Surgery

A PROSPECTIVE RANDOMISED CONTROLLED STUDY FOR EVALUATION OF INTRAPERITONEAL BUPIVACAINE INSTILLATION FOR POST CHOLECYSTECTOMY ANALGESIA

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ABSTRACT

Background: Intraperitoneal instillation of local anesthetic agents in laparoscopic cholecystectomy (LC) has been used to reduce postoperative pain and to decrease the need for postoperative analgesia.

Aims: This study aimed to evaluate the effectiveness of intraperitoneal instillation of bupivacaine (0.25%) for post operative analgesia in LC.

Settings And Design: This was a prospective, randomized, single-blind study.

Materials And Methods: After obtaining ethical committee's clearance and informed consent, 204 patients, aged 18–80 years, of either gender, and scheduled for LC were included and categorized into two groups (n = 102). Group A patients received 20 mL of 0.25% bupivacaine intraperitoneally, as well as at trocar site, after cholecystectomy, and Group B patients received the drug only at trocar site.

Statistical Analysis: The data were analyzed using paired t-test. The results were analyzed and compared to previous studies. SPSS software version 22 was used, released 2013 (IBM Corp., Armonk, NY, USA).

Results: The Numerical Rating Scale (NRS) score was significantly lower in Group A for the first 8 hours post operatively. Rescue analgesia was given when NRS was more than or 5. Rescue analgesic requirement was also less in Group A for the first 8 hours.

Conclusion: The instillation of bupivacaine intraperitoneally is an effective method of postoperative pain relief in LC. It provided good analgesia in the early postoperative period. Requirement of rescue analgesics was also decreased.

KEYWORDS : Bupivacaine, intraperitoneal, laparoscopic cholecystectomy, postoperative analgesia.

INTRODUCTION

Laparoscopic cholecystectomy has become the surgical procedure of choice for symptomatic cholelithiasis due to the improved postoperative course. However, pain is a common post-operative complaint of patients undergoing laparoscopic cholecystectomy during the first 24 hours.

In abdominal surgeries, the cause of pain is either somatic or visceral. Somatic pain is due to skin incision and the visceral pain is due to handling of the intestine and peritoneal inflammation. During open surgeries, both somatic and visceral pain is present which may not be tolerable to a patient without adequate analgesia. In Laparoscopic surgeries somatic pain is very less due to a small skin incision. But visceral pain is more prominent due to visceral nociceptor stimulation.

Visceral pain may occur due to rapid distension of peritoneum, intraperitoneal inflammation, traction of nerves and vessels, diaphragmatic irritation (shoulder tip pain).

Post laparoscopic pain can be minimized by following ways:

- creating the pneumoperitoneum slowly,
- keeping gas drain,
- using low pressure and heated gas,
- instillation of local anaesthetics under the diaphragm,
- rectus sheath block,
- surgery under subarachnoid block,
- peri-operative NSAID'S and opioids.

The use of intraperitoneal local anaesthesia is a simple and safe method of providing post operative analgesia.

This study was performed to evaluate the effectiveness of intraperitoneal instillation of bupivacaine for post operative analgesia after laparoscopic cholecystectomy.

MATERIALS AND METHODS:

The study was conducted in the Department of General Surgery, GSVM Medical College and Associate LLR Hospitals, Kanpur, India. Written and informed consent was obtained after due counselling.

Patients were familiarised with the Numerical Rating Scale (NRS), where 0 represented no pain and 10 represented maximum possible pain.

204 patients were randomised into two groups, based on systematic randomization (102 each). The effect of 20 ml of intraperitoneal bupivacaine (0.25%) instillation done intra-operatively at gall bladder fossa after removal of gall bladder during laparoscopic cholecystectomy was compared with control patients receiving no such intervention. Both groups were infiltrated with 0.25% bupivacaine at the port sites.

Study was performed after clearance from the Institutional Ethical Committee, based on its guidelines.

Inclusion Criteria-

Consenting patients between the age of 18 – 80 years age with symptomatic gallstone disease posted for standard 4 port laparoscopic cholecystectomy under general anaesthesia.

Exclusion Criteria-

Patients with allergy to bupivacaine, pregnant patients, patients with Acute Pancreatitis, Cholelithiasis, current opioid use; history of cardiovascular disease which required treatment, and history of chronic pain disease at any site other than that related to gallstone were excluded from the study. Cases that required conversion of laparoscopic cholecystectomy to open cholecystectomy were also excluded from the study.

General anaesthesia was induced by butorphanol 0.04 mg/kg, followed by 1.5-2.5 mg/kg propofol and 0.1 mg/kg vecuronium to facilitate tracheal intubation. Maintenance was done by propofol infusion @ 200 ug/kg/minute and injection of 0.01-0.02 mg/kg vecuronium every 15 minutes.

Vitals (pulse rate, blood pressure, respiratory rate and SpO₂) monitoring was done hourly in first 4 hours then four hourly till 24 hours of post operative period.

Post-operatively, the patients were assessed for pain using NRS pain

rating scale at 1, 2, 3, 4, 8, 12, 16, 20 and 24 hours. Total number of analgesic doses used were also assessed. First dose (rescue) analgesia was used when the pain score was above 5. The analgesic used was injection diclofenac sodium 75mg intravenously, given after test dose.

PAIN SCORE 0-10 Numerical Rating Scale (NRS)

RESULTS:

The following results were observed and statistically analyzed. In the present study, both the groups were comparable with respect to mean age and sex.

Table 1. Demographic Profile:

Demographic factors	Group A, n (%)	Group B, n (%)	p
1. Age	40.73±8.86	38.86±9.08	0.13
2. Sex			
A) Male	36 (47.37)	40 (52.63)	0.31
B) Female	70 (54.69)	58 (45.31)	

Table 2.: Trend Of Pain At Different Intervals Between Patients In Both Groups:

Ser No.	Post op hour	NRS PAIN SCORE BETWEEN 0-5				NRS PAIN SCORE MORE THAN 5			
		Group A		Group B		Group A		Group B	
		No.	%	No.	%	No.	%	No.	%
1.	1 st hour	48	47.05	32	31.37	54	52.95	70	68.62
2.	2 nd hour	64	62.75	50	49.01	38	37.25	52	50.98
3.	3 rd hour	64	62.75	55	53.92	38	37.25	57	55.88
4.	4 th hour	68	66.67	46	45.09	34	33.33	56	54.90
5.	8 th hour	65	63.72	48	47.05	37	36.27	54	52.95
6.	12 th hour	69	67.64	62	60.78	33	32.35	40	39.21
7.	16 th hour	70	68.62	65	63.72	32	31.37	37	36.27
8.	20 th hour	70	68.62	61	59.80	32	31.37	41	40.19
9.	24 th hour	86	84.31	75	73.52	16	15.69	27	26.47

Table 3.: Mean Numerical Rating Scale (NRS) Score Of Patients In Both Groups:

Serial No.	Post op hour	Group A		Group B		p value	Inference
		Mean	SD	Mean	SD		
1.	1 st hour	4.23	1.4	5.90	1.7	<.001	Significant
2.	2 nd hour	4.20	1.27	5.34	1.46	<.001	Significant
3.	3 rd hour	4.11	1.19	5.38	1.37	<.001	Significant
4.	4 th hour	3.54	1.35	5.03	1.74	<.001	Significant
5.	8 th hour	3.80	1.24	4.75	1.49	<.001	Significant
6.	12 th hour	4.20	1.10	4.51	1.33	.0712	Not Significant
7.	16 th hour	3.98	1.13	4.10	1.40	.28	Not Significant
8.	20 th hour	3.57	1.13	3.7	1.23	.43	Not Significant
9.	24 th hour	3.46	1.25	3.78	1.4	.09	Not Significant

Table 4.: Number Of Doses Of Rescue Analgesia Used:

Number of doses of Inj. Diclofenac	Group A N (%)	Group B N (%)	p value
1	32 (31.37)	14 (13.72)	0.0001
2	54 (52.94)	48 (47.05)	
3 or more	16 (15.68)	40 (39.21)	
TOTAL	102	102	

DISCUSSION:

Laparoscopic techniques have become popular recently, because of the small incision, short hospital stay and early ambulation. However, the peritoneal stretching due to the insufflation of gases results in pain postoperatively.

Various methods of providing analgesia have been tried for providing pain relief in laparoscopic surgeries. The techniques that can be used include surgery under subarachnoid block, parenteral opioids and NSAIDs, instillation of local anaesthetics intraperitoneally, etc., Surgery under subarachnoid block provided adequate analgesia both intraoperatively and postoperatively, but the level of sensory block required intraoperatively is very high (Thoracic level 4), which resulted in higher hemodynamic instability. The time for ambulation

postoperatively was also extended.

The use of parenteral opioids provided adequate analgesia, but the amount of drug required was higher, resulting in various complications such as respiratory depression, postoperative nausea vomiting, constipation and pruritis which need adequate postoperative monitoring thereby increasing the hospital stay.

Instillation of local anaesthetic solution intraperitoneally, as a mode of providing postoperative analgesia, has been studied extensively in the recent years. It also leads to early ambulation, reduced incidence of postoperative nausea and vomiting, and reduces the use of parenteral opioids and NSAIDs.

This study was done to compare the analgesic efficacy of bupivacaine instilled intraperitoneally as well as at the trochar site (GROUP A); and bupivacaine infiltrated only at the trochar site (GROUP B). Both groups were comparable with respect to demographic variables such as age and sex. They were also comparable in terms of the duration of surgery.

According to our study, number of patients with NRS score between 0-5 and more than 5 in the 2 groups, in the post operative period was studied. The number of patients with NRS score between 0-5 was more in Group A, compared to Group B for the first 8 hours post operatively.

The mean NRS pain score in Group A was less than that of Group B, which was statistically significant for the 1st 8 hours post operatively. However, beyond 8 hours there was no statistical significance between the two groups.

Tarig Chundrigar et al. (1993) in a similar study stated that there was a significant reduction in pain scores at the 1st hour (4.00 vs 1.99, P<0.01) and 2nd hour (2.53 vs 1.23, P<0.05) after laparoscopic surgery. However, at the 4th hour, and at subsequent time intervals pain scores were low in both groups and no significant difference was found.

Sanjowal, L. et al. (2020) in a study stated that the mean VAS score of Group A (bupivacaine given) was significantly less than that of the Group B (bupivacaine) at 4, 8 and 12 hours (p value 0.003, 0.009 and 0.027 respectively). But the VAS score at 24 hours showed no difference between two groups (p value 0.771).

Patients having NRS score more than 5 in both groups were given injection diclofenac sodium 75mg intravenously. The mean total doses used during first 24 hours post-operatively was less in Group A than Group B. (p=0.042).

CONCLUSION:

Post operative pain has always been a major issue in patient management for all surgeons and anaesthesiologists, because of the expanding role of ambulatory surgery and the need to facilitate an earlier hospital discharge.

Adequate post-operative pain control is an important factor in determining when a patient can be safely discharged from surgical facility, and has a major influence on the patient's ability to resume their normal activities.

In our study, it was found that there is significant reduction in post operative pain after using intraperitoneal bupivacaine along with at the trochar site, in comparison to using bupivacaine only at trochar site, for the first 8 hours after surgery. However, no significant advantage was seen after 8 hours, upto a period of 24 hours.

This study concludes that intraperitoneal instillation of local anesthetic solution in laparoscopic cholecystectomy provides an effective postoperative analgesia and thus it's routine use is advocated. However, further studies are necessary to identify other agents that can be used for the same.

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