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Levobupivacaine & Ropivacaine for Epidural Analgesia in Lower Limb Surgery.

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Abstract:
Background: *Post-operative pain is a major concern for patients undergoing surgery. The fear of pain keeps on preying on their minds leading to various stress related dysfunctions. The present study was designed to compare the efficacy and safety of Levobupivacaine & Ropivacaine in preventing post-operative pain in patients undergoing lower limb surgery.*
Patients and Methods: *60 ASA I and II patients undergoing lower limb surgery were randomly assigned to two groups of thirty patients each, receiving either 50mg Tramadol with 20mg Ropivacaine (Group A) or 50mg Tramadol with15mg Levobupivacaine (Group B) epidurally. Total volume injected was 10ml in each case. Epidural top-ups were given every 8 hourly for post-operative analgesia till 48 hrs after surgery. VAS was used to assess analgesia.*
Results: *Demographic data and baseline parameters were comparable in both the groups. Analgesia, as measured by the VAS score was comparable in the two groups. Hypotension was seen more in Group B. Other side-effects were similar in both the groups.*
Conclusion: *Levobupivacaine or Ropivacaine combined with Tramadol provide good analgesia in lower limb surgery without significant side-effects.*
Key Words: *Ropivacaine, Tramadol, VAS, Post-operative Analgesia.*

I. Introduction

Pain is not a straightforward sensory "perception" but an "experience"[1]. It disrupts the normal physiological and psychological homeostasis, manifesting clinically as organ dysfunction and altered human behaviour. Failure to relieve pain is morally and ethically unacceptable and adequate pain relief could be considered a basic human right[2,3].

It is widely believed that pain is an inevitable consequence of surgery. In fact, the fear of postoperative pain preys on the patients' mind more than the consequences of surgery. Therefore the treatment of pain after surgery becomes central to the care of the postoperative patient. Epidural analgesia with local anesthetics gives good pain relief and the addition of various adjuvants has made it even more popular.

II. Aim

The present study was designed to compare the efficacy and safety of Levobupivacaine & Ropivacaine combined with Tramadol in preventing post-operative pain in patients undergoing lower limb surgery.

III. Patients and Methods

After requisite approval from the Institutional Ethics Committee, the current study was undertaken as a prospective, double blind random study & 60 patients of either sex between the ages of 18 and 80 years were included. Only patients categorized as ASA physical status I or II scheduled to undergo surgery on the lower limbs were included. Post-operative analgesia was provided by intermittent epidural administration of 10 ml of the study drug. Written informed consent was taken from all the patients and the procedure was explained to them in detail. The visual analog scale (VAS) was used to measure pain and the method was explained to them prior to surgery.

Patients having any history of drug or alcohol abuse; any hepatic, renal, circulatory or respiratory abnormality; any history of drug allergy; chronic headache, backache or any neurological deficit, bleeding diathesis or abnormal coagulation profile, pregnant females and caesarean sections were not included in the study.

All the patients were premedicated with 5mg of diazepam orally on the night before surgery and 5mg orally 3 hours before surgery. The patients were kept fasting after midnight prior to surgery.

Two groups of thirty patients each were made and patients were randomly allocated to one of the two groups –

1. Group A – Patients in this group received 20mg of Ropivacaine + 50 mg of Tramadol (Total volume = 10ml).
2. Group B – Patients in this group received 15mg of Levobupivacaine + 50 mg of Tramadol (Total volume = 10ml).

Both the groups were matched for age, sex and weight of the patients; and the type and duration of surgery. Epidural 'top-up' was provided postoperatively just after conclusion of surgery before shifting the patient out of the recovery room. Subsequent 'top-ups' were provided every 8 hours for the next 48 hours. VAS scores and vital parameters were recorded at 1, 2, 3, 6, 12, 18, 24, 36 and 48 hours after the end of surgery. VAS scores were recorded at rest, on movement (touching the side of bed opposite the side of surgery) and while coughing. Vital parameters and any complications or side effects were also recorded at the same time. The epidural catheter was removed 48 hours after surgery.

In case of inadequate analgesia or patient complaints of pain before the expiry of eight hours, rescue analgesic was provided to the patients in the form of intramuscular Inj Diclofenac Sodium, 1.5mg/kg body weight.

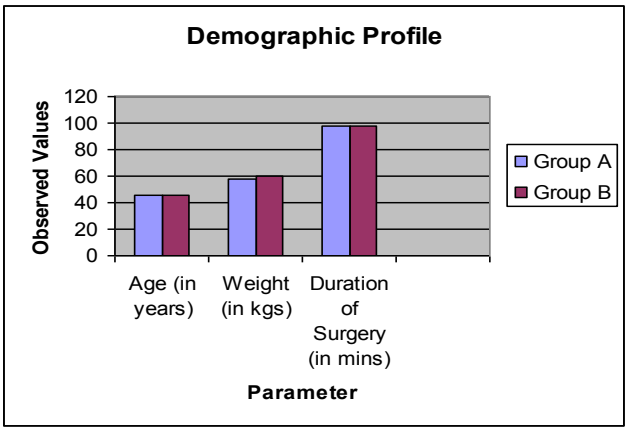
At the end of 48 hours, the patients were evaluated for the quality of analgesia, sedation, amnesia and the side effects. Rescue analgesic requirement for each group was calculated and compared at the end of the study. Data was analyzed applying the Chi-square test & 'p' value < 0.05 was taken as significant.

IV. Results

A. Demographic Data:

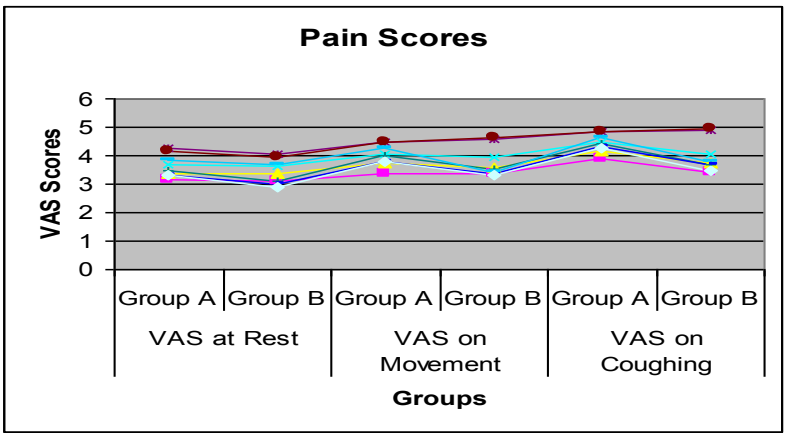
Demographic data and baseline parameters were comparable in both the groups.

Parameter	Group A			Group B		
	Male	Female	Group mean ± S.D.	Male	Female	Group mean ± S.D.
Age (in years)	49.1	44.4	46.1 ± 13.03	47.5	45.5	46.1 ± 11.19
Weight (in kgs)	64.8	53.0	57.3 ± 12.11	63.5	59.2	60.5 ± 7.74
Duration of Surgery (in mins)	108.6	92.2	98.2 ± 32.16	113.7	90.8	97.7 ± 26.53



B. Pain Scores:

Pain scores (VAS scores) were recorded at Rest, on Movement & on Coughing at various intervals. Scores in both the groups were comparable and the differences were not significant.



i) VAS Scores 'At Rest'

The mean visual analog scale score 'at rest' in the two groups was 3.56 (Group A) & 3.42 (Group B), $p > 0.05$.

ii) VAS Scores 'On Movement'

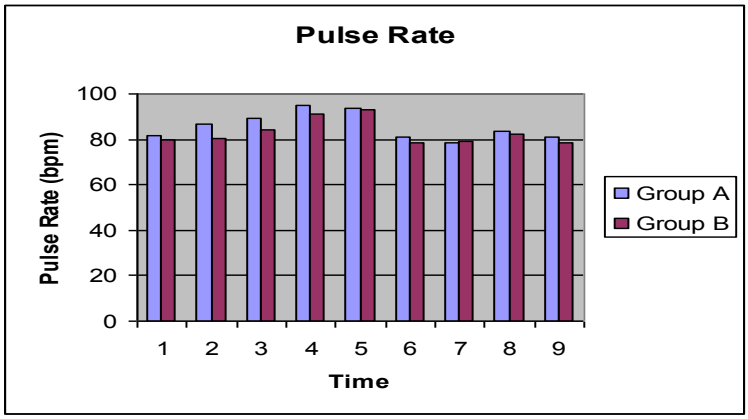
The mean visual analog scale score 'on movement' in the two groups was 3.99 (Group A) & 3.76 (Group B), $p > 0.05$.

iii) VAS Scores 'On Coughing'

The mean visual analog scale score 'on coughing' in the two groups was 4.43 (Group A) & 3.99 (Group B), $p > 0.05$.

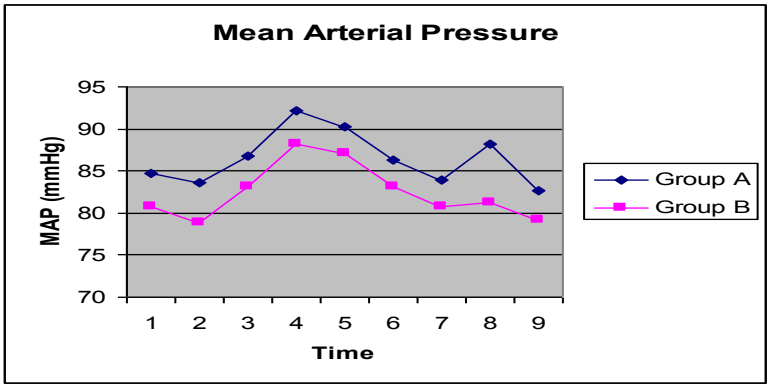
C. Vital Parameters –

a. Pulse Rate –



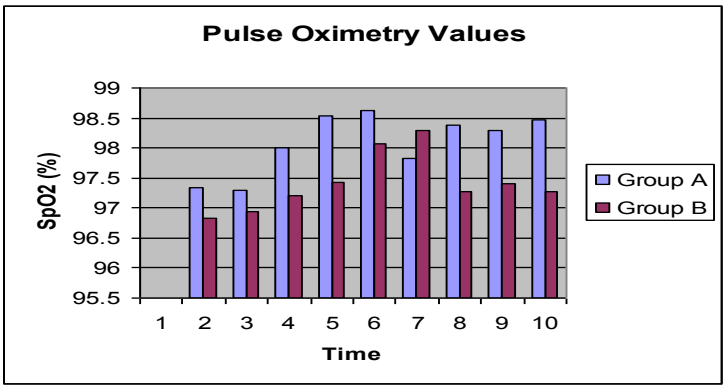
The mean pulse rates in the two groups were 85.6 (Group A) & 83.1 (Group B). Pulse rates in the two groups were comparable and the differences were not significant ($p > 0.05$).

b. Mean Arterial Pressure –



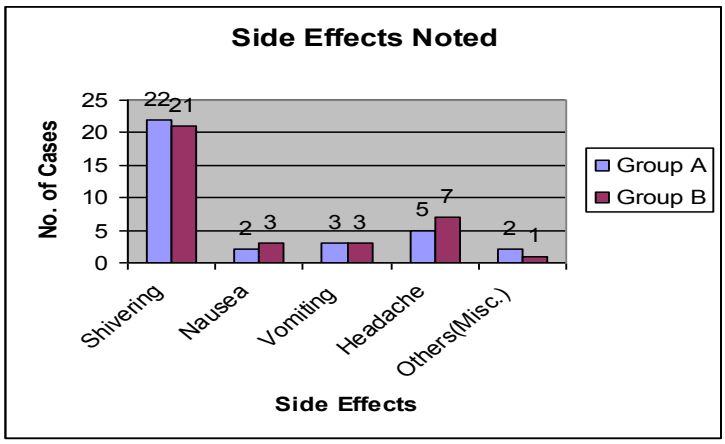
The mean arterial pressure recordings in the two groups were 86.5 ± 3.14 mmHg (Group A) & 82.5 mmHg ± 4.18 (Group B) & the difference was statistically significant (p = 0.017792). However, the differences were not significant clinically.

c. Oxygen Saturation (SpO_2%) –



The mean oxygen saturation (SpO_2) in the two groups was 98.1% ± 0.47 (Group A) and 97.4% ± 0.46 (Group B). SpO2 measurements in the two groups were comparable and the difference was not significant, p > 0.05.

D. Side Effects Noted –



Side effect profile in the two groups was comparable and did not reveal any significant differences. Shivering was the most common complication in the postoperative period in both the groups and was seen in 71.7% patients (43 out of 60). Shivering was observed only in the postoperative recovery area in the immediate postoperative period and was not observed in the wards. Nausea (8.33%), vomiting (10%) and headache (20%) were other common side effects seen. Urinary retention was not considered as almost all of our patients were catheterized in the postoperative period.

IV. Discussion:

In recent years levobupivacaine, the pure S (−)-enantiomer of bupivacaine, has emerged as a safer alternative for regional anesthesia than the racemic mixture. It has demonstrated less myocardial and CNS depressant effects and a superior pharmacokinetic profile. Clinically, levobupivacaine is well tolerated in a variety of regional anesthesia techniques and reports of toxicity are scarce[4].

Ropivacaine is a new aminoamide local anaesthetic and is prepared as the pure S-enantiomer. Ropivacaine was developed after bupivacaine was noted to be associated with cardiac arrest, particularly in pregnant women. Ropivacaine was found to have less cardiotoxicity than bupivacaine in animal models[5].

Though the quality of analgesia with epidural top-ups has been described as equivalent to (if not better than) opioids, the need for adjuvants is frequently felt so as to decrease the dose of the local anesthetics injected as well as to increase the duration of analgesia. Side effects of opioids like pruritus, respiratory depression & urinary retention are also avoided. Tramadol has emerged as a safe and effective adjuvant to epidural therapy in recent times, though various other adjuvants like butorphanol, midazolam, ketamine, adrenaline, clonidine, dexmedetomidine, etc have also been tried[6].

In our study, we used Levobupivacaine and Ropivacaine in combination with Tramadol and got almost similar results in both the groups. No significant side effects were noted in any group. These results are in concurrence to those of Hilmi Koputan et al[7], Scott DA[8], Behdad S et al[9] and Ozyilmaz K et al[10].

V. Conclusion:

Levobupivacaine or Ropivacaine combined with Tramadol provides good analgesia in lower limb surgery without significant side-effects.

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