

## Comparison of Ropivacaine 0.2% Versus Bupivacaine 0.125% in Ultrasound Guided Continuous Interscalene Analgesia for Shoulder and Upper Arm Surgeries: A Randomized Prospective Study

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### Abstract

**Background and Aims:** Shoulder surgery is associated with significant postoperative pain. A continuous interscalene brachial plexus block provides an excellent postoperative analgesic modality for early rehabilitation and recovery. The aim of this study was to compare the efficacy between Ropivacaine 0.2% and Bupivacaine 0.125% with respect to Quality of analgesia, Motor block, Patient satisfaction, Hemodynamic effects and Complications. **Methods:** Hundred patients scheduled for shoulder and upper arm surgeries between 18-75yrs of ASA 1,2,3 were prospectively randomized by sealed envelope technique into 2 groups of 50 each. GroupA: 0.125%Bupivacaine, GroupB: 0.2% Ropivacaine. Patients with COPD, localized infection and Catheter dislodgement were excluded. Ethics committee approval was granted and patients consent was taken. Data was analyzed with the help of Mann-Whitney test, Chi-square test and SPSS software version 21.0. Interscalene catheter was placed using ultrasound following which all patients received general anaesthesia. At the end of the surgery, 10 ml of either bupivacaine or ropivacaine was given followed by continuous infusion at 5ml/hour post extubation that continued upto 48 hours. A 5ml bolus of same drug was given as rescue analgesia. Quality of analgesia was assessed by VAS score, motor block was assessed by hand strength scoring them on a scale of 1 to 3. **Results:** VAS score remained less than 2 in both groups(p >0.05). Motor blockade was 19% in Bupivacaine, compared to 2% in Ropivacaine (p <0.05). Catheter dislodgement was found to be 16%. **Conclusion:** Ropivacaine 0.2% and Bupivacaine 0.125% provide good and comparable post-operative analgesia with bupivacaine causing statistically significant motor blockade.

**Keywords:** Bupivacaine; Ropivacaine; Interscalene Block; Shoulder Surgery; Pain Management.

### Introduction

Shoulder surgery is associated with significant postoperative pain, but mobilization and rehabilitation often begin on the first postoperative day. Therefore, excellent postoperative analgesia is essential to provide a good functional recovery after both open and shoulder arthroscopic surgeries like rotator cuff repair, acromioplasty and Bankart's repair.

Analgesic options for shoulder surgeries include conventional oral and parenteral analgesia, interscalene analgesia, intra-articular analgesia or

suprascapular nerve block combined with local anaesthetic wound infiltration. Among these, the interscalene brachial plexus block for analgesia is considered the best. Today, perineural interscalene brachial plexus catheters with local anaesthetic infusions are becoming increasingly popular as they prolong postoperative analgesia.

Bupivacaine is the first long acting amino-amide local anaesthetic agent which has been used extensively for spinal, epidural and nerve blocks but little is known about the comparative effects of bupivacaine with ropivacaine. Most chiral drugs, like mepivacaine and bupivacaine, exist as racemates, i.e. they are composed of equal amounts of the S and R

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enantiomers, while ropivacaine is the pure - S-enantiomer only. The current study was designed to compare the efficacy of Ropivacaine 0.2% and Bupivacaine 0.125% in ultrasound guided continuous interscalene analgesia for shoulder and upper arm surgeries with respect to Quality of analgesia, Motor block, Patient satisfaction, Hemodynamic effects and Complications.

## Methods

The study was conducted on 100 patients of physical status ASA grade 1, 2 and 3 undergoing shoulder and upper arm surgeries in Department of Anaesthesiology in our institute from June 2012 to May 2013. Hospital ethics committee approval for the conduct of study was taken. This was a hospital based, prospective, randomized control study.

The sample size was calculated taking into account the results of a previous study on interscalene brachial plexus block performed with 0.5% Ropivacaine [1] accepting a 2-tailed alpha error of 5% and a beta error of 20%. Power analysis was performed for postoperative analgesia.

For pain score, VAS was chosen as an end point. Based on our prior experience (standard deviation was 12), assuming a 2-tailed type 1 error 0.05 and a power of 0.80, minimum 50 patients in each group were required to detect a difference of 2 in the pain score (VAS) between the groups. We studied 50 patients in each group; thus, our study reached a power of 80%.

### Method of Randomization

Patients were randomized into two groups by the use of computer generated method.

- Group 1: 0.125% Bupivacaine
- Group 2: 0.2% Ropivacaine

### Inclusion Criteria

Patients informed consent, Age between 18 to 75 years of either sex. And ASA 1, 2 and 3 patients.

### Exclusion Criteria

Patient refusal, Local infection, Neuropathy, Allergy to LA, Bleeding disorders, COPD and Catheter dislodgement.

### Materials Used

Ultrasound machine(M Turbo Sonosite), with Linear Array (8-12MHz) probe, 18 G Tuohy needle,

20 G catheter, 2cc, 5 cc, 10 cc sterile syringes, Hypodermic needles- 18G & 26G, Bowl, Sponge holding forceps, Swabs, Chlorhexidine solution, Povidone iodine, Tegaderm for fixing catheter, Local anaesthetics - 2% Lignocaine, Bupivacaine 0.125% and Ropivacaine 0.2% and Sterile gel.

### Scanning Technique - 'Traceback' Approach [2,3]

The supraclavicular fossa is scanned first to identify the subclavian artery. This is achieved by placing the probe in the fossa against the clavicle and scanning in a caudad direction. The brachial plexus resembles a "bunch of grapes" lying supero-lateral to the artery. The plexus is followed medially and cephalad along its course till hypoechoic round or oval structures in the interscalene groove are seen. These are classically described as the Traffic signal sign.

While holding the ultrasound transducer with the non-dominant hand, 18G Tuohy needle fixed with 10ml of 5% Dextrose filled syringe used for hydrodissection is introduced in plane. After placing the needle nearer to C5-C6 nerve roots, catheter is advanced at least 3 cm beyond needle tip and its placement is confirmed. Needle is withdrawn over the catheter and secured with tunnelling and tegaderm.



Fig. 1: Sonographic appearance of catheter (a) arrow→Tuohy needle (b) arrow→Catheter (c) arrow→ C5-C6 nerve roots)



Fig. 2: Tunnelling

Patient was administered general anaesthesia with propofol, fentanyl and atracurium. Maintained on nitrous oxide, oxygen and sevoflurane. Duration of surgery was 2 to 3 hours.

Intraoperatively fentanyl provided analgesia. As its effect was declining at the end of surgery, 30 minutes before extubation, analgesia was supplemented with 10 ml of either bupivacaine 0.125% or ropivacaine 0.2% which was followed by continuous infusion started at 5ml/hour post extubation that continued upto 48 hours. Patients were assessed at regular intervals with regards to patient satisfaction, quality of analgesia, motor block, hemodynamic stability and untoward effects.

These drugs are used as continuous infusion in a 50 ml syringe, using syringe pump at 5ml per hour. A bolus of 5ml drug was given as rescue analgesia through the catheter when patient complained of pain and patient was followed up. If pain continues to be same, second rescue analgesia, tramadol 50 mg by intravenous route was given. Position of catheter was confirmed with ultrasound by injecting 2ml of dextrose water through the catheter and checking the spread of solution. Catheter was removed if not in place and patient was excluded from the study.

*Motor Block [4]*

To evaluate motor function of the operated arm, the patient was asked to squeeze with both hands, the hands of the observer, who scored motor function using a three-point scale.

- No motor block, similar strength in both hands.
- Partial motor block, operated hand weaker than the non-operated.
- Complete motor block, unable to squeeze with the operated hand.

*Quality of Analgesia [4]*

Patients were assessed with a 10-cm visual analog scale (VAS).

VAS 1: VAS at rest

VAS 2: VAS at movements, while asking the patients to move the hand and flex the elbow joint.

0 - No Pain

1 - 3 Mild Pain

4 - 6 Moderate Pain

7 - 10 Severe Pain

*Satisfaction Score [5]*

Patient’s satisfaction was evaluated 48 hr after surgery with a 4-point score:

- Poor
- Moderate
- Good
- Excellent

At the end of the 48 hr study period, the interscalene catheter was removed and patients were discharged from the hospital with oral analgesics, as routine in our institutions.

At the end of study, data was pooled and analyzed with the help of Mann-Whitney test, Chi-square test, The Excel and SPSS software version 21.0. Conclusion was drawn regarding the effectiveness of postoperative analgesia and relative efficacy of the two drugs.

**Results**

In demographics with respect to age, sex, weight no significant difference between two groups noted.

*Motor Block*

Sample Distribution in the two groups based on motor block (Table 1).

The difference in motor block between bupivacaine and ropivacaine group was found to be statistically significant (p<0.05).

**Table 1:** Sample Distribution in the two groups based on motor block(Chi-squared test)

Motor block	Bupivacaine		Ropivacaine		χ <sup>2</sup>	p-Value
	N	%	N	%		
Present	8	19%	1	2%	6.098	0.014*
Absent	34	81%	41	98%		
<b>Total</b>	<b>42</b>	<b>100%</b>	<b>42</b>	<b>100%</b>		

*Quality of Analgesia – VAS Score*

Comparison of VAS-R between the 2 drug groups at different time intervals Table 2 and Table 3.

Mean VAS M at different time intervals.

*Hemodynamics*

Systolic BP, Diastolic BP, Heart rate, Respiratory rate, Saturation has been stable throughout the study

period. There is no statistically significant difference between 2 groups.

*Satisfaction Score*

Mean Satisfaction in Bupivacaine group is 3.61 and mean satisfaction in ropivacaine group is 3.73. There is no significant difference between 2 groups.

**Table 2:** Comparison of VAS-R between the 2 drug groups at different time intervals

VAS-R	Drug	n	Mean	Std Dev	SE of Mean	Mean Difference	Z	p-Value
At Extubation	Bupivacaine	42	0.88	0.71	0.11	0.119	-0.782	0.434
	Ropivacaine	42	0.76	0.69	0.11			
1 hr	Bupivacaine	42	0.88	0.63	0.10	-0.024	-0.245	0.807
	Ropivacaine	42	0.90	0.53	0.08			
2 hrs	Bupivacaine	42	0.93	0.51	0.08	0.024	-0.239	0.811
	Ropivacaine	42	0.90	0.62	0.10			
4 hrs	Bupivacaine	42	0.98	0.52	0.08	-0.190	-1.485	0.138
	Ropivacaine	42	1.17	0.70	0.11			
8 hrs	Bupivacaine	42	0.90	0.69	0.11	-0.048	-0.079	0.937
	Ropivacaine	42	0.95	0.79	0.12			
16 hrs	Bupivacaine	42	1.10	0.76	0.12	-0.238	-1.112	0.266
	Ropivacaine	42	1.33	0.85	0.13			
24 hrs	Bupivacaine	42	1.10	0.79	0.12	-0.119	-0.804	0.421
	Ropivacaine	42	1.21	0.72	0.11			
36 hrs	Bupivacaine	42	1.19	0.80	0.12	-0.119	-0.575	0.565
	Ropivacaine	42	1.31	0.87	0.13			
48 hrs	Bupivacaine	42	0.95	0.66	0.10	-0.190	-1.124	0.261
	Ropivacaine	42	1.14	0.81	0.13			

**Table 3:** Comparison of VAS-M between the 2 drug groups at different time intervals

VAS-M	Drug	N	Mean	Std Dev	SE of Mean	Mean Difference	Z	p-Value
At Extubation	Bupivacaine	42	0.88	0.71	0.11	-0.190	-1.095	0.273
	Ropivacaine	42	1.07	0.78	0.12			
1 hr	Bupivacaine	42	1.12	0.55	0.08	-0.190	-1.419	0.156
	Ropivacaine	42	1.31	0.56	0.09			
2 hrs	Bupivacaine	42	1.05	0.58	0.09	-0.167	-1.311	0.190
	Ropivacaine	42	1.21	0.56	0.09			
4 hrs	Bupivacaine	42	0.90	0.48	0.07	-0.119	-0.689	0.491
	Ropivacaine	42	1.02	0.75	0.12			
8 hrs	Bupivacaine	42	0.95	0.70	0.11	-0.190	-1.281	0.200
	Ropivacaine	42	1.14	0.65	0.10			
16 hrs	Bupivacaine	42	1.12	0.71	0.11	-0.214	-1.274	0.202
	Ropivacaine	42	1.33	0.61	0.09			
24 hrs	Bupivacaine	42	1.24	0.76	0.12	-0.190	-0.960	0.337
	Ropivacaine	42	1.43	0.63	0.10			
36 hrs	Bupivacaine	42	1.07	0.78	0.12	-0.238	-1.394	0.163
	Ropivacaine	42	1.31	0.60	0.09			
48 hrs	Bupivacaine	42	1.31	1.05	0.16	0.262	-1.228	0.219
	Ropivacaine	42	1.05	0.70	0.11			

## Discussion

Surgery on the shoulder and upper arm region is often associated with severe postoperative pain. Intravenous analgesics are the most common form of treatment for postoperative pain relief and opioids form the cornerstone of this.

In recent trend, a single-shot interscalene brachial plexus block (ISB) has been used which provides pain relief for upto 15-18 h, after which the patient is again reliant on conventional analgesia. Hence, the use of a continuous interscalene brachial plexus block evolved that reduces the postoperative requirements for opioids and provides better analgesia, reduced opioid-related side effects, and better patient satisfaction compared to IV patient-controlled analgesia.

Due to the great amount of periarticular structures rich with nociceptors in the shoulder, postoperative pain is not only severe during movement, but also at rest, making a bolus technique alone inadequate in this context, as shown by Singelyn et al [6].

Thus, continuous infusion technique with a basal infusion and supplemental boli is the most appropriate technique for analgesia after major shoulder surgery [7].

Various studies used different concentrations and rates of basal infusion for postoperative analgesia.

Scott DA et al [8] has done a dose finding study for postoperative analgesia in patients undergoing abdominal surgery and demonstrated that 0.2% ropivacaine provided the best balance between analgesia and motor block.

In a study by Borgeat et al [9] compared Ropivacaine 0.2% and Bupivacaine 0.15%, using patient controlled analgesia, rate fixed at 5mL/hr plus a bolus of 4mL with a lockout time of 20 min for 48 hours. They concluded that both drugs provided similar pain relief and statistically significant motor block was observed in patients with bupivacaine.

To avoid the possible confounding factor induced by the patient (use of PCA pump), a continuous infusion of ropivacaine and bupivacaine without the option of patient-controlled doses was chosen for this study, despite evidence that patient controlled doses improve analgesia for this type of surgery [6]. Moreover, fixed-rate infusion is the optimal way to compare different local anaesthetic concentrations. Hence infusion rate was fixed at 5ml/hr for either drug infusion in the present study. Also concentrations of ropivacaine 0.2% and bupivacaine 0.125% were used as these concentrations would be equipotent as per studies conducted in the past [10-13].

### *Comparison of the Hemodynamic Variables*

In the present study, there was no clinically relevant difference observed between the two drug groups in terms of blood pressure, pulse rate, respiratory rate, and oxygen saturation throughout the study. The same results were obtained in studies by Eroglu et al [5], Casati et al [4], Fredrickson et al and Borgeat et al [9].

### *Assessment of pain by VAS*

*Quality of Analgesia:* Pain was assessed by Visual analog scale (VAS) score from 0 to 10, measured as VAS R(Pain at rest) and VAS M (Pain on movements).

VAS score, both at rest and on movements remained less than 2 throughout the study in both groups and was not clinically or statistically significant.

In the study by Eroglu et al [5], pain assessment was done by VAS scores (1-10) at movements similar to the scale used in the present study. VAS scores were similar in both groups at the time the PCIA was started (t0) and at the given observation times (t2, 4, 6, 12, 18, 24, 32, 40, 48). No patient from either group had VAS >3 before the starting of the PCIA. They found that the use of the same concentration of bupivacaine and ropivacaine (0.15%) provided similar postoperative analgesia as shown in the Table 4.

**Table 4 :** VAS scores in present study versus Eroglu et al

Time	0.15%Bupivacaine Eroglu et al	0.125%Bupivacaine Present study	0.15%Ropivacaine Eroglu et al	0.2%Ropivacaine Present study
2 hr	2	1.05	2	1.21
4 hr	3	0.90	3	1.02
16 hr	1	1.12	1	1.33
24 hr	1	1.24	1	1.43
48 hr	1	1.31	1	1.05

In the above study by Eroglu et al [5], VAS scores were high till 4 hours post-surgery compared to present study in both groups bupivacaine and ropivacaine, that might be attributed to nature of surgery which was open procedure. After 4 hours VAS scores were almost similar in both studies.

In another study, Borgeat et al [4] showed that the administration of 0.2% ropivacaine or 0.15% bupivacaine through an interscalene catheter after major open shoulder surgery provided good and comparable control of postoperative pain with few side effects and a high degree of patient satisfaction.

Our results with 0.125% bupivacaine and 0.2% ropivacaine agree with those of Borgeat's [4]. This similarity may be due to same concentration of drugs used with similar infusion rates at 5ml/hr. Their previous experience has shown that smaller concentration than the above of either ropivacaine or bupivacaine do not produce adequate postoperative pain control. Sensory and motor blocking properties of equal concentrations of ropivacaine and bupivacaine have been compared previously [11] and ropivacaine is found to be 40% less potent than bupivacaine.

#### *Rescue Analgesia*

Considering the total amount of rescue analgesia used over and above the constant infusion, in the present study where number of patients receiving rescue analgesia in the first 24 hours (16 bolus - bupivacaine, 20 bolus - ropivacaine) was more than in the next 24 hours (5 bolus - bupivacaine, 7 bolus - ropivacaine) in both drug groups. There was no significant difference with respect to requirement of rescue analgesia between the drug groups. This may be due to surgical pain which is most severe in first 24 hours post-surgery, increasing the requirement of rescue analgesia.

In the study by Casati et al [4], there was 10% increase in total volume of local anaesthetic solution infused during the first 24 hr after surgery in the ropivacaine group as compared with the levobupivacaine group.

#### *Motor Block*

The hand grasp was chosen to assess motor function because this is the most reliable way to assess this variable after rotator cuff repair.

Motor blockade as assessed by hand strength in the present study was observed in 8 patients in Bupivacaine group (19%), compared to 1 patient (2%) in Ropivacaine group and the difference between them was found to be statistically significant. Patients in

Ropivacaine group had better preservation of motor component compared to Bupivacaine. However, as Ropivacaine is less toxic, and has fewer propensities to cause motor blockade due to differential sensory-motor block, it is usually preferred over bupivacaine for providing analgesia.

Alain Borgeat et al [9] compared 0.2% ropivacaine and 0.15% bupivacaine and found that, the strength of the hand on the operated side decreased by 48% at t24 in Ropivacaine group versus 66% in the Bupivacaine group ( $p < 0.05$ ). At 48 h, the decrease in strength was 21% versus 54% in the Ropivacaine and Bupivacaine groups, respectively ( $p < 0.05$ ). Thus concluded that ropivacaine 0.2% is associated with a decreased incidence of paraesthesia in the fingers and offers a better preservation of motor function as assessed by hand strength. In the present investigation, motor block was assessed with a semi-quantitative scale because we only compared the strength of the operated hand with that of the nonoperated one. Results of our study are similar to above study as motor block in bupivacaine group (19%) is more than that in ropivacaine group (2%) which is statistically significant. This may be due to the fact that concentration of bupivacaine used in our study (0.125%) is almost near to their concentration (0.15%).

#### *Patient Satisfaction*

In the study by Eroglu et al [5], patient satisfaction was high in both drug groups comparing bupivacaine 0.15% and ropivacaine 0.15% ( $3.7 \pm 0.3$  in group B and  $3.8 \pm 0.2$  in group R; good-excellent). We observed same results having high satisfaction score between 3 and 4 (3-Good, 4-Excellent) comparing both drug groups bupivacaine 0.125% and ropivacaine 0.2% as compared to above study and all patients in the study were satisfied with the procedure.

In the study by Casati et al [4], no severe complications were reported in either group comparing levobupivacaine 0.125% and ropivacaine 0.2%. But four patients complained of nausea or vomiting in ropivacaine group and no patient in the levobupivacaine group complained of any such symptoms. In the present study there were no side effects like nausea, vomiting.

Catheter dislodgement is a known complication in this procedure. Various studies [14,15] have quoted this to be between 15% to 25%. In the present study catheter displacement was noticed in 16% of the patients.

## Conclusion

Ropivacaine 0.2% and Bupivacaine 0.125% provide good and comparable post-operative analgesia with bupivacaine causing statistically significant motor blockade.

## Recommendations

- Continuous Interscalene brachial plexus block is considered superior to other modes of postoperative analgesia in shoulder and upper arm surgeries.
- Bupivacaine 0.125% and Ropivacaine 0.2% both can be considered for postoperative analgesia, as these concentrations are equipotent in their action.
- The use of ultrasound for interscalene brachial plexus block and catheter placement improves the success rate, speed and efficacy compared to nerve stimulator.
- The technique employed in the present study is ideal and safe for providing analgesia in shoulder and upper arm surgeries.
- The problem of catheter dislodgement should be kept in mind. It can be overcome by tunnelling and tegaderm fixation.

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