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A COMPARITIVE EVALUATION OF INTRAPERITONEAL SUBDIAPHRAGMATIC INSTILLATION OF LEVOBUPIVACAINE VERSUS ROPIVACAINE FOR SHOULDER TIP PAIN AFTER LAPAROSCOPIC CHOLECYSTECTOMY; A DOUBLE BLIND PLACEBO CONTROLLED STUDY

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ABSTRACT:

Background: Shoulder tip pain associated with laparoscopic surgeries may cause more discomfort to the patient than the pain at the incision sites. Direct intraperitoneal sub diaphragmatic instillation of local anaesthetics (LA) can provide a simple and effective means to overcome this problem. This randomized, double-blind, placebo controlled trial compared the effects of intraperitoneal sub diaphragmatic instillation of ropivacaine and levobupivacaine for the relief of shoulder tip pain after laparoscopic cholecystectomy.

Methods: After approval from the ethical committee of our institute ninety patients of either sex belonging to American Society of Anesthesiologists (ASA) physical status class I or II, between 20-60 years of age, scheduled to undergo laparoscopic cholecystectomy were randomly allocated using sealed envelopes to one of the three groups: Group L (n=30), Group R (n=30) and Group S (n=30) Patients received 10ml of 0.25% levobupivacaine, 0.25% ropivacaine and saline under each dome of diaphragm respectively before deflation of pnuemoperitonem. Shoulder tip pain(STP) and abdominal pain was assessed by using the visual analogue scale (VAS) at 0, 2, 4, 8 and 24 hours after the completion of the procedure at rest, on movement (sitting up in bed and/or turning sideways in bed) and on coughing. Also time for first request for analgesia by the patient, the total consumption of analgesic in 24 hours and incidence of nausea and/or vomiting was observed.

Results and Conclusion: Use of levobupivacaine and ropivacaine significantly reduced the incidence and intensity of STP, total amount of analgesic used and increased the mean time for first request for analgesia. Both levobupivacaine (0.25%) and ropivacaine (0.25%) are effective for this purpose, though levobupivacaine relieved pain for a longer duration.

Keywords: Shoulder tip pain, acute pain, intraperitoneal local anaesthetic, subdiaphragmatic local anaesthetic, Laparoscopic cholecystectomy, levobupivacaine, Ropivacaine, postoperative.

INTRODUCTION:

Laparoscopic procedures are being increasingly accepted for surgeries as these are associated with smaller incisions, lower morbidity, shorter hospitalizations, earlier return to normal activity, and less postoperative pain.[1] The incidence of shoulder pain varies from 35% to 80% and ranges from mild to severe. The quest for searching newer and safer anaesthetic agents has always been one of the primary needs in anaesthesiology practice. Regional anaesthesia techniques have

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seen numerous modifications over the last two decades with the advent of many new and safer local anaesthetics. Very few studies are available in literature, for relief of shoulder tip pain, which is a common complication of laparoscopic surgeries. Local anaesthetics have been used in a numerous ways to relieve post operative pain after laparoscopic surgeries. Postulated mechanism of shoulder tip pain after laparoscopic surgeries is phrenic nerve irritation due to pneumoperitoneum. Direct intraperitoneal sub diaphragmatic instillation of LA can provide a simple and effective means to overcome this problem.[2,3]

We designed this randomized, double-blind, placebo controlled, single-centre trial to compare the effects of intraperitoneal subdiaphragmatic instillation of ropivacaine and levobupivacaine for the relief of shoulder tip pain after laparoscopic cholecystectomy.

METHODS

After approval from the ethical committee of our institute ninety patients of either sex between 20-60 years of age, scheduled to undergo laparoscopic cholecystectomy were included in the present prospective, randomized, controlled, double blind study. The patients with history of previous open surgery in the upper abdomen, acute cholecystitis posted for laparoscopic cholecystectomy, inability to understand VAS, history of allergy to Local anaesthetic agents (LA), BMI>35 and need for more invasive procedure (for e.g. insertion of T-Drain, or conversion to open cholecystectomy) were not excluded from the study.

All the patients were examined during the preoperative visit a day prior to surgery. They were subjected to a detailed clinical history and a complete general physical examination and routine investigations. Patients were explained about the details of anaesthesia plans and the procedure during the preoperative visit. They were also explained about scoring on the visual analogue scale for pain (VAS; 0: no pain and 10: worst possible pain). Informed written consent was obtained from the patient. Each patient received oral tablet alprazolam 0.25 mg, tablet ranitidine 150 mg at bedtime and in morning and tablet metoclopramide 10 mg in the morning at 6 am on the day of surgery.

The patients were randomly allocated using sealed envelopes to one of the three groups as follows-

Group L (n=30) Patients received 10ml of 0.25% levobupivacaine under each dome of diaphragm.

Group R (n=30) Patients received 10ml of 0.25% ropivacaine under each dome of diaphragm.

Group S (n=30) Patients received 10 ml of normal saline under each dome of diaphragm.

On patient's arrival in the operating room, after establishing non-invasive monitoring (electrocardiogram, heart rate, blood pressure, respiratory rate, pulse oximetry), an intravenous line was secured. Injection glycopyrrolate 0.2 mg i.v. was given to all patients.

After recording the baseline vital signs, general anaesthesia was induced with injection propofol 2 $mgkg^{-1}$, injection morphine 0.1 $mgkg^{-1}$ and injection vecuronium bromide 0.1 $mgkg^{-1}$ intravenously. Anaesthesia was maintained with isoflurane (1%) in nitrous oxide and oxygen in ratio of 67/33. Endotracheal tube was used to secure the airway. Ventilation was controlled with a tidal volume of 8 to 10 $mlkg^{-1}$ and the respiratory rate adjusted to maintain $EtCO_2$ value of 30 to 35 mmHg. Nasogastric tube was then placed.

Laparoscopic surgery was performed by using the same technical principles for all the patients. Pneumoperitoneum was established with CO_2 insufflation at pressure of up to 12mm of Hg. All the patients were monitored continuously for ECG, HR, RR, SpO_2 and $EtCO_2$ throughout the surgery. The surgeons were asked to infiltrate 2 ml of 0.25% bupivacaine at all the port sites in all the patients.

Before the removal of the last port, each patient received the drugs under each hemi diaphragm as allotted to them in the group by direct instillation through the laparoscopic port using a 10 ml syringe.

At the end of surgery injection ondansetron 4 mg i.v. was given to all patients and residual neuromuscular block was antagonized with 2.5 mg of neostigmine methylsulfate and 0.4 mg glycopyrrolate.

Patients were observed for up to 24 hrs. Rescue analgesia, was given with paracetamol infusion 1g intravenously (over 15mins) in post operative period if VAS score >4 or if the patient demanded analgesia. In the post operative period abdominal pain and STP,at rest,on coughing and on movement were compared between the three groups in terms of intensity on a VAS scale of 10, total analgesia required in the first 24hrs, the time before first request of analgesia by the patient, nausea and vomiting and other side effects if any. The research assistants involved in data collection, and nurses and doctors taking care of the patients were unaware of the study group assignment.

STATISTICAL ANALYSIS

The collected data was subjected to appropriate statistical analysis. Statistical analysis was performed by the SPSS program for Windows, version 17.0. Data were checked for normality before statistical analysis using Shaipro Wilk test. Continuous variables are presented as mean ± SD or median (IQR) if the data was skewed, and categorical variables are presented as absolute numbers and percentage. Normally distributed continuous variables were compared using ANOVA. If the F value was significant and variance was homogeneous, Tukey multiple comparison test was used to assess the differences between the individual groups; otherwise, Tamhane's T2 test was used. The Kruskal Wallis test was used for those variables that were not normally distributed and further comparisons were done using Mann Whitney U test. Categorical variables were analyzed using the chi square test. Spearman's For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

RESULTS

The demographic profile of all the patients was comparable as there were no significant differences among the groups with respect to age, weight, gender ratio and ASA class ratio. The mean age in rovivacaine group was 40.23±13.17 yrs, in levobupivacaine group it was 42.70±11.4 yrs and in saline group it was 41.17±10.56 yrs. The sex ratios were also comparable. In group R it was 23:7, in group L it was 24:6 and in group S it was 23:7. Most of the patients in all three groups were ASA I. In group R and L 76.7% of patients were ASA I, whereas in saline group 805 were ASA I.

On comparing the pain intensity on VAS pain score for abdominal pain at rest, on coughing and on movement, it was observed that the pain scores in all the three groups were comparable except at 4hr wherein the patients in Group S had more pain than Group L and Group R but this difference was not statistically significant ($p<0.1$)

On comparing pain intensity on VAS pain score for shoulder tip pain on coughing and on movement it was observed that patients in Group S experienced more pain than patients in Group R and Group L. This difference was found to be statistically significant at 8 and 24 hrs postoperatively. There was no significant difference in pain scores found between patients in Group R and Group L for STP at rest on coughing and on movement.

The total amount of analgesic used for patients in Group S was found to be significantly higher in Group S vs. Group L and Group R (p value <0.005) . Three patients in Group S and one patient in Group R required inj. Tramadol for pain relief as a part of multimodal analgesia as paracetamol alone could not provide adequate pain relief in these patients. No significant difference was found in the total analgesic consumption in 24hrs between Group L and Group R.

The mean time for first request for analgesia by the patients was 2hrs in group S which was considerably earlier when compared with Group R (9hrs) and Group L (11hrs). This difference was found to be statistically significant (p value <0.05). No significant difference was found in the time for first request of analgesia between Group L and Group R, though the duration was longer for Group L

There was no significant difference found in the incidence of nausea and vomiting between the three groups. One patient in levobupivacaine group complained of shivering in the post operative period, which was managed successfully by giving inj Tramadol (50 mg) IV.

DISCUSSION

The precise mechanism of shoulder pain after laparoscopy remains unclear, the leading hypothesis is that carbon dioxide (CO_2) induced phrenic nerve irritation causes referred pain to fourth cervical root (C_4) dermatome which is further projected to shoulder. Various drugs have been used to reduce postoperative shoulder tip pain like nonsteroidal anti-inflammatory drugs (NSAIDs), opioids and local anaesthetics (LAs), both at surgical site and intraperitoneally, with varying success. Post operative postural variation i.e. head down tilt has also shown to improve pain scores. Most have shown some effectiveness; however these, were not effective enough to prevent post operative shoulder tip pain.[4]

Local anaesthetics have been used in a numerous ways to relieve post operative pain after laparoscopic surgeries. Various techniques discussed in literature include instillation of LA in the gall bladder bed, placement of surgicel soaked LA in gall bladder bed, sub diaphragmatic catheters with repeated intraperitoneal instillation, nebulization with LA, these maybe with or without periportal infiltration with LA with varying success. In the present study intraperitoneal instillation was used as the proposed mechanism of STP is CO_2 induced phrenic nerve irritation leading to referred pain to fourth cervical root (C_4) dermatome which is further projected to shoulder. Sub diaphragmatic instillation was used as direct action of LA on the phrenic nerve between the liver and diaphragm could be achieved with minimal dose.[5] Thus intraperitoneal subdiaphragmatic instillation of LA is a cost effective method with minimal side effects and no chance of increased infection due to catheter.

Therefore the present study was planned to compare effects of levobupivacaine and ropivacaine on STP on subdiaphragmatic intraperitoneal instillation. The demographic profile of the patients was comparable in terms of age, sex, weight, gender ratio and ASA grade.

On comparing the abdominal pain scores at rest on coughing and at movement the pain scores were found to be comparable except at 4 hours wherein the patients in group S had more pain that other 2 groups though the difference was not statistically significant. The patients in group R experienced less pain than group S at 4 hours period though this result was not statistically significant. This was comparable to the study of Callesen et al who observed that the abdominal pain scores were lower during the first hour postoperatively in ropivacaine group as compared with placebo.[6]

Similar results were seen by Gupta et al who conducted a study to assess the effect of intermittent injections of ropivacaine through an indwelling catheter placed in the gall bladder bed after laparoscopic cholecystectomy.[7] Statistically significant less pain was seen in ropivacaine group during first 4 hours in deep pain and during coughing. Engelmo et al who evaluated the effect of intraperitoneal ropivacaine nebulization in laproscopic cholecystectomy, obtained comparable results.[8]

The results of our study were however in contrary to Papdima et al who used repeated intraperitoneal instillation of levobupivacaine in laparoscopic cholecystectomy.[9] They concluded that patients had lesser mean VAS scores at rest and at movement at all points of time. This differs from our results, but they did not differentiate between abdominal, STP or port site pain.

The results obtained in our study differ from Callesen et al. They observed that only 5 patients in ropivacaine group and 3 patients in placebo group had STP during first 8 hours postoperatively and this was found to be insignificant.[6] On the contrary we observed a significant difference in the incidence and intensity of pain scores for STP among the three groups, with least pain in L group. Similar results were observed by engelmo et al using ropivacaine in their study.[8]

On comparing group R with group L it was observed that VAS scores for STP at rest were lower in Group L which was not statistically significant. No difference in pain scores was found in both these groups for STP on coughing or movement. These results were in concurrence with Papagiannopoulou P et al who observed that the Lev and Rev groups did not differ significantly in their VAS scores at 2 hours postoperatively, but the Lev group suffered significantly less pain than rev and placebo group at 4 and 24 hours postoperatively.[10]

The total amount of analgesic consumption in 24 hours was significantly more in saline group among the three groups and 3 patients required inj tramadol as part of multimodel analgesia. Similar observations were made by Callesen et al in their study using ropivacaine and found that consumption of morphine was significantly less in 72 hours.[6] Contrary results were observed by Gupta et al who found no significant difference in total analgesic consumption in ropivacaine and saline group.[7] This may be because all patients received paracetamol irrespective of demand and also intermittent ropivacaine and saline injections were self administered using elastomeric home pump over 6 mints. The reduced consumption of analgesics was also observed by Lepner et al in their study using intraperitoneal and intraincisional infilteration of 0.125% bupivacaine as LA. A significant reduction of pethidine consumption was seen in group using LA for infilteration. Papdima et al also had similar results for levobupivacaine who observed significant reduction in fentanyl consumption.[9]

We also observed that the saline group had a significantly greater and an earlier demand for analgesics. The patients in ropivacaine group were pain free for 9 hours whereas the same in levobupivacaine group was 11 hours which is considerably better than saline group i.e. 2 hours. This reflects the effect of morphine used for intraoperative and postoperative analgesia. The patients in saline group demanded analgesia as morphine effect wore off. However due to the prolonged effect of LA other two groups did not demand analgesia for a longer period.

There was no significant incidence of nausea and vomiting in either group. This may be because of antiemetic effect of ondansetron as shown by Kang et al and Engelmo et al.[8,11] Only one patient in group L complained of shivering in postoperative period. No other side effect of LA was observed.

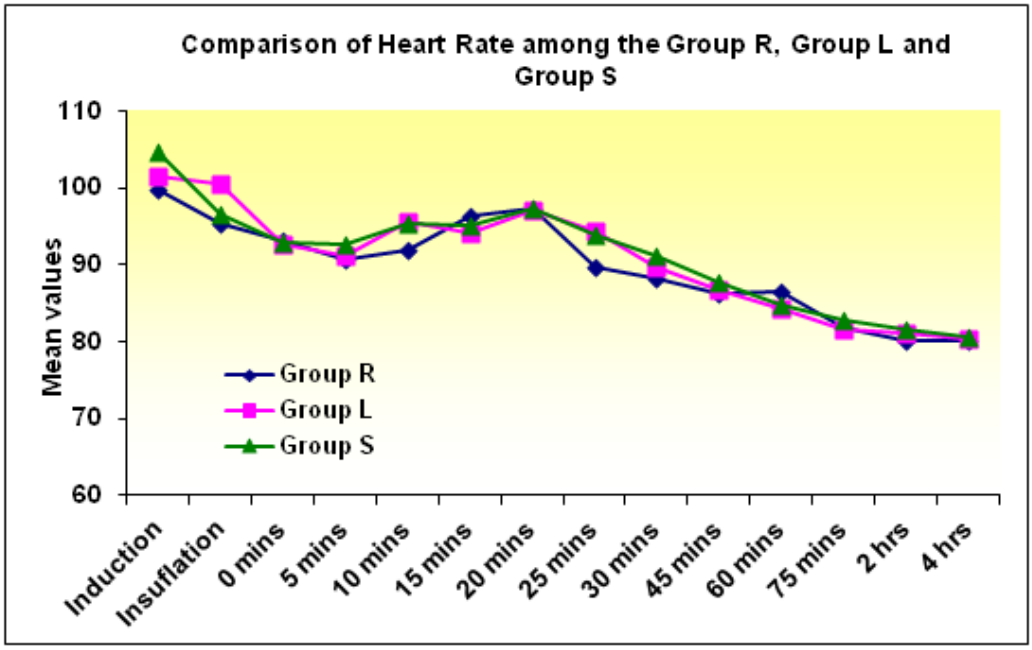

Figure 1:

Table 1:

Abdominial pain -at rest	Gp R (Median)	Gp L(Median)	Gp S (Median)	P value
0hr	1	0.5	1	0.860
2 hr	2	1	2	0.162
4 hr	2	1	2	0.099
8 hr	1	2	2	0.501
24 hr	1	1	1	0.428

Table 2:

Abdominial pain on coughing	Gp R (Median)	Gp L (Median)	Gp S (Median)	P Value
0 hr	1	0.5	2	0.757
2 hr	3	2	3	0.157
4 hr	3	2	3	0.112
8 hr	3	3	3	0.650
24 hr	2	2	2	0.417

Table 3:

Abdominial pain on movement	Gp R (Median)	Gp L (Median)	Gp S (Median)	P value
0 hr	1	0.5	2	0.712
2 hr	3	2	3	0.157
4 hr	3	2	3	0.068
8 hr	3	3	3	0.492
24 hr	2	2	2	0.087

Table 4:

Pain at shoulder tip at rest	GP R (Median)	GP L (Median)	GP S (Median)	P Value
0 hr	0	0	0	0.002
2 hr	0	0	0	0.132
4 hr	0	0	0	0.540
8 hr	0	1	1	0.059
24 hr	0	0	0.5	0.066

Table 5:

Pain at shoulder tip on coughing	Group L (n=30)			P Value
	Median(GP R)	Median(GP L)	Median(GP S)	
0 hr	0	0	0	0.002
2 hr	0	0	0	0.149
4 hr	0	0	0	0.510
8 hr	0	1	1	0.032
24 hr	0	0	0.5	0.025

Table 6:

Pain at shoulder tip on movement	Group L (n=30)			P Value
	Median(GP R)	Median(GP L)	Median(GP S)	
0 hr	0	0	0	0.002
2 hr	0	0	0	0.089
4 hr	0	0	0	0.299
8 hr	0	1	2	0.008
24 hr	0	0	1	0.020

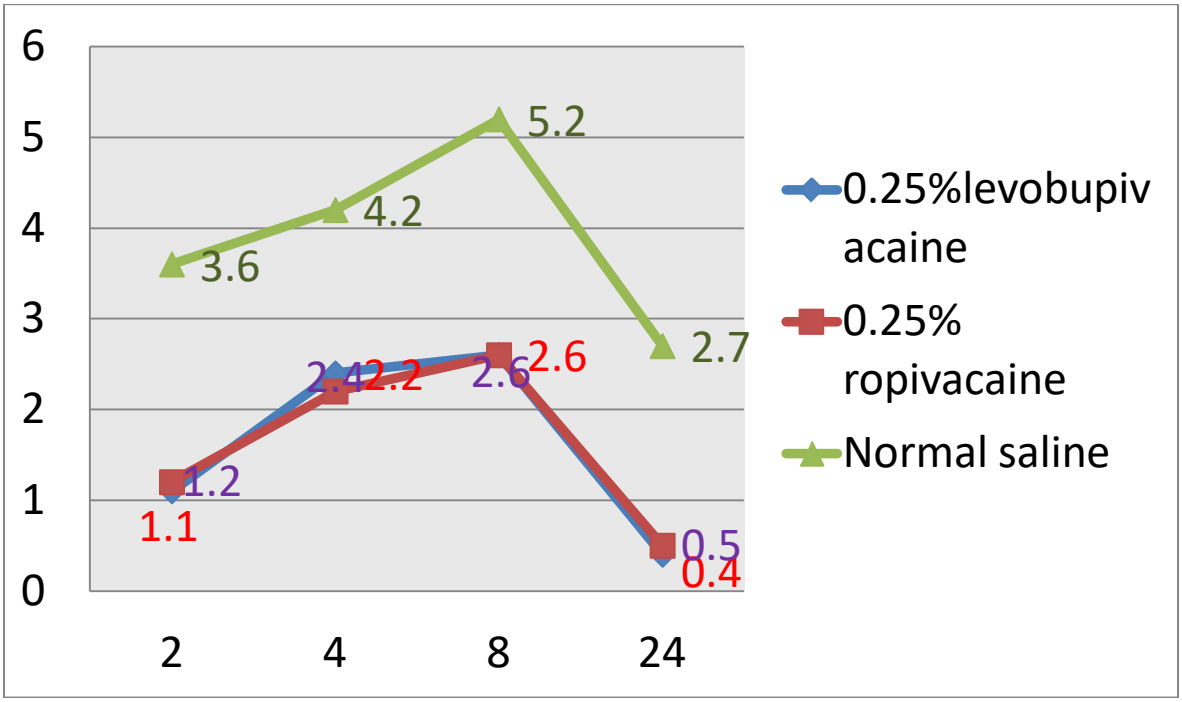

Figure 2: Visual analogue scale (VAS) pain scores

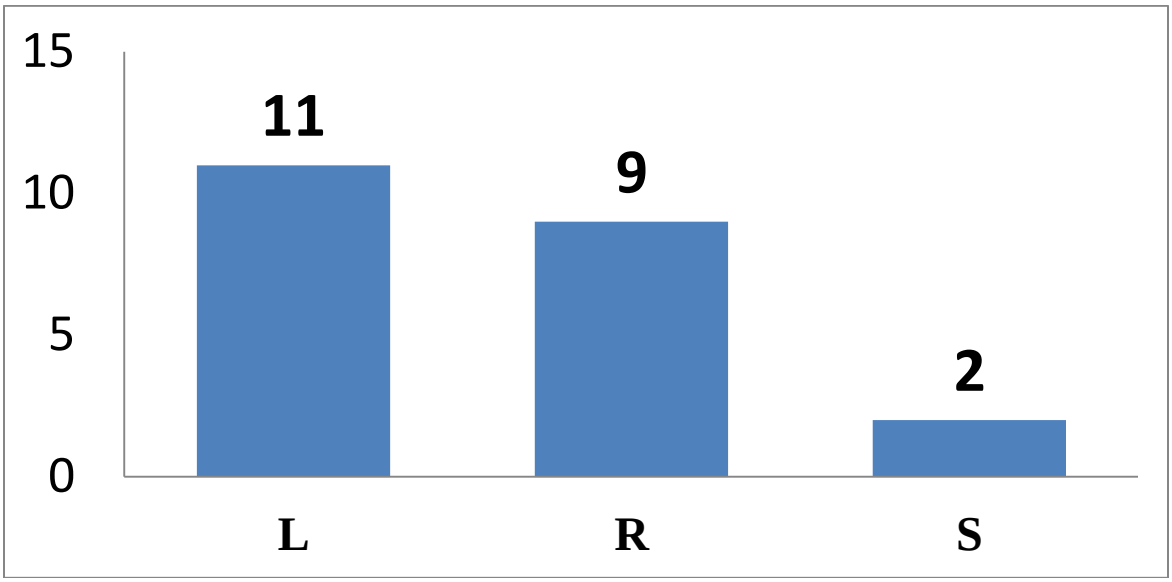

Figure 3- First Request for Analgesia (When VAS Score >4)

CONCLUSION:

Intraperitoneal subdiaphragmatic instillation of local anaesthetics is an effective means of pain control for shoulder tip pain in patients undergoing laparoscopic cholecystectomy in the postoperative period. Both levobupiuvacaine (0.25%) and ropivacaine (0.25%) are effective for this purpose, though levobupivacaine relieved pain for a longer duration, without increasing any other complication or side effects.

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