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A study of Efficacy and Safety of Ropivacaine (0.5%) versus Levo Bupivacaine (0.5%) in Cervical Epidural Anaesthesia for Upper Limb Surgery

Fumakiya Pooja Hasmukhbhai[1],Asodariya Nidhi Chandreshbhai[2], Sheikh Iramnaaz Ahmedhussain[3]

[1]Assistant Professor, [2]2nd Year Resident Doctor, [3]Assistant Professor, Dept. of Anaesthesiology, Gujarat Adani Institute of Medical Sciences, Bhuj, Gujarat 370001, India.

Abstract

Regional anaesthesia is preferred technique over general anaesthesia due to its overall less side effects. Cervical Epidural Anaesthesia (CEA) has been upcoming technique since past few years which provide safe and reliable anaesthesia for upper limb surgery. *Objective:* To compare efficacy and safety of cervical epidural blockade with 0.5% Ropivacaine and 0.5% Levobupivacaine in upper extremity surgeries. *Methods and Material:* 50 patients were divided into two groups:- Group R: CEA block will be given with Injection Ropivacaine 10 ml (0.5%). Group L: CEA block will be given with Injection Levobupivacaine 10 ml (0.5%). Assessment of sensory and motor blockade was done in terms of onset and duration. Perioperative complications were recorded and managed accordingly. *Results:* The onset of sensory block with levobupivacaine was (6.28 ± 1.75min) and with ropivacaine was (5.56 ± 1.62 min) ($p>0.05$). Mean duration of sensory blockage was longer with levobupivacaine (296 ± 31.46 min) than with ropivacaine (192 ± 21.07min).The mean time of onset of motor blockade(9.52±2.04 min) was shorter and duration (219 ± 31.74 min) was longer with Levobupivacaine than Ropivacaine (14.2 ± 3.75 min) and (165 ± 25.45 min) respectively. Postoperative Visual Analogue Score was higher in Ropivacaine. The mean time of duration of analgesia was longer in Levobupivacaine (315.6 ± 48.08 min). *Conclusions:* In an equal dose, Levobupivacaine has a faster onset (sensory and motor block) and longer duration (motor block and analgesia) as compared to Ropivacaine.

Keywords: Cervical Epidural Technique, Levobupivacaine, Ropivacaine, Upper Limb Surgery.

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Introduction

Anaesthesia for surgeries of upper extremity is commonly provided using brachial plexus block or general anaesthesia. At the same time epidural anaesthesia can also be used as a regional anaesthesia.[1] Regional anaesthesia is a technique to render part of body insensitive to pain without affecting consciousness. It is preferred technique over general anaesthesia due to its overall less side effects.

CEA was first reported by Dogliotti in 1993.[2] CEA involves the administration of local anaesthetics into the epidural space resulting in the blockage of cervical nerve roots.[2]

Cervical epidurals are predominantly performed by interventional pain physicians. CEA has been

Corresponding Author: Asodariya Nidhi Chandreshbhai, Dept. of Anaesthesiology, Gujarat Adani Institute of Medical Sciences, Bhuj, Gujarat 370001, India.
E-mail: : ncasodariya1312@gmail.com
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employed successfully for various types of surgical procedures involving upper limb surgeries, thyroid and breast surgery, head and neck surgery.[2]

CEA offers some advantage over brachial plexus block for upper limb surgery like lower total dose of local anaesthetics and single needle insertion with no need to elicit paresthesia or muscle movement. Considering its advantages of stable hemodynamics, early postoperative ambulation with reduction in stress response, less intraoperative blood loss, postoperative morbidity, low cost and postoperative analgesia and better control of tourniquet pain,[3] we used CEA as sole anaesthetic technique to evaluate onset, extent, duration of analgesia and hemodynamic status in upper limb surgery.

Materials and Methods

A study including 50 patients aged 18 to 60 years with ASA grade I-III, either sex, scheduled for upper extremity surgery and shoulder surgery under cervical epidural anaesthesia (CEA). The study was done in a prospective, randomised double blinded comparative manner. Patients refusal, patients with respiratory, CNS and CVS disorders, history of allergy to local anaesthetics, local site infection, intake of anticoagulant drugs, altered coagulation profile, patients with any contraindication to CEA were excluded from the study.

For elimination of bias in the assigned study, randomization was done by computer generated random number table and care was taken that each patient should get equal chance. All patients were divided into two groups:-

Group R (Ropivacaine): CEA block will be given with Injection Ropivacaine 10 ml (0.5%)

Group L (Levobupivacaine): CEA block will be given with Injection Levobupivacaine 10ml (0.5).

All patients were thoroughly assessed day before surgery and screened for any associated medical illness, drug allergy, family history etc. Routine investigations like Hb, blood sugar, serum creatinine, blood urea, chest X-ray and electrocardiogram were documented. Patients were assessed for vitals like temperature, pulse rate (PR), blood pressure (BP) and respiratory rate(RR). Thorough Airway assessment, systemic and Cervical spine examination was done in every patient. All patients were well informed about the benefit and the adverse reaction of the drug under study and surgery and written consent was obtained. Intravenous line was secured with 18 G or 20 G IV cannula and fluids was started (8 ml/kg).

All monitors were attached to the patients including (ECG) leads, BP cuff and pulse oximeter. Baseline PR, BP, RR and SpO_2 were recorded. All patients were premedicated with Inj. Glycopyrolate **(**0.04 mg/kg**)** IV, Inj. Ondansatron (0.08 mg/kg) IV, Inj. Ranitidine (1mg/kg) IV, Inj. Midazolam (0.05 mg/kg) IV and Inj. Tramadol (1mg/kg).

Methods

Under all aseptic and antiseptic precautions CEA was performed in all the patients with 18 G touhy epidural needle at the C7-T1/C6-C7 interspace using loss of resistance technique via a midline cephalic approach in sitting position with neck flexed and chin on the chest(figure 1). Patients were given either Inj. Ropivacaine 0.5% 10 ml or Inj. Levobupivacaine 0.5% 10 ml according to group allotment.

After recording the time of injection patients were immediately placed in supine position on operation table. PR, RR, BP and SpO_2 were recorded every 5 min after block till half an hour than every 30 min till the end of procedure. Sensory and motor function were evaluated after the block at 5, 10, 15, 20, 25, 30, 45 and 60 mins, then every 30 minute till the end of surgery.

Assesment of Sensory blockage was graded via pin prick method**:**

Grade 0: no loss of sensation to pin prick.

Grade 1: analgesia (patient feels touch but not sharp).

Grade 2: anaesthesia (patient does not feel touch).

Onset time for sensory blockade: It is defined as time taken from the end of the injection till the achievement of sensory block. (Grade 2)

Total duration of sensory blockade: It is defined as time interval between onset of sensory block and complete recovery of sensation. (Grade 0)

Assessment of Motor blockage was done by asking the patient to abduct arm at the shoulder and graded as:

Grade 1: Absence of motor block

Grade 2: Weakness appreciable but movement against resistance

Grade 3: Possible movement but not against resistance

Grade 4: Absence of movement

Patient were kept in the state of conscious sedation to alley anxiety with Inj. Dexmedatomidine

1 µg/kg in 100 ml NS over 10 min loading dose followed by infusion drip at the rate of 0.2 to 0.5 µg/kg/hr started and continued till the end of surgery. Ramsay sedation score was assessed intraoperatively.

Ramsay sedation Score (RSS) as follow:

Grade 0: Patient wide awake

Grade 1: Patient is sleeping comfortably, but responding to verbal commands.

Grade 2: Deep sleep, but arousable.

Grade 3: Deep sleep, unarousable.

Post-operatively PR, BP, SpO_2, RSS were assessed in post-operative period and at 30 min, 1 hr, 2 hr, 4 hr, 6 hr, 8 hr and 12 hr. Postoperative pain would be assessed using Visual analogue score (VAS) from 0 to 10 in which score "0" was "No pain" and score "10" was "Unbearable pain". Analgesia was considered satisfactory if the score was <4. If score was ≥ 4, rescue analgesic Inj. Diclofenac sodium 75 mg IV given.

The incidence of perioperative complications like hypotension, bradycardia, nausea, vomiting, respiratory difficulty, shivering were monitored and treated accordingly. All the observations were recorded as mean and standard deviation. All the results were analysed statistically using the student's unpaired `t` test. *p* value <0.05 was considered as significant.

Results

The patients were randomly and equally divided into two groups of 25 each.

Group L(n= 25):- Levobupivacaine 0.5% 10 ml

Group R (n=25):- Ropivacaine 0.5% 10 ml

Demographic data between two groups were comparable (Table 1).

The onset of sensory block with levobupivacaine was (6.28 ± 1.75 min) and with ropivacaine was (5.56 ± 1.62 min) ($p > 0.05$).Not statistically significant (Fig. 2).

Mean duration of sensory blockage was longer with levobupivacaine (296 ± 31.46 min) than with ropivacaine (192 ± 21.07 min) (Fig. 3).

The mean time of onset of motor blockade (9.52±2.04 min) (Fig. 2) was shorter and duration (219 ± 31.74 min) (Fig. 3) was longer with Levobupivacaine than Ropivacaine (14.2 ± 3.75 min) (Fig. 2) and (165 ± 25.45 min) (Fig. 3) respectively.

Postoperative Visual Analogue Score was higher in Ropivacaine (Fig. 4). The mean time of duration of analgesia was longer in Levobupivacaine (315.6 ± 48.08 min) (Fig. 5).

Perioperative complication were comparable between two groups (Table 2).

Table 1. Demographic parameters

	Group L	Group R	*p* value	Significance
Age	40.92 ± 13.79252	39.52 ± 16.53873	0.75154	NS
Weight	60.6 ± 7.657676	59.6 ± 6.05	0.612	NS
Duration of surgery (min)	146.4 ± 35.31	141.6 ± 35.51	0.640834	NS
Sex (m/f)	16:9	18:7	-	NS

Table 2. Perioperative Complications

Types of complication	Group L N=25	Group R N=25
Hypotension	2 (8%)	1 (4%)
Bradycardia	3 (12%)	2 (8%)
Nausea/Vomiting	-	-
Respiratory distress	-	-
Dura puncture	-	-
Diaphragmatic paresis	-	-

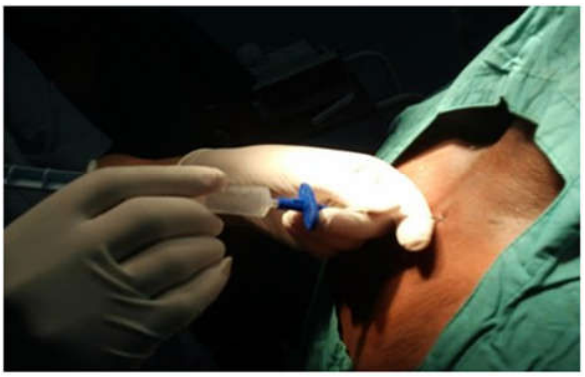

Fig. 1: Technique of Cervical Epidural Anaesthesia.

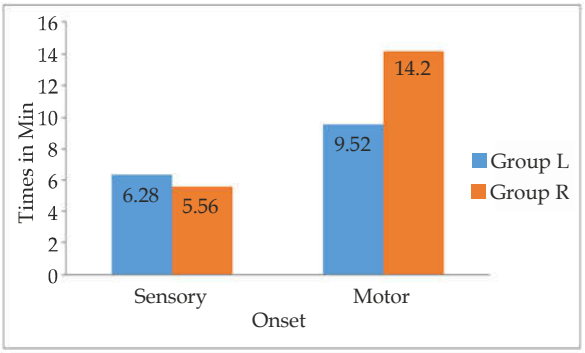

Fig. 2: Duration of Sensory and Motor Block

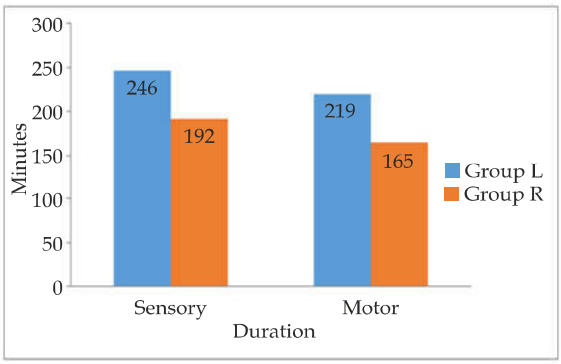

Fig. 3: Duration of sensory and motor block

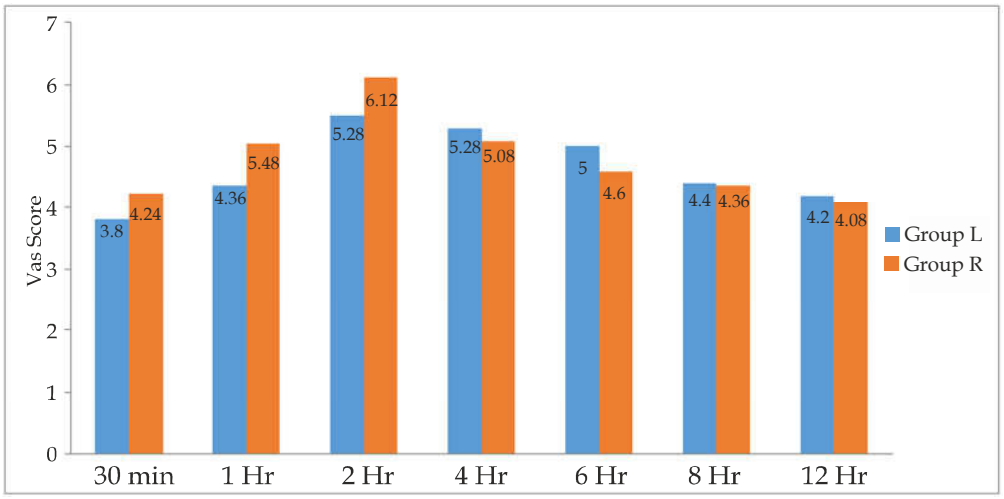

Fig. 4: VAS pain score in postoperative period.

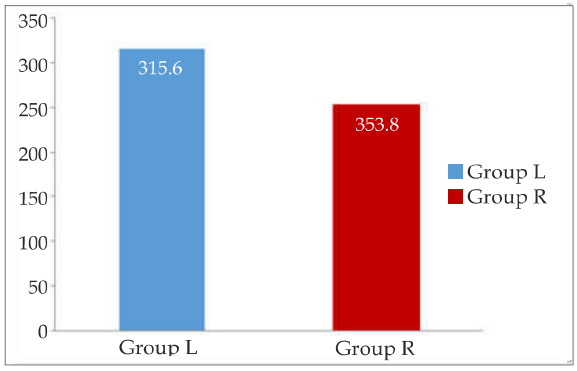

Fig. 5: Duration of Analgesia.

Discussion

There are several modalities used in shoulder surgery and upper extremity surgery such as interscalene brachial plexus block (ISB). ISB and suprascapular nerve block are both effective anesthetic modalities for intraoperative analgesia, but are limited by the duration of local anesthetics and re-admission of the drug for pain control in the postoperative period. CEA was reported in few studies to provide excellent postoperative analgesia for patients undergoing upper extremity surgery.

It is well known that CEA selectively blocks sympathetic fibers followed by sensory fibers and finally motor fibers with an increasing dose of local anesthetics. However, ISB may not achieve the effective separation of motor and sensory block as sensory nerve are in the core bundle, surrounded by motor nerves.[4] Regional anesthesia technique are safer than general anesthesia in high risk patient and old aged patients.

CEA is more effective with patient having bilateral upper limb fracture due to bilateral blockade so,patient are comfortable in positioning throughout procedures as compared to interscalene block.

Kushizak H et al.[5] used CEA for pain management during rehabilitation after surgery of

upper extremities.

On reviewing the literatures, we decided to see anaesthetic safety and the clinical efficacy (onset of sensory and motor block, duration of analgesia and hemodynamic stability) of CEA for upper extremity surgeries by using Levobupivacaine 0.5% with Ropivacaine 0.5% in cervical epidural anaesthesia for upper limb surgery.

CEA blocks the sympathetic cardiac accelerator fibres that arise at T1-T4 consequently decrease heart rate, cardiac output and contractility. Excessive bradycardia and hypotension was found mainly with higher dose and concentration with >12 ml of local anaesthetics.[6] So most of the studies used concentration <15 ml like Agrawal M et al.[6] used 10-12 ml of 0.25% Bupivacaine for neck arm and upper thoracic surgery.

Dominguez F et al.[7] conducted shoulder surgeries under CEA with 10-12 ml of 0.75% Ropivacaine and concluded that Ropivacaine provides an effective sensory block and a restricted motor blockade, reducing the probability of the restrictive pulmonary syndrome associated with cervical epidural anaesthesia**.**

Marodker K et al. studied CEA for shoulder arthroscopy using 8 ml 0.25% Bupivacaine and 25 µg Fentanyl.

Other study done by Michalak P et al.[8] states that CEA with Ropivacaine may be used safely and effectively for combined procedure involving neck and upper limb.

Most of studies have successfully conducted surgeries under CEA using 10-15 ml of local anaesthetic (LA) volumes. The rationale behind using these volume is that the requirement of LA is approximately 1.2 ml/segments in cervical space (i.e., nearly 10-15 ml volume for spread to 8- 10 segments). Therefore, we had choose minimum effective concentration of studied drug in optimal and equal volume 10 ml (to ensure blinding) for our study.[1.]

Characteristic of sensory blockade Onset

Onset, spread, quality and duration of anaesthesia depends on the local anaesthetic agent selection, dose, concentration, volume, and physical characteristics. In our study onset of sensory block is defined as time taken from the end of the epidural injection till the achievement of sensory block (grade 2). The onset of sensory block in Group L was (6.28 ± 1.75 mins) and in Group R was (5.56 ± 1.62 mins) ($p > 0.05$).There were no statistical significant difference between both groups.

Similar results were reported by Kulkarni M et al.[9] They also observed no significant difference in the onset of sensory block (5.05 min and 5.4 min in group B and group R respectively, p>0.05).

Duration

In our study the total duration of sensory blockade is defined as time interval between onset of sensory block and complete recovery of sensation (grade 0). Mean duration of sensory blockage was in Group L (296 ± 31.46 mins) and in Group R (192 ± 21.07 mins) which was statistically significant ($p < 0.001$). The duration of sensory blockade was longer with Levobupivacaine as compared with Ropivacaine because Levobupivacaine is higher lipid soluble and more potent than Ropivacaine when used for epidural analgesia.

In contrast to our study results, Kulkarni K et al.[9] observed that the duration of sensory block was 91.8 min in Bupivacaine (0.25%) group and 90 min in Ropivacaine (0.375%) group. Lower concentration of both the drugs might be the reason for such result.

Characteristic of motor blockade

Onset

Onset of motor block is defined as time from the end of the epidural injection till the patient was unable to abduct arm at shoulder (grade 3). In our study mean time for onset of motor blockade was faster in Group L (9.52 ± 2.04 mins) as compared to Group R (14.2 ± 3.75 mins) $p < 0.001$, which was statistically highly significant. Slower onset of motor block with Ropivacaine might be due to its lesser lipid solubility which may cause the drug to penetrate the large myelinated A fibers more slowly than the more lipid-soluble Levobupivacaine.

Similar to our study result, Michalek P et al.[10] found that the onset of motor blockade was 15 min using 12 mL of 0.75% Ropivacaine plus 10 µg of Fentanyl for upper extremity procedure.

Duration

In our study total duration of motor blockade is defined as time interval between onset of motor block and complete recovery of motor power (grade 0). Mean time of duration of motor blockade in Group L was 219 ± 31.74 mins (3.65 hrs) and in Group R was 165 ± 25.45 mins (2.75hrs), $p < 0.001$. The duration of motor blockade was longer with Levobupivacaine as compared with Ropivacaine

because the Levobupivacaine have intrinsic vasoconstrictor property and high lipid solubility of which is likely to penetrate the large myelinated motor fibres better in comparison to Ropivacaine. This might be the reason for longer duration of motor blockade in Group-L compared to Group-R. Ropivacaine is particularly useful when early mobilization is important to enhance recovery.

With contrary to our result, Kulkarni K et al.[9] observed that the mean time required to achieve motor blockade was significantly longer in group B (22.5mins) as compared to group R (18.3 mins), time to grade I motor recovery was also significantly longer in group B than in group R(79.5 and 66.3 minutes respectively) $p < 0.001$.

Perioperative side effects in both the groups

Although Levobupivacaine has very similar pharmacokinetic properties to those of racemic Bupivacaine, several studies support that its faster protein-binding rate reflects a decreased degree of toxicity. The decreased cardiovascular and central nervous system toxicity makes Ropivacaine and Levobupivacaine interesting alternative to racemic bupivacaine in procedures requiring large doses of local anaesthetic but this might not be true in cervical epidural anesthesia where the dosage of drug is comparatively small.

In our study three patients in Group L and two patient in Group R had bradycardia and hypotension in two patients with Group L and one patient with Group R. Hypotension was managed with vasopressors and rapid IV fluids and bradycardia was treated with Inj. Atropine (0.02 mg/kg). SpO_2 remained stable throughout the observation period in both the groups. None of the patient had respiratory dysfunction, dural puncture, nausea, vomiting. Eight patients who had failed epidural block were converted to GA and excluded from the study.

Similarly, Agrawal M et al.[6] also observed hypotension in 30% cases with the Bupivacaine 10-12 ml of 0.25%.

Post operative visual analogue score

In our study, Visual Analog Score (VAS) was higher in Group R as compared with Group L for up to 2 hrs postoperatively which was statistically significant ($p < 0.05$) than it was comparable between both groups. Higher VAS scores with Ropivacaine might be due to wearing off the effect of cervical epidural anesthesia due to shorter action. Total duration of analgesia was defined as interval between end of injection and first requirement of rescue analgesic dose.

Kulkarni K et al.[9] observed equal mean VAS score upto 24 hrs in both group B (2.9) and group R (3.1). The reason behind same VAS scores in both groups might be due to postoperative analgesia with 5ml of 0.125% Bupivacaine and 0.2% Ropivacaine in group B and R respectively via epidural catheter, when VAS score reached >3.

Duration of analgesia

In the present study, duration of analgesia was longer in Levobupivacaine (Group L) was 315.6 ± 48.08 mins (5.26 hrs) as compared with Ropivacaine (Group R) was 253.8 ± 28.11mins (4.23 hrs) $p < 0.001\%$. Levobupivacaine is a highly lipid soluble drug and tends to penetrate the nerve membrane more easily, so that less molecules are required for conduction blockade resulting in enhanced potency. This might be the reason for prolonged duration of analgesia with Group L as compared to Group R.

In contrast to our study, Kulkarni K et al.[9] observed that there was no statistically significant difference in mean duration of analgesia between Bupivacaine and Ropivacaine (6.6 hrs vs 6.8 hrs) $p > 0.05\%$.

Conclusion

Cervical epidural anaesthesia is a safe and reliable anaesthetic technique for upper limb surgery with stable hemodynamic and respiratory parameters. In an equal dose (10 ml) Levobupivacaine (0.5%) has a faster onset (sensory and motor block) and longer duration (motor block and analgesia) as compared to Ropivacaine (0.5%). Due to long duration of motor block and analgesia of Levobupivacaine can be used as replacement for other local anaesthetic agent.

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