Section: Anaesthesiology

Original Research Article

POST-OPERATIVE ANALGESIC EFFECT OF INTRAPERITONEAL ROPIVACAINE WITH OR WITHOUT TRAMADOL IN LAPAROSCOPIC CHOLECYSTECTOMY-A PROSPECTIVE RANDOMIZED CONTROL STUDY

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Abstract

Background: Laparoscopic cholecystectomy (LC) performed for various indications, though offers less pain than open cholecystectomy, is still not pain‐free. Different modalities of post-operative pain relief has been tried after laparoscopy one among which is intraperitoneal (IP)instilation of local anaesthetics. The rationale behind being the blockade of visceral nociceptive conduction, thereby providing an additional mechanism of analgesia. The aim is to compare the efficacy of intraperitoneal instillation of local anaesthetics for post operative pain relief after laparoscopic cholecystectomy. **Materials and Methods:** After institutional ethical committee approval and informed consent 70 patients were randomly allocated into 2 groups to receive 28 ml of 0.5% Ropivacaine with 2 ml of normal saline (Group R)or 2 ml of tramadol(Group RT) intraperitoneally at the end of the surgery, before the removal of the trocar. Duration of post operative pain relief, 24 hour post operative analgesic requirement, Post operative hemodynamic changes like pulse rate, Blood pressure and Incidence of Complications were studied. **Result:** The patient demographics and hemodynamic parameters were comparable to the baseline in both the groups. There was a statistically significant difference in the NRS score (P< 0.001) from 30 mins to 3 hrs 30 mins ,5hrs to 7 hrs,9 hrs to 12 hrs. There was a statistically significant difference in the time of first rescue dose of analgesia(group R 227.50 ± 23.27 Mins and group RT 432.86±41.96 Mins-(P<0.0001)) and the total dose of paracetamol given group R was 1469.38 ± 569.29 g and group RT mean was 1138.00 ±119.18 g-(P=0.033)) between the two groups. **Conclusion:** We concluded that intraperitoneal instillation of inj.0.5% Ropivacaine with Tramadol is a better analgesic without much side effects when compared to inj 0.5% Ropivacaine without Tramadol.

INTRODUCTION

Laparoscopy is a modern, minimally invasive surgical /diagnostic procedure, in which abdominal cavity is visualized with a scope. This surgery can be performed with minimal surgical incision thereby leading to less pain, less paralytic ileus, short hospital stay and early ambulation.[1]

Laparoscopic cholecystectomy (LC) is the treatment of choice for symptomatic cholelithiasis substituting the conventional open method of cholecystectomy.[2] Although post‐operative pain is much less severe than that induced by open cholecystectomy, it is still not a pain‐free procedure, which is why many patients refrain from early recovery,[3] a major hurdle in enhanced recovery after surgery (ERAS). Different modalities have been proposed to relieve post-operative pain after laparoscopy, for example, nonsteroidal anti-inflammatory drugs (NSAIDS), opioids, intraperitoneal (IP) local anaesthetics, IP saline, removal of insufflations gas or gas drains, low‐pressure abdominal insufflations, acetazolamide administration, use of nitrous oxide instead of carbon dioxide, and so on.[4]

Among the various local anaesthetics (LA) techniques, IP use of LA has gained attention and various researches have been done to study its efficacy for post‐operative analgesia. The rationale to use the IP route is that the peritoneum is exposed to block of visceral nociceptive conduction, thereby providing an additional mechanism of analgesia. Most of the previous studies have shown that local

anaesthetic with or without opioids can provide post‑operative pain relief when instilled intraperitoneally.[5] Few literatures are available on administration of tramadol alone or in combination with bupivacaine intraperitoneally for post‑operative pain relief.[6,7] We thus decided to conduct this study with the aim of evaluating the analgesic efficacy of these two drugs (ropivacaine, tramadol) when used in combination and intraperitoneally for post‑operative analgesia.

MATERIALS AND METHODS

A Prospective Double Blind Randomized Control Trail was conducted on 70 patients undergoing laporoscopic cholecystectomy, under General anaesthesia.after institutional ethical committee approval and written informed consent.Patients of age 16 to 50 years weighing between 50 kg – 80 kg belonging to ASA physical status I&II posted for elective laparoscopic cholecystectomy were included. Patients of ASA PS III, IV&V, pregnant mothers, patients with local anesthetics allergy, combined laproscopic surgeries and those who refused to participate in the study were excluded.

The patients were randomly allocated into 2 groups using the closed envelope approach as Group R and Group RT to receive 28 ml of 0.5% Ropivacaine with 2 ml of normal saline and 28 ml of 0.5% Ropivacaine with 2 ml of tramadol intraperitoneally respectively.

All the patients were anesthetized with intravenous (IV) midazolam 0.02 mg/kg; fentanyl 2 µg/kg and propofol 2 mg/kg Intravenously given. Orotracheal intubation was facilitated with succinylcholine 2mg/kg Intravenously. General anaesthesia (GA) was maintained with oxygen, nitrous oxide, isoflurane and neuromuscular blockade wuth graded doses of atracurium (0.1 mg/kg). At the end of the surgery, before the removal of the trocar the study drug according to the group allocation was instilled over the gall bladder bed, hepato-duodenal ligament and hepatodiaphragmatic space by the operating surgeon who was blinded to the study drug.

After instillation, to obtain thorough diffusion of LA, 2 min of trendelenburg position was maintained. The reversal of neuromuscular blockade was done with neostigmine 0.05 mg/kg IV and glycopyrrolate 0.01 mg/kg IV.

The Numerical Rating Scale (NRS) score was collected every 30 min till 6 hrly, every 1 hr till 12 hrly and every 2 hrly till 24hrs

Duration of analgesia was defined as the time from which the drug was instilled to the time patient requested for first analgesic medication or NRS 4 and above. Intravenous paracetamol 15 mg/kg Intravenously was given as rescue analgesia when required. Time of the first rescue analgesic requirement was noted. Cumulative consumption dose of rescue analgesia over 24 h was recorded. Side effects such as nausea, vomiting and shoulder pain were also recorded.

SPSS version was used for statistical analysis. Student t test used for comparison of age, weight, BMI, post op pain scores, episodes of rescue analgesia use, dose of analgesics (parametric data).Chi square test used for comparison of gender, ASA grading, time of the first rescue analgesic requirement and number of patients receiving rescue analgesics (non parametric data) P<0.05 considered statistically significant.

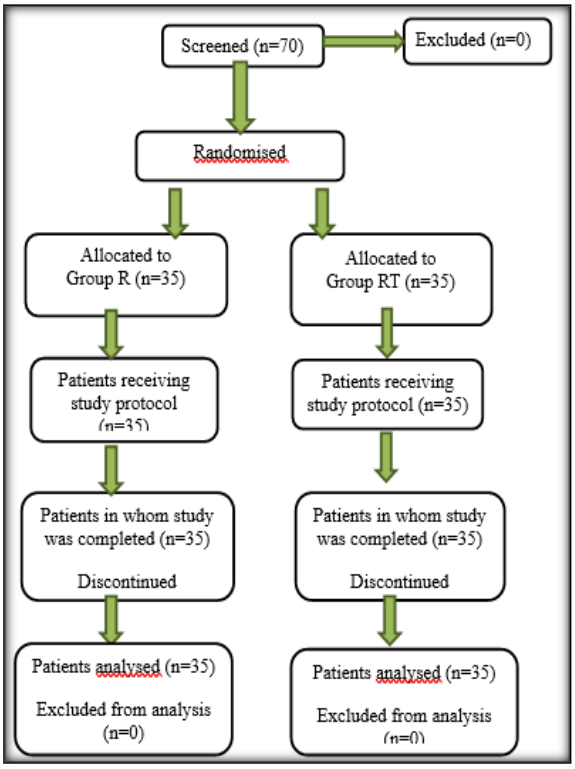

Figure 1: Consort Diagram

RESULTS

The patient demographic data like age, gender, weight and BMI were comparable between the two groups and the difference was not statically insignificant. The hemodynamic parameters namely the systolic and diastolic blood pressures and heart rate were comparable to the baseline in both the groups.

There was a statistically significant difference in the NRS score (P< 0.001) from 30 mins to 3 hrs 30 mins ,5hrs to 7 hrs,9 hrs to 12 hrs with lesser pain scores in the Group RT and the fuctuation in the pain scale is probably because of the early requirement of first dose rescue analgesia in the Group RT.

There was a statistically significant difference in the time of first rescue dose of analgesia(group R 227.50 ± 23.27 Mins and group RT 432.86±41.96 Mins-(P<0.0001)). The time of first dose rescue analgesia was much earlier in the Group R when compared to the Group RT.

Similarly the total dose of paracetamol given as rescue analgesia also showed a statistically significant difference between the two groups (group R was 1469.38 ± 569.29 g and group RT mean was

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1138.00 ±119.18 g-(P=0.033)) The dosage of rescue drug was far greater in Group R when compared to Group RT between the two groups.

Our results showed that that intraperitoneal instillation of local anaesthetic inj.0.5% Ropivacaine with Tramadol offered better analgesia without much side effects when compared to inj 0.5% Ropivacaine without Tramadol.

Table 1: Demographic data.

	GROUP R	GROUP RT	P value
AGE (in years)	38.69±7.89	37.91±7.61	0.679
Gender	F 22(62.9%)	F 18(51.4%)	0.334
	M 13(37.1%)	M 17(48.6%)	
WEIGHT (Kg)	71.91±8.56	75.63±10.40	0.107
BMI	28.71±3.35	30.23±4.04	0.091

Table 2: Comparison of NRS score postoperatively between the two groups

NRS	GROUP R		GROUP RT		P value
	Mean	Standard Deviation	Mean	Standard Deviation	
30 min	0.54	0.51	0.14	0.36	<0.0001
1 hr	0.66	0.59	0.17	0.38	<0.0001
1 hr 30 min	0.97	0.79	0.29	0.46	<0.0001
2 hr	1.31	0.90	0.57	0.65	<0.0001
2 hr 30 min	1.71	1.07	0.71	0.67	<0.0001
3 hr	2.06	1.16	0.91	0.66	<0.0001
3 hr 30 min	2.63	1.46	1.00	0.64	<0.0001
4 hr	1.26	1.54	1.20	0.76	0.845
4 hr 30 min	0.77	1.26	1.37	0.69	0.016
5 hr	0.41	0.50	1.49	0.74	<0.0001
5 hr 30 min	0.60	0.55	1.71	0.93	<0.0001
6 hr	0.74	0.56	1.86	1.09	<0.0001
7 hr	0.89	0.58	1.86	1.35	<0.0001
8 hr	1.11	0.68	1.31	1.32	0.429
9 hr	1.34	0.68	0.66	0.54	<0.0001
10 hr	1.54	0.66	0.83	0.51	<0.0001
11 hr	1.71	0.79	1.00	0.42	<0.0001
12 hr	1.89	0.90	1.03	0.38	<0.0001
14 hr	1.74	0.95	1.51	0.56	0.225
16 hr	1.69	0.87	1.60	0.50	0.613
18 hr	1.74	0.74	1.77	0.43	0.844
20 hr	1.91	0.66	1.86	0.43	0.669
22 hr	2.20	0.76	2.00	0.24	0.142
24 hr	2.34	0.76	2.11	0.32	0.108

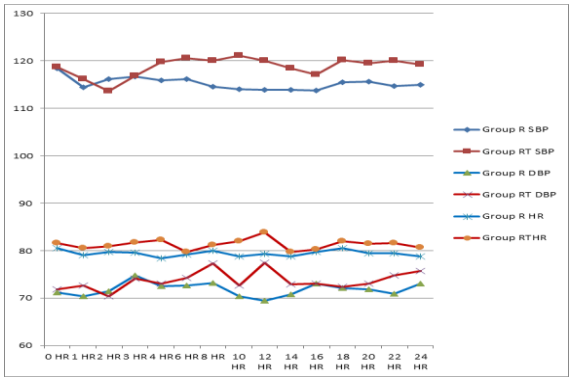

Figure 2: Comparison of hemodynamic parameters in both groups.

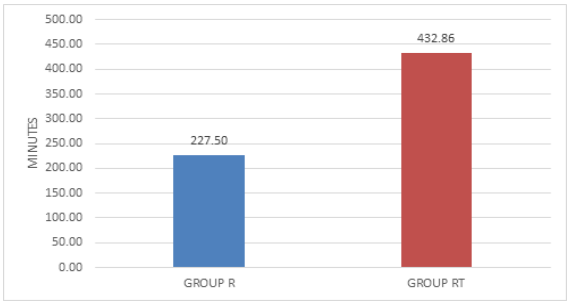

Figure 3: Comparison of time of analgesic request between the two groups

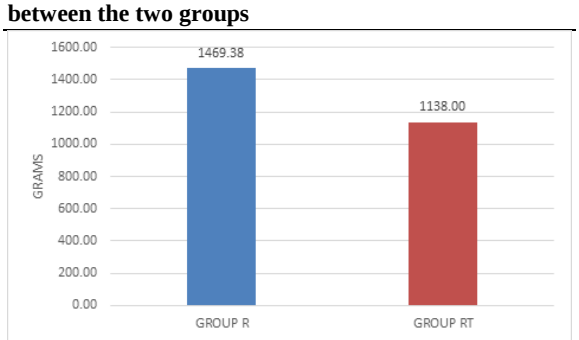

Figure 4: Comparison of total dose of Paracetamol given between the two groups

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DISCUSSION

In a related research, Kumari A et al,[14] reported that the mean NRS score in both groups reached its peak 2 hours after surgery. Between the two groups, there was a significant difference in the mean NRS score at 2.5, 3, 3.5, 4, 6, and 12 hours (P 0.05). The need for rescue analgesia (fentanyl) was statistically significantly higher in Group R (75%) than in Group RT (42.5%). The difference between Groups R and RT's minimum times to get their initial rescue analgesia was not statistically significant at 5 minutes and 10 minutes, respectively. The difference between the median total analgesic consumption (TAC) in Group R and Group RT—40 g vs. 0 g—was statistically significant. Group R consumed a total of 1800 grammes of analgesics, whereas Group RT consumed 785 grammes. In current study, NRS score was statiscally significant between both group R and group RT between 30 min – 3.30 hrs,5-7 hr and 9-12 hr.

Memis et al,[15] investigation of the effects of tramadol or clonidine combined with intraperitoneal bupivacaine on postoperative pain following complete abdominal hysterectomy discovered that the combination was more effective than bupivacaine alone. While lipophilic opioids, such as tramadol and buprenorphine, can diffuse across the intact perineural barrier and provide better analgesia when administered intraperitoneally, hydrophilic opioid molecules, such as morphine, are prevented from entering peripheral intact perineurium as a result of their interaction with opioid receptors. It has also been demonstrated that local anaesthetic administered intraperitoneally can lessen nausea and vomiting. A second method of analgesia is provided by intraperitoneal injection, which exposes the peritoneum to inhibit the visceral nociceptive conduction from the location of tissue injury and the peritoneum.[16]

In a related study Soni et al,[17] A total of 60 patients were examined. 30 patients in each group 20 ml of an intraperitoneal solution (18 ml of 0.5% ropivacaine and 2 ml of normal saline) were administered to Group R. The intraperitoneal 20 ml solution for group RT contained 2 mL (100 mg) tramadol and 18 mL of 0.5% ropivacaine. Time for 1st analgesia request (in min.) for both groups are 165.3 ± 35.4 and 288.3 ± 19.3 respectively. Amount of Paracetamol needed (gm) for both groups are 2.5 ± 1.6 and 1.1 ± 0.4 respectively. In current study, we used 28 ml of 0.5% Ropivacaine with 2 ml of normal saline intraperitoneally in one group and 2ml tramadol in another group.

Time for 1st analgesia request (in min.) for both groups are 227.50 ± 23.27 and 432.86 ± 41.96 respectively. Amount of Paracetamol needed (gm) for both groups are 1.4 ± 0.5 and 1.1 ± 0.1 respectively. Compared to previous study, duration of analgesia increased and rescue analgesia drugs consumption reduced in the current study due to increased volume of local anaesthesia. In the initial postoperative period following laparoscopic cholecystectomy, a simple, inexpensive, and noninvasive approach that offers adequate analgesia is intraperitoneal instillation of local anaesthetic. The present study has a limited sample size as a drawback.

CONCLUSION

We conclude that intraperitoneal instillation of inj.0.5% Ropivacaine with Tramadol is a better analgesia in terms of lower NRS score, delay in first dose rescue analgesia and decrease in total dose of rescue analgesia when compared to inj 0.5% Ropivacaine without Tramadol without much side effects.

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