ORIGINAL RESEARCH

A Comparative study of efficacy of Epidural 0.2%Ropivacaine versus 0.2%Bupivacaine for postoperative analgesia in abdominal surgeries

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ABSTRACT

Background and Aims: Postoperative pain remains the most important cause of morbidity. Thus, a good postoperative analgesia is required but at the same time any untoward complication is to be avoided as patient is in a ward setting which is not a continuous monitoring setting always. Epidural local anaesthetics with good safety profile remain a safe modality in such settings. Our aim is to compare the efficacy, haemodynamics and side effects of Epidural 0.2%Ropivacaine versus 0.2%Bupivacaine for post-operative analgesia in abdominal surgeries.

Materials and Methods: A comparative study of 80 patients undergoing elective abdominal surgeries were allocated into two groups using Computer generated randomization. Postoperatively, one group received epidural Bupivacaine 0.2%, upto10cc and other received ropivacaine 0.2% 10cc. Pre-emptive epidural analgesia in the form of Bupivacaine/Ropivacaine administered at the time of closure and duration of analgesia was taken from time of extubation till analgesic is asked for the first-time post operatively. Rescue analgesia administered in the form of epidural Bupivacaine or Ropivacaine in the respective groups. Assessment done by a blinded anesthesiologist. Statistical analysis done using SPSS software version 20 and Epi Info 7.2.1.

Result: Though both the drugs maintained a comparable hemodynamic profile, there was better patient comfort at rest in ropivacaine group with lower VAS scores and lesser demand for rescue analgesia. Significantly higher number of adverse effects were found in bupivacaine group (n=36) as compared to ropivacaine group (n=6), specifically, fall in blood pressure and motor deficit.

Conclusion- Ropivacaine provided better post-operative analgesia as patients required lesser amount of rescue analgesia as well as mean time was comparatively longer for the first top up in comparison to Bupivacaine. Ropivacaine was also found to have a better safety profile alongwith distinct motor sensory differentiation.

Keywords: epidural, bupivacaine, ropivacaine

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INTRODUCTION

Pain remains the most important cause of suffering and disability that impairs the quality of life of millions of people throughout the world especially in the post- operative period, which if treated inadequately, it may lead to development of complications, which may not be related to surgery itself and can cause a hyperalgesic condition known as Persistent Post-operative Pain (PPP).⁽¹⁾

Effective analgesia in postoperative period decreases patients' suffering and induces sense of wellbeing, and also improves early ambulation. It allows chest physiotherapy to decrease lung collapse thereby reducing postoperative complications. The various modalities for postoperative pain control are intravenous analgesia, patient control analgesia, epidural analgesia, and regional blocks. Postoperative use of epidural analgesia has the potential to reduce pulmonary morbidity by providing better analgesia, improved diaphragmatic function, and reduced frequency and severity of postoperative hypoxemia. ⁽¹⁾⁽²⁾

Epidural analgesia using local anaesthetic, opioid, and especially both provides better analgesia than systemic opioid. Epidural anaesthesia is being considered as a good and relatively inexpensive technique for providing surgical anaesthesia and postoperative analgesia. It is also useful in preventing operative pain by blunting somatic, endocrine and autonomic responses of pain. It would also obtund central sensitization and pain-induced organ dysfunction, leading to improved outcome. ⁽³⁾

Both Bupivacaine and Ropivacaine are long acting, amide, local anaesthetic agents with Ropivacaine being produced in a pure enantiomer(S) form. ⁽⁴⁾ The major difference lying in the lipophilicity of the drugs which renders ropivacaine with better motor sensory differentiation.

The main aim of our study was to compare the efficacy of Epidural Ropivacaine and Bupivacaine for post-operative analgesia in abdominal surgeries. The main objectives of the study were to assess the onset and duration of analgesia post operatively, to study the effects of both drugs on haemodynamics and to study and compare the adverse effects of both drugs.

MATERIAL & METHODS

It is a comparative study of 80 patients aged 18-60yr falling in ASA class I or II

undergoing any elective abdominal surgery requiring General Anaesthesia and epidural analgesia. Patients who were pregnant or with difficult airways were excluded from the study. Patients were allocated into two groups using Computer generated randomization, wherein one group received Bupivacaine 0.2%, upto10cc and other group received ropivacaine 0.2% 10cc, postoperatively for epidural analgesia.

After obtaining permission from the departmental review board and hospital ethics committee and ascertaining selection criteria, written valid informed consent was obtained from all 80 patients for participation in the study.

Patients were assigned to either of the two groups-: Group-B: Inj. Bupivacaine 0.2%, 10cc Group-R: Inj. Ropivacaine 0.2% 10cc. Baseline vitals(heart rate, blood pressure) were recorded. Under all aseptic precautions, after local infiltration, with 18 G Tuohy needle, epidural catheter was inserted using loss of resistance technique. Afterwards, patients were premedicated with Inj. Glycopyrrolate 0.004 mg/kg IV, Inj. Ondansetron 0.08 mg/kg IV, Inj. Midazolam 0.05mg/kg, Inj. Pentazocine 0.5mg/kg or Fentanyl 2 microgram/kg. General anaesthesia was induced with a 1%(w/v) solution of Propofol 2mg/kg. Muscle relaxation was produced by the inj. Suxamethonium 1.5mg/kg for intubation. Anaesthesia was maintained with oxygen, nitrous oxide, and muscle relaxant ,Vecuronium 0.1 mg/kg and inhalational agents like Isoflurane/Sevoflurane with controlled Ventilation with a circle absorber throughout this period. The subsequent anaesthetic management was according to surgical requirements.

Pre-emptive epidural analgesia in the form of Bupivacaine/Ropivacaine was administered at the time of closure. After the surgical procedure, patients of both the groups were reversed with Inj. Neostigmine 2.5mg + Inj. Glycopyrrolate 0.5mg i.v. Post-operative pain assessment started in the recovery room. Visual Analogue Scale(VAS) was used to measure pain score. Duration of analgesia was taken from the time of extubation till the time the analgesic is asked for the first-time post operatively. Frequency of analgesic requirement noted. Rescue analgesia was administered in the form of epidural top up with either Bupivacaine or Ropivacaine in the respective groups. Pain assessments were repeated every 30 minutes in first 2 hours, then 2 hourly for 6 hours and then at 12 and 24 hours. Side effects like nausea, vomiting, respiratory depression, hallucination and emergence delirium were noted. Nausea and vomiting were treated with Inj. Metoclopromide10 mg i.v. Hypotension and was treated with fluids and RR< 10/min considered as a sign of respiratory depression and patient was given assisted ventilation.

Appropriate statistical tests applied using SPSS software version 20 and Epi Info 7.2.1 for analysis. Statistical analysis was performed. Two-tailed probability value equal to or less than 0.05 was regarded as significant. All patients were enrolled after informed consent from the patient.

RESULTS

1. The demographic profile was comparable in both the study groups. (p>0.05)

2. VAS Score in study groups

On comparing the VAS scores between the study groups at various time points post Extubation, it was found the mean VAS score in the ropivacaine group was found to be significantly lower (p<0.05) at 30 minutes, 1 hour, 1.5 hours, 2 hours and 12 hours post-extubation. At 6 hours post-extubation, the mean VAS scores were significantly higher in the ropivacaine group as compared to bupivacaine group (p<0.05). At 24 hours post-extubation, the VAS scores in the both the study groups were comparable (p>0.05). (Table 1).

Time point of	Bupivacaine	Ropivacaine	P value
assessment	group (n=40)	group (n=40)	
At time of Extubation	1.23 <u>+</u> 0.66	0.88 <u>+</u> 0.46	<0.01*
30 minutes	1.43 <u>+</u> 0.5	1.05 <u>+</u> 0.5	<0.01*
1 hour	2 <u>+</u> 1.06	1.15 <u>+</u> 0.77	<0.01*
1.5 hours	3 <u>+</u> 1.59	1.43 <u>+</u> 0.96	<0.01*
2 hours	4 <u>+</u> 2.09	2.75 <u>+</u> 1.21	<0.01*
6 hours	3.33 <u>+</u> 1.67	4.28 <u>+</u> 1.63	<0.01*
12 hours	4.03 <u>+</u> 1.82	2.03 <u>+</u> 1.4	<0.01*
24 hours	1.78 <u>+</u> 0.77	1.6 <u>+</u> 0.67	0.28

Table 1. Comparison of VIIS Scores in study group	Table 1	l: Co	mparison	of V	AS	Scores	in	study	grou	ps
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p<0.05 considered significant by unpaired t test

Figure 1 below gives a graphical representation of the VAS scores in both the bupivacaine and the ropivacaine groups at various time-points after extubation.

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Figure 1: Mean VAS scores in study groups

3. <u>Rescue analgesia requirement in study groups</u>

All the patients in both the study groups required first top-up of rescue analgesia. 34 patients in the bupivacaine group required second top-up, while the number was just 10 patients in the ropivacaine group. Overall, significantly higher number of patients in bupivacaine group required rescue analgesia top-up (p<0.05) (Table 2)

Time point of	Bupivacaine	Ropivacaine	P value
assessment	group (n=40)	group (n=40)	
1 st top-up	40 (all)	40 (all)	<0.01*
2 nd top-up	34	10	
3 rd top-up	4	0	
4 th top-up	0	0	

Table 2: Patients requiring rescue analgesia in study groups

p<0.05 considered significant by chi-square test

On comparing the time to rescue analgesia, the mean time was significantly shorter in the bupivacaine group as compared to ropivacaine group for the first top-up (p<0.05), while it was statistically comparable for the second top-up (p>0.05) (Table 3).

Time point of assessment	Bupivacaine group (n=40)	Ropivacaine group (n=40)	P value
1 st top-up	2.4 <u>+</u> 2.47	4.99 <u>+</u> 2.22	<0.01*
2 nd top-up	10.41 <u>+</u> 4.41	9 <u>+</u> 3.16	0.21
3 rd top-up	12 ± 0	-	-

Table 3: Comparison of time to rescue analgesia in study groups

Time in hours, p<0.05 considered significant by unpaired t test

4. <u>Adverse effects in study groups</u>

On comparing the adverse effects noted in the two study groups, higher number of adverse effects was found in bupivacaine group (n=36) as compared to ropivacaine group (n=6), and this was significant finding (p<0.05). Specifically, fall in blood pressure and motor deficit was significantly higher in the bupivacaine group (p<0.05). (Table 4)

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Adverse effect	Bupivacaine group (n=40)	Ropivacaine group (n=40)	P value
Nausea	9	6	0.56
Vomiting	3	0	0.24
Fall in blood pressure	16	0	<0.01*
Fall in SpO2	0	0	1
Delirium	1	0	1
Motor deficit	7	0	0.01*
TOTAL	36	6	<0.01*

Table 4: Patients with adverse effects in study groups

p<0.05 considered significant by chi-square test

5. <u>Blood pressure (BP) in study groups</u>

At all the evaluated time-points, the mean systolic and diastolic blood pressure in the both the study groups were found to be comparable (p>0.05) indicating no difference between the study groups. (Table 5)

Time point of	Bupivacaine	Ropivacaine	P value
assessment	group (n=40)	group (n=40)	
Baseline	119.7 <u>+</u> 11.5/	117.25 <u>+</u> 12.15/	0.24/
	76.5 ± 8.49	74 ± 8.46	0.21
10 minutes	117.25 + 12.17/	120.7 + 11.5/	0.16/
	75.85 ± 9.62	78.4 ± 9.02	0.11
20 minutes	118.45 <u>+</u> 12/	121.2 <u>+</u> 11.38/	0.14/
	76.9 <u>+</u> 9.02	79.2 <u>+</u> 8.19	0.09
30 minutes	121.2 <u>+</u> 11.96/	120.95 <u>+</u> 11.6/	0.53/
	78.4 <u>+</u> 8.41	79.35 <u>+</u> 8.03	0.48
2 hours	119.3 <u>+</u> 13.56/	120.75 <u>+</u> 10.97/	0.66/
	78 <u>+</u> 10.03	79.3 <u>+</u> 8.59	0.37
6 hours	120.95 <u>+</u> 12.92/	122.25 <u>+</u> 9.83/	0.28/
	78.2 <u>+</u> 9.7	80.3 <u>+</u> 7.69	0.26
12 hours	119.8 <u>+</u> 12.5/	119.95 <u>+</u> 9.94	0.83/
	77.95 <u>+</u> 8.74	78.1 <u>+</u> 7.47	0.71
24 hours	121.45 + 10.08/	119.85 + 10.56/	0.38/
	79.35 <u>+</u> 7.25	77.5 <u>+</u> 7.74	0.28

 Table 5: Comparison of SBP /DBP in study groups

p<0.05 considered significant by unpaired t test

DISCUSSION

Major abdominal surgeries with upper abdominal incisions lead to severe abdominal pain which can lead to various complications such as shallow breathing, lung atelectasis, retention of secretions and lack of cooperation in physiotherapy increasing the incidence of postoperative morbidity leading to delayed recovery.

The various modalities for postoperative pain control are intravenous analgesia, patient control analgesia, epidural analgesia, and regional blocks. A well-managed epidural can provide excellent analgesia in the postoperative period allowing the patient to be pain free at rest and when mobilizing, also obtunds the acute stress response to surgery. Consequently, along with the analgesic benefits, patients are less likely to suffer cardiac, respiratory, or gastrointestinal side-effects. Postoperative use of epidural analgesia has the potential to reduce pulmonary morbidity by providing better pain relief, improved diaphragmatic

function, reduced incidence of ileus, reduced thromboembolic or cardiovascular complications and reduced frequency and severity of postoperative hypoxemia.

Bupivacaine is a well-established long acting, amide group, local anaesthetic agent that has been used commonly in epidural analgesia for pain relief. Bupivacaine,like all commonly used local anaesthetics have vasodilator activity. It possesses moderate onset of action and 95% plasma protein binding activity.most of the recent developments in local anaesthetics have been a direct consequence of the recognition, 20 years ago, of the acute, life threatening cardiotoxicity of bupivacaine. All local anaesthetics produce a dose dependant delay in transmission of impulses through the cardiac conduction system by their action on the cardiac sodium and potassium channels. However, overt cardiotoxicity usually only becomes apparent as the last feature of a reasonably predictable sequence of changes. ⁽⁴⁾⁽⁵⁾ **Ropivacaine** is a comparatively newer drug used in epidural analgesia which is less

lipophilic than bupivacaine and is thus less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Thus, ropivacaine has a greater degree of motor sensory differentiation which could be useful when motor blockade is undesirable, especially in post operative period. the reduced lipophilicity is also associated with a decreased potential for central nervous system toxicity and cardiotoxicity. The drug has a very safe profile as it gets extensively metabolised (in liver) and excreted in urine. ⁽⁶⁾

Our study aimed to study the comparative efficacy of Bupivacaine Vs Ropivacaine Epidurally for postoperative analgesia in elective abdominal surgeries.

A total of 80 patients were enrolled in the study, 40 patients in the bupivacaine group and 40 patients in the ropivacaine group.

On comparing the VAS scores between the study groups at various time points post extubation, it was found the mean VAS score in the ropivacaine group was found to be significantly lower (p<0.05) at 30 minutes, 1 hour, 1.5 hours, 2 hours and 12 hours post-extubation. Table 1 shows that at 6 hours post-extubation, the mean VAS scores were significantly higher in the ropivacaine group as compared to bupivacaine group (p<0.05). At 24 hours post-extubation, the VAS scores in the both the study groups were comparable (p>0.05). A similar study was conducted by Bhasin et al where a comparison was done between epidural ropivacaine in two concentrations (0.1% and 0.2%) and 0.125% bupivacaine where he found that the daily average VAS scores of 0.1% ropivacaine group was significantly higher on day 1 and 2 while the VAS scores of the other two groups were comparable.⁽⁷⁾

Table 2 shows that all the patients in both the study groups required first top-up of rescue analgesia. 34 patients in the bupivacaine group required second top-up, while the number was just 10 patients in the ropivacaine group. Overall, significantly higher number of patients in bupivacaine group required rescue analgesia top-up (p<0.05) On comparing the time to rescue analgesia, the mean time was significantly shorter in the bupivacaine group as compared to ropivacaine group for the first top-up (p<0.05), while it was statistically comparable for the second top-up (p>0.05) as shown in table 3. My study results slightly differ from the one conducted by Mehta S et al on major orthopaedic where he found comparative need of rescue analgesia in both the groups.⁽⁸⁾

In table 4, the adverse effects are compared in the 2 study groups. Higher number of adverse effects was found in bupivacaine group (n=36) as compared to ropivacaine group (n=6), and this was significant finding (p<0.05). Specifically, fall in blood pressure and motor deficit were significantly higher in the bupivacaine group (p<0.05). other adverse effects such as vomiting and delirium were also found in few patients in group B. nausea was seen in both the groups but patients from group B had higher incidence. Thus, we conclude that bupivacaine has higher rate of adverse effects than ropivacaine rendering it safer to use in practice.

Table 5 shows that at all the evaluated time-points, the mean systolic blood pressure and the mean diastolic blood pressure in the both the study groups were found to be comparable (p>0.05) indicating no difference between the study groups.

Similar study was done by Bhasin S et al Comparing the Efficacy of Epidural Ropivacaine versus Bupivacaine for Postoperative Pain Relief in Total Knee Replacement Surgeries in which he found ropivacaine to be having better safety profile than bupivacaine in terms of less hypotension and lesser motor block. ⁽⁷⁾

In a similar study conducted by Mehta S et al on major orthopaedic surgeries, a distinct sensory motor differentiation was found in ropivacaine group resulting in analgesia without motor blockade. ⁽⁸⁾ Also, other adverse effects like hypotension and nausea were noted more with bupivacaine than ropivacaine.

CONCLUSION

From our study, hence, we can conclude that Ropivacaine provided better post-operative analgesia in patients of major abdominal surgeries as the patients required lesser amount of rescue analgesia top ups as well as the mean time was comparatively longer for the first top up in comparison to Bupivacaine. Though both the drugs maintained a comparable hemodynamic profile, there was better patient comfort at rest for Ropivacaine group patients as they had lower RR rates at evaluated time. Ropivacaine is also found to have a better safety profile in comparison to bupivacaine as it caused less incidence of adverse effects along with distinct motor sensory differentiation thus decreasing post op morbidity and hospital stay as well as better patient cooperation

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