

Original Research Article

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Multisite ropivacaine for pain relief after laparoscopic cholecystectomy: a placebo controlled study at a tertiary care teaching hospital

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ABSTRACT

Background: Laparoscopic cholecystectomy has emerged as the gold standard for gallstone diseases. The preference of laparoscopic cholecystectomy (LC) over open cholecystectomy (OC) is because of decreased pain and early discharge. Still pain remains as a major cause of concern. In this current study, we have evaluated the effect of Intraperitoneal instillation of Ropivacaine along with subcutaneous injection around the trocar sites in patients undergoing LC.

Methods: In this prospective study two groups of patients were selected 50 patients in each group. Control groups were given 100ml of 0.9% NS and other group received 2mg/kg intraperitoneal ropivacaine 0.25% diluted in 100ml of NS. All the outcome results were documented and analyzed for conclusion.

Results: When we compared the pattern of pain in both the groups over the period of 24 hours postoperative, it was revealed that in the group C shoulder pain was seen in 30% of cases, followed by incisional pain in 76%. Right hypochondriac pain was 84% and diffuse abdominal was 82%. In group R they were being 10%, 20%, 32% and 70% respectively. The postoperative rescue analgesia for group C was demanded after around 1 to 2 hours of reaching the ward whereas in the group R it was around 4 hours. Discharge after adequate pain relief was seen early in group R (24 hours) than in the group C (36-48hours).

Conclusions: The database of our retrospective study regarding age and sex incidence, clinicopathological features and therapeutic outcome was comparable to other studies in various literatures.

Keywords: Laparoscopic cholecystectomy, Open cholecystectomy, Pain, Ropivacaine

INTRODUCTION

With the role of laparoscopy increasing exponentially in all the surgical fields, surgeons have started to search for methods to facilitate early discharge and ambulation. Postoperative pain carries a considerable morbidity like pulmonary complication, restriction of early ambulation, distress of patients, increase of cardiac work, delayed discharge and increased stay in hospital causing financial burden to patients.¹ Several studies have shown that visceral pain is the major component apart from shoulder pain and parietal pain.

Perioperative analgesia has been traditionally provided by opioid analgesics, but it has been seen that the doses of analgesics varies for different patients. The main advantage of using local anaesthetics is that they do not have the adverse effects of opioids like postoperative nausea, sedation, impairment of return of gastrointestinal mortality, and pruritus which may delay recovery and discharge from hospital. Local anaesthetics have been administered into the peritoneal cavity during minimally invasive procedures, such as laparoscopic cholecystectomy and gynaecological laparoscopy for sterilization and diagnosis.² In addition to open

abdominal procedures, such as total abdominal hysterectomy.

Laparoscopic cholecystectomy has emerged as the gold standard for gallstone diseases. One of the causes of why LC is preferred over OC is because of decreased pain and early discharge. Still pain remains as a major cause of concern this current study, we have observed the effect of intraperitoneal instillation of ropivacaine along with subcutaneous injection around the trocar sites in patients undergoing LC.

METHODS

This study was conducted in IMS/SUM Hospital over a period of 1 year from January 2016 to January 2017. The patients of a single surgical team comprising of 2 laparoscopic surgeons were taken. Both the surgeons are equally trained and efficient with identical approaches to LC. Patients aged 20 - 70 years of either sex belonging to ASA physical status I or II planned for laparoscopic cholecystectomy were included in this prospective, randomized, double blind, placebo-controlled study. The total number of patients taken for study were 100.

Exclusion criteria

Patients who were excluded from the study were those with ASA Grade 4,5 patients with history of cardiac diseases, asthma, COPD, converted to OC.

All the patients who were fit for surgery were divided into broad groups;

- Group C (control) 50 Patients received 100ml of 0.9% NS, on the other hand
- Group R 50 Patients given 2mg/kg Intraperitoneal Ropivacaine 0.25% diluted in 100ml of NS.
- Group R was further categorised into Group A (acute cases operated within 72 hours) and Group B (elective cholecystectomy).
- Males and females were separately studied. Each group C and R were randomly assigned 50 cases.

Routine investigations were done as per our hospitals protocol. Patients were kept nil orally for 6 hours. All the LC were done by the 2 surgeons of the team. Cases were randomly assigned amongst them. Ports were given as per the recommended guidelines. The intra-abdominal pressure was kept below 15mmHg. The time taken for the completion of procedure was recorded for each case.

Drug solution was prepared by an anaesthesiologist who had not participated in the study, and drug was filled in pre-coded 20ml syringes. Surgeon and the anaesthesiologist in the post-anaesthesia care unit were unaware of the treatment to which each patient was randomized. Ropivacaine (2mg/kg) was diluted with 100ml of NS and instilled intra-peritoneally before the removal of trocar at the end of the surgery, in

Trendelenburg's position to facilitate dispersion of drug solution in the sub diaphragmatic space, gallbladder bed and was also injected around the trocar sites in the group R. NS 100ml was intraperitoneally given in the group C

Postoperative pain management

To control the postoperative pain, we used NSAIDS (Diclofenac) at a recommended dose of 75mg/3ml intravenous 2 times daily. Patients were told to demand for extra-analgesic (rescue analgesia) when their pain increased beyond their tolerance. The timing of the extra doses was duly recorded by our resident doctor. Pattern of pain was asked to the patients as to whether it was incisional, generalised abdominal, right hypochondriac shoulder. It was recorded till the patients were discharged. After 24 hrs the patients were given oral analgesics.

Variables studied

For each patient were studied by author like age, gender, American Society of Anaesthesiology (ASA) class, operation time (from incision to skin closure), pain intensity by Visual Analog score (VAS), extra dose of analgesia, discharge time, resumption of normal activity after discharge.

RESULTS

We had taken 100 patients in present study. 50 patients were in the control group (GROUP C) who did not get ropivacaine instillation and 50 patients were in the Group R who had intraperitoneal instillation and trocar site infiltration of ropivacaine. The age of the patients ranged from 20 yrs to 70 yrs. The male: female ratio was almost comparable in both. In the group C 30% were acute cases who were operated within 72 hours of attack and 70% were electively operated. In the group R it was 24% and 76% respectively.

Table 1: Demographic data.

Parameters	Group C	Group R
Gender (M/F)	17/33(34%/66%)	11/39 (22%/78%)
Difficult/simple	8/42 (16%/84%)	15/35(30%/70%)
Acute/elective	15/35(30%/70%)	12/38(24%/76%)
ASA I	28 (56%)	32 (64%)
ASA II	22 (44%)	18 (36%)
Operation time (mins)	51.2	53.2

The majority of patients in both the group were in the ASA I/II. The operative time were almost the same taking into consideration the acute and chronic cases (around 50-60 minutes). In the control group 16% of the cases had difficult Calots and in the Group R 30% were difficult.

Table 2: Pattern of pain.

Type of pain	Group C (n=50)	Group R (n=50)
Incisional	38 (76%)	10 (20%)
RT HQ	42(84%)	16 (32%)
Diffuse ABD	41 (82%)	35 (70%)
Shoulder	15 (30%)	5(10%)

When we compared the pattern of pain in both the groups over the period of 24 hours postoperative, it was seen that in the group C shoulder pain was seen in 30% of cases, followed by incisional pain in 76%.

Right hypochondriac pain was maximum in 84% and diffuse abdominal was 82%. In the group R they were comparatively less being 10%, 20%, 32% and 70% respectively. In the group R we found diffuse abdominal pain at a higher range.

Table 3: Post-operative analgesia requirement.

Rescue analgesia (hours)	Group C (n=50)		Group R (n=50)	
	Group A (n=15)	Group B (n=35)	Group A (n=12)	Group B (n=38)
1-4	12(80%)	24(68%)	6(50%)	12(31%)
4-8	10(66%)	20(57%)	4(33%)	15(39%)
8-12	11(73%)	24(68%)	3(25%)	9(23%)
12-16	8(53%)	15(42%)	4(33%)	9(23%)
16-24	4(26%)	8(22%)	2(16%)	4(10%)
24-48	2(13%)	4(11%)	1(8%)	1(2%)

The postoperative rescue analgesia for group C was demanded after around 1 to 2 hours of reaching the ward whereas in the group R it was around 4 hours. In the group R the rescue analgesia in the first 12 hrs were significantly less than group C.

In the acute cases it was slightly higher but still significantly less than group C. There was more demand for analgesics in the acute and difficult calots cases in both the groups.

Table 4 Other variables.

Variables	Control group	Ropivacaine group
Hospital stay	36-48 hrs	24-36hrs
Return to normal activity	7-8 days	3-4 days

Discharge after adequate pain relief was seen early in group R (24 hours) than in the group C (36-48hours). It was observed that patients of group R returned early to their jobs (3-4 days), whereas in the group C it was 7-8 days.

DISCUSSION

LC is considered as the gold standard for gallstone diseases world-wide. It is gradually being considered as a

OPD procedure, but pain remains as the most important factor against this.

Pain after LC comprises of 3 different aspects Incisional pain, visceral pain, and shoulder pain.²⁻⁵ Shoulder pain occurs after LC due to diaphragmatic stretching, excessive traction on triangular ligament during CO₂ insufflation.⁵⁻⁷ It occurs in about 35-63% of cases.⁸ The proposed mechanisms include phrenic nerve neuropraxia of short duration due to stretching of diaphragmatic fibres by CO₂ insufflation. Visceral pain results due to rapid distention of abdomen causing tearing of the blood vessels, traction of nerves and local irritation and inflammation of gallbladder bed. Several studies suggested that parietal pain is the predominant cause of pain.^{3,9} Incisional pain was more dominant than visceral pain which in turn dominated shoulder pain. By contrast the visceral component of pain occupies a major portion than the parietal component because of the small incision and less trauma to the abdominal wall.¹⁰⁻¹³

Pain is subjective and accurate measurement is very difficult. In the different studies done all had taken the VAS score as the scale. In present study we have taken the VAS scale for measuring as well as patients own subjective assessment as to the time of discharge and return to activity

Various local anesthetics such as lignocaine, bupivacaine, ropivacaine, and levobupivacaine have been evaluated in many trials.^{14,15} Several factors are important for intraperitoneal instillation of drug to decrease postoperative pain, which include choice of drug, concentration of drug, volume of drug, and timing of drug administration.^{16,17} Various studies have been done using different drugs, combinations, and different costly equipment's to instill the local anaesthetic in the intraperitoneal cavity.

In present study we simply instilled Ropivacaine with 100ml of NS in the peritoneal cavity at the end of the procedure. We used ropivacaine for intraperitoneal instillation because of its low toxicity and longer duration of action. Ropivacaine is a long-acting amide type local anaesthetic used as regional anaesthetic. It is a pure S(-) enantiomer, developed for the purpose of reducing potential cardiac toxicity and improving relative sensory and motor block profiles. When ropivacaine is given intraperitoneally it starts acting within 10-20 min, and duration of action lasts for 4-6 h.¹⁸

In present study there was a significant reduction of pain (visceral, shoulder and parietal) and the need of rescue analgesia was significantly less than the control group. VAS scores were lower in group R (ropivacaine) than group C (placebo) during the overall estimated time and as well as the interval times of estimation. Patients were also willing to be discharged early and resumed their normal activities early.

Apart from the visceral pain, LC patients also experienced parietal pain from the trocar sites. Present study also demonstrated that there was significantly less complaint of the parietal component of pain as compared to the control group because of local infiltration of Ropivacaine.

In the study of intermittent injections of 0.5% ropivacaine through a catheter reduced early postoperative pain after laparoscopic cholecystectomy.¹⁹

In present study the instillation of intraperitoneal ropivacaine reduced pain significantly after LC specifically shoulder and visceral. In the study of Labaille thirty-seven ASA physical status I or II patients received in double-blinded fashion 20ml of 0.9% saline solution (placebo), ropivacaine 0.25%, or ropivacaine 0.75% immediately after trocar placement and at the end of surgery.²⁰

They observed visceral pain and total consumption of morphine were significantly less in the study group. Similar findings were also reported in other studies.²²⁻²⁵ Similarly, in present study intraperitoneal ropivacaine reduced the pain after laparoscopic surgery as compared to placebo. The findings of the present study are similar to the study by Pasqualucci A. and Kucuk who compared the effect of intraperitoneal ropivacaine (150mg) in patients undergoing a laparoscopic cholecystectomy.²⁶⁻²⁷

Present data clearly show that patients who received both a local anaesthetic infiltration of port sites and intraperitoneal instillation of ropivacaine suffer a significantly less intense parietal, visceral, and shoulder tip pain, if compared to patients who received normal saline only. This was also true for acute cases as well as for elective cases. Although there are various studies regarding the different local anaesthetics, timing, method of instillation, doses, the fact that a simple manoeuvre like local instillation of Ropivacaine can reduce the postoperative pain significantly is an attractive option in the peripheral centres where laparoscopy is being practised.

CONCLUSION

From present study we can safely assume that intraperitoneal instillation of Ropivacaine is a safe method to decrease the postoperative pain facilitating early discharge and ambulation.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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