Supraclavicular Brachial Plexus Block For Upper Limb Orthopedic Surgery: A Randomized, Double Blinded Comparison Between 0.5%Ropivacaine And 0.5% Bupivacaine.

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Abstract:

Purpose: This prospective double blinded study designedwith the aim of comparing the onset, duration of sensory and motor block and analgesic effect of ropivacaine 0.5%with bupivacaine 0.5% when used in supraclavicular brachial plexus block in patients undergoing upper limb orthopedic surgeries. **Materials and method:** 60 patients of either sex, aged 20-66 yrs, scheduled for elective upper limb orthopedic surgeries under supraclavicular brachial plexus block, were randomly divided into two groups containing 30 patients in each. Group B received 0.5% 30ml bupivacaine and group R received 0.5% 30ml ropivacaine. Patients were observed for onset, duration of sensory and motor blockade, post-operative analgesia using visual analogue scale and complications if any. **Results:** In comparison to equal volume of 0.5% bupivacaine, 0.5% ropivacaine provides significant earlier onset of sensory block (9.5±2min& 7.46 ±2.54 min respectively) and motor block (12.6±2.2min& 10.66±2.24 min respectively).There is statistically significant longer duration of motor block with bupivacaine (486.16±56.74)as compared to ropivacaine (359±55.66 min). However duration of sensory blockade, duration of analgesia and haemodynamics were comparable in both groups. We observed convulsions in one patient in bupivacaine group which was successfully managed. No complications were encountered in ropivacaine group.**Conclusion:** Ropivacaine provides faster onset of sensory and motor block with less duration of motor block, equal postoperative analgesia and higher safety profile as compared to bupivacaine.

Key words: Supraclavicular brachial plexus block, bupivacaine, ropivacaine, upper limb orthopaedic surgery, postoperative analgesia.

Introduction:

Regional anaesthesia, particularly peripheral nerve blockade like Supraclavicular brachial plexus block (SBPB) is a useful technique for day care surgery of upper limb. An ideal drug for day stay patients should have faster sensory onset time and a differential offset, with an earlier offset of motor than sensory blockade, enabling them to move their arm while having continued analgesia. [1]

Ropivacaine and bupivacaine are amide based long acting local anaesthetic belonging to pipecoloxylidides group. A commonly used drug for this technique was bupivacaine 0.5% which was a well-established long acting local anaesthetic, which like all amide anaesthetics has been associated with cardiotoxicity, when used in high concentration or when accidentally administered intravascularly. Ropivacaine a local anaesthetic similar to bupivacaine but with lower cardiotoxic potential, has greater degree of separation between sensory and motor blockade for the extradural route[2]. Although this might be more a result of relative potency, this property could be clinically useful in other areas.

We conducted this study with primary aim of comparing the onset and duration of sensory and motor block of 0.5% ropivacaine and 0.5% bupivacaine, with secondary aim of comparing the haemodynamic parameters, duration of analgesia and any complications throughout the perioperative period.

Materials and methods:

After Institutional ethics committee approval, we recruited 60 adult patients (20-66 years) of ASA grade of I or II posted for upper limb orthopaedic surgeries under supraclavicular brachial plexus block, in this prospective, randomised, double-blind study.

Patients with history or evidence of skin infection, injury at supraclavicular site, any lymph node enlargement, drug allergy, sepsis, pregnancy, morbid obesity, upper limb neurological deficit, bleeding disorders were excluded from the study.

Patients were randomly allocated, by distributing sealed envelopes, to one of the two groups of 30 patients each. Group B received 30 ml of 0.5% bupivacaine and group R received 30 ml of 0.5% ropivacaine. The drugs were prepared by the anaesthesiologist not involved in the study. The anaesthesiologist performing the block and observing the patient were blinded to the treatment group. Data collection was done by the same anaesthesiologist who was unaware of the group allocation.

All the patients underwent a pre-anaesthetic check-up before surgery and were kept nil per oral for 8 hours before surgery. Written informed consent was taken and intravenous line secured in all the patients. Standard monitors like electrocardiogram (ECG), non-invasive blood pressure (NIBP) and pulse oximeter were applied. Patient's baseline parameters like pulse, blood pressure (BP), respiratory rate (RR) and peripheral oxygen saturation (SpO_2) were recorded. An 18 gauge intravenous (i.v) cannula was secured and lactated Ringer's solution was started at 5ml/kg/h. Patients were premedicated with Inj. Glycopyrrolate (0.2mg), Inj. Ondansetron (4 mg), Inj. Ranitidine (50 mg) and Inj. Midazolam (1 mg) given i.v.

SBPB was given using classical approach in supine position with arm adducted, under strict aseptic and antiseptic precautions. Subclavian artery was palpated 1 cm above the midpoint of the clavicle. 1.5 inch 23G hypodermic needle was introduced just lateral to the subclavian artery pulsation in backward, downward and medial direction. Anaesthetic solution injected beneath the deep fascia after paraesthesia was elicited, and before every incremental dose negative aspiration for blood was performed to avoid i.v. placement. End of the injection was considered time 0(zero). Patients were evaluated for sensory and motor characteristics of the block (onset and duration), hemodynamic variables and side effects if any at 1, 3, 5, 10, 15, 30, 60 minutes and then, at hourly interval till sensory and motor block were offset. Patients were monitored at four hourly intervals for hemodynamic variations and side effects for next 24 hours.

Patients were assessed for sensory blockade by using pinprick. The palmer surface of Index and little fingers were used to test the median and ulnar nerve in the hand respectively. The dorsal surface of thumb was used to test the radial nerve. Onset time for sensory blockade was defined as the time taken from the end of the local anaesthetic administration and the complete sensory blockade (no sensation reported to pinprick) in all three sensory nerves in the hand. Motor block was assessed by asking the patient to do abduction of arm and flexion of forearm. Onset time for motor blockade was defined as the time from the end of the injection to time when the patient was unable to abduct arm. Duration of sensory and motor blockade was defined as interval between injection and complete recovery. Cases with failure to achieve satisfactory block after initial dose were excluded from study.

Postoperatively, pain was assessed using visual analogue scale (VAS), explained to the patient preoperatively where 0 represented no pain and 10 meant worst possible pain. When VAS score was equal to or more than 4, Inj. Diclofenac75 mg IV was given as rescue analgesic. Total duration of analgesia was defined as time interval

between end of injection and requirement of first rescue analgesic. Tourniquet inflation and deflation time and duration of surgery were noted.

All the data were filled up in Performa, presented in the tabulated form and expressed as mean ± SD (standard deviation) and were statistically analysed by applying student's unpaired t-test and chi-square test for analysis among both groups for various parameters. The results were considered significant if $P < 0.05$. After allowing α error to be 0.5, power of study stands out to be 80%.

Results:

Table 1 shows demographic profile (age, weight, height and gender) and operative data. It shows that both the groups were comparable in their demographic profiles and duration of surgery.

Mean time of onset of sensory block was faster in group R (7.46 ±2.54 min) than group B (9.5 ± 2 min) ($p < 0.05$) which was statistically significant. However duration of sensory blockade was comparable in group B (544±61.17 min) and in group R (531.13±47.23 min.) ($p > 0.05$). Onset of motor block was significantly early in group R (10.66 ± 2.24min) as compared to group B (12.6±2.2min), but duration was significantly less ($p<0.001$) in group R (359±55.66min) compared to group B (486.16±56.74min) as shown in table 2.

Figure 1 shows that changes in mean pulse rate (MPR)and mean arterial pressure (MAP)at different time interval were comparable between both groups (p value > 0.05).

The mean duration of analgesia were comparable between group B (618.16 ±56.209min) 10.30 hrs and group R (614.33±41.91min) 10.24 hrs as shown in figure 2.

We observed convulsions in one patient in group B shortly after receiving bupivacaine which was treated with Inj. sodium thiopentone and IPPV with 100% oxygen and recovered consciousness within 26 min without any sequel. There was no CNS toxicity seen in ropivacaine group in our study. There was no incidence of headache, nausea, vomiting, hypotension, bradycardia, chest pain, coughing and respiratory depression or any procedure related complication. There was no cardiovascular toxicity seen in either group in our study. Two patients in ropivacaine group were excluded from the study due to unsatisfactory block. One patient in group R required rescue analgesia and sedation intra-operatively.

Discussion

Local anaesthetic agent selection, dose, concentration, volume and physical modifications can affect onset, spread, quality and duration of anaesthesia. An important clinical consideration is the ability of local anaesthetics to cause a differential sensory and motor block. Bupivacaine, with its wide and unpredictable latency of nerve block and enhanced neuro and cardio toxicity[3,4] needed replacement with a drug of better anaesthetic and safety profile.

Ropivacaine, a long acting local anaesthetic, has been reported to be less toxic than bupivacaine. In vitro studies have demonstrated that ropivacaine is a potent blocker of Aδ and C fibers (pain fibers).[5,6] Ropivacaine is a long acting, pure S(-) enantiomer, amide local anaesthetic with a high pKa and low lipid solubility. The R(+) enantiomer of bupivacaine has high affinity for voltage gated sodium channels, so binds more firmly and has high incidence of side effects like more arrythmogenic and slowing of ventricular conduction.

Numerous studies abroad have compared ropivacaine 0.5% or 0.75% in brachial plexus block for upper limb surgery and results suggest comparable clinical profile with bupivacaine 0.5% or levobupivacaine with remarkable safety in favour of ropivacaine.[3, 4 & 7-10] For this purpose we decided to compare the clinical profile of ropivacaine with bupivacaine.

In our study 0.5 % ropivacaine had faster mean onset time of sensory block (7.4min) and motor block (10.6 min). Similar findings were observed by Rosemary hickey et al[11]and Klein et al [12] mean onset of sensory block were <4mins, and < 6 min. respectively with 0.5 % ropivacaine and motor blockade between 7 to 9 min.

Because ropivacaine is a pure S-enantiomer having greater anaesthetic potency[13]and hence has faster onset time. It is reported by various investigators that the total volume and concentration of local anaesthetic used are crucial factors for the speed with which the neural blockade begins.[14-17]

The addition of epinephrine to ropivacaine or bupivacaine did not alter pharmacokinetic properties, [18] and we therefore chose plain local anaesthetic. Ropivacaine has mild vasoconstrictive property of its own[19]. Although, prolonged sensory blockade provides excellent postoperative analgesia, extended motor blockade is not desirable as it limits patient's ability to be self-caring.

In present study Ropivacaine and bupivacaine, both provided prolonged duration of sensory blockade extending into the postoperative period and are comparable in this respect. The duration of motor blockade was significantly less ($p<0.001$) in ropivacaine group (5.98 hours) compared to bupivacaine group (8.10 hours).Similar results were observed by Laura Bertini et al[3] and O. Liisanantti.[20]

Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate the large myelinated motor fibers; therefore, it has selective action on pain transmitting Aδ and C nerves rather than Aβ fibers which are involved in motor functions.[21] this may be the reason for faster recovery of motor functions in our study.

In our study BP, HR, RR and SpO_2 remained stable throughout the procedure and postoperatively in both the groups ($p>0.05$).We observed convulsions in one patient in group B only. There was no cardiovascular toxicity seen in either group in our study.

Systemic toxicity of local anaesthetics may occur as a consequence of unwanted intravascular or intrathecal injection, or after the administration of an excessive dose of these drugs. Usually, the CNS is more susceptible to the actions of local anaesthetics than the cardiovascular system. Data regarding the incidence of seizure after brachial plexus blockade with ropivacaine was not available, but an incidence of 1.2 per 1000 has been described after use of bupivacaine. Ropivacaine is less lipophilic than bupivacaine and that together with its stereo selective properties contributes to ropivacaine having a significantly higher threshold for cardiotoxicity and CNS toxicity than bupivacaine in animals and healthy volunteers.

Vaghadia et al [22] observed a grand mal seizure in one patient shortly after receiving bupivacaine and recovered consciousness within 30 min.

Conclusion:

Ropivacaine provides faster onset of sensory and motor block with less duration of motor block, higher safety profile and equal postoperative analgesia as compared to bupivacaine when used in brachial plexus block. Less duration of motor block with ropivacaine is a desirable property as it enhances patients self-caring and comfort.

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Table 1: Patients characteristics and operative data

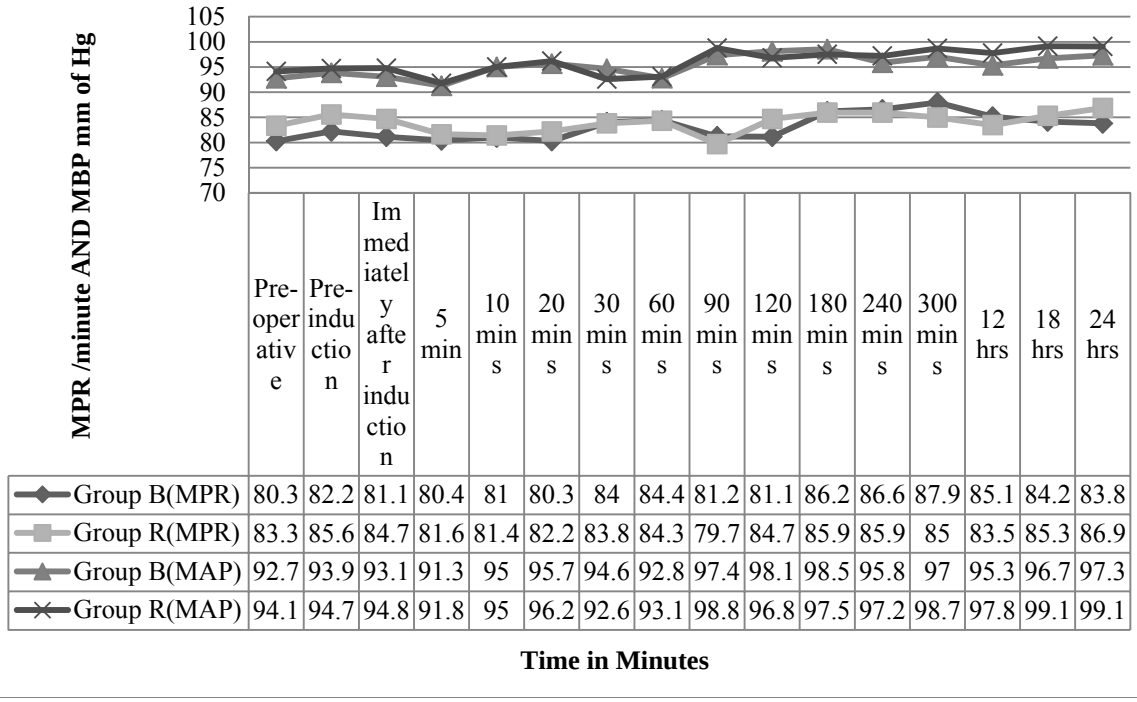
Demographic profile	**Group B Mean ± SD**	**Group R Mean ± SD**	**p value**
Age (Years)	39.53±11.31	40.7 ±10.52	>0.05
Weight (Kg)	58.3±7.35	57.97± 8.04	>0.05
Height (cm)	158.57±7.67	159.13 ±7.42	>0.05
Gender (M:F)	20/10	22/8	>0.05
Duration of surgery (min)	129.5±14.2	119.9±17.1	>0.05

Table 2: Sensory and motor characteristics of neural blockade

	GroupB(mean±sd)	**GroupR(mean±sd)**	**t-value**	**p-value**
Sensory block (minutes)				
Onset	9.5 ± 1.99	7.46±2.54	3.44	0.001*
Duration	544± 61.17 (9.06±1.02 hrs)	531.13±47.23 (8.85±0.79 hrs)	0.91	0.36
Motor block (minutes)				
Onset	12.6±2.2	10.66±2.25	3.37	0.001*
Duration	486.17±56.7 (8.10±0.9hrs)	359±55.66 (5.98±0.93 hrs)	8.76	<0.001*

*p < 0.05(statistically significant)

Figure 1: Comparison of intraoperative vitals



	Pre-operative	Pre-induction	Immediately after induction	5 min	10 mins	20 mins	30 mins	60 mins	90 mins	120 mins	180 mins	240 mins	300 mins	12 hrs	18 hrs	24 hrs
Group B(MPR)	80.3	82.2	81.1	80.4	81	80.3	84	84.4	81.2	81.1	86.2	86.6	87.9	85.1	84.2	83.8
Group R(MPR)	83.3	85.6	84.7	81.6	81.4	82.2	83.8	84.3	79.7	84.7	85.9	85.9	85	83.5	85.3	86.9
Group B(MAP)	92.7	93.9	93.1	91.3	95	95.7	94.6	92.8	97.4	98.1	98.5	95.8	97	95.3	96.7	97.3
Group R(MAP)	94.1	94.7	94.8	91.8	95	96.2	92.6	93.1	98.8	96.8	97.5	97.2	98.7	97.8	99.1	99.1

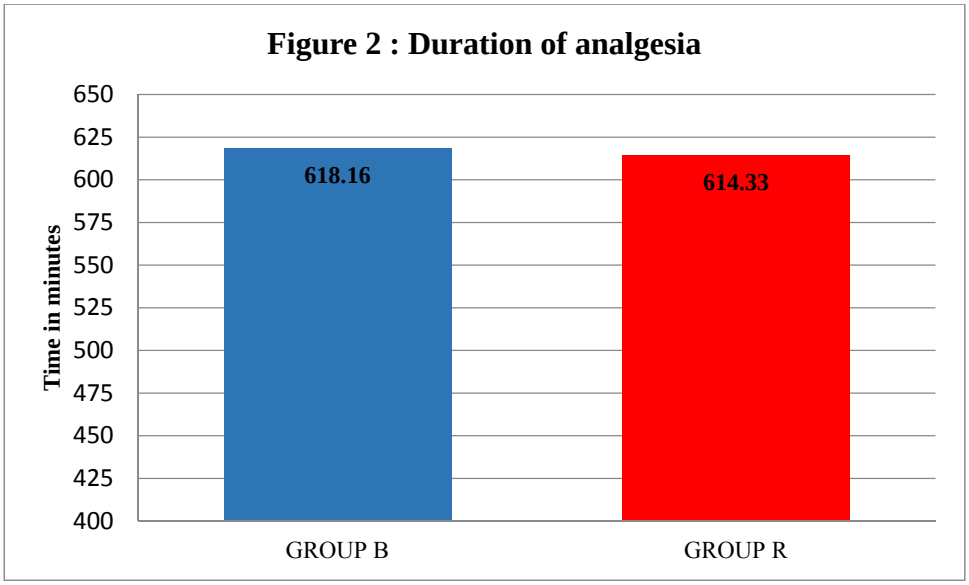


Figure 2 : Duration of analgesia
650
625
600
575
550
525
500
475
450
425
400
Time in minutes
618.16
614.33
GROUP B
GROUP R