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An Observational Study to Compare Ropivacaine and Bupivacaine Along with Tramadol to Provide Post Operative Epidural Analgesia in Patients Undergoing Elective Pyelolithotomy Surgery

KEYWORDS: Ropivacaine, Bupivacaine, epidural analgesia, Tramadol, Postoperative pain

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ABSTRACT *'AN OBSERVATIONAL STUDY BETWEEN 0.125% ROPIVACAINE AND 0.125% BUPIVACAINE ALONG WITH TRAMADOL TO PROVIDE POST OPERATIVE EPIDURAL ANALGESIA IN PATIENTS UNDERGOING ELECTIVE PYELOLITHOTOMY SURGERY'***AIMS AND OBJECTIVES:** *The aim of this study was to compare the analgesic effect, duration of action and hemodynamic changes of 0.125% Bupivacaine with that of 0.125% Ropivacaine along with tramadol in patients undergoing pyelolithotomy for post-operative analgesia.***MATERIAL AND METHODS :** *60 patients were taken scheduled for pyelolithotomy surgery ranging from 18-55 years in ASA grade I and II. Clearance from institutional ethics committee was obtained. They were randomly allocated to two groups of 30 each. An epidural catheter was introduced in L1-L2, L2-L3 space under strict aseptic and antiseptic precautions. First dose of the study drug was given to all patients at the time of closure.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.*

- *All the patients were induced with Inj. Propofol 2mg/kg, Inj. Succinylcholine 2mg/kg followed endotracheal intubation by direct layringoscopy. Tube was fixed after checking bilateral air entry.*
- *Patient were maintained on O2/N2O 50%-50% with isoflorane and Inj. Atracurium 0.5 mg/kg bolus followed by intermittent dose as per train of four responses. Intraoperative fluid were calculated and managed.*
- *Patients were reversed with Inj. neostigmine and Inj. glycopyrrolate and Extubated.*
- *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. Pain was assessed by visual analogue scale.*

RESULT:*The R Group experienced significantly longer duration of effective postoperative analgesia, with significantly shorter duration of motor blockade and lesser total analgesic requirement in comparison to the B Group. Hemodynamicaly, patients in both the groups, were equally stable*

CONCLUSION: *Ropivacaine, with an equipotent analgesic efficacy and a lesser duration of motor block, however, a similar hemodynamic and side-effect profile. Thus, Ropivacaine can be used as an alternative to Bupivacaine for postoperative pain relief through the epidural route in patients undergoing pyelolithotomy ,as a safe and effective agent.*

INRODUCTION

"Life is short, and the art is long, the right time an instant and treatment precarious and crisis grievous. It is necessary for the physician not only to provide the treatment needed, but to provide for the patient himself and for those beside him"

Hippocrates 460-370 BC

- Postoperative pain, especially when poorly controlled, results in harmful acute effects (i.e., adverse physiologic responses) and chronic effects (i.e., delayed long-term recovery and chronic pain).
- One of the major issues of concern to patients presenting for major surgery is post-operative analgesia, an epidural analgesia is considered by many as gold standard analgesic technique, for post-operative analgesia after abdominal surgeries. It provides dynamic analgesia, allowing patient to resume normal activities unlimited by pain. Apart from providing pain relief it also helps in attenuation of stress response
- Analgesia delivered through an indwelling epidural catheter is a safe and effective method for management of acute postoperative pain. 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.
- The following study was taken up to compare the analgesic effect, duration of action and hemodynamic changes of 0.125% Bupivacaine with that of 0.125% Ropivacaine along with tramadol in elective pyelolithotomy surgery for post-operative analgesia.

AIMS AND OBJECTIVES OF STUDY:

- The aim of the study is to compare.
- Hemodynamic effects post operatively.
- Duration of Analgesia.
- Complication related to drug.

MATERIAL AND METHODOLOGY

- In this observational study 60 patients were scheduled for elective pyelolithotomy ranging from 18-55 years in ASA grade I and II. Clearance from institutional ethics committee was obtained. They were allocated to two groups of 30 each. Patients were subjected to pre-anesthetic checkup and informed consent was obtained from all the patients. After informed consent

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under strict aseptic and antiseptic precautions epidural catheter was introduced in L1-L2, L2-L3 space.
- First dose of the study drug was given to all patients at the end of surgery.
- 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.
- All the patients were induced with Inj. Propofol 2mg/kg, Inj. Succinylcholine 2mg/kg followed endotracheal intubation by direct layringoscopy. Tube was fixed after checking bilateral air entry.
- Patient were maintained on O_2/N_2O 50%-50% with isoflorane and Inj. Atracurium 0.5 mg/kg bolus followed by intermittent dose as per train of four responses. Intraoperative fluid were calculated and managed.
- Patients were reversed with Inj. neostigmine and Inj. glycopyrrolate and Extubated.
- 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. Pain was assessed by visual analogue scale.
- Drug related complications like dizziness, somnolence, vomiting, confusion, vertigo, visual disturbances, and urinary retention were recorded in first 24 hours.

INCLUSION CRITERIA
1. Patients in the age range 18-55 years.
2. Scheduled for pyelolithotomy surgery to be performed under General Anaesthesia and Epidural Anaesthesia.
3. ASA risk category I and II.
4. No known history of allergy, sensitivity or other form of reaction to local anesthetics.
5. Patient willing to sign informed consent.

EXCLUSION CRITERIA:
1. Patient refusal.
2. Patients with coagulopathy.
3. Patients on potent anti-epileptics, analgesics, anti-platelets, or on anticoagulants.
4. Patients with spine deformity.
5. Patients with local skin infections at site of injection.
6. Known allergy to the trial drugs.
7. ASA III or more.

PREOPERATIVE ASSESSMENT:
All the patients posted for planned surgery were assessed for height, weight and general parameters- vitals namely pulse rate, blood pressure, respiratory rate, temperature and systemic examination of respiratory system, cardiovascular system, gastrointestinal system, central nervous system will be done.

INVESTIGATIONS
The patient were investigated for:
1. Complete blood count
2. Urine routine and microscopy
3. Random blood sugar
4. Liver function test
5. Renal function test
6. ECG
7. Chest x-ray PA view
8. Serum Electrolytes & Serum Total Protein
9. HIV &HBsAg
10. Other special investigations, if required.

All the patients were kept nil by mouth for at least 6 to 8 hours.

Post operative management:
With stable hemodynamic, all patients were transferred to the recovery room. Patient were constantly monitored for pain as well as for as associated complains and also look for hypotension and bradycardia.

Postoperative Monitoring
All patients of both groups were monitored for:
- Heart rate (HR).
- Mean arterial blood pressure (MAP)
- Systolic blood pressure/ Diastolic blood pressure
- Duration of analgesia
- Delayed post-operative complications like dizziness, confusion, nausea, vomiting.

STATISTICAL ANALYSIS:
Data were collected, tabulated, coded & then analyzed using GRAPHPAD PR

- Numerical variables were presented as Mean & Standard Deviation (SD). While categorical variables were presented as percentage (%).
- As regard numerical variables; unpaired student-t test was done.
- The inferences based on 559p value were made as follows:

ISM computer software version 6.0

p>0.05	Not Significant
p<0.05	Significant
p<0.00 1	Strongly Significant

OBSERVATION AND RESULTS
Table 1: Demographic Data

Parameters		Group – R (n = 30)	Group – B (n = 30)	Significance
Age (years)		37.77 ± 2.098	36.53 ± 1.668	P = 0.6471; not significant
Sex (M / F)		25 / 05	27 / 03	Not significance
Height(cms)		161.5 ± 1.255	161.8 ± 1.146	0.8605; not significant
Weight(kg)		56.60 ± 0.6637	56.30 ± 0.6884	0.7548; not significant
ASA grade	I	16	17	Not significant
	II	14	13	

Both groups were comparable.
Table 2: Onset of Sensory Block

Parameter	Group – B(n = 30)	Group – R(n = 30)	Significance
Time (mins)	13.83 ± 2.449	9.567 ± 2.072	P < 0.0001 Strongly significant

Significant reduction in onset of sensory block in Group-R compared to Group-B with p<0.0001 (statistically strongly significant). Out of 30 patients in Group-B, earliest onset of sensory block was at 11 min and most delayed onset was at 16min(13.83 ± 2.449). In Group-R, earliest onset of sensory block was at 8 min and most delayed was at 12 min(9.567 ± 2.072**).**

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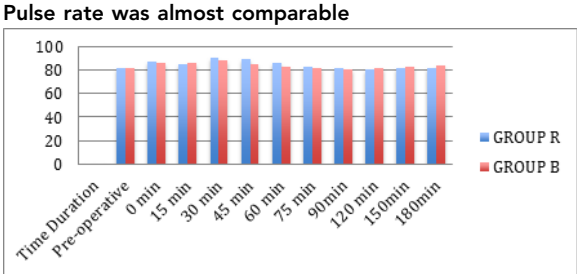
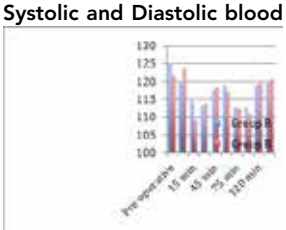
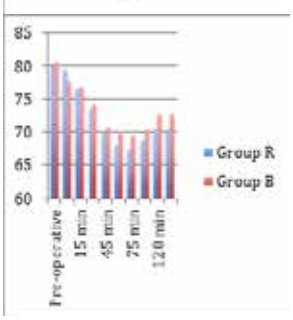
Pulse rate was almost comparable



Systolic and Diastolic blood pressure:



There was fall in **systolic BP** at 15 min after injection of epidural solution in Group-B in three cases as compared to Group-R. **Overall, though systolic blood pressure remained stable in both groups and no statistically or clinically significant change was observed.**



There was fall in **diastolic BP** at 15 min after injection of epidural solution in Group-B as compared to Group-R. **Overall, diastolic blood pressure remained stable in both groups and no statistically or clinically significant change was observed.**

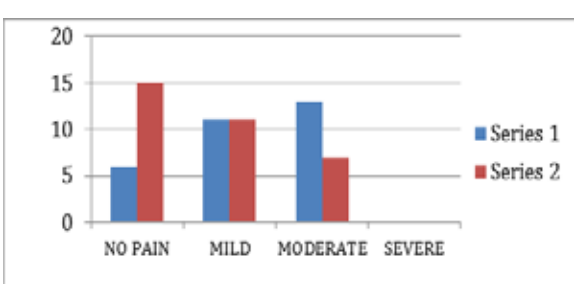
Table 6: Duration of Analgesia

Parameter	Group – B(n = 30)	Group – R(n = 30)	Significance
Time(mins.)	275.0 ± 33.56	408.0 ± 41.98	P< 0.0001*Strongly significant

VISUAL ANALOGUE SCALE

0	1	2	3	4	5	6	7	8	9	10
No	Mild Pain			Moderate Pain			Severe Pain			

Pain	Group b(N-30)	Group R(N-30)
NO PAIN	6	15
Mild	11	11
Moderate	13	4
Severe	0	0



Group B was having visual analogue score higher then group R

Table 7: Side-Effects/ Complications

Side Effects	No. of patients affected		Treatment
	Group-R	Group-B	
Bradycardia	---	02	Inj. Atropine 0.6mg i/v
Hypotension	---	03	Inj. Mephentermine 6mg i/v
Nausea/ vomiting	---	---	
Sedation	---	02	No treatment was required
Pruritus	---	---	
Others	---	---	

No detrimental side effects or complications were observed in both the groups. In Group-B 2 patients had bradycardia, 3 patients had hypotension & 2 patients had sedation which was treated accordingly as shown in Table.

DISCUSSION

- Epidural analgesia have been demonstrated to improve postoperative outcome improve pain relief and satisfaction in patients and reduce morbidity operated for major abdominal surgery. Rodger A et al shows reduction of post op mortality and morbidity with epidural anaesthesia.(1)
- Ropivacaine is a long-acting amide-type local anesthetic. In comparison with bupivacaine, it is equally effective for epidural analgesia. Ropivacaine because of its pure S-enantiomer form is less cardio toxic than Bupivacaine(2). The use of opioids with local anesthetic for epidural anesthesia has been associated with decreased pain scores and reduced analgesic requirement in the post-operative period . Gunion et al reported that opiate analgesia provide effective pain relief and are widely used for control of mild to severe pain.(3,8)
- The demographic data were comparable in both the groups of our study.(5)
- In this study all the hemodynamic parameters (Pulse, Blood pressure, &SpO2) of both the groups were comparable and were clinically & statistically insignificant. BHAVAN R et al, mentioned that stable intraoperative hemodynamic parameters were achieved with epidural Ropivacaine 0.75% as compared to bupivacaine 0.5%.
- Duration of sensory blockade was longer in group R compared to group B which was clinicaly significant. Finucane BT et al have also shown that increasing the concentration of ropivacaine (from 0.5 to 0.75%) resulted in greater degree & longer duration of sensory block, a positive correlation between the total dose of ropivacaine and the sensory block profile have also been demonstrated(7).
- The time for first request of analgesic (duration of analgesia) was between 365-450 min(408±41.9)min in group R which was significantly higher as compared to 245-300 min(275.0±33.5)min in Group-B. (P < 0.0001)
- VAS was significantly higher value in Group-B than Group-R. There was significantly prolonged duration of analgesia in all the patients enrolled in the group R over group B(8,4)
- A low incidence of side effects was observed in our study. Three patients (10%) had hypotension, two patients (6.66%) had bradycardia and two patients

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(6.66%) had sedation in the group B.SARA K et al, also noted that vital sign were stable in al the patients throughout the study. They also noted that hypotension was the most common side effect with bupivacaine.

CONCLUSION

From our study we have concluded that ropivacaine is better agent then bupivacain for providing better analgesia with longer duration and less side effects in patients operated for elective pylolithotomy surgeries.

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