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ORIGINAL ARTICLE

Ropivacaine Hydrochloride Instillation *vs* Parenteral Analgesia (Tramadol) for Pain Control following Laparoscopic Cholecystectomy

[1]Mahmoud AL Bahram, [2]Ahmed A Monem, [3]Amir K Saleh

ABSTRACT

Background: The use of laparoscopic techniques in general surgery has gained increasing popularity in the last few decades. Patients undergoing laparoscopic cholecystectomy do experience postoperative pain mainly in the upper abdomen, back, and shoulder region that needs narcotic injection as a pain reliever. Intraperitoneal injection of local anesthetic has been proposed to minimize postoperative pain after laparoscopic cholecystectomy.

Aim: The aim of this study is to compare the effectiveness of intraperitoneal ropivacaine hydrochloride installation with intramuscular tramadol injection for postoperative pain.

Materials and methods: In this study, 400 patients of either sex in the age group of 23 to 62 years with American Society of Anesthesiologists grade I and II, who were scheduled to undergo elective laparoscopic cholecystectomy, were allocated to two groups of 200 patients each with regard to postoperative analgesia. In group I (n = 200) the patients received ropivacaine (0.5%), instilled in gallbladder bed and the undersurface of diaphragm and infiltration of port wounds. In group II (n = 200) the patients were provided with postoperative analgesia with tramadol (100 mg) given intramuscularly (IM) at the completion of procedure. The intensity of postoperative pain using visual analogue scale (VAS) and shoulder pain was evaluated and also other pain-related sequelae were recorded.

Results: Both VAS and shoulder pain score had significantly improved postoperatively in group I in comparison with group II. At the same time, ropivacaine instillation in group I lowers significantly postoperative nausea and vomiting resulting from either postoperative pain or tramadol injection.

Conclusion: Intraperitoneal installation of ropivacaine hydrochloride reduces the intensity of visceral, parietal, and shoulder pain in comparison with IM tramadol injection.

Keywords: Cholecystectomy, Laparoscopy, Pain.

[1]Assistant Professor, [2,3]Lecturer

[1]Department of General Surgery, Faculty of Medicine Menoufia University, Al Minufya, Egypt

[2]Department of General Surgery, Faculty of Medicine Mansoura University, Mansoura, Egypt

[3]Department of Anesthesia, Faculty of Medicine, Ain Shams University, Cairo, Egypt

Corresponding Author: Mahmoud AL Bahram, Assistant Professor, Department of General Surgery, Faculty of Medicine, Menoufia University, Minufya, Egypt, Phone: +0020462228302, e-mail: mahmoudbahreem@yahoo.com

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INTRODUCTION

Laparoscopic cholecystectomy has been proven to reduce postoperative pain significantly and shorten the recovery period, therefore reducing discharge time from 1 to 3 days to same day discharge with an earlier return to normal activities.[1]

After laparoscopic cholecystectomy, 35 to 63% of patients complain more of visceral pain as a result of stretching of the intra-abdominal cavity, peritoneal inflammation, and phrenic nerve irritation caused by residual carbon dioxide in the peritoneal cavity. Postoperative abdominal pain usually occurs during the first 24 hours, while shoulder pain most commonly appears the second day after laparoscopic cholecystectomy.[2]

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 respiratory depression, drowsiness, postoperative nausea and vomiting, ileus, and constipation that can delay hospital discharge.[3]

Intraperitoneal administration of some drugs can be effective for relief of pain after laparoscopic cholecystectomy.[2] Clinical studies have investigated the use of regional local anesthetics, in combination with other modalities for pain relief following laparoscopic cholecystectomy to avoid the adverse effects of opioids.[4]

This study (double-blind, prospective controlled study) was designed for patients undergoing elective laparoscopic cholecystectomy to compare the degree of postoperative pain relief, nausea, and vomiting following intraperitoneal ropivacaine hydrochloride instillation and parenteral analgesia (tramadol).

MATERIALS AND METHODS

After obtaining written consent, 400 patients with American Society of Anesthesiologists physical status

I and II, scheduled to undergo elective laparoscopic cholecystectomy, were enrolled in this study, which was approved by the hospital ethics committee. Patients were excluded if they had clinical diagnosis of acute pancreatitis, had acute preoperative pain other than biliary colic, required chronic pain treatment or antiepileptic drugs, had history of alcohol or drug addiction, had severe hepatic or renal impairment, had allergy to the study drugs, or had cognitive impairment or communication problems [i.e., who did not understand visual analog scale (VAS)].

Preanesthetic check-up was done the day before surgery and included a detailed history and complete general physical and systemic examination. Baseline values of pulse, blood pressure, and respiratory rate were recorded. Basic demographic characteristics like age, sex, and weight were noted. Routine investigations included hemoglobin, clotting time, bleeding time, X-ray chest, electrocardiogram, renal function tests, serum electrolytes, blood glucose level, and liver function tests. Patients were kept fasting overnight and were premedicated with tablet diazepam 10 mg at bed time.

At the same visit (preanesthetic check-up) patients were instructed on how to use a 100-cm VAS, with anchors ranging from "no pain" to "worst possible pain."

Patients were randomized into two groups using a computer-generated randomization sequence. Patients in the instillation group (Group I) received intraperitoneal instillation of ropivacaine 0.5%, 10 ml (50 mg) on the gallbladder surgical bed, and ropivacaine 0.5%, 10 ml (50 mg) solution was sprayed on the upper surface of the liver and on right subdiaphragmatic space, to allow it to diffuse into the hepatodiaphragmatic space, near and above the hepatoduodenal ligament and above gallbladder before finishing the procedure. This was done using a catheter inserted into the subcostal trocar under direct laparoscopic control and the patient was kept in the Trendelenburg position. In addition, each four-portal site was infiltrated with ropivacaine 0.3%, 3 ml after completion of the surgery. Patients in group II received 100 mg tramadol intramuscularly (IM) at the end of procedure.

The degree of postoperative pain was assessed using VAS in case of spontaneous pain upon patient's arrival in the recovery room, immediately postoperatively, and thereafter every 1 hour for a period of first 4 hours then every 4 hours for the rest of the first 24 hours postoperatively. Shoulder pain was evaluated at immediate postoperative time, and at 12 and 24 hours from the termination of surgery. Those patients with VAS more than 40 were administered diclofenac sodium 75 mg IM as rescue analgesia. Time to first analgesic requirement, total analgesic consumption in the first 12 hours postoperatively, and occurrence of adverse events were also recorded.

RESULTS

After obtaining written consent, 400 patients with American Society of Anesthesiologists physical status I and II, who were scheduled to undergo elective laparoscopic cholecystectomy, were included in this study. No significant difference between both groups as regarding their age and sex ratio was observed (Table 1).

During the early postoperative assessment of pain, the score on the VAS scale was highly significantly lower in group I than in group II just immediately postoperative in the recovery area and remained significant till 4 hours postoperatively. After 4 hours, there was no significant difference between both groups (Table 2).

The timing of first dose of rescue analgesia needed was significantly longer in group I than in group II. Also the dose of nonsteroidal anti-inflammatory drugs (NSAIDs, in mg) needed as rescue analgesia was significantly lower in group I than in group II. Also shoulder pain was significantly lower in group I than in group II (Table 3).

Table 1: Age and sex of both groups

		Group I (n = 200)	*Group II (n = 200)*
Age (years)	Mean range (min-max)	27.51 years 18–65 years	29.07 years 21–64 years
Sex	Male: Female Ratio	71:129 (1:2)	64:146 (1:2)

Table 2: Postoperative visual analog scale for patients in both groups

	VAS ≤ 40		*VAS < 40*		
	I	*II*	*I*	*II*	*p-value*
Immediate postoperative	169	66	31	134	HS
After 1 hour	157	98	43	102	S
After 2 hours	152	107	48	93	S
After 3 hours	145	112	55	88	S
After 4 hours	124	119	76	81	NS
After 8 hours	132	135	68	65	NS
After 12 hours	141	144	49	56	NS
After 16 hours	159	163	41	37	NS
After 20 hours	171	170	29	30	NS
After 24 hours	181	178	19	22	NS

HS: Highly significant; S: Significant; NS: Nonsignificant; VAS: Visual analog score

Table 3: Shoulder pain postoperative analgesia for both groups

		Group I	*Group II*	*p-value*
Shoulder pain		47 (23.5%)	117 (58.5%)	S
Mean timing after surgery to give first analgesic requirement (in minutes) ± SD		115 ± 38.36 min	16 ± 9.43 min	S
No. of NSAIDs	Min–Max	75–150 mg[2]	75–225 mg	S
Mean	45 ± 10.5 mg	85 ± 25.2 mg		

S: Significant; SD: Standard deviation; NSAID: Nonsteroidal anti-inflammatory drug

Table 4: Postoperative complications in both groups

	Group I	*Group II*	*p-value*
Nausea	27	105	S
Vomiting	4	56	S
Bradycardia	0	3	NS
Respiratory depression	0	2	NS
Hospital stay	1 ± 0.12 days	1 ± 0.42 days	NS
Intra-abdominal infection	1	0	NS

S: Significant; NS: Nonsignificant

During hospital stay and early postoperative follow-up, the incidence of nausea and vomiting was significantly lower in group I than in group II. There was no significant difference between both groups regarding complications and hospital stay (Table 4).

DISCUSSION

The establishment of laparoscopic cholecystectomy as an outpatient procedure has accentuated the clinical importance of reducing early postoperative pain and nausea as both are the most common complications of laparoscopic surgery, including cholecystectomy. Both, particularly pain, prolong recovery and discharge times and contribute to unanticipated admission after ambulatory surgery. Pain also contributes to postoperative nausea and vomiting.[1]

Interestingly, the type of pain after laparoscopy differs considerably from that seen after laparotomy. Although it is the belief of patients that laparoscopy has ushered a pain-free era, the fact remains that patients complain more of visceral pain after laparoscopy in contrast to parietal pain experienced in laparotomy.[5]

Visceral pain is caused by inflammation or local irritation around the gallbladder bed, liver, diaphragm, or peritoneum. Also, the incidence of postoperative shoulder pain due to diaphragmatic irritation by residual carbon dioxide following laparoscopic surgery may reach up to 80%.[6]

Intraoperative use of large bolus doses or continuous infusions of potent opioid analgesics may actually increase postoperative pain as a result of their rapid elimination and/or the development of acute tolerance. Also, opioid analgesics are associated with a variety of perioperative side effects, such as respiratory depression, drowsiness, bradycardia, postoperative nausea, and vomiting.[7]

Therefore, anesthesiologists and surgeons are increasingly turning to nonopioid analgesic techniques as adjuvant for managing pain during the perioperative period to minimize the adverse effects of analgesic opioids.[8]

This study showed that VAS scores are highly significantly lower in group I in comparison to group II immediately postoperative and remained significant up to 4 hours postoperative. However, the difference was not significant between both groups after 6 hours; this may be due to the rescue analgesia doses of NSAIDs given to patients in group II. The results in this study conform with the results in the study done by Singh et al[9] and Golubovi et al.[2]

A study done by Gupta et al[10] also showed that intraperitoneal instillation of fentanyl (100 µg) along with bupivacaine (0.5% 20 ml) significantly reduces immediate postoperative pain. It also reduces intensity of pain even after 24 hours.

In group II, about two-thirds of the patients required a first dose of rescue analgesia immediately postoperatively and the remaining third of the patients required this dose within the next 6 hours, whereas in patients in group I receiving ropivacaine, 25% of the patients required the first dose immediate postoperatively and the remaining 75% of patients required analgesia within 24 hours postoperatively. There was a significant difference between both groups regarding timing of first dose of rescue analgesia. Further requirement of rescue doses of analgesia was significantly lower in group I than in group II.

Shoulder pain is a common outcome after laparoscopic cholecystectomy and can delay return to normal activities. The proposed mechanism of shoulder pain seems to be a diaphragmatic stretching with phrenic nerve neuropraxia, which is possibly due to increased concavity of diaphragm induced by pneumoperitoneum and reference of pain from the traumatized area.[10]

Shoulder pain was significantly lower in group I than in group II early in the postoperative period, but was not significant after 6 hours postoperatively. The reason could be the blocking of nociceptive inputs generated by inflamed diaphragm peritoneum caused by instillation of ropivacaine. Joris et al[8] obtained similar results using ropivacaine and showed that use of ropivacaine decreased incidence of shoulder pain even after 24 hours postoperatively.

Studies by Gupta et al[10] using bupivacaine and Kim et al[11] using ropivacaine showed similar results, which further supports these results.

In this study, the incidence of nausea, vomiting, bradycardia, respiratory depression, and intra-abdominal infection was recorded in both groups. There was a significantly lower incidence of postoperative nausea and vomiting in group I than in group II, but no significant difference between both groups as regarding bradycardia, respiratory depression, or postoperative intra-abdominal infection. This shows ropivacaine instillation reduces the incidence of nausea and vomiting. The cause could be lower incidence of pain and avoiding the side effect

of intravenous tramadol injection. Similar results were obtained by Kucuk et al,[12] Trikoupi et al,[13] and Gupta et al.[10]

CONCLUSION

Intraperitoneal ropivacaine instillation reduced postoperative abdominal pain and shoulder pain significantly in comparison to postoperative tramadol injection, reflected on the number of rescue postoperative analgesia doses which was significantly lower with intraperitoneal ropivacaine. At the same time, it lowers significantly postoperative nausea and vomiting resulting from either postoperative pain or tramadol injection, but does not affect significantly the duration of hospital stay.

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