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Original Research Article

Comparison of Intraperitoneal Instillation of Ropivacaine with Normal Saline in Laparoscopic Cholecystectomy at SKMCH, Muzaffarpur, Bihar

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Abstract:

Background: Local anesthetics are now widely used, as they have a good safety profile and are available in long acting preparation. They provide the benefit of analgesia without systemic side effects that may result from use of enterally and parenterally administered drugs.

Methods: This prospective randomized study was conducted on 100 patients with symptomatic gallstones disease undergoing laparoscopic cholecystectomy. Patients were randomized to receive either 0.5% of 3mg/kg of Ropivacaine diluted in 100 ml NS, instillation at intraperitoneal space before creation of pneumoperitoneum (group or 100 ml NS instillation at intra peritoneal space before creation of pneumoperitoneum (group II). VAS score for pain abdomen as well as shoulder were recorded postoperatively at various time intervals and compared in both the groups. Total analgesic consumption in 24hrs was also noted and compared.

Results: The mean postoperative VAS score for abdomen and shoulder pain was significantly (p values<0.05) lower in group I than in group II till 24 hrs postoperatively. The latency time from end of operation to first analgesic requirement was significantly longer in group I than in group II.

Conclusion: Intraperitoneal instillation of Ropivacaine before the creation of pneumoperitoneum significantly decreased the total abdominal pain, shoulder tip pain with lower analgesic consumption. As it is safe and without apparent side effects, we believe that intraperitoneal instillation of local anaesthetic in patients undergoing elective laparoscopic cholecystectomy is an effective modality for postoperative pain management.

Keywords: Intraperitoneal instillation, Laparoscopic cholecystectomy, Post-operative pain.

Introduction

Laparoscopic cholecystectomy reduces the postoperative pain significantly and thus allows a shorter hospital to stay and recovery period, which is reflected in patient's earlier return to normal life and work activities. In some of the centres, patients are discharged home on the first post-operative day. Pain following laparoscopic cholecystectomy is multifactorial and can be differentiated into three components- visceral, abdominal wall, and referred pain to shoulder. Pain is worst in the first 24 hours with visceral pain being worse than abdominal wall pain.

Different modalities have been proposed to relieve post-operative pain after laparoscopy. These include parenteral NSAIDS/ opioids, preemptive and post-operative intraperitoneal local anaesthestic instillation, port site infiltration of local anaesthetic, intraperitoneal saline, removal of insufflation gas/ gas drains, low pressure abdominal insufflations, Acetazolamide administration, use of N_2O in place of CO_2 etc. Local anesthetics are now widely used, as they have a good safety profile and are available in long acting preparations. They provide the benefit of analgesia without systemic side effects that may result from use of enterally and parenterally administered drugs. Russ maries et al conducted a study on intraperitoneal Bupivacaine for effective pain relief after laparoscopic cholecystectomy by giving Bupivacaine in test group and NS in control group after completion of surgery. They concluded that intraperitoneal Bupivacaine reduces pain in initial post-operative period after laparoscopic cholecystectomy and it is easy to administer with no adverse effects.

However, Zmora O et al and Elfberg et al evaluated the effect of intraperitoneal Bupivacaine on pain following laparoscopic cholecystectomy and concluded that intraperitoneal Bupivacaine does not attenuate pain following laparoscopic cholecystectomy. Various studies have shown that

intraperitoneal instillation of local anaesthetics reduce pain in initial postoperative period while there are some suggesting that it does not attenuate pain following laparoscopic cholecystectomy. Due to conflicting results in different studies. This study was conducted to evaluate and compare the effect of intraperitoneal instillation of ropivacaine with normal saline on post-operative pain in patients undergoing laparoscopic cholecystectomy.

Material and Methods

This prospective randomized study was conducted in the Department of Anesthesiology and Intensive Care, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar from January 2019 to December 2019 after informed consent from all the patients. 100 patients with symptomatic gall stones disease undergoing laparoscopic cholecystectomy were randomly allocated using computer generated random number and concealed opaque envelopes to one of the two groups.

Group I (n=50) patients received 0.5% of 3mg/kg of Ropivacaine diluted in 100 ml NS, instillation at intraperitoneal space before creation of pneumoperitoneum; Group II(n=50) patients received 100 ml NS instillation at intra peritoneal space before creation of pneumoperitoneum. All cases were performed by experienced laparoscopic surgeons.

Patients with hypersensitivity to Ropivacaine, acute cholecystitis, acute pancreatitis, pregnancy, prolonged administration of NSAIDS or other analgesics, cirrhosis, bleeding disorders, history of peritonitis, carcinoma gall bladder, splenomegaly, converted to open cholecystectomy were excluded from the study. All patients were assessed by detailed history and clinical examination, abdominal ultrasonography and haematological and Biochemical investigations.

Visual analogue scale (VAS)of 0-10 was explained to all the patients as below.

- 0.....no pain
- 1-3.....mild pain
- 4-7.....moderate pain
- 8-10.....severe pain

All patients were kept fasting for at least 6 hr preoperatively and a tablet of Alprazolam 0.25mg was given orally at night after meal.

After shifting the patient to operation theatre, preinduction vital parameters such as heart rate, blood pressure, respiratory rate, temperature and SpO_2 were recorded and intravenous access was secured. Preoxygenation with 100% oxygen via an anatomical face mask for 3 minutes was done. After induction with 0.2 mg glycopyrrolate, fentanyl 2µg/kg and propofol 2-2.5 mg/kg i.v, succinylcholine 1.5mg/kg i.v. was given to facilitate oral endotracheal intubation with appropriate size endotracheal tube. After checking and securing the endotracheal tube, anaesthesia was maintained with intermittent positive pressure ventilation using closed circuit and 0.5-2% Isoflurane. Muscle relaxation was achieved with intermittent Vecuronium Bromide. Drug solution was administrated using veress needle before creation of pneumoperitoneum.

Patients were placed in 15-20degree reverse Tren delenburg's position with left side down tilting position. During laparoscopy, intra-abdominal pressure was limited to 10-12 mm of Hg. Anaesthesiologist in post-anaesthesia care unit was unaware of treatment to which each patient was randomized. During surgery non-invasive blood pressure, heart rate, $EtCO_2$ and peripheral oxygen saturation were recorded regularly.

All patients were given Inj. Ondansetron 4mg I/v before shifting to recovery room. Careful note was made of anaesthesia time, operation time, operative procedure or any technical difficulty.

All patients were assessed post operatively in terms of following parameters

- Abdomen pain and shoulder tip pain (immediate after recovery, at 1hr, 3hr, 6hr,12hr, 18hr, 24hr)
- Total analgesic consumption in 24 hrs
- Nausea / Vomiting
- Any other complications.

Those patients with VAS >4 were administered an infusion of 1 gm paracetamol (i.v) as rescue analgesia. Another dose of paracetamol infusion repeated only after at least 8 hrs. However, if patient again complains of pain with VAS >4, they were given an additional dose of inj. Tramadol 100 mg i.v. Patients were administered inj. Ondansetron 4mg on complain of nausea/vomiting. Nausea and vomiting were assessed depending upon the episodes, number and need for antiemetic medication and occurrence of any other adverse effects were also recorded.

Continuous variables were analysed with student t-test and categorical variables were analysed with the Chi-square test and Fisher exact test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 22 and Microsoft Excel 2007.

Results

There was no significant difference between groups with respect to age, sex, weight, and duration of surgery. (Table 1) As shown in the Table 2 and Table 3, the mean postoperative VAS score for abdomen and shoulder pain was significantly lower (p values<0.05) in group I than in group II till 24 hrs postoperatively. The latency time from end of

operation to first analgesic requirement was significantly longer in group I than in group II. The number of rescue analgesic requested was significantly lower in group I as compared to group II and the difference was highly significant (p values<0.001) as shown in Table 4. The mean paracetamol consumption for 24hrs was 1.3409±0.52gm in group I and 4.7000±0.97416 gm in group II which was also significantly lower in group I than in group II. (p value<0.001).

Table 1: Demographic profile

	Group I (mean±SD)	Group II (mean±SD)	p-value
Age (year)	41.76±11.53	46.46±10.36	0.148
Weight (kg)	62.42±6.70	58.84±3.36	0.303
Female : Male	30:10	35:15	0.434
Duration of surgery (min).	60.30±3.22	60.80±2.74	0.376
ASA I/II	40/10	30/20	0.421

Table 2: VAS score for pain abdomen

VAS (PA)	Group I (mean±SD)	Group II (mean±SD)	p-value	p-value
0 hrs	2.50±0.76	3.50±1.88	0.001	HS
1 hrs	2.68±0.84	3.40±1.84	0.001	HS
3 hrs	2.46±0.76	3.20±1.86	0.001	HS
6 hrs	2.88±0.82	3.80±1.86	0.001	HS
12 hrs	2.28±1.17	3.16±1.99	0.001	HS
18 hrs	1.46±1.59	3.64±1.97	0.001	HS
24 hrs	0.38±0.66	2.56±0.07	0.001	HS

Table 3: VAS score for shoulder pain

VAS Shoulder pain	Group I (mean±SD)	Group II (mean±SD)	p-value	Significant
0 hrs	1.05±0.84	2.22±1.44	0.025	S
1 hrs	0.10±0.30	2.28±1.26	0.028	S
3 hrs	0.14±0.35	2.88±1.30	0.025	S
6 hrs	0.04□0.19	1.20±1.21	0.024	S
12 hrs	0.04±0.19	1.24±1.18	0.010	S
18 hrs	0.00±0.00	1.40±0.60	0.006	S
24 hrs	0.00±0.00	1.00±0.00	0.008	S

Table 4: Requirement of analgesia

Requirement of analgesia	Group I		Group II		p-value	Significant
	No.	Percentage	No.	Percentage		
0 hrs	6	12.0%	36	72.0%	<0.001	HS
1 hrs	7	14.0%	24	48.0%	0.003	HS
3 hrs	8	16.0%	29	58.0%	0.006	HS
6 hrs	9	18.0%	23	46.0%	0.003	HS
12 hrs	11	22.0%	27	54.0%	0.001	HS
18 hrs	8	16.0%	19	38.0%	0.603	HS
24 hrs	14	28.0%	19	38.0%	0.640	HS

Discussion

Laparoscopic cholecystectomy has been widely accepted as an alternative of open cholecystectomy and has many advantages including cosmetically better, less postoperative pain and short hospital stay. Although patients complain less postoperative pain compared to open cholecystectomy but still it is not a pain free procedure. Pain after laparoscopic cholecystectomy arises from three main components: pain from skin incision, creation of pneumoperitoneum and trauma created by cholecystectomy. Most severe pain reported by patients is abdominal port wound, visceral, shoulder and the right upper abdominal quadrant. In our study, group I (n=50) received intraperitoneal instillation of Ropivacaine while group II (n=50) received intraperitoneal instillation of saline before creation of pneumoperitoneum. VAS score for pain abdomen as well as shoulder pain were recorded postoperatively at various time intervals which were significantly less in group I for upto 24 hrs.

This shows that the application of peritoneal instillation of ropivacaine before the creation of pneumoperitoneum decreases postoperative pain. These results are comparable with studies

conducted by Berczynski et al and Maestroni et al. Maestroni et al also observed that pain was significantly less in patients who received ropivacaine as compared to saline before creation of pneumoperitoneum. However, Lee et al concluded that no significant difference in abdominal pain occurred by preemptive instillation of Bupivacaine in laparoscopic cholecystectomy. This lack of effect in their study might be due to small dosage of intraperitoneal Bupivacaine used (0.25% 40 ml) as compared to our study in which we used 0.5% Ropivacaine 3mg/kg diluted in 100 ml normal saline for intraperitoneal instillation.

The traditional approach to postoperative analgesia is to start therapy when surgery is completed and pain is experienced. Newer evidence from basic research into the mechanisms of pain suggests that the administration of analgesic drugs may be more effective if given before, rather than after nociceptive stimuli. Lepnur et al by comparing both lignocaine and bupivacaine proved that bupivacaine is more effective then lignocaine for postoperative pain after intraperitoneal instillation. [12] Kucuk et al suggested that ropivacaine at adequate dose (150 mg) is significantly more effective than bupivacaine and low dose ropivacaine (100 mg).

The mean dose of ropivacaine used in our study was well tolerated and had no secondary effect. Ropivacaine as local anaesthetic has low toxicity and longer duration of action. 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.

The total analgesic requirement was significantly less in patients who received intraperitoneal instillation of drug before creation of pneumoperitoneum (1.34±0.52gram paracetamol) than patients who received normal saline (4.7±0.97gram paracetamol). Maestroni et al also observed a significantly lower total pain intensity and total analgesic requirement during initial 8 hrs postoperatively. But Lee et al have concluded that intraperitoneal bupivacaine had no significant effect on duration of first analgesic requirement and total analgesic requirements. Alper I et al also studied the effects of intraperitoneal administration of levobupivacaine on pain after LC by intraperitoneal instillation of either 40 mL of 0.25% levobupivacaine in study group or normal saline in control group under direct vision into the hepatodiaphragmatic lodge and above the gallbladder after creation of pneumoperitoneum. They concluded useful effects of levobupivacaine on postoperative pain relief after laparoscopic cholecystectomy, especially in the early postoperative period and reduced postoperative rescue analgesic requirement.

Labaille T et al studied clinical efficacy of intraperitoneal Ropivacaine by instillation of 20 mL of 0.9% saline solution, Ropivacaine 0.25%, or Ropivacaine 0.75% immediately after trocar placement and at the end of surgery. Visceral pain at rest, during cough, and on movement and total consumption of morphine were significantly smaller in groups Rop 0.25% and Rop 0.75% when compared with placebo and they concluded that intraperitoneal Ropivacaine injected during laparoscopic cholecystectomy significantly decreased postoperative pain when compared with injection of intraperitoneal placebo. Because the smaller dosage provided similar analgesia and was associated with significantly smaller plasma concentrations than the larger dosage so this smaller dosage seems more appropriate. Choi GJ et al have also concluded that intraperitoneal local anesthetic as an analgesic adjuvant in patients undergoing laparoscopic cholecystectomy exhibited beneficial effects on postoperative abdominal, visceral, and shoulder pain.

Conclusion

In conclusion, intraperitoneal instillation of Ropivacaine before the creation of pneumoperitoneum significantly decreased the total abdominal pain, shoulder tip pain with lower analgesic consumption. As it is safe and without apparent side effects, we believe that intraperitoneal instillation of local anaesthetic in patients undergoing elective laparoscopic cholecystectomy is an effective modality for postoperative pain management.

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