Research Paper

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Comparison of Intra-Peritoneal Bupivacaine and Ropivacaine for Postoperative Pain Relief After Laparoscopic Cholecystectomy - A Randomised Clinical Trial.

Medical Science

KEYWORDS : Laparoscopic cholecystectomy, Postoperative pain, Ropivacaine, Bupivacaine.

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ABSTRACT

Background: Efficacy of local anaesthetics as a component of multimodal analgesia after laparoscopic surgery had been evaluated by many studies. We compared the efficacy of two long acting local anaesthetics in decreasing postoperative pain and analgesic consumption. Materials and methods: Sixty patients were randomly assigned to receive either intra-peritoneal installation of 40 ml and port site infiltration of 10 ml of 0.25% bupivacaine or 0.25% ropivacaine after a standard general anaesthesia.10 point Visual Analogue Pain score at 12th postoperative hour and total tramadol consumption over 12 hours were evaluated. Results: There was no significant variation in the mean pain score at 12th postoperative hour between the bupivacaine (3.133±1.008) and ropivacaine (3.166±1.08) groups (p 0.9024). Mean tramadol consumption in 12 hours was more in Ropivacaine group than Bupivacaine Group B, but the difference was not statistically significant (p 0.2859). Conclusion: Both bupivacaine and ropivacaine exhibit equal efficacy in decreasing postoperative pain after laparoscopic cholecystectomy.

Introduction

The introduction of laparoscopic technique has dramatically changed the postoperative course after surgical procedures. Laparoscopy is safe and feasible even as an outpatient procedure in properly selected patients1. Effective pain relief during early post operative period becomes increasingly important, to meet the discharge criteria2,3,4. Pain following laparoscopy is typically a diffuse abdominal pain, more so in the right upper quadrant and right shoulder tip5. There exists a controversy regarding the principal source of pain following laparoscopic procedures. Pain following laparoscopic cholecystectomy is secondary to surgical trauma to the parietal wall and gall bladder bed and due to peritoneal inflammation and phrenic nerve irritation by residual carbon dioxide in the peritoneal cavity 6,7,8. Hence a multimodal analgesic regimen should be administered for effective treatment of postoperative pain after laparoscopic cholecystectomy. Various studies demonstrated the efficacy of local anaesthetics in mitigating post cholecystectomy pain1,6,9. Both ropivacaine and bupivacaine are long acting amide local anaesthetics. They vary in the proportion of S and R enantiomers resulting in less cardiotoxicty and differential sensory and motor blockade of ropivacaine10.

Our study was designed to compare the efficacy of intra-peritoneal and port site infiltration of bupivacaine or ropivacaine in reducing the pain at 12th hour after laparoscopic cholecystectomy. We also aimed to assess the analgesic consumption in the two groups in 12 hours.

Materials and methods

After obtaining institutional ethical committee approval and written informed consent, 60 adult American Society of Anaesthesiologist physical class 1 and 2 patients of either sex aged 20-60 years scheduled for laparoscopic cholecystectomy under general anaesthesia were enrolled in this prospective, randomized, double-blind study. Patients with a history of allergic reaction to study drugs, history of upper abdominal surgeries, contraindication for laparoscopic surgery, and history of psychological disturbance or chronic pain before laparoscopy were excluded from the study. Patients were randomly allocated into 2 groups. The randomization was conducted by sealed envelope on patient's arrival at the operating theatre until planned number of equivalent groups were reached. The patients were given intraperitoneal installation of 40ml and port site infiltration of 10ml of either 0.25% bupivacaine (Group B) or o.25% ropivacaine (Group R) after surgical resection and straightening the operation table to neutral position. All the patients were pre-medicated with 0.5mg alprazolam, the night before surgery. Following administration of 0.05mg/kg glycopyrrolate, anaesthesia was induced with 0.04 mg/kg midazolam, 2μg/kg fentanyl, and titrated doses of propofol. Endotracheal intubation was facilitated with 0.1mg/kg of vecuronium bromide and mechanical ventilation commenced with a tidal volume of 8 ml/kg and frequency adjusted to achieve an end-tidal carbon dioxide of 35-40 mm of Hg. Sevoflurane 1-2%, in a mixture of oxygen and nitrous oxide, was used for anaesthetic maintenance. Intra abdominal pressure was limited to 12 mm Hg during the surgical procedure. Surgical drain was avoided in all the patients. An independent surgeon was responsible for the randomization and preparation of an unmarked syringe containing bupivacaine or Ropivacane. The operating surgeon, the staff, and the patients were blinded to this procedure. Mean duration of surgery was 60 min in both the groups. All the patients received 2mg/kg of intramuscular diclofenac sodium and ondansetron 4mg before extubation. The postoperative data collection was done by a resident physician. The time of arrival in the postoperative ward was defined as zero hour postoperatively. Assessment of postoperative pain was based on a 10 point visual analogue scale (VAS, 0: no pain, 10: the worst imaginable pain) at 12th hour postoperatively. Any patient with a VAS score of 3 or above received 2m/kg of intravenous tramadol. If the patient had VAS score more than 3, one hour after administration of tramadol, he received a repeat dose of 1mg/kg of tramadol. 75 mg of diclofenac sodium was administered intramuscularly if VAS score > 3, 30 minutes after administration of 3mg/kg tramadol. The primary outcome measure of the study was to compare the postoperative VAS score at 12th postoperative hour between the two groups. The secondary outcome measure was to compare postoperative analgesic requirements between the two groups in 12 hours.

Statistics

Med cal c statistical software, version (13.3) was used to analyse the data. Summary statistics, mean and standard deviation were calculated for different parameters under the study. The observed results were analysed using Chi-square test for qualitative data and student 't' test for quantitative data. A p-value of <0.05 was considered statistically significant.

Results

Both the groups were comparable in demographic data (age, sex and weight). There was no significant variation in the mean duration of surgery between the two groups.The mean VAS pain score was (3.133±1.008) in group B and (3.166±1.08) in group R at 12th postoperative hour(Table 1). There was no statistically significant difference between the two groups in mean VAS score at 12th postoperative hour (p 0.9024). Mean total tramadol consumption in 12 hours was 105±15.256 mg in bupivacaine group and 110±20.341 mg in ropivacaine group. There was no statistically significant variation in mean total tramadol consumption in 12 hours between the groups (p 0.2859) (Table 1). No patient required administration of diclofenac sodium in either groups. No patient complained of shoulder tip pain in ei-

ther groups.

Table 1:Visual analogue pain score and tramadol consumption in Bupivacaine and Ropivacaine groups.

Parameter	Group B	Group R	p- value
Mean pain score at 12th postoperative hour	3.133±1.008	3.16±1.08	0.9024
Mean total Tramadol consumption over 12 hours postoperatively	105±15.256	110±20.341	0.2859

Results are expressed as mean± standard deviation. B: Bupivacaine group, R: Ropivacaine group. p<0.05 considered statistically significant.

Discussion

The present study showed that administration of either ropivacaine or bupvacaine is equally effective in reducing the postoperative pain after laparoscopic cholecystectomy. Analgesic consumption is more in ropivacaine group than in bupivacaine group, but the variation was not statistically significant. Though laparoscopic cholecystectomy is associated with less postoperative pain than the open procedure, there is a significant shoulder and abdominal pain in the early postoperative period. The growing trend, of this procedure in our population demands an effective means of pain control to facilitate an comfortable postoperative coarse and to decrease the postoperative hospital stay.

Use of local anaesthetics is a simple, safe, inexpensive, non-invasive and effective modality to improve the postoperative course after laparoscopic cholecystectomy. Factors that can affect the benefit of intra peritoneal instillation of local anaesthetic are: the site, dose and concentration of the local anaesthetic used, presence of an acute inflammation (acute cholecystitis), volume of residual CO_2 and the spillage of bile and blood during the surgical procedure [11].

Rakesh Babu, et al compared intra-peritoneal administration of 20 ml of 0.2% ropivacaine with 20 ml of 0.25% bupivacaine using ten point VAS scale and reported that the mean total VAS over 24 hours was higher in the ropivacaine group (mean 4.573) when compared to the bupivacaine group (mean 4.185). But the variation was statistically insignificant. The difference in the VAS scores of the two Groups at the four time points(0,4,8 and 12) across the 12 hour time period was not significant (p 0.702). There was a significant reduction in VAS over the 12 hour period in both the Groups (p> 0.05)[12]. Port sites were not infiltrated with local anaesthetic in their study and we use a higher volume of local anaesthetic, but the dose used by us was within the recommended toxic limits. Ayaz Gul, et al compared intraperitoneal installation of 50 ml of bupivacaine (0.25%) with 50 ml of 0.9% normal saline and reported that there was a significant variation (p 0.036) in the mean pain score between the two groups (3.619 ± 0.676 in bupivacaine group and 3.837 ± 0.667 in normal saline group) at 12th hour after laparoscopic cholecystectomy[6]. Canan Kucuk, et al randomised 80 patients in to 4groups to receive 21ml 0.9% normal saline or 20ml (100mg) bupivacaine or 20ml of 100mg ropivacaine or 20ml of 150 mg ropivacaine intra peritoneally after laparoscopic cholecystectomy and concluded that the last three groups showed a significant reduction in total morphine consumption, first 24 hours after laparoscopic cholecystectomy.150mg ropivacaine was more effective in reducing the postoperative pain than other groups[13].

Further studies using different concentrations and volumes of local anaesthetics are needed to suggest a ideal dose of local anaesthetic for effective control of postoperative pain after laparoscopic surgery.

Conclusion

Ropivacaine and Bupivacaine are equally effective in decreasing the postoperative pain 12th hour after laparoscopic cholecystectomy. Both the drugs exhibit equal efficacy in decreasing the postoperative analgesic consumption.

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