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Comparative study of preincisional infiltration of ropivacaine 0.375% and levobupivacaine 0.25% for post operative analgesia in adult after lower abdominal surgery under general anaesthesia.

Anaesthesiology

Kanchan Chauhan Professor, Department of Anaesthesia, S.M.S Medical College, Jaipur

Shailesh sharma Third year P.G. student, Department of Anaesthesia, S.M.S Medical College, Jaipur

ABSTRACT

BACKGROUND: Improvement and prevention of postoperative clinical complications related to pain can be easily brought about by an effective post operative analgesia. Preoperative infiltration of local anaesthetics at the incision site along with general anaesthesia significantly eases the postoperative pain management.

OBJECTIVE: The aim of this study was to compare the analgesic effect of preincisional infiltration of levobupivacaine HCl 0.25% and ropivacaine HCl 0.375% in patients undergoing lower abdominal surgery.

METHOD: Hundred American Society of Anesthesiologist (ASA) grade I and II patients (20-60 years) posted for elective lower abdominal surgery under general anesthesia were selected for this study. The anaesthetic technique was standardized for both groups. Patients were assigned randomly into two groups and preincisional surgical field infiltration with 5 ml of 0.75% ropivacaine plus 5 ml of 0.9% normal saline (group A: n=50) or 5 ml of 0.5% levobupivacaine plus 5 ml of 0.9% normal saline (group B: n=50) was performed. The quality of analgesia was assessed by visual analogue scale (VAS) for pain recorded at multiple time intervals in post operative period.

RESULTS: Both the study groups showed similar post operative analgesic effect.

CONCLUSION: Preoprative infiltration with 0.375% ropivacaine or 0.25% levobupivacaine is similarly effective in reducing the postoperative pain associated with lower abdominal surgery.

KEYWORDS:

ropivacaine, levobupivacaine, preincisional infiltration, lower abdominal surgery.

INTRODUCTION

Preemptive analgesia is sensory blockade of nociceptive afferent pain pathways of the peripheral and central nervous system, before incision. It intends to prevent the establishment of central sensitization caused by incisional and inflammatory injuries which amplifies postoperative pain. Central sensitization can occur from preoperative pain to intraoperative tissue injury and postoperative inflammatory processes.[1] Pharmacological agents used for post operative analgesia include Opioids, NSAIDs and Local anaesthetics. Local anaesthetics function by inhibiting the transmission of pain from nociceptive afferent at the site of incision. Further more local anaesthetics can block the local inflammatory response to injury which in turn sensitizes nociceptive receptors adding to pain and hyperalgesia.[2] When local anesthetics used in addition with general anesthesia they can reduce the need for systemic medication and improve postoperative pain management.[3,4] The aim of this study was to compare the analgesic effects of preincisional ropivacaine HCl 0.375% and levobupivacaine HCl 0.25% in patients undergoing lower abdominal surgery.

METHOD

The study was conducted under the department of anesthesiology and department of general surgery, S.M.S. Medical College and attached group of hospitals, Jaipur after approval by the institutional Ethics Committee. All patients were explained the study design and informed consent was taken. All of the drugs used in the study were prepared by the same researcher, who was not involved in the intraoperative or postoperative treatment of the patients; the anesthesiologist and surgeon were blinded to the composition of the solution injected in the surgical area. Identical volumes of ropivacaine and levobupivacaine were compared. Medications were similar in appearance with respect to color and viscosity. Also, syringes themselves were similar in appearance. The blinding process remained complete until all data were entered in the trial database and the accuracy of the data and the database was confirmed. Afterwards, the database was forwarded to the statistician for analysis. Patients were hospitalized during the postoperative 24 hour period. Postoperative data were collected by the same anesthesiologist, who was blinded to the local anesthetic used. Hundred American Society of Anesthesiologists (ASA) grade I and II patients scheduled for elective lower abdominal surgery under general anesthesia were recruited for this prospective, randomized, double-blinded study. The exclusion criteria included Patient refusal, Major organ dysfunction, Inability to provide informed consent, Coagulation disorders or treatment with anticoagulants, Chronic alcohol or drug abuse, Chronic pain requiring major analgesic, weight <40 kg& >80 kg, Deaf and dumb patients, Patients having known allergy to anaesthetic agents used in study, Psychiatric patient.

Perioperative conditions were similar in the 2 groups. During the preoperative visit on the day before the operation, the patients were introduced to the concept of the visual analogue scale (VAS), which ranged from 0 = no pain to 10 = worst pain imaginable. Patients were assigned randomly to 1 of 2 study groups in a 1:1 ratio, by means of a computer-generated list of random numbers. The allocation sequence remained concealed for all investigators and patients throughout the study period. During the operation and 30 minutes postoperatively, standard noninvasive monitoring, including electrocardiogram, pulse rate, end-tidal CO2, systolic and diastolic blood pressure measurement and pulse oximetry, was applied for all the patients. All 100 Patients were premedicated with inj. Glycopyrolate 0.2mg iv, inj.Midazolam 1mg iv, inj.Fentanyl 2µg/kg iv. Preoxygenation was done with 100% oxygen for 3 minutes. Patients were induced with inj.Propofol 2mg/kg iv administered until loss of eyelash reflex, followed by inj.Succinylcholine 1.5mg/kg iv and ventilated with 100% oxygen. Direct laryngoscopy was done and patient was intubated with appropriate size E.T.T. Bilateral air entry was checked & tube was fixed. Preincisional surgical field infiltration with 5 mL of 0.75% ropivacaine plus 5 mL of 0.9% saline (group A; n=50) or 5 mL of 0.5% levobupivacaine plus 5 mL of 0.9% saline (group B; n=50) was performed by the surgeon after tracheal intubation. Then surgery was allowed to commence & anaesthesia was maintained with 60% Nitrous Oxide + 40% Oxygen + 0.4% to 1.0% V/v isoflurane + inj.Atracurium(NDMR) SOS. At the end of the operation, residual muscle relaxation was reversed with inj.Glycopyrrolate 0.5mg + inj.Neostigmine 2.5mg i.v. Patient was extubated when fully satisfied with patient recovery (ability to open the eyes, ability to obey anaesthesiologist's verbal commands and ability to maintain a regular breathing pattern. Patient vital signs were recorded at baseline, after pre medication, just after intubation, at 30 min,60 min,90 min,120 min,150 min,180 min intraoperatively and at 0min,10

min,20 min, 30 min,1 hr,2 hr,4 hr,8 hr,12 hr,24 hr. The degree of pain was recorded at 0 min, 10 min, 20 min, 30 min, 1 hr, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr after surgery. Patients were asked about (or were visually observed for) possible adverse effects such as postoperative nausea and vomiting, bleeding, dizziness, and allergy in the first 24 hours after surgery. Hypotension (defined as MAP value <25% of baseline value on two consecutive recordings within 2-3 minutes), not responding to a decrease in the inspired Isoflurane concentration and a 200 ml fluid bolus, was treated with inj.Ephedrine i.v / inj.Mephentermin i.v. Hypertension (defined as MAP value > 25% of baseline value on two consecutive readings within 2-3 min.) despite an increase in inspired isoflurane concentration, was managed by additional bolus of inj.Fentanyl 1µg/kg i.v. Any patient who was not responding to above measures managed with hypotensive agents accordingly to maintain MAP within ± 25% of baseline value. Bradycardia (defined as decrease in H.R. < 20% of baseline value.) was managed by inj.Atropine. Tachycardia (defined as HR > 20% of baseline value). Any patient developing intraoperative tachycardia was given inj.fentanyl 1µg/kg i.v. Inj.Ondansetron 2 mg i.v. was given 30 minutes prior to extubation. Any complications such as laryngospasm, bronchospasm or desaturation were managed according to the standard protocols.

Statistical Analysis

The sample size was calculated at 80% study power and α(alpha) error 0.05 assuming variability (S.D.) of 17 points in 100 points VAS score as found in reference study "comparison of preincisional infiltration of levobupivacaine and ropivacaine for acute post operative pain relief after septorhinoplasty" by Bicer et al.[12(5)]For minimum detectable difference in mean VAS score after 30 minutes in PACU of 10 points 46 cases in each group were required as a sample size. It was further enhanced and rounded off to 50 cases in each group expecting 10% dropout.

Statistical analysis was performed with the SPSS, Trial version 23 for Windows statistical software package (SPSS inc., Chicago, il, USA) and Primer. The Categorical data were presented as numbers (percent) and were compared between groups using Chi square test. Groups were compared for quantitative data presented as mean and standard deviation and using by students t-test. Probability P value < 0.05 was considered statistically significant.

No differences in demographic parameters or in intraoperative and postoperative hemodynamic variables such as heart rate, systolic, diastolic and mean arterial blood pressure measurement were observed between the two groups ($P > 0.05$).

Analysis for the VAS pain scores at rest is presented in Table I. The VAS pain scores at different time intervals postoperatively did not differ significantly between the ropivacaine group and levobupivacaine group ($P > 0.05$).

Table I. Post operative VAS score expressed as median (max-min) after preincisional infiltration of ropivacaine or levobupivacaine in lower abdominal surgery at rest.

Time interval	Group A	Group B	p value
	median (min to max)mean Rank	median (min to max)mean Rank	
0 min	0(0 to 0) 50.5	0(0 to 0)50.5	1
10min	0(0 to 0)50.5	0(0 to 0)50.5	1
20min	0(0 to 0)50.5	0(0 to 0)50.5	1
30min	0(0 to 0)50.5	0(0 to 0)50.5	1
1hr	0(0 to1)49.5	0(0 to1)51.5	0.631
2hr	1(0 to 1)50.5	1(0 to 1)50.5	1
4hr	1(0 to 2)49.66	1(0 to 2)51.34	0.753
8hr	3(2 to 4)50.98	3(2 to 4)50.02	0.821
12hr	3(1 to 5)50.98	3(1 to 4)50.02	0.856
24hr	2(0 to5)49.44	2(0 to5)51.56	0.649

VAS = Visual analogue scale. P < 0.05 considered significant.

Analysis for the VAS pain scores on coughing is presented in Table II. The VAS pain scores at different time intervals postoperatively did not differ significantly between the ropivacaine group and the levobupivacaine group ($P > 0.05$).

Table II. Post operative VAS score expressed as median (max-min) after preincisional infiltration of ropivacaine or levobupivacaine in lower abdominal surgery on coughing.

Time interval	Group A	Group B	p value
	median (min to max) mean Rank	median (min to max) mean Rank	
0 min	0(0 to 0) 50.5	0(0 to 0)50.5	1
10min	0(0 to 0)50.5	0(0 to 0)50.5	1
20min	0(0 to 0)50.5	0(0 to 0)50.5	1
30min	0(0 to 1)51.5	0(0 to 0)49.5	0.155
1hr	1(0 to2)48.58	1(0 to2)52.42	0.452
2hr	2(1 to 3)51.72	2(0 to 3)49.28	0.618
4hr	3(1 to 4)57.44	3(1 to 4)43.56	0.550
8hr	4(3 to 7)53.38	4(3 to 7)47.62	0.277
12hr	4(3 to 7)55.71	4(3 to 6)45.29	0.053
24hr	3(2 to5)54.94	3(2 to5)46.06	0.077

VAS = Visual analogue scale. P < 0.05 considered significant.

17 patients (34%) in the first 24 hours who received ropivacaine required rescue tramadol postoperatively, compared with 16 patients (32%) in the first 24 hours in the levobupivacaine group. No differences were reported between the 2 groups for the proportion of patients requiring rescue tramadol in first 24 hours postoperatively. No side effects were observed in the patients of both the study groups that have been associated with ropivacaine and levobupivacaine. All patients were discharged uneventfully.

DISCUSSION

Crile at the beginning of the previous century described a possible relationship between intraoperative tissue damage and an intensification of acute pain on the basis of clinical observations.[6] He advocated the use of regional blocks with local anesthetics in addition to general anesthesia to prevent intraoperative sensitivity and the formation of painful scars caused by changes in the central nervous system during surgery. In the 80s this idea was reborn by Woolf, who showed evidence for a central component of post injury pain hypersensitivity in experimental studies.[7] The concept of preemptive analgesia was proposed in 1988 by Wall.[8] Preemptive analgesia is defined an intervention given before incision or surgery, which makes it more effective than the same treatment administered after incision or surgery.[9,10] It is important to remember the timing of pre-emptive analgesia. It is an antinociceptive treatment given prior to incision or surgery to prevent the development of altered processing of afferent input.[11] The use of local anesthetics for post operative pain management has the potential to decrease the magnitude of pain following surgery and hence lead to better patient outcomes.Surgery leads to generation of pain signals and produces a secondary inflammatory response which can significantly amplify postoperative pain. Therefore the administration of local anesthetics at the site of injury, the incision site, can block the transmission of pain signals at local level. It is considerably safe approach and additionally limits the unwanted side effects related to opioids use. Opioids have long been the mainstay for postoperative pain relief.[12] The aim of our study was to compare the analgesic potency of preincisional tissue infiltration with ropivacaine and levobupivacine in treating pain after elective lower abdominal surgeries. We demonstrated that preemptive analgesia given by preincisional infiltration with both the study drugs, has a significant and beneficial effect on postoperative pain in the first 24 hours following in lower abdominal surgeries.

In this hospital based prospective randomized comparative double blind observational study we included 100 patients (age 20-60 years, ASA grade I and II) undergoing elective lower abdominal surgeries under GA.

In the present study, 20% of patients who received ropivacaine and 18% of patients who received levobupivacaine required rescue analgesic tramadol in 8 hours in postoperative period.10% of patients in both the study groups required rescue analgesic at 12 hours in postoperative period. 4% of patients in both the study groups required rescue analgesic at 24 hours in postoperative period.

The VAS scores were monitored postoperatively for 24 hours after completion of surgery. VAS scores increased gradually as time elapsed after the completion of surgery. Our study demonstrated similar VAS scores at different time intervals postoperatively both at rest and on coughing in both the study groups. This was in concordance to the findings of Bicer C et al 2011. They included 60 patients in their study and divided into two groups of 30 patients each. One received 0.375% Ropivacaine and the other received 0.25% Levobupivacaine for local tissue infiltration combined with general anesthesia. This improved significantly the management of postoperative pain for patients who underwent septorhinoplasty.[5]

Our results are also supported by Kasapoglu F et al 2013 who conducted a study to evaluate the efficacy of levobupivacaine infiltration into the post-tonsillectomy analgesia in 40 adults. Patients were divided in two groups, study group which received levobupivacaine infiltration to peritonsillary fossae prior to surgery or control group with no medication. They found that there were significant differences between the groups regarding pain scores.[13]

Another study by Song J et al 2015 in 60 patients also validates our results. They compared the analgesic efficacy of 1% lidocaine and 0.5% ropivacaine in scalp infiltrations on the postoperative pain after craniotomy. Patients were divided in two groups. In group A, local anesthetic was injected throughout the entire thickness of the scalp before skin incision. In group B, it was injected before skin closure. They found that postoperative pain scores were lower in group A than in group B within the first 6 h after surgery.[14]

Our results were different from findings of Papagiannopoulou et al 2003 who compared the analgesic efficacy of 20 ml ropivacaine 1% and 20 ml levobupivacaine 0.5% for tissue infiltration before trocar placement in 57 patients who underwent laparoscopic cholecystectomy. Patients were divided in 3 groups, Placebo group, n=18, 0.9% saline solution, Rop group, n=20, ropivacaine 1% and Lev group, n=19, levobupivacaine 0.5%. They found that there was no significant difference between the Levobupivacaine and Ropivacaine groups in their VAS scores at 2 h postoperatively, but the Levobupivacaine group experienced significantly ($p < 0.001$) lesser pain than the Placebo and Ropivacaine groups at 4 h and 24 h postoperative period. The Ropivacaine group registered significantly lower VAS scores ($p < 0.001$) than the Placebo group at 4 h postoperatively. This may be due to difference in concentration of the study drugs.[15]

Conclusion

In summary it was concluded that both ropivacaine and levobupivacaine effectively controlled the postoperative pain after lower abdominal surgeries. Tissue infiltration with ropivacaine 0.375% or levobupivacaine 0.25% appears similarly effective in reducing the postoperative pain associated with lower abdominal surgeries under general anesthesia.

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