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A COMPARATIVE STUDY OF 0.2% ROPIVACAINE VERSUS 0.2% ROPIVACAINE PLUS TRAMADOL FOR EPIDURAL POSTOPERATIVE ANALGESIA FOR ORTHOPAEDIC SURGERIES"

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ABSTRACT **Background And Objective:** Postoperative analgesia can be achieved by various modalities. Out of which epidural analgesia offers a good reliable pain relief. Addition of opioids enhances the onset of analgesia and prolongs the duration. This study aims in comparative evaluation of 0.2% ropivacaine versus 0.2% ropivacaine plus tramadol for postoperative analgesia. **Methods:** 60 patients of age 18-70 years with ASA grade I & II, undergoing elective lower limb surgeries under epidural anaesthesia were randomly taken into each of the 2 groups. For post operative pain management 0.2% ropivacaine 10ml in group R and 0.2% ropivacaine 9ml plus tramadol 1 ml (50mg) total of 10ml in group RT. Patients were monitored for onset, duration and quality of analgesia, hemodynamic stability and for any side effects. **Results:** The groups were similar with respect to age, sex, ASA, HR, SBP, DBP and Spo2. VAS after top up significantly lower in the group N ($p<0.001$). Anti-emetic therapy use was significantly lower in the group R ($p<0.001$). Rescue analgesic use was significantly lower in the group RT ($p<0.001$). Mean time interval between top ups was significantly higher in group R ($p<0.001$). Duration of analgesia is significantly higher in Group RT ($p<0.001$). **Conclusion:** Addition of tramadol to 0.2 % Ropivacaine in epidural route for post operative pain management provides better pain relief and patient satisfaction than 0.2 % Ropivacaine alone.

KEYWORDS : Postoperative pain, Blood pressure, Pulse rate, SPO2.

INTRODUCTION:

Pain is one of the main complaints of patients referred to the hospital and comprises almost 80% of the causes for referral to the emergency department.[1] The current IASP definition of pain is "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[2] Pain management in the emergency department is one of the quality of care indicators and can be used as a marker for assessing the care in the emergency department. Factors such as race, age, gender, ability to express pain, underlying illness, physician awareness, and fear of complications can all prevent patients from receiving proper pain management.[1]

Spinal block is a simple method that requires only a small amount of local anaesthetic to quickly establish an intense and reliable block. The catheter technique for epidural block (EDA) is technically more difficult, but it allows for the extension of the block during surgery as well as pain relief with a local anaesthetic and/or opioids in the postoperative period.[3]

Role of epidural analgesia is well known. It is extremely effective in alleviating intraoperative or postoperative pain following major upper abdominal, thoracic, orthopaedic surgeries. The side effects or complications might be related to procedure or the drug used like dural perforation, epidural hematoma, infection, urinary retention, hypotension, pruritus and respiratorydepression.[4]

Because opioids lower painful impulses arriving at the dorsal horn neuron and local anaesthetics reduce excitability of the cell, local anaesthetics and opioids have synergistic impact. Effective pain reduction with motor sparing for postoperative analgesia is one of the benefits. The present study aimed to Compare 0.2% Ropivacaine versus 0.2% ropivacaine plus tramadol for epidural postoperative analgesia for orthopaedic surgeries.

Objectives Of Study:

1. To evaluate the impact of 0.2% Ropivacaine plus Tramadol for postoperative analgesia.
2. To assess the incidence of side effects due to combinations of 0.2% Ropivacaine and Tramadol.
3. Onset ofanalgesia
4. Duration of analgesia
5. Quality of analgesia
6. Surgical outcome
7. Level of patient satisfaction.

METHODOLOGY:

The study was conducted between AUGUST 2020 to JUNE 2022 at the Chigateri General Hospital and Bapuji Hospital, all of which are attached to J.J.M. Medical College in Davangere. After receiving ethics committee approval, institutional approval, and informed consent from the patients, sixty patients of ASA class I and II of either sex, ranging in age from 18 to 70 years old, were randomly assigned to one ofthe two groups for the study. The two groups are:

- Group R: 0.2% ropivacaine 10ml in group R
- Group RT: 0.2% ropivacaine 9ml plus tramadol 1 ml(50mg) total of 10ml in group RT Pre-anaesthetic evaluation:

On the day before surgery, patients were visited, a comprehensive medical history was collected, and a systemic examination was performed.

Inclusion Criteria:

Age: 18 -70 years Gender :Both male and female ASA physical status I- III Mallampatti grade 1 and 2 Undergoing elective orthopaedic surgeries.

Exclusion Criteria:

Patients with Coagulation disorders, Preexisting neurological disorder Spinal deformity, Paediatric age group, Patient not willing to give consent Pregnant females, Mentally retarded patients. Basic laboratory tests such as Hb%, FBS/RBS, blood urea, and serum creatinine were performed on all patients on a regular basis. When indicated, an ECG was performed and a chest X-ray was taken. The procedure was explained to the patients the day before surgery, and they provided written consent. Patients were asked to notify their doctors if they felt any pain after surgery. Patients will be informed about the visual analogue score (VAS) on the day before scheduled surgery during the preanaesthetic check-up. For comparing pain relief and patient satisfaction after epidural bolus and top up, use VAS 0 for no pain, 1 to 3 for mild pain, 4-6 for moderate pain, and 7-10 for severe pain. Sixty ASA grade 1 and 2 patients, aged 18-70 years, of either sexes, scheduled for orthopaedic surgery under combined spinal epidural anaesthesia will be given 0.2% ropivacaine or 0.2% ropivacaine plus tramadol. To top up, i.e., post-operative pain management 0.2% ropivacaine 10ml in group R and 0.2% ropivacaine 9ml plus tramadol 1 ml (50mg) in group RT for a total of 10ml. Prior to top up, Inj Ondan 4mg iv is given to the RT group, and hemodynamic parameters are monitored in both groups. Top ups will be given at regular intervals until 48 hours after the surgical procedure, with hemodynamic parameters monitored after each top up dose. The

epidural catheter will be removed after 48 hours. Sixty ASA grade 1, 2 and 3, age 18-70 yrs, of either sex, scheduled to undergo orthopaedic surgeries under combined spinal epidural anaesthesia will be allocated to receive 0.2% ropivacaine or 0.2% ropivacaine plus tramadol. If patients complains of pain (VAS>4) within 6hrs of top up, rescue analgesic will be given intravenously or intramuscularly. Post- top-up hemodynamic parameters such as pulse rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation will also be measured and compared. Also noted will be the various side effects caused by each, such as nausea and vomiting (by measuring frequency of antiemetic usage).

RESULTS:

Sixty patients of ASA I and ASA II between age group of 18-70 years posted for elective lower limb orthopaedic surgeries were studied. The objective of the study is to compare the 0.002% Ropivacaine with combination of 0.002% Ropivacaine and tramadol for postoperative pain management in terms quality of analgesia with lesser side effects. Equal number of patients in 2 groups are noticed n= 30 in group R and n=30 in group RT. In group R, 18 male and 12 female are noticed whereas in group RT, 20 male and 10 female are noticed. P value is 0.789 which is insignificant

ASA I and ASA II patients are included in present study out of which in group R 11 patients are included in ASA I and 19 patients are included in ASA II. In Group RT 15 members were included in ASA I and 15 patients were included in ASA II. And there is no statistical significance (p value is 0.435) in distribution of ASA patients.

On comparision of Mean age among group R and group RT showed a value of 52 and 48 respectively and the p value is statistically not significant

Heart rate, SpO2, DBP, showed no statistical significance whereas VAS showed statistically significant change between all 5 doses. On calculating p value in group R is 0.000437, in group RT is 0.0005932 which shows the results to be statistically significant (p<.005) (Table 1).

Mean value of duration of analgesia in group R and group RT after 1st dose is 6.25and 7.466 , after 2nd dose is 6.477 and 7.5 , after 3rd dose is 6.3and 7.65, after 4th dose is 6.469 and 7.5 , after 5th dose is 6.417 and 7.783 which is statistically significant.(Table 2)

Patients with a need of rescue analgesia in group R is 8 out of 30 whereas Patients with a need of rescue analgesia in group RT and p value is 0.011 which is highly significant (Table 3)

Table 1 : VAS of all 5 doses

		Mean	SD	Mean	SD
	VAS	Group R		Group RT	
1st dose	Pre topup	9.37	0.56	9.33	0.48
	Post topup	2.83	0.75	3.1	0.31
2nd dose	Pre topup	7.37	0.93	6.93	0.98
	Post topup	1.67	0.8	1.47	0.78
3rd dose	Pre topup	7.43	0.86	7.3	0.65
	Post topup	1.13	0.35	1.17	0.38
4th dose	Pre topup	6.03	1.59	6.23	1.36
	Post topup	1.2	0.41	1.4	0.5
5th dose	pre topup	4.07	0.98	4.13	0.9
	Post topup	1.03	0.18	1.07	0.25

Table 2: Mean and SD of duration of action of all doses.

DOA	Group R		Group RT		p value
	Mean	SD	Mean	SD	
After 1st dose	6.25	0.58	7.46	0.57	< 0.001 (S)
After 2nd doe	6.477	0.49	7.5	0.56	< 0.001 (S)
After 3rd dose	6.3	0.43	7.65	0.48	< 0.001 (S)
After 4th dose	6.467	0.49	7.5	0.44	< 0.001 (S)
After 5th dose	6.417	0.51	7.78	0.43	< 0.001 (S)

Table 3: Distribution of rescue analgesia in study population

Group	Rescue Analgesia		Total	p Value
	Given	Not Given		
R	8	22	30	0.01(HS)
RT	1	29	30	
total	9	51	60	

Table 4: Distribution of vomiting in study population

Group	vomitings		Total	p value
	Present	Absent		0.0055(HS)
R	1	29	30	
RT	9	21	30	
TOTAL	10	50	60	

DISCUSSION:

Analgesia is provided by epidural opioids without producing motor or sympathetic blockage. Several studies have found differences between the most commonly used opioids for epidural analgesia. The highly lipid soluble opioids produce analgesia more quickly. [5]

Tramadol hydrochloride is an opioid with the additional property of inhibiting noradrenaline and serotonin intersynaptic reuptake, giving it a dual mode of analgesic action. Tramadol has a unique place in the pain-relieving arsenal because it not only provides analgesia across a wide range of pathologies, but it also has significant advantages over other opioids. These advantages include a lack of signficant respiratory depressant effects, a low risk f tolerance and dependence, and a low adverse event profile. [6]

In adult patients having nasal surgery, intraoperative tramadol administration was successful in lowering the incidence of Emergence agitation without impeding recovery or escalating the frequency of adverse events. [7]

There were no cases of bradypnea or obvious respiratory depression in this trial with ropivacaine or ropivacaine + tramadol. The groups R and RT each included 60 patients who were ASA grade I and II, ranging in age from 18 to 60 years old, with the majority of them being between 48 and 55 years old. With 10–12 patients in each group being female, the gender distribution in both groups was practically same.

Intraoperative Haemodynamic Parameters Intraoperatively bolus top-up given before the end of procedure and patient was monitored for 30 minutes. There were no significant differences between hemodynamic parameters (HR, SBP, DBP and SpO2) among both group R and group RT and Inj onden was given for allpatients under group RT. And rescue analgesia is given to Group R.

Krishnadas et al [7] studied the efficacy of tramadol or midazolam addition to caudal ropivacaine for post-operative analgesia in children undergoing subumbilical surgeries and noticed no significant difference in the duration of time to rescue analgesia between RT and RM groups. Motor block and sedation scores were comparable between groups.

Veena Charath et al [8] studied by comparing bupivacaine hydrochloride with nalbuphine versus bupivacaine with tramadol and found that VAS score was always lower in Rt2.

Group in comparison to other group during the study. Hemodynamic parameter remained stable in all three groups which is similar to the present study.

Post Top Up Hemodynamic Parameters There were no significant differences between hemodynamic parameter changes after top up amongst both groups. The changes that occur with respect to pre top up parameters can be attributed to the local anaesthetic rather than the additive opioid.

These findings were similar to the studies by **Veena Charath, Saravana Babu** [9]**, Nama Nagarjuna Chakravarthy** in all of these individual studies, there was no significant differences in hemodynamic parameters after top up amongst both groups.

Duration of Analgesia:

Time interval between intraoperative bolus dose to next top up given was considered. In group R, the mean duration of analgesia requiring next top up is 5.50+2.0 hours.

In group RT, the mean duration of analgesia requiring next top up is 6.50+2.5 hours, with p value of 0.001 which is highly significant.

Signh AP et al [10] compared postoperative analgesic efficacy and safety

of epidural tramadol as adjuvant to ropivacaine (0.2%) in adult upper abdominal surgery. They found that the mean duration of analgesia after epidural bolus drug was significantly longer in Group RT2 (584 ± 58 min) than in Group RT1 (394±46 min) or R Group (283±35 min).

Senel AC et al [11] assessed the effect of tramadol and ketamine, 50 mg, added to ropivacainein brachial plexus anesthesia and found that duration of analgesia was significantly longer in ropivacaine + tramadol group which is similar to the results in our study. Contrasting results with respect to duration of analgesia could be because of differences in the doses of additive opioids used in this study fromthat of Veena Charath et al.

Quality of analgesia assessed by VAS score:

On Comparison of VAS between R and RT group, Group R has a shift of mean from 9.37 to 2.83 after and group RT shifted from 9.33 to 2.53 which has a p value of 0.075 post top up. After second dose, group R has a shift of mean from 7.37 to 1.67 and group RT shifted from 6.93 to 1.47 and p value being 0.33. After 3rd dose, group R has a shift of mean from 7.43 to 113, group RT shifted from 7.3 to 1.17 and a p value of 0.723. After 4th dose, group R has a shift of mean from 6.03 to 1.2, group RT has a shift of 6.23 to 1.4 and p value of 0.094. After 5th dose, group R has a shift of mean from 4.07 to 1.03 and group RT has a shift of mean from 4.13 to 1.07 with a p value of 0.561.

On examination, there is significant difference in VAS score before and after top up and the score is gradually decreased from 1st dose to last dose which is statistically significant. Although the p value of intra group analysis is not significant, there is significance decrease in VAS score on Intra group analysis.

Biswajit Sutradhar [12] et al in 2017, showed that VAS score in nalbuphine group (4.35+1.2) which is less and in tramadol group (6.23+2.5) which is similar to our study where in VAS score is less in group received nalbuphine.

Requirement Of Rescue Analgesics:

Rescue analgesia in Group R is given to 8 patients among 30 as a supplemental drug therapy for pain management when compared to group RT 1 among 30 patients has a need of rescue analgesia and p value is significantly high.

In a study conducted by **Krishnadas et al** [7] the mean duration of time to rescue analgesia was significantly longer ($P < 0.001$) in Group RT (913 ± 315.5 min) and Group RM (769.2 ± 331.9 min) compared to Group R (437.75 ± 75.68 min). However, there was no significant difference in the duration of time to rescue analgesia between RT and RM groups. Motor block and sedation scores were comparable between groups.

CONCLUSION

The following things are concluded bythis study

- There were no significant hemodynamic parameter changes with Ropivacaine and Ropivacaine combined with Tramadol both during intraoperative bolus dose and postoperative top up.
- Even thought the results were statistically insignificant, Ropivacaine with Tramadol provides better VAS score, prolonged duration of analgesia when compared Ropivacaine alone.
- Rescue analgesic requirement was less when Tramadol was used as an adjuvant to Ropivacine when compared to Ropivacaine alone.

The incidence of adverse effects like nausea, vomiting more with tramadol as an adjuvant to Ropivacaine when compared to Ropivacaine alone.

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