, and 1.78±1.59 at time 0, 2, 6, 12, 18, and 24 h, respectively. There was significant increase in VAS at 6 h post-operatively compared with pre-operative mean value (P=0.001). In group 1, NRS mean value was 0.79±0.72, 1.46±1.28, 1.58±1.21, 4.50±2.17, 1.29±1.60, and 1.50±1.25 at pre-operative, 2, 6, 12, 18, and 24 h, respectively. There was significant increase in NRS at 12 h compared with pre-operative mean value (p=0.001) (Table 4). There was significant increase in group 2 regarding the amount of rescue analgesia of diclofenac needed (p=0.001). Total diclofenac consumption in group 2 was 90 mg, with a mean value of 3.91±1.41 mg, whereas in group 1, it was 57 mg, with a mean value of 2.38±1.53 mg. A significantly higher number of patients in group 2 required rescue analgesia, with 46 (100%) patients, compared with only 12 (25%) patients in group 1 (p=0.001) (Table 5). The recovery from anesthesia, in terms of ambulation after surgery, was significantly faster for the patients in the 1st group than those in the 2nd group. Recovery from anesthesia was significantly faster (p value<0.05) for patients in the 1st group than those in the 2nd group (Table 6).

Table 1: Patients characteristics in the studied groups.

Characters	Range	Mean±SD	t test or X^2	P value
Age (years)				
Group 1	22-62	38.7±10.9	0.478	0.634
Group 2	22-55	37.4±9.06		
Weight (kg)				
Group 1	60-99	76.4±11.19	1.160	0.252
Group 2	65-100	79.84±9.72		
Duration (min)				
Group 1	65-120	94.8±12.69	0.854	0.841
Group 2	60-119	95.83±13.62		

Table 2: Comparison of heart rate changes in the studied groups (beats/min).

Heart rate changes	Range	Mean±SD	t test	P value
HR (baseline)				
Group 1	67-90	80.44±6.91	1.365	0.248
Group 2	65-91	78.04±7.60		
HR (5 min)				
Group 1	67-93	81.40±7.30	0.192	0.663
Group 2	70-90	80.52±6.90		
HR (30 min)				
Group 1	70-89	80.39±5.71	2.028	0.161
Group 2	67-89	77.79±6.74		
HR (60 min)				
Group 1	67-90	81.26±6.70	3.451	0.07
Group 2	65-90	77.50±7.16		
HR (90 min)				
Group 1	65-90	80.96±6.71	1.984	0.166
Group 2	65-90	78.08±7.25		
HR (120 min)				
Group 1	67-92	81.61±6.31	3.888	0.055
Group 2	67-91	77.63±7.46		

Note: HR- Heart rate.

Table 3: Comparison of mean arterial blood pressure changes in the studied groups (mmHg).

Mean arterial BP changes	Range	Mean±SD	t test	P value
MAP (baseline)				
Group 1	79-101	88.88±5.87	0.698	0.408
Group 2	73-110	90.56±8.17		
MAP (5 min)				
Group 1	67-103	86.96±6.97	0.080	0.779
Group 2	67-106	86.28±9.80		
MAP (30 min)				
Group 1	75-96	86.57±5.03	0.076	0.785
Group 2	74-99	87.08±7.58		
MAP (60 min)				
Group 1	78-97	86.96±5.22	0.054	0.817
Group 2	76-98	87.33±5.86		
MAP (90 min)				
Group 1	79-97	87.04±4.74	0.194	0.662
Group 2	75-104	87.83±7.23		
MAP (120 min)				
Group 1	66-95	86.09±5.87	1.230	0.273
Group 2	72-106	88.17±6.92		

Note: MAP- Mean arterial pressure.

Table 4: Numerical rating scale in the studied groups.

NRS	Range	Mean±SD	t test	P value
NRS (T_0)				
Group 1	0-2	0.79±0.72	1.634	0.208
Group 2	0-4	1.17±0.72		
NRS (2 hr)				
Group 1	0-4	1.46±1.28	2.227	0.143
Group 2	0-6	2.09±1.59		
NRS (6 hr)				
Group 1	0-6	1.58±1.21	46.614	0.001
Group 2	0-7	4.87±2.01		
NRS (12 hr)				
Group 1	0-7	4.50±2.17	44.778	0.001
Group 2	0-5	0.91±1.41		
NRS (18 hr)				
Group 1	0-6	1.29±1.60	0.224	0.638
Group 2	0-5	1.52±1.73		
NRS (24 hr)				
Group 1	0-4	1.50±1.25	0.459	0.201
Group 2	0-5	1.46±1.28		

Note: NRS- Numerical rating scale.

Table 5: The need for rescue analgesia in the studied groups.

Study group	Group 1 (N=48)	Group 2 (N=46)	t test	P value
Amount of rescue analgesia (mean±SD) (mg)	2.38±1.53	3.91±1.41	12.829	0.001
Patients who received rescue analgesics [N (%)]	12 (25)	46 (100)	6.591	0.001

Table 6: Mean time taken for ambulation.

Mean time (in hours)	Group 1 (N=48)	Group 2 (N=46)	P value
	6.4	12.8	0.001

DISCUSSION

Patients receiving intra-peritoneal instillation of bupivacaine showed a significant relief of postoperative pain as indicated by the lower values of NRS and the significantly lower need for postoperative rescue analgesia.

It is because of the local effects of bupivacaine. Bupivacaine is an anilide compound which inhibits NMDA receptor mediated synaptic transmission in the dorsal horn of the spinal cord.[12] In the present study, post-operative right shoulder tip pain was recorded at 12, 24 and 48 hours after operation by using NRS and was slightly lower in study group. These results were comparable to other studies conducted by Kumari A et al who explained that intra-peritoneal instillation of local anaesthetics has been shown to minimise post-operative pain after laparoscopic surgery.[13]

In this study, the recovery from anesthesia, in terms of ambulation after surgery, was significantly faster for the patients in the 1st group than those in the 2nd group very comparable to the study of Liang et al.[14]

In this study, amount of rescue analgesia requirement was much less in study group than control group which was comparable with the studies conducted by Sharan et al.[15]

Limitations

The sample size was small. Only 100 cases are not sufficient for this kind of study. The study has been done in a single centre. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out. Ongoing COVID 19 pandemic and lockdown has further hampered the study.

CONCLUSION

According to this study intraperitoneal Bupivacaine instillation is a simple, safe and effective technique to prevent post-operative shoulder tip pain and requirement of rescue analgesia which can be easily learned and should be more widely used in laparoscopic cholecystectomy.

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REFERENCES

1. NIH. Gallstones and Laparoscopic Cholecystectomy. NIH Consens Statement Online. 1992;10(3):1-20.
2. Nakayama DK. The minimally invasive operations that transformed surgery. NC: Chapel Hill; 2017.
3. Stinton LM, Shaffer EA. Epidemiology of gallbladder disease: cholelithiasis and cancer. Gut Liver. 2012;6(2):172-87.
4. Lo CM, Liu CL, Lai EC, Fan ST, Wong J. Early versus delayed laparoscopic cholecystectomy for treatment of acute cholecystitis. Ann Surg. 1996;223(1):37-42.
5. Polychronidis A, Laftsidis P, Bounovas A, Simopoulos C. Twenty years of laparoscopic cholecystectomy: Philippe Mouret--March 17, 1987. JSLS. 2008;12(1):109-11.
6. Rosenblum A, Marsch LA, Joseph H, Portenoy RK. Opioids and the treatment of chronic pain: controversies, current status, and future directions. Exp Clin Psychopharmacol. 2008;16(5):405-16.
7. Barash P. Clinical Anesthesia. 8th ed. Philadelphia, PA: Wolters Kluwer; 2017: 3159.
8. Suma S, Suresh V, Nikhil M, Sreeramulu P. Intra-Peritoneal Bupivacaine Instillation for Post-Operative Pain Relief after Laparoscopic Cholecystectomy. 2019.
9. Zmora O, Stolik-Dollberg O, Bar-Zakai B, Rosin D, Kuriansky J, Shabtai M, et al. Intraperitoneal bupivacaine does not attenuate pain following laparoscopic cholecystectomy. JSLS. 2000;4(4):301-4.
10. Rademaker BM, Kalkman CJ, Odoom JA, Wit L, Ringers J. Intraperitoneal local anaesthetics after laparoscopic cholecystectomy: effects on postoperative pain, metabolic responses and lung function. Br J Anaesth. 1994;72(3):263-6.
11. Joris J, Thiry E, Paris P, Weerts J, Lamy M. Pain after laparoscopic cholecystectomy: characteristics and effect of intraperitoneal bupivacaine. Anesth Analg. 1995;81(2):379-84.
12. Tripathi KD. Local Anaesthetics. Essentials of Medical Pharmacology. India: Jaypee Brothers Medical Publisher; 2015.
13. Kumari A, Acharya B, Ghimire B, Shrestha A. Post-operative analgesic effect of intraperitoneal ropivacaine with or without tramadol in laparoscopic cholecystectomy. Indian J Anaesth. 2020;64(1):43-8.
14. Liang M, Chen Y, Zhu W, Zhou D. Efficacy and safety of different doses of ropivacaine for laparoscopy-assisted infiltration analgesia in patients undergoing laparoscopic cholecystectomy: A prospective randomized control trial. Medicine (Baltimore). 2020;99(46):e22540.
15. Sharan R, Singh M, Kataria AP, Jyoti K, Jarewal V, Kadian R. Intraperitoneal Instillation of Bupivacaine and Ropivacaine for Postoperative Analgesia in Laparoscopic Cholecystectomy. Anesth Essays Res. 2018;12(2):377-80.

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