Original research article

Observational Study to Compare Bupivacaine & Tramadol with Ropivacaine & Tramadol Among Patients Undergoing Abdominal Surgeries.

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Received: 07-12-2022 / Revised: 06-01-2023 / Accepted: 23-01-2023

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Abstract

Introduction: Ropivacaine, a newer long acting amide local anaesthetic and it has lesser side effects compared to Bupivacaine and is increasingly replacing Bupivacaine because of its similar analgesic profile and lesser cardiotoxicity. Tramadol hydrochloride is a weak centrally acting analgesic commonly used as adjuvant with local anaesthetic agents in epidural analgesia.

Aims and objectives: The aim of this study was to compare the hemodynamic changes of 0.125% Bupivacaine with that of 0.125% Ropivacaine along with tramadol in patients undergoing intra abdominal surgery for post-operative analgesia.

Material and Methods: Total 60 patients were taken scheduled for intra operative surgery ranging from 18-55 years in ASA grade I and II. They were randomly allocated to two groups of 30 each. Group R (n = 30) received an Epidural loading dose of 10ml 0.125% of Ropivacaine with 50mg tramadol. Group B (n =30) received an Epidural loading dose of 10ml 0.125% Bupivacaine with 50mg tramadol. Patients were assessed post-operatively every 15 min for heart rate, blood pressure, SPO2 for first hour and then after every 30 min till patient complained of pain.

Result: Hemodynamically, patients in both the groups, were equally stable. Group-R (412 ± 46.56 min) was having much longer duration of post-operative analgesia as compared to Group-B (348 ± 48.31 min, $p < 0.001$).

Conclusion: Ropivacaine and Bupivacaine shows a similar hemodynamic profile. Thus, Ropivacaine can be used as an alternative to Bupivacaine for postoperative pain relief through the epidural route in patients undergoing intra abdominal surgeries ,as a safe and effective agent.

Keywords: Bupivacaine, Epidural anesthesia, Hemodynamic stability, Ropivacaine, Tramadol

Introduction

Pain is an unpleasant effect associated with significant psychological and physiological changes. This can be overcome by the use of suitable anaesthesia and analgesia techniques.[1] Clinical indications for epidural anaesthesia and analgesia have expanded significantly over past several decades. Central neuraxial blockade in the form of epidural anaesthesia is considered a good technique to provide complete and dynamic anaesthesia. Its benefits include suppression of stress response by sympatholysis, stable hemodynamics with reduction in cardiac morbidity, reduction in pulmonary complications due to its allowance for active physiotherapy, reduced blood loss and decrease in thromboembolic complications due to early mobilization following surgery[4]. It also avoids the disadvantages associated with general anaesthesia such as airway manipulation, poly-pharmacy etc.[2,3,4]

Bupivacaine is the most commonly used local anaesthetic agent having satisfactory sensory and motor blockade but with limited duration of action.[5] Ropivacaine, a newer long acting amide local anaesthetic, is the stereoisomer of Bupivacaine. Being an S-enantiomer, it has lesser side effects compared to Bupivacaine and is increasingly replacing Bupivacaine because of its similar analgesic profile and lesser cardiotoxicity. [6]

Postoperative epidural analgesia can provide analgesia superior to that with systemic opioids. An ideal local anaesthetic will provide quick onset, sufficient sensory blockade by maintaining hemodynamic stability and minimal systemic side effects. nowadays bupivacaine, Ropivacaine and levobupivacaine are in current use. Tramadol is a centrally acting atypical opioid analgesic with additional serotonin-norepinephrine reuptake inhibiting effects. Tramadol is used primarily to treat moderate-severe pain, both acute and chronic. [7] Tramadol hydrochloride is a weak centrally acting analgesic commonly used as adjuvant with local anaesthetic agents in epidural analgesia.[8,9]

Aims & Objectives

The present study was designed to compare hemodynamic stability by epidural 0.125% Bupivacaine with 50mg Tramadol versus 0.125% Ropivacaine with 50mg Tramadol in cases of intra-abdominal surgeries for providing post-operative analgesia.

Materials & Methods

Study design: Observational study

Study Population-The study was conducted among patients for post-operative epidural analgesia after getting approval from institutional ethics committee.

Inclusion Criteria:

- Age between 18-55 years
- American Society of Anaesthesiologists (ASA) Grade I / II
- Patients undergoing elective abdominal surgeries under general anaesthesia.

Exclusion criteria:

- Patient's refusal.
- Patients with coagulopathy, spinal deformity and infection at the site of anaesthesia.
- Patients with a history of drug allergy.
- Patients with a history of alcohol or drug abuse, head injury or psychiatric illness.

– Patients using any drug that modifies pain perception & on anticoagulants.

Sampling Technique: Simple Random Sampling was used. The patients were randomly divided into two groups (n=30). Group B: received injection 10 ml of 0.125% Bupivacaine + 50mg Tramadol. Group R: received injection 10 ml of 0.125% Ropivacaine + 50mg Tramadol.

Pre-anaesthetic assessment: All patients included in the study were thoroughly examined on the day prior to surgery and detailed pre-anaesthetic examination was carried out. The procedure & VAS score was explained and written informed consent was taken. Patients were advised to maintain nil by mouth for 6 to 8 hours.

Preparation: Monitoring gadgets were attached to patients like ECG, Non-Invasive Blood Pressure (NIBP) and Pulse oxymeter.Baseline vitals like Pulse, Blood Pressure and SpO_2 were recorded.An IV cannula was inserted and Lactated Ringer's solution or Normal Saline was started at the rate of 10 ml/kg/hour.

Technique: Epidural + General anaesthesia

Position of the patient: Sitting

Under all aseptic and antiseptic precautions, via a midline approach, epidural space was located at the L3-L4/L2-L3 level with the help of an 18G Tuohy needle using the hanging drop / loss of resistance method. The space is confirmed by negative aspiration and Epidural catheter is inserted and fixed at the 12^{th} mark.The patients were then positioned in supine position and Pre-oxygenated for 3 minutes with 100% oxygen.

Premedication was done with Inj. Ondansetron 4 mg i.v,Inj. Glycopyrrolate 0.004mg/kg i.v, Inj. Fentanyl Citrate 1mcg/kg i.v, Inj. Lignocaine hydrochloride 1mg/kg i.v. Induction was done with Inj.Thiopentone Sodium 6mg/kg i.v and Inj.Suxamethonium Chloride 2mg/kg i.v. Intubation was done with appropriate sized portex Endo-tracheal tube. For Maintainance-50% O_2+50% N_2O+sevoflurane was given. Inj.Atracurium 0.5mg/kg loading dose followed by 0.1mg/kg maintainance dose.

For Group R: At the time of skin closure Epidural injection of Ropivacaine 0.125% along with 50mg Tramadol 10ml given and patients were examined at 5 mins, 10 mins, 15 mins 30 mins in the operation theatre.

For Group B: At the time of skin closure Epidural injection of Bupivacane 0.125% along with 50mg Tramadol 10ml given and patients were examined at 5 mins, 10 mins, 15 mins 30 mins in the operation theatre.

Reversal- Inj.Neostigmine 0.05mg/kg and Glycopyrrolate 0.008mg/kg. Patients were extubated after return of spontaneous respiration, adequate reflexes and tone and power and then shifted to post-operative ward.All 60 patients were extubated within 30 minutes after giving Epidural doses of these drugs and duration of surgery was noted.

In post-operative ward all monitoring gadgets like pulse oximetry, non-invasive blood pressure monitoring and ECG were attached and patients were observed for any complications and changes in vital parameters and for complain of pain every hourly.

Results

Table 1:Demographic data

Variable	Group-R(n=30)	Group-B(n=30)	p value
Age(years)	32.13±5.49	31.83±5.81	0.83
Weight(kg)	56.63±6.12	58.77±3.70	0.10
Height(cm)	156.33±8.44	160.13±8.34	0.08
Gender			
Male	13 (43.3%)	12 (40.0%)	0.76
Female	17 (56.7%)	18 (60.0%)	
ASA Grading			
Grade I	8 (26.7%)	7 (23.3%)	0.79
Grade II	22 (73.3%)	23 (76.9%)	
Duration of surgery	117.5±21.45	121.67±15.50	0.39

Table 1 shows that demographic data such as age, weight, height and gender were comparable among both these groups (P>0.05).It also shows that ASA grading and duration of surgery were also comparable among both these groups.

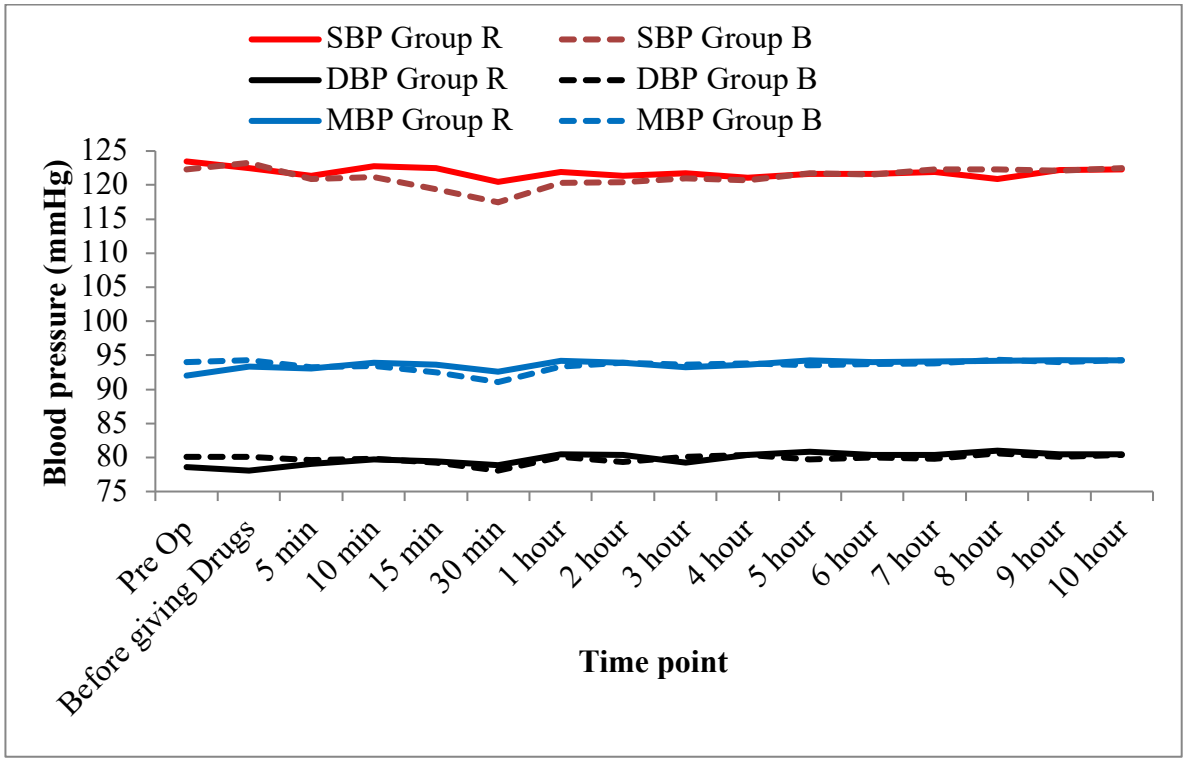

Figure 1: Comparison of Blood pressure between two groups: combine graph of SBP, DBP, and MBP

Figure 1 shows changes in SBP, DBP and MBP between both Group- R and Group-B in peri-operative period and post operative period. Statistical analysis (applying t test) shows there was no significant difference in SBP, DBP and MBP among 2 groups (p value>0.05 for all variables). Though after 15-30 minutes there is slight fall in DBP in both these groups but no significant difference among 2 groups.(p value>0.05).

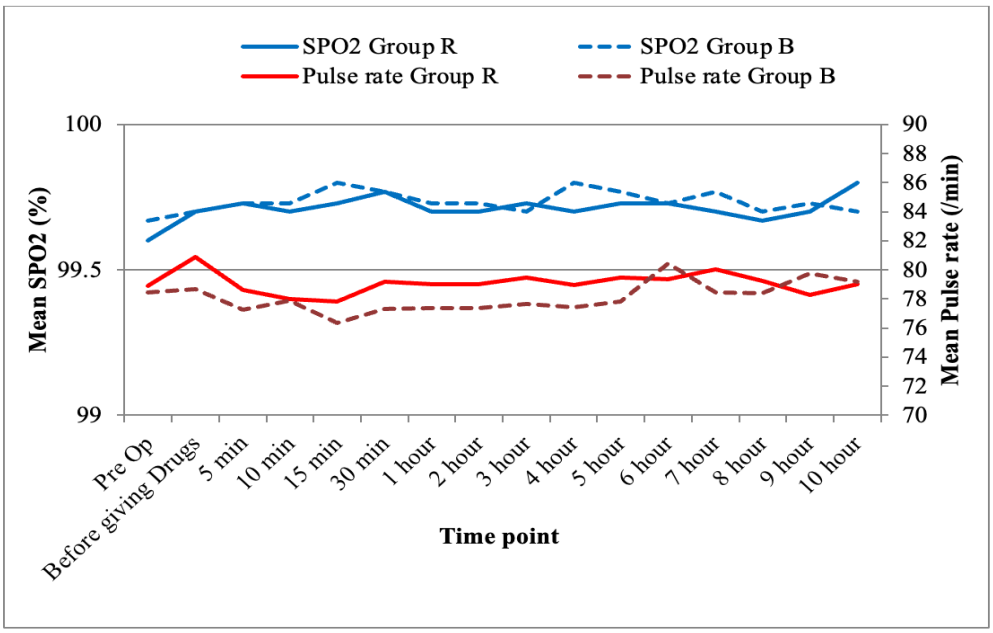

Figure 2: Comparison of SPO2 and pulse rate between two the groups

Figure 2 shows changes in Pulse Rate and SPO2 between both Group- R and Group-B in peri-operative period and post operative period. Statistical analysis shows there was no significant difference in Pulse Rate and SPO2 between two groups (p value>0.05 for both).

Table 2: Comparison of side effects between two groups

Side effects	Group-R	Group-B	p value
Hypotension	0 (0.00%)	1 (3.33%)	1.00
Bradycardia	0 (0.00%)	2 (6.66%)	0.49
Dryness of Mouth	0 (0.00%)	0 (0.00%)	NA
Itching	0 (0.00%)	0 (0.00%)	NA
Nausea/Vomiting	0 (0.00%)	0 (0.00%)	NA
Headache	0 (0.00%)	0 (0.00%)	NA
Giddiness	0 (0.00%)	0 (0.00%)	NA
Sedation	0 (0.00%)	0 (0.00%)	NA

Only one of the 30 patients experienced hypotension (treated with 6 mg of mephentermine), and only two patients in group B experienced bradycardia (given with 0.6 mg of atropine sulphate). All patients in group R remain stable. There were no other negative effects discovered, such as dry mouth, itching, nausea/vomiting, headache, giddiness, or sedation.

Table 3: Comparison of Time to first rescue analgesia and duration of analgesia between two groups

Time to first rescue analgesia (minutes)	Group-R	Group-B	p value
280-340	0 (0.00%)	13 (43.33%)	p < 0.0001
340-400	11 (36.66%)	10 (33.33%)	
400-460	12 (40%)	7 (23.33%)	
460-520	7 (23.33%)	0 (0.00%S)	
Duration of analgesia (min)	412 ± 46.56	348 ± 48.31	p < 0.0001

As shown in table 3, requirement for giving rescue analgesia timing was early in Group-B patients as compared to Group R patients ($p < 0.0001$). There was a significant difference between duration of analgesia provided by these drugs. Group-R (412 ± 46.56 min) was having much longer duration of post-operative analgesia as compared to Group-B (348 ± 48.31 min, $p < 0.001$).

Discussion

Effective control of post-operative pain remains one of the most important and pressing issue in field of surgery and anaesthesia with significant impact on our health care system. Epidural analgesia is considered to be safe and effective technique for providing good post-operative analgesia.[10] Ropivacaine is a long-acting amide local anaesthetic with a potentially improved safety profile when compared to bupivacaine.[11] Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Ropivacaine has a greater degree of motor sensory differentiation. It has selective action on the pain-transmitting A β and C nerves rather than Aβ fibres, which are involved in motor function. Numerous comparative studies between ropivacaine and bupivacaine suggested that ropivacaine produces less cardiac as well as central nervous system toxic effects, less motor block and a similar duration of action of sensory analgesia as bupivacaine.[12]

In the present study, changes in pulse Rate, SBP, DBP and MBP between both Group- R and Group-B in peri-operative period and post operative period shows no significant difference among 2 groups.(p value>0.05). Similar results were seen in a study by Upadhyaya R et al. also demonstrated that pulse rate, SBP and DBP were comparable after epidural injection of 0.125% Ropivacaine with Tramadol and 0.125% Bupivacaine with Tramadol in patients undergoing pyelolithotomy surgery. The R Group experienced significantly longer duration of effective postoperative analgesia, with significantly shorter duration of motor blockade and lesser total analgesia.[7]

Another study conducted by Ninu M et al. on T local anaesthetics ropivacaine and bupivacaine for caudal epidural anaesthesia in children undergoing lower abdominal surgery found that there were no statistically significant differences in AIIMS pain scores between groups A and B at all postoperative time points. The quality and duration of analgesia were comparable in both the groups.[13]

In the present study, no any side effect was seen in patients of Group-R and very few side effects (Hypotension in 1 patient, Bradycardia in 2 patients) were reported in patients of Group-B. Korula S et al.[14] observed that bradycardia and hypotension are typical Bupivacaine side effects. In the study of Patil S et al.[15], the most common side effect was motor block (7 in Group B as against 2 in Group R) followed by hypotension (4 in Group B vs. 1 in Group R).
In the present study, a considerable lengthening of post-operative analgesia was observed in group R patients as compared to group B patients, with the mean duration of analgesia in group R patients being 412 ± 46.56 min as opposed to 348 ± 48.31 min for group B patients.

A comparison study of epidural Fentanyl with Bupivacaine and epidural Tramadol with Bupivacaine for post-operative pain treatment following lower abdominal procedures was carried out by Patil S et al.[16] They examined 60 patients for their investigation. Other 30 patients received 50 mg of Tramadol and 8 mg of 0.125% bupivacaine, while 30 patients received 50 mg of Fentanyl. Mean duration of analgesia in patients getting Tramadol with

Bupivacaine was 378.64 minutes and that it was 472.24 minutes in patients receiving Fentanyl with Bupivacaine. Therefore, the duration of analgesia was longer in patients who received Fentanyl as an adjuvant. Sharma N et al.[17] conducted study to compare 0.5% Ropivacaine with 0.25% Bupivacaine in ultrasound guided TAP Block for abdominal surgeries. Mean duration of analgesia was longer in Ropivacaine group (12.61±5.13 hours) as compared to Bupivacaine group (9.92±4.81). Studies by Patil S et al., Casati et al., and Surabathuni et al. reported that the need for rescue analgesia was more in the ropivacaine group than the bupivacaine group.[15,18,19]

Conclusion

Ropivacaine and Bupivacaine shows a similar hemodynamic profile in abdominal surgeries. Ropivacaine provides a longer duration of analgesia as compared to Bupivacaine. Thus, Ropivacaine can be used as an alternative to Bupivacaine for postoperative pain relief through the epidural route in patients undergoing intra abdominal surgeries, as a safe and effective agent.

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