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Efficacy of Ropivacaine and Bupivacaine on Postoperative Analgesia through Epidural Route in Spine Surgeries- A Comparative Clinical Study

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Abstract
This study was conducted to compare the post-operative analgesic efficacy and safety of Bupivacaine and Ropivacaine through epidural route after spine surgeries. It includes 100 patients, randomly allocated into two groups B & R, 50 patients for each group. Patients with ASA class I and II between the age of 18 and 60 years of both sexes were included. Group B patients received Bupivacaine 0.125%, 2ml/ segment and Group R patient received Ropivacaine 0.2% 2ml/segment, depending on incision length. The difference in mean baseline VAS score between the two groups was not found to be statistically significant. A VAS score of 0 reached at 22 mins in Ropivacaine compared to 24 mins in group Bupivacaine and lasted till 90 minutes as compared to 28 minutes in group B. thereafter also higher mean VAS scores were observed in group B (Bupivacaine) until the entire period of observation (240 minutes). Ropivacaine was found to be significantly more effective onset of analgesia (5.36±1.30 min and7.32±2.03min) peak level of analgesia (17.22±2.30 min and 21.36±2..54). And requirement of supplemental analgesia less than bupivacaine. Motor blockade assessed by the mean modified Bromage score was significantly less in Group Ropivacaine as compared to that observed in group Bupivacaine. These drugs were comparable in terms of haemodynamic parameters. This study concludes that Ropivacaine 0.2% was more efficient analgesic than Bupivacaine 0.125% in epidural anaesthesia.

Keywords: *Ropivacaine, Bupivacaine, analgesia, epidural and spinal surgery.*

Introduction

Spinal procedures are generally associated with intense pain in the postoperative period, especially for the initial three days[1]. Adequate pain relief is, therefore, an important facet of postoperative care of these patients and has become an indispensable component in anaesthesiology. Various methods have been tried for the management of post-operative pain in spine surgeries out of which epidural techniques have become most promising[2]. Epidural drug administration provides good safety, extended analgesia and decreased incidences of respiratory and thrombo-embolic events making it a promising route of drug delivery for postoperative analgesia. It produces substantial reduction in pain

scores and narcotic consumption[3]. Local anaesthetics, opioids and steroids are the usual drugs that are used for epidural analgesia. Long-acting local anaesthetics reversibly inhibit the nerve impulses and thus cause a prolonged sensory or motor blockade appropriate for anaesthesia[4].

Bupivacaine, an amide anaesthetic is a well-established long-acting regional anaesthetic. It offers the advantage of providing a long duration of action and a favourable ratio of sensory to motor neural block[5]. Bupivacaine binds to the intracellular portion of sodium channels and blocks sodium influx into nerve cells, which prevents depolarization[5,6].

Ropivacaine is a long-acting amide local anaesthetic agent and was first produced as a pure enantiomer. It produces effects similar to other local anaesthetics via reversible inhibition of sodium ion influx in nerve fibres. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres, resulting in a relatively reduced motor blockade. Thus, it has a greater degree of motor sensory differentiation, which could be useful when motor blockade is undesirable[5].

To compare the post-operative analgesic efficacy and safety of Bupivacaine and Ropivacaine through epidural route after spine surgeries

Materials & Methods

The present study is a comparative randomized controlled study conducted at Kakatiya Medical College, Warangal. it includes 100 patients, randomly allocated into two groups B & R, 50 patients for each group undergoing elective spine surgeries. Approval was taken from the Institutional Ethical Committee before commencing the study. The participants were informed regarding the purpose, procedures, risks and benefits of the study. Written and Informed Consent was obtained from all participants**.**

Patients with ASA class I and II between the age of 18 and 60 years of both sexes were included. Patients with ASA class 3 & 4, haematological disease, bleeding or coagulation test abnormalities, psychiatric diseases, upper thoracic (above T8) and cervical spine surgeries, tubercular spine and any permanent neurological disorders were excluded from study.

All cases of spine surgery were conducted under General Anaesthesia with the patient in prone position. After completion of the surgical procedure and before closure of the surgical wound, an 18 gauge/16 gauge epidural catheter was placed under direct vision in the epidural space when epidural space opened during surgery or through a separate skin puncture in the interspinous space above the incision (about 2.5 cm above the main surgical incision in the midline of the spine) with 16 gauge or 18 guage Touhy's needle. The catheter was then anchored in place on the back of the patient using an adhesive tape. After closing and dressing the surgical wound, patients were made supine from prone position and extubated after adequate reversal. Patients were shifted to post-operative room and monitored. A test dose of 3 ml lignocaine with adrenaline (1:200,000) is injected through epidural catheter. . Group B patients received Bupivacaine 0.125%, 2ml/ segment and Group R patient received Ropivacaine 0.2% 2ml/segment, depending on incision length.

After administering the drug, the parameters like pain score, by using VAS every 2 min for 30 min and then every 30 min until the need for next epidural top up, onset, peak level, duration of analgesia, rescue analgesics and complications were monitored. Catheters were kept in space 72 hrs for postoperative analgesia.

Results

The present study was carried out with a total of 60 patients who were randomly allocated into two groups, Group R (Ropivacaine) and Group B (Bupivacaine). The demographic data was shown in table.1 the difference in mean baseline VAS score between the two groups was not found to be statistically significant. A VAS score of 0 reached at 22 mins in Ropivacaine compared to 24 mins in group Bupivacaine and lasted till 90 minutes as compared to 28 minutes in group B. thereafter also

higher mean VAS scores were observed in group B (Bupivacaine) until the entire period of observation (240 minutes). The VAS scores at different time intervals were shown in graph 1.

Table 1: Demographic & Clinical Characteristics of both the Study Groups.

	Group R (Ropivacaine)	Group B (Bupivacaine)
Age(yrs)(m(+-sd)	45.36±9.56	44.36±10.23
Gender (M/F)	15/15	16/14
ASA(I/II)	(25/5)	(28/2)

Table 2: Comparison of analgesia characteristics between Groups

Analgesia characteristics	Group R (Ropivacaine)	Group B (Bupivacaine)	P value
Onset (VAS<4)	5.36±1.30	7.32±2.03	<0.001 **
Peak level (VAS=0)	17.22±2.30	21.36±2.54)	<0.001 **
Duration	316.36±22.36	296.32±26.59	<0.05*
Motor blockade Modifed Bromage score	6.21±1.02	5.06±1.25	0.001*

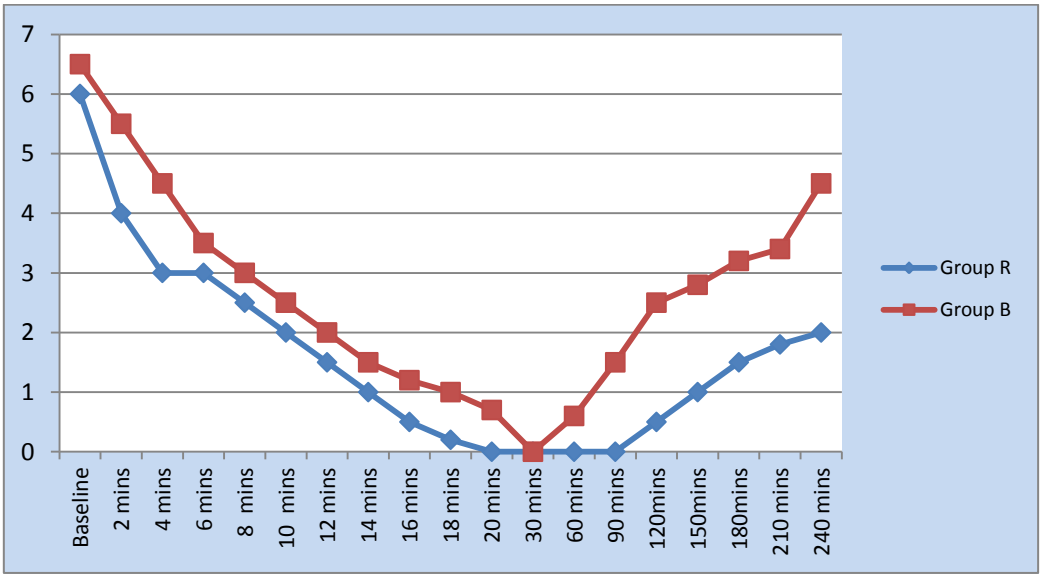
No serious adverse effects were observed in any of patients of either study group. In group B (Bupivacaine), requirement of analgesia was observed in 8(16%) patients. In group R (Ropivacaine) there was no requirement of rescue analgesia observed in any of the patients. The difference in requirement of rescue analgesia among both study groups was found to be statistically significant. (P<0.05)

Discussion

Epidural analgesia has been used for all kinds of spine surgery such as microdiscectomy, laminectomy, major spinal surgery, with or without instrumentation and scoliosis correction. Local anaesthetics, opioids and steroids are the usual drugs that were used epidurally. In this study we compared the analgesic effects of ropivacaine and bupivacaine.

Sawhney KY et al.[7] compared ropivacaine 0.2 %, ropivacaine 0.1 % with fentanyl 2µg/ml, bupivacaine 0.2% and bupivacaine 0.1 % with fentanyl 2µg/ml in 4 groups. Patients who received 0.2 % ropivacaine had the lowest VAS scores and least consumption of supplemental analgesics, signifying better analgesic effect. At the same time, motor blockade was lesser as compared to the patients who received bupivacaine. Meghana S et al.[8] compared Group 1 (0.125%bupivacaine) with Group 2 (0.2%ropivacaine), reported that the pain score was similar in both groups at different time intervals, except at 15 and 30 min after starting epidural infusion, where the pain score was significantly lower and patient satisfaction score was observed in Group 2.

In the study by Bindra TK et al.[9] the postoperative pain VAS scores were higher in Group I (0.5% ropivacaine) patients throughout the study period than Group II (0.75% ropivacaine) and III (0.5% bupivacaine).



Graph 1 The VAS scores at different time intervals in both groups.

In the study by Paddalwar S et al.[10] Ropivacaine (0.125%) showed no difference in the mean VAS scores and the quality of analgesia, as compared to Bupivacaine (0.125%). At 20 min, all the patients in both groups were absolutely pain free with the VAS score of 0. The findings are similar to those of the present study.

In patients undergoing lumbar epidural anaesthesia for lower limb surgery, ropivacaine provided a similar anaesthetic profile (with regard to onset of analgesia or anaesthesia and onset of motor block) to those of levobupivacaine[11] or bupivacaine[12]. There were in contradictory to our study but purely depends on dose of drugs.

In the present study, in Group R the onset of analgesia and peak level of analgesia was attained significantly earlier than in group B. In the study by Zaric D et al.[13] Ropivacaine 0.1% produced limited analgesia and minimal motor block and with 0.2 and 0.3% ropivacaine, analgesia was more extensive and it is dose dependent.

Berti M et al.[14] reported no differences in pain relief, motor block, degree of sedation, pulse oximetry and other side effects were observed between the two groups and using a ropivacaine 0.2%/2 microg/ml fentanyl mixture for patient supplemented epidural analgesia after major abdominal surgery provided similar successful pain relief as bupivacaine 0.125%/2 microg/ml fentanyl.

The duration of analgesia was significantly more in group R (Ropivacaine) than in group B (Bupivacaine). In a study duration of procedure for the ropivacaine (0.2%) group was 160.5 +40.7 minutes and for the bupivacaine (0.125%) group it was 153.7 +34.9 minutes. This difference was statistically not significant[15].

The difference in motor blockade observed in both groups was found to be significant statistically ($p>0.05$) and in group R (Ropivacaine) patients had significantly less motor blockade than in group B (Bupivacaine).The decreased motor block with epidural ropivacaine confers an advantage in terms of early mobility over bupivacaine when the sensory block potency is approximately equivalent amongst the two groups. Rapid patient mobilization is an integral part of speedy recovery after spine surgeries, and this leads to a decrease in duration of hospitalization by one to two days. In the study by Surabathuni S et al.[15] modified Bromage Score value was uniformly 6 during the post-operative period for both the groups (0.125% bupivacaine and 0.2% ropivacaine) Ropivacaine causes reversible inhibition of sodium ion influx, and thereby blocks impulse conduction in nerve fibres[4]. This action is potentiated by dose-dependent inhibition of potassium channels. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres; therefore, it has selective action on the pain-transmitting A β and C nerves rather than Aβ fibres, which are involved in motor function. Thus, bupivacaine is more likely to penetrate large myelinated motor fibres, resulting in a relatively increased motor blockade[6].

In the study by Chandran S et al.[16] in 64% of patients of Group R (Ropivacaine 0.75%), time to rescue analgesia was between 390 and 450 min, compared to only 18% in Group B (Bupivacaine 0.5%). This difference was statistically significant. In our study 8 members in group required analgesics in group B and none in group R. Ropivacaine is bound to plasma proteins to an extent of 94%, mainly to α1-acid glycoprotein. The total plasma concentration increase during continuous epidural infusion of ropivacaine is caused by an increase in the degree of protein binding and subsequent decrease in clearance of ropivacaine.

In the present study group R and group B were comparable in terms of baseline mean heart rate, mean systolic and diastolic blood pressure. These results were in accordance with other studies [12,15,16], but in study by Bindra et al.[17] there was statistically significant decrease in blood pressure and heart rate from the baseline in all the three groups after 10–15 min.

In the present study no serious adverse effects were observed in any of the patients in both study groups. Epidural administration of ropivacaine for surgery generally produced dose-dependent adverse events similar to those observed with equal doses of bupivacaine[18]. Ropivacaine is less lipophilic than

bupivacaine and that, together with its stereo-selective properties[19], contributes to ropivacaine having a significantly higher threshold for cardiotoxicity and CNS toxicity than bupivacaine in healthy volunteers[20].

Conclusion

Ropivacaine was more effective when compared to Bupivacaine as a post operative analgesic through Epidural route after spine surgeries. It also had lesser duration of motor blockade and no adverse effects.

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