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Comparative Study of Post-Operative Pain Relief in Laparoscopic Cholecystectomy with Intraperitoneal Instillation of 0.5% Bupivacaine with Adrenaline and Placebo

Dr. Ramesh H[1], Dr. M.R.Viswas[2*]

[1]Associate Professor, Department of General Surgery, KIMS, Hubli, Karnataka, India
[2]Postgraduate Student, Department of General Surgery, KIMS, Hubli, Karnataka, India

Original Research Article

***Corresponding author**
Dr. M. R. Viswas

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Abstract: ***Introduction:*** Laparoscopic cholecystectomy is the surgical procedure of choice for symptomatic cholelithiasis due to the improved postoperative course, but patients undergoing laparoscopic cholecystectomy during the first 24 hours postoperatively complain of pain. This study was designed to study the efficacy of intraperitoneal Bupivacaine in reducing the initial postoperative pain and nausea and vomiting. ***Aim and Objectives:*** To study the post-operative analgesic effect of 0.5% bupivacaine with adrenaline following intra-peritoneal instillation in laparoscopic cholecystectomy and to assess the need of rescue analgesics in post-operative period in both groups. ***Settings and Design:*** Randomised control study. ***Methods and Material:*** This is a randomised comparative study of 30 patients who were divided into 2 groups of 15 patients each. Patients in Group A received 20 ml of 0.5% bupivacaine with 1:200000 adrenaline instilled intraperitoneally in Gall bladder fossa & undersurface of Diaphragm and Group B received 20 ml of Normal saline. Post-operative pain was assessed using visual analogue scale (VAS) and visual rating Prince Henry scale (VRS) at 1,4,8 and 24 hours and the need of rescue analgesics. ***Results:*** Postoperative pain using VAS was lower in Group A at 1,4,8 and 24 hours and was statistically significant (p value of 0.001,0.004,0.012 and 0.007 respectively). VRS was lower in Group A at 1,4,8 and 24 hours and was only statistically significant at 1 and 4 hours postoperatively (p value of 0.005, 0.001, 0.06 and 0.08 respectively). There was significantly lower need of rescue analgesics in Group A (p value 0.001). ***Conclusion:*** Intraperitoneal bupivacaine for laparoscopic cholecystectomy reduces pain in the initial postoperative period, it is easy to administer with no adverse effects and may become a routine practice for this procedure.

Keywords: Laparoscopic Cholecystectomy, Bupivacaine, Visual Analogue scale, Cholelithiasis.

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INTRODUCTION

With the expanding role of ambulatory surgery and the need to facilitate an earlier hospital discharge, improving postoperative pain control has become an increasingly important issue for all surgeons and anaesthesiologist [1].

Adequacy of postoperative pain control is one of the most important factors 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 of daily living [2]. Control of acute postoperative pain and the timing, and duration (e.g., preemptive analgesia), is important in facilitating short and long-term patient convalescence [3].

Perioperative analgesia has traditionally been provided by opioid analgesics. However, extensive use of opioids is associated with a variety of perioperative side effects, such as ventilatory depression, drowsiness and sedation, postoperative nausea and vomiting, pruritus, urinary retention, ileus and constipation, thus can delay hospital discharge.

In addition, it has been suggested by the Joint Commission on Accreditation of Health Organizations that excessive use of postoperative opioids Analgesics leads to decreased patient satisfaction [4].

In addition the use of conventional method of administration of intramuscular opioids in standard prescribed doses, may be too large (causing side effects), or too small (causing inadequate analgesia).Therefore, anaesthesiologist and surgeons are increasingly turning to non-conventional techniques as adjuvant for managing pain during perioperative period to minimize the adverse effects of analgesic medications5.

From the non-conventional methods, the infiltration of long-acting local anaesthetics as an adjuvant for regional or local anaesthetic techniques, improve postoperative pain management, furthermore, when administrated before surgery, these simple techniques can also decrease anaesthetic and analgesic requirement during surgery as well as reduce the need for opioid containing analgesic postoperatively[5].

Intraperitoneal instillation of local anaesthetic in combination with general anaesthesia has been investigated in several interventional studies during laparoscopic cholecystectomy. Approximately half of these studies showed reduction in the postoperative pain significantly.

Inspite of several advantages of laparoscopic procedures over laparotomy it does not take away the disadvantage like the post-operative pain which results in an unpleasant experience for the patient and there by delay the discharge. Pain usually occurs on the first day following surgery and it may be a visceral, parietal or shoulder pain [6].

By evaluating the pathophysiology of pain it is shown that we can prevent or reduce pain by blocking the nociceptors before their stimulation by use of local anaesthetics [7].

Bupivacaine is one such local anaesthetic which has a good safety profile, is long acting and free of side effects like gastritis due to NSAID's or nausea and vomiting and fear of drug dependence as in opioids.

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, irritative effects of residual carbon dioxide in the abdominal cavity and prolonged elevation of diaphragm by pneumoperitoneum.

Decrease in postoperative pain after infiltration of local anaesthetics into the operative wound have been observed among patients who undergo herniorrhaphy and gynaecological procedures [8.9]. Postoperative catheter infusion of bupivacaine into the subcostal incision during open cholecystectomy has been shown to decrease atelectasis, and reduce narcotic usage [10]. Continuous postoperative infusion of local anaesthetic agent into the abdominal wounds has reduced both postoperative pain and narcotic requirements [11, 12].

Bupivacaine has a half-life of 2.5 to 3.5 hours and has been reported to provide pain control for an average of 6hours [13]. The margin of safety of the bupivacaine needed for analgesia is wide. Thus, pain relief and patient comfort during the early postoperative period becomes increasingly important, as the need for analgesic may delay discharge.

Several studies have described pain according to the presumed mechanism: visceral pain, which can theoretically be blocked by intraperitoneal instillation, and parietal pain, which can be blocked by port site infiltration [9, 11, 12].

Our study is designed to evaluate the effect of intraperitoneal instillation of 0.5% bupivacaine with adrenaline for pain relief following laparoscopic cholecystectomy.

MATERIALS AND METHODS

Source of data

Patients admitted in department of General surgery at Karnataka institute of Medical sciences, Hubli posted for elective laparoscopic cholecystectomy between age group 18 to 60 years. Approval from the ethical committee of the institution was obtained. All the patients were explained about the basis of the study and informed consent were obtained.

Method of collection of data

Study design: Randomised clinical trial

Sample size

30 patients of either sex between age group 18 to 60 years undergoing elective laparoscopic cholecystectomy were divided into two groups of 15 patients each randomly who fulfilled the inclusion and exclusion criteria.

Inclusion criteria

Patients of either sex between 18 and 60 years, with symptomatic cholelithiasis who is posted for elective laparoscopic cholecystectomy and who give consent for the study.

Exclusion criteria

- Patient below 18 and above 60 years
- Patient with underlying respiratory and cardiac abnormalities
- Patients with acute cholecystitis
- Patient who do not understand the visual analogue score
- Patients who undergo any additional procedure
- Patients on prolonged use of pain medication

- Patients in whom drain is placed after the procedure
- Patient who do not give consent for the study.

30 adult patients of either sex between age group 18 to 60 years undergoing elective laparoscopic cholecystectomy were divided into two groups of 15 patients each randomly. All patients underwent similar general anaesthetic procedure.

GROUP (A) – STUDY GROUP: Patients received 20 ml of 0.5% bupivacaine with 1:200000 adrenalines intraperitoneally at gall bladder bed and under right hemidiaphragm (10ml each) at the end of surgery through laparoscope port in trendelenburg position.

GROUP (B) - PLACEBO GROUP: Patients received 20 ml of normal saline intraperitoneally at the same location.

Patients in group A (Study group) received intraperitoneally in gall bladder fossa and sub diaphragmatically 0.5% bupivacaine with 1 in 2 lakh adrenaline (10+10 ml) at the end of surgery before the trochars were withdrawn; after instillation patient was maintained in trendelenburg position for 5 minutes for the drug to stay at the injected site.

Patients in group B (Placebo group) received intraperitoneal and subdiaphragmatic normal saline (10+10 ml) at the end of surgery before the trochars were withdrawn and trendelenburg position was given for 5minutes.

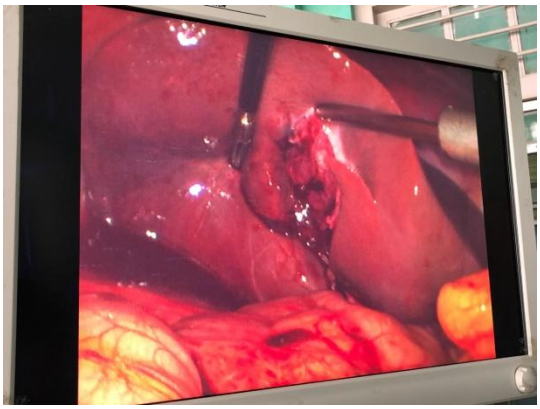

Fig-1: Protocol Drug Being Instilled Over Gall Bladder

Fig-2: Protocol Drug Being Instilled Into Right Subdiaphragmatic Space

The surgeon was blinded for the nature of the solution used. The residual CO2 was evacuated carefully at the end of surgery by manual compression of the abdomen with open trocars. The nasogastric tube was removed after recovery from anaesthesia.

Post operatively the patients were assessed for pain utilizing visual analogue scale (VAS) and verbal rating Prince Henry scale (VRS). The time of arrival in the postoperative ward was defined as zero hour postoperatively. Pain intensity was measured at fixed time interval.

The patients were also enquired about nausea - vomiting, whether rescue analgesics were given or not using a predesigned proforma, which were assessed at 1,4,8 and 24 hours.

VAS - visual analogue scale consists of a 10 point scale representing varying intensity of pain from 0 (no pain) to 10 (worst pain).

VRS-Verbal rating scale has up to 4 grades

0 - No pain on cough

1 – Pain on cough but not on deep breathing

2 - Pain on deep breathing but not on rest.

3 - Pain at rest- slight.
4 - Pain at rest - severe.

Rescue analgesic Inj. Diclofenac 75 mg IM, was given when VAS was more than 6 or VRS was more than 3 postoperatively. Pain assessment was done at 1,4,8 and 24 hours.

Statistical methods

Data entry was done in Microsoft Excel spreadsheet and all the statistical analysis wasperformed in SPSS version 23.0.

VAS scores and VRS scores at different time points was expressed as mean and standard deviation. Gender distribution and rescue analgesia between the two groups were compared using Chi square test.

VAS scores and VRS scores between the two groups were compared using Independent t test. A p value of less than 0.05 was considered as statistically significant for Chi square analysis and Independent T test. Charts were prepared in Microsoft Excel spreadsheet.

RESULTS

Postoperative pain using VAS was lower in Group A at 1, 4, 8 and 24 hours and was statistically significant (p value of 0.001, 0.001, 0.007 and 0.003 respectively). VRS was lower in Group A at 1, 4, 8 and 24 hours and was only statistically significant at 1, 4 and 8 hours postoperatively (p value of 0.028, 0.025, 0.043 and 0.15 respectively). There was significantly lower need of rescue analgesics in Group A.

Table-1: Age distribution

Age groups	Group A		Group B	
	N	%	N	%
11-20	0	0	0	0
21-30	6	40	5	33.3
31-40	4	26.6	0	0
41-50	1	6.7	4	26.7
51-60	4	26.7	6	40
Total	15	100	15	100

Table-2: Gender distribution

Gender	Group A		Group B	
	n	%	N	%
Male	3	20	4	26.7
Female	12	80	11	73.3
Total	15	100	25	100

Table-3: VAS scores at different time points

VAS Score	Group A Mean (SD)	Group B Mean (SD)	P value
At 1 hr	1.8 (0.99)	3.6 (0.81)	<0.001
At 4 hrs	3.6 (1.8)	5.86 (0.99)	<0.001
At 8 hrs	4.4 (1.4)	5.80 (1.08)	0.007
At 24 hrs	3.2 (0.7)	4.1 (0.63)	0.003

Table-4: VRS scores at different time points

VRS Score	Group A Mean (SD)	Group B Mean (SD)	P value
At 1 hr	0.8 (0.83)	1.5 (0.74)	0.028
At 4 hrs	1.9 (0.7)	2.4 (0.5)	0.025
At 8 hrs	2.1 (0.5)	2.5 (0.5)	0.043
At 24 hrs	1.8 (0.35)	2 (0)	0.15

DISCUSSION

The results of the present study demonstrate that intraperitoneal instillation of bupivacaine with adrenaline produces lower VAS upto 24 hours postoperatively whereas it produces lower VRS upto 4 hrs postoperatively. The postoperative analgesic requirements are also less but there is no difference in the shoulder pain between the two groups.

Narchi *et al*. found intraperitoneal local anaesthetics to be more effective in reducing pain upto 48 hrs postoperatively in patients undergoing diagnostic laparoscopy [13]. Subsequent studies failed to demonstrate the beneficial effect of intraperitoneal instillation of local anaesthetics in patients undergoing laparoscopic cholecystectomy.

Utilizing 20 ml of either 0.25% bupivacaine or 0.5% lignocaine, Rademaker *et al.* failed to demonstrate any reduction in postoperative pain [14]. A possible explanation of the failed effect given by them was the small amount of local anaesthetics used as compared to Narchi *et al*. Also instillation of local anaesthetics in the supine position prevented its flow over the coeliac plexus and phrenic nerve endings.

Joris *et al.* studied the characteristics of pain after laparoscopic cholecystectomy and the effect of intraperitoneal instillation of 80 ml of 0.125% bupivacaine with adrenaline [15]. They found that visceral pain accounts for the major discomfort experienced in early postoperative period whereas shoulder tip pain becomes the main complaint on the second day. The intensity of shoulder pain in their study was less than the study of Narchi *et al.* probably because of careful emptying of carbon dioxide pneumoperitoneum. The author felt that because of existence of several components of pain, its relief will depend on therapy for each of these components. In addition an anatomic intraperitoneal flow directs local anaesthetics away from cholecystectomy wound and therefore cannot attain sufficient concentration to block the nociceptive input from abdominal wall incisions.

Keeping in view the importance of positioning while instilling the local anaesthetic Scheinin *et al*. administered 100 ml of either 0.15% plain bupivacaine or with adrenaline in 200 head down tilt maintained for 20min [16]. They found no relief of pain after laparoscopic cholecystectomy. The lack of analgesic efficacy can be attributed to the lower concentration of bupivacaine used and more extensive and longer duration of surgery compared to gynaecological laparoscopies.

Using 20 ml of 0.5% bupivacaine, Pasqulucci et al noted a decrease in pain and consumption of analgesics probably due to a complete block of afferents using higher concentrations and volumes than used by other authors [17]. Secondly enrolling patients with acute cholecystitis may have triggered a neuronal sensitization in previous studies. The good results of our study may be related to the use of higher concentration of bupivacaine compared to other studies because it is the concentration which may be important in laparoscopic cholecystectomy rather than volume. Also the drug was instilled in 200 trendelenberg position so as to encourage its accumulation in gall bladder bed.

Although similar concentrations and volume of local anaesthetics was used in our study and that of pasqualucci the results were dissimilar. In our study pain relief was noted up to 8 hrs postoperatively (VAS-8 hrs, VRS -4 hrs) whereas this was seen upto 24 hrs in Pasqualucci's study. The reason for this discrepancy could not be ascertained. Chundrigar et al also noted pain relief only upto 2 hrs with intraperitoneal administration of 0.25% bupivacaine [18]. This could be related to the lower concentrations used by them compared to our study. Also they could not ascertain any difference in analgesic consumption. Pasqualucci *et al.* also noted significant difference in analgesic consumption between the groups up to 24 hrs.

Neerja *et al.* who used 0.5% bupivacaine with 1:200000 adrenaline intraperitoneal instillation also showed similar findings of VAS being significantly low at 1, 4 and 8 hours and lower need of rescue analgesics in study group [19].

Chundrigar *et al*. using 0.25% bupivacaine noted a significant reduction in pain scores at the 1 h (4.00 vs 1.99, $P<0.01$) and 2 h (2.53 vs 1.23, $P<0.05$) time intervals after laparoscopic surgery. By 4 h, and at subsequent time intervals pain scores were low in both groups and no significant difference was found [18].

CONCLUSION

To conclude, intraperitoneal instillation of 0.5% Bupivacaine with 1:200000 adrenalines in Laparoscopic cholecystectomy reduces post-operative pain significantly for 4-6 hours and significantly reduces the need of rescue analgesics. It is easy to administer with no adverse effects and may become a routine practice for this procedure.

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