



COMPARING THE POST-OPERATIVE ANALGESIA USING ROPIVACAINE IN LAPAROSCOPIC CHOLECYSTECTOMY BY THREE DIFFERENT METHODS-A COMPARATIVE STUDY

Anaesthesiology

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ABSTRACT

Introduction: Laparoscopic cholecystectomy is a minimally invasive surgical procedure for cholecystectomy. In present time local anesthesia is widely used as analgesic by various routes including port site intraincisional infiltration, transverse abdominis plane (TAP) block and intraperitoneal instillation.

Aim: Comparing The Post-Operative Analgesia Using Ropivacaine in Laparoscopic Cholecystectomy by three Different Methods ; Intraperitoneal instillation, USG-guided subcostal transversus abdominis plane block and Incisional infiltration at port site.

Materials and methods: This study was conducted among elective general surgical patient undergoing laparoscopic cholecystectomy in S.N. Medical College, Agra and completed in the study period of 18 months. Study population was elective surgical patients posted for elective laparoscopic cholecystectomy. Patients were divided in to 3 groups: Group A- Intraperitoneal instillation, Groups B- ultrasound guided subcostal transversus abdominis plane block and Groups C- intraincisional infiltration at port site.

Results: Intraincisional infiltration of ropivacaine provide significant Postoperative pain relief in comparative to USG -guided subcostal TAP block and intraperitoneal instillation with ropivacaine.

Conclusion: Intraincisional infiltration of ropivacaine provide significant Postoperative pain relief and decrease post operative analgesia requirement in comparative to USG -guided subcostal TAP block and intraperitoneal instillation with ropivacaine. Shoulder tip pain incidence, postoperative nausea and vomiting incidence lower in intraincisional infiltration of ropivacaine.

KEYWORDS

Post-Operative, Analgesia, Ropivacaine, Laparoscopic Cholecystectomy, Intraperitoneal instillation, transversus abdominis plane block and Incisional infiltration.

Introduction

Laparoscopic cholecystectomy is a minimally invasive surgical procedure for cholecystectomy. Associated morbidity and hospital stay duration increases due to post-operative pain in laparoscopic cholecystectomy which can worsen post operative outcome. Therefore multiple methods of analgesia are required to provide effective control of post operative pain.[1]

NSAID's, opioids and local anesthetics at incisional and intraperitoneal local anesthetics with variable success. In present time local anesthesia is widely used as analgesic by various routes including port site intraincisional infiltration, transverse abdominis plane (TAP) block and intraperitoneal instillation.

Many trials have been carried out using intraperitoneal or incisional local anesthetic infiltration , but results relating to pain reduction and parenteral analgesia consumption are conflicting.[2-5] These techniques have advantage over opiates in term of adverse effect which lead to prolonged hospitalization.[6] Intraincisional infiltration of local anesthetic at trochar port site can reduce post operative pain and analgesic requirement. Instillation of intraperitoneal lignocaine, bupivacaine, levo-bupivacaine and ropivacaine has been used following laparoscopic gynaecological and general surgical procedures to reduce postoperative pain in randomized trials for many years.[7-10]

Pain experienced following laparoscopic cholecystectomy derives significantly from the incisions made in the anterior abdominal wall which has segmental innervation provided by nociceptor afferents in the transversus abdominis fascial plane between the internal oblique and transversus abdominis muscles.

So that the transversus abdominis plane (TAP) block has been shown to reduce perioperative opioid use in lap cholecystectomy.[11] The ultrasound (USG)-guided subcostal transversus abdominis (STA) block is a recently described variation on the TAP block which produces reliable unilateral supraumbilical analgesia.[12]

This study is designed to access comparative efficacy of ropivacaine in USG guided subcostal transversus abdominis plan block, intra incisional infiltration and intraperitoneal instillation for post operative analgesia in laparoscopic cholecystectomy under general anaesthesia.

Materials and methods:

This study was conducted among elective general surgical patient undergoing laparoscopic cholecystectomy in S.N. Medical College, Agra and completed in the study period of 18 months.

Study population was elective surgical patients posted for elective laparoscopic cholecystectomy of age of 20-60 years, either sex, who gave voluntary consent for participation in the study. Selected patients were divided in three groups of 40 patients each.

As per inclusion criteria patients with age group more than 20 yrs and less then 60 yrs, ASA grade 1 & 2, posted for laparoscopic cholecystectomy, signed informed written consent, without cognitive impairment and mental retardation and free from pain in preoperative period (apart from biliary colic pain) were selected for the study.

As per exclusion criteria patients not giving consent, conversion of laparoscopic approach to open surgery, allergy to study drug, any preexisting source of abdominal pain apart from biliary colic, patient on chronic pain treatment and with history of cardiovascular, and hepatic and renal disease were not selected for the study.

After obtaining clearance from institutional ethical committee and informed written consent 120 patients (ASA 1 and 2) posted for laparoscopic cholecystectomy randomized in to three groups .

- Group A- Intraperitoneal instillation
- Groups B- ultrasound guided subcostal transversus abdominis plane block
- Groups C- intraincisional infiltration at port site.

In all groups ropivacaine 0.75% of 3 mg/kg was used as local anesthetic agent. Randomization of patients into three groups was

done by sealed envelope technique. During pre anaesthetic check-up following parameters were recorded for each patients: gender , age , body weight, BMI, ASA class, adequacy of neck movement , mallampati score, thyromental distance , status of dentition, acute and chronic pain history, antiepileptic treatment history and drug allergy history. All patients were fasted overnight and received tablet ranitidine 150mg and tablet alprazolam 0.25mg orally the night before surgery. Night before surgery, all patients were instructed how to use a visual analogue scale in 0 to 10 measurement on which 0 represents no pain and 10 represents worse possible pain.

Standard anaesthesia protocol was followed for all patients. In the operation theatre heart rate, blood pressure, mean arterial pressure, electrocardiogram, oxygen saturation, temperature were monitored and baseline value were recorded. All patients were uniformly premeditated with IV midazolam 0.02mg/kg, IV glycopyrrolate 0.2 mg and IV fentanyl 2 mcg/kg prior to induction of anaesthesia. Pre-oxygenation was carried out for 3 minutes with 100% oxygen, and anaesthesia was induced in supine position with patients head in neutral position using IV propofol 2mg/kg and IV vecuronium 0.1mg/kg. Intubation by the oral route was done with cuffed PVC endotracheal tube of appropriate size.

Anaesthesia was to be maintained with inhalational isoflurane +50% O₂ +50 % N₂O + IV vecuronium 0.02mg/kg. Mechanical ventilation with tidal volume 8-10 ml/kg was adjusted to maintain end tidal carbon dioxide between 35 and 40 mmHg. Standard 4 port laparoscopic cholecystectomy technique was applied for all patients for cholecystectomy in reverse Trendelenburg position with left side down tilting position. Pneumoperitoneum was achieved with nonhumidified CO₂ and intraabdominal pressure of 10-12 mmHg was maintained.

During surgery all patients receive intravenous infusion of lactated ringer's solution at the rate of 5-7 ml/kg/hr with non-opioid analgesia with IV paracetamol (15-20 mg/kg) and IV ketorolac 30mg. Group A received Intraperitoneal instillation, Group B received ultrasound guided subcostal transversus abdominis plane block and Groups C received intraincisional infiltration at port site.

Compare the Postoperative analgesia effectiveness in laparoscopic cholecystectomy on the basis of visual analogue pain scale (VAS) in Intraperitoneal instillation , USG-guided subcostal transversus abdominis plane block and Intrincisional infiltration. Duration of action of methods applied for post-operative analgesia, time of requirement of rescue opioid analgesia used, total requirement of rescue of analgesia in first 24 hrs. Post-operative nausea and vomiting, respiratory depression (less than 10/minutes) and local anaesthetic systemic toxicity.

All data were expressed as means $\pm$ standard deviation, with the exception of time of first dose of rescue analgesic requirement ,the occurrence of right shoulder pain and incidence of PONV that were percentages (%). Parametric data were compared between groups by analysis of variance (ANOVA). Chi-square method were used for discrete variables . A two-sided probability value (P-value) less than 0.05 and differences less than critical differences was considered statistically significant.

Observation and Results:

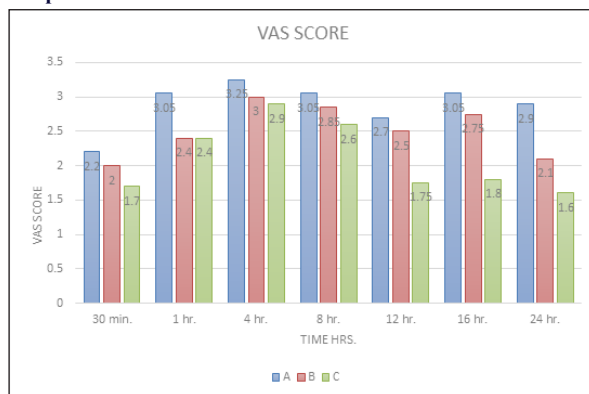
In this study 120 patients were enrolled, mean $\pm$ SD of age in group A was 48.05 $\pm$ 6.27, group B was 45.35 $\pm$ 5.84 and group C was 46.20 $\pm$ 5.40. Mean $\pm$ SD of weight in group A was 63.05 $\pm$ 4.12, group B was 64 $\pm$ 4.92 and group C was 65.4 $\pm$ 4.71. There is no significant differences between the groups with respect to age and weight, p-value being 0.112 and 0.100 respectively. Male percentage in group A, B, and C was 14(35%), 15(37.50%) and 12(30%) respectively. Female percentage in group A, B, and C was 26(65%), 25(62.50%) and 28(70%). Gender distribution of all group was also comparable. Mean $\pm$ SD of duration of surgery in group A, B and C was 0.94 $\pm$ 0.40, 0.97 $\pm$ 0.44 and 0.95 $\pm$ 0.38 respectively. There was no statistical difference between the groups.

Table 1: Comparison Of Groups On The Basis Of Visual Analogue Scale (VAS) In First 24 Hours (n=120) :

Group		30 min.	1 hr.	4 hr.	8 hr.	12 hr.	16 hr.	24 hr.
A (N=40)	Mean	2.20	3.05	3.25	3.05	2.70	3.05	2.90
	SD	0.61	0.81	0.95	0.92	0.85	0.93	0.55

B (N=40)	Mean	2.00	2.40	3.00	2.85	2.50	2.75	2.10
	SD	0.64	0.50	0.72	0.65	0.94	0.90	0.30
C (N=40)	Mean	1.70	2.40	2.90	2.60	1.75	1.80	1.60
	SD	0.65	0.50	0.55	0.75	0.90	0.80	0.30
f-value		6.311	14.618	2.263	3.331	13.907	22.074	106.94
p-value		0.002	<0.0001	0.109	0.039	<0.0001	<0.0001	<0.0001
CD		0.37	0.36		0.45	0.52	0.51	0.23

Graph 1



Post-operative abdominal pain was significantly lower in group C (intra-incisional infiltration) than group A (intra peritoneal nebulization). This significant difference was reported from 30 minutes, 1st hour, 12th hours , 16th hours and 24th till 24 hours post operatively. Although at every assessment of VAS score Postoperatively patients in the group -A (intra- Peritoneal instillation) , reported significant higher VAS score in first 24 hrs (p value <0.05 and significant critical difference value) except 4th hour (p value 0.109).

There was statistically significant differences in reduction of VAS score in group C in comparative to group B at postoperative 12th , 16th and 24th hours on the base of significant critical differences and p values.

There was statistically significant differences in between group A and B , VAS score which showed that group A have higher significant VAS score at Postoperative 1st and 24th hour (p value < 0.05 , significant CD). (Table 1 and graph 1).

Time of first rescue analgesia after surgery was shortest in group A in which 30% patients got IV fentanyl at 1st hour and 40% participants received at 4th hour after surgery. In Group B 20% participants received first rescue analgesia at 4th hour and 30 % each at 8th and 12th hours. In group C time of first analgesia at 4th hour only by 10% participants and 25% each at 8 and 12 hours.

Table 2: Comparison Of Variable Group In Term Of Total OPIOID Requirement (MCG) In First 24 Hours (n=120)

Group	N	Mean	SD	f-value	p-value	CD
A	40	111.00	39.73	14.287	<0.05	19.31
B	36	80.59	32.75			
C	26	69.29	21.59			

Total consumption of rescue analgesia in first 24 hrs. postoperatively higher in Group A (mean 111.00 mcg), Which is significantly lower than Group B (mean 80.59 mcg) and Group C (69.29mcg) , (p value <0.05). There is no significant differences in total consumption of rescue analgesia in first 24 hours in Group B and Group C (CD – 19.31). (table 2).

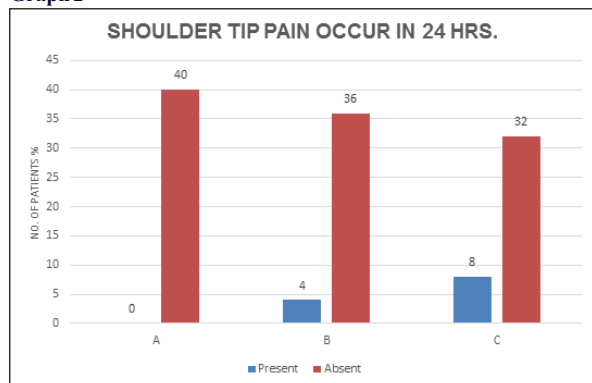
Table 3: Association Between Groups And Shoulder Tip Pain Incidence In First 24 Hours (n=120) :

Shoulder tip pain in first 24 hrs.	A (n=40)		B(n=40)		C(n=40)	
	No.	%	No.	%	No.	%
Present	0	0	4	10.00	8	20
Absent	40	100.00	36	90.00	32	80.00
Total	40	100.00	40	100.00	40	100.00

chi-square = 8.89

p-value = 0.012

Graph 2



Regarding the distribution of shoulder tip pain in first 24 hours, there was statistically significant differences between various groups (p value-0.012). Group A showed statistically significantly lower incidence compared to Group B and Group C. Although statistically insignificant, shoulder pain incidence was less in Group B than Group C.

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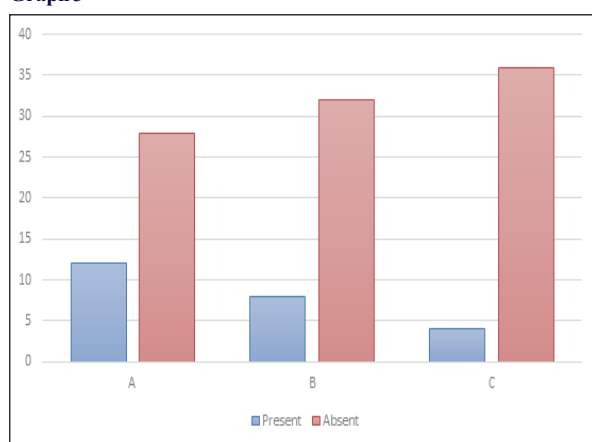
Table 4: Comparison Of Groups On Basis Of Total Episode Of Nausea In First 24 Hours (n=120):

Nausea episode in 24 hrs.	A (n=40)		B(n=40)		C(n=40)	
	No.	%	No.	%	No.	%
Present	12	30.00	8	20.00	4	10.00
Absent	28	70.00	32	80.00	36	90.00
total	40	100.00	40	100.00	40	100.00

Chi-square = 5.00

P-value = 0.082

Graph 3



Incidence of episode of nausea (PONV) in participants in each group in first 24 hours are different in each group. On observation group C have minimum incidence of nausea comparative to group A and group B. There was 20% participants in group A, have single episode of nausea and 10% participants have two episode of nausea in first 24 hours. In group B, 15% participants had single episode of nausea and 5% participants had two episode of nausea in first 24 hours. In group C, single nausea episode in 5% participants and 5% participant feel two episode of nausea in first 24 hours. There was 30% incidence of nausea in group A, 20% nausea incidence in group B and 10% incidence in group C in first 24 hours. On the base of statistically there was no any significant differences in incidence of nausea in first 24 hours after surgery. (Table 4 and graph 3)

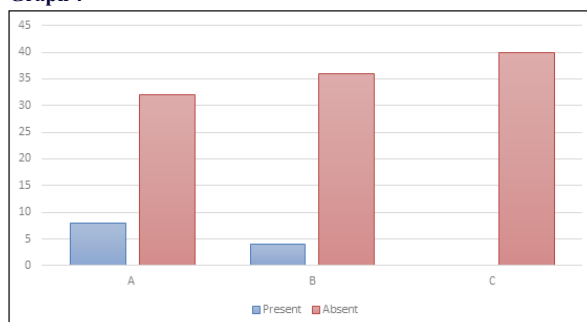
Table 5: Comparison Of Incidence Of Vomiting In First 24 Hours In Three Variable Group (n=120):

Vomiting episode in first 24 hours	A (n=40)		B(n=40)		C(n=40)	
	No.	%	No.	%	No.	%
Present	8	20.00	4	10.00	0	0.00
Absent	32	80.00	36	90.00	40	100.00
Total	40	100.00	40	100.00	40	100.00

chi-square = 8.89

p-value = 0.012

Graph 4



Incidence of vomiting episode are higher in group A in which consumption of rescue analgesia was also higher, in comparative to group B and group C. There were 20% participants in group A who had vomiting in first 24 hours after surgery. 10% participants in group B had vomiting in first 24 hours after surgery.

There was no participant who had vomiting in group C in first 24 hours after surgery which is significantly low comparative to group A and Group B. (P value 0.012) (Table 5 and graph 4)

There was no incidence of pruritus, respiratory depression (respiratory rate less than 10/minute) in any participants in all three variable participants. Local anaesthetic systemic toxicity such as seizures, hypotension, cardiovascular collapse was not recorded in first 24 hours after laparoscopic cholecystectomy in all three group.

Discussion:

In the present study we compared intraperitoneal instillation, USG-guided subcostal transversus abdominis plane (TAP) block and intra-incisional infiltration (up to preperitoneal space) of local anaesthesia using 0.75% ropivacaine. We found that intra-incisional infiltration of ropivacaine (up to the fascial plane) and USG-guided subcostal TAP block are more effective than intraperitoneal instillation.

A similar decrease in VAS score till Postoperatively 24 hours also found by El-labbam GM et al., [13] and Lepner et al., [14] in which intra-incisional infiltration of local anaesthesia is more effective than intraperitoneal instillation of local anaesthesia.

We recorded that there was early requirement of first rescue analgesic dose in intraperitoneal instillation as compared to USG guided subcostal TAP block and Intra-incisional infiltration of local anaesthesia. The studies El labban GM et al.[13] and Elfberg BA et al.[15] also favour our this result.

Total consumption of rescue analgesia was significant higher in intraperitoneal instillation group comparative to USG guided subcostal TAP block and intra-incisional Infiltration of ropivacaine in first 24 hours after laparoscopic cholecystectomy. The studies El labban GM et al., [13] and Elfberg BA et al., [15] also favoured our this result.

While comparing the side effect as such post-operative nausea and vomiting there was significant difference in nausea incidence among intraperitoneal instillation and USG guided Subcostal TAP block and intra-incisional Infiltration. incidence of vomiting in patients receiving intra-incisional infiltration of local anaesthesia have significant reduction of PONV incidence in first 24 hours.

Pain aggravates nausea and vomiting through neurohormonal

mechanisms. Joris j et al [16] also found that Postoperative pain in laparoscopic cholecystectomy also increases nausea and vomiting due to the increased consumption of opioids. Shoulder tip pain was significantly reduced in intraperitoneal instillation as compared to intra-incisional infiltration and USG guided TAP block. There was no incidence of respiratory depression (respiratory rate below 10 /minutes), and pruritus recorded in any participants in any groups.

None of patients involved in our study were found to have sign and symptoms of local anaesthetic systemic toxicity (seizures, hypotension, cardiovascular collapse).

This study finding is also in concordance with Various studies as Tolchard, S et al., [17] "Efficacy of the subcostal transversus abdominis plane block In laparoscopic cholecystectomy: Comparison with conventional port-site infiltration" in which concluded that STA block provides superior postoperative analgesia and reduces opioid requirement following laparoscopic cholecystectomy.

Our study had limitation such as intra-incisional infiltration of local anaesthesia cause reduction of somatic pain while intraperitoneal instillation cause reduction of visceral pain while subcostal transversus abdominis plane block provides reliable analgesia in T6 to T10 dermatome. Due to multifactorial pain in post-operative laparoscopic cholecystectomy various methods work on their specific factor. Patients in three groups also received paracetamol and ketorolac as standard practice for analgesia in our study, hence the VAS scores in both groups may have decreased because of these medications. We did not consider the influence of the timing of ropivacaine treatment (preoperative vs end of the surgery) on post-operative pain relief.

Conclusion:

Intra-incisional infiltration of ropivacaine provide significant Postoperative pain relief and decrease post operative analgesia requirement in comparative to USG-guided subcostal TAP block and intraperitoneal instillation with ropivacaine. Shoulder tip pain incidence, postoperative nausea and vomiting incidence lower in intra-incisional infiltration of ropivacaine.

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