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Original Research Article

A Comparative Study of Pulmonary Function after Interscalene Brachial Plexus Block with Equipotent Doses of Ropivacaine and Bupivacaine in Adult Patients Undergoing Elective Upper Limb Surgery

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Conflict of interest: Nil

Abstract

Background: Interscalene brachial plexus block (ISB) is a gold standard regional block for surgical procedures on the shoulder girdle and humerus shaft. Hemidiaphragmatic paralysis following ISB is almost inevitable . Its reduction would benefit patients with borderline respiratory function. To the best of our knowledge no study has compared the reduction in spirometric values by equipotent doses of Ropivacaine and Bupivacaine for ISB.

Aims: to compare the degree of phrenic nerve blockade through measurement of reduction in FEV1 and PEF caused by equipotent doses of Bupivacaine and Ropivacaine for ISB (group B and group R) using bedside spirometry.

Methods: Patients were randomly assigned to two groups: the Bupivacaine group [Group B (n=25): 20ml of 0.25% Bupivacaine for ISB] or the Ropivacaine group [Group R(n=25): 20ml of 0.375% Ropivacaine for ISB] .

Before performing the ISB, bedside spirometry was performed using best of the three readings for FEV1 and PEF as baseline values. Readings were again taken at time points five minutes after performing the block, ten minutes, fifteen minutes and final readings were taken at the end of surgery.

Results: FEV1 and PEFR values dropped in both groups. At the end of fifteen minutes, the PEFR in Group R was more than that in Group B (p=0.038) and the FEV1 in Group R was more than Group B (p=0.044).

Conclusions: At fifteen minutes the Group R showed a smaller drop in PEFR and FEV1. Thus Ropivacaine 0.375% may be used preferentially over Bupivacaine 0.25% for ISB in patients with borderline respiratory function.

Keywords: Interscalene block, spirometry, pulmonary function, Ropivacaine.

Introduction

Interscalene brachial plexus block (ISB) is a gold standard regional block for surgical procedures on the shoulder girdle and humerus shaft and has been extensively used. The incidence of hemidiaphragmatic paralysis following ISB is reported to be close to 100%.[1] The incidence of transient phrenic nerve palsy is virtually

100% after landmark and paresthesia-guided ISB techniques that use a large-volume injection of 20 ml or greater. [1]Patients who cannot tolerate a 25% reduction in Forced Expiratory Volume in 1 sec (FEV1) or Forced Vital Capacity (FVC) that is, patients with very poor respiratory function, the very obese, patients exhibiting sleep apnoea or the hypoxemic would benefit from avoidance of an ISB altogether.[2] Despite this, the vast majority of patients in clinical trials of ISB exhibit few symptoms and require no specific treatment.[3]

Several studies have been conducted to see the extent of pulmonary function impairment with the use of different drugs, different volumes or different concentrations of drugs.[4–8]

Many strategies have been adopted to reduce the severity of phrenic nerve palsy in regional anaesthesia for the shoulder. Many studies have been done to quantify the effect of local anaesthetic volume, concentration, site of injection, and injection methods on severity of phrenic nerve palsy.[9]

To our knowledge, no study has quantified the difference in severity of phrenic nerve palsy by spirometry, between equipotent doses of Ropivacaine and Bupivacaine for ISB.

The impact of phrenic nerve palsy on respiratory function may be quantified by several bedside methods, including pulse oximetry, pulmonary function tests, and sonographic evaluation of the diaphragm.[9]Unilateral phrenic nerve palsy after ISB reduces FEV1 by 16 to 40%, the FVC by 13 to 40%, and the Peak Expiratory Flow (PEF) by 15 to 43% [3]

Potency studies between Ropivacaine and Bupivacaine have shown a ratio of approximately 1.3:1.[10]

Furthermore, Ropivacaine has a degree of separation between its sensory and motor effects [10], which is more pronounced at lower concentrations.10 We wondered if an equipotent dose of Bupivacaine and Ropivacaine (approximately .25% and .375% respectively) showed a greater motor blockade in case of Bupivacaine. Consequently, a greater drop in the measured variables of FEV1 and PEF may happen with Bupivacaine given for ISB. Our hypothesis is that the group given Ropivacaine will show a smaller drop in the measured variables of FEV1 and PEF compared to baseline values.

If it is indeed so, Ropivacaine might be a better choice than Bupivacaine in those patients in whom ISB is deemed necessary and advantageous for good analgesia, but who might be borderline cases such as the obese or those with sleep apnoea. In these cases, along with reducing volume, concentration, injection technique, the drug Ropivacaine may be preferentially chosen over Bupivacaine.

Aim: The aim of the current study was to compare the degree of phrenic nerve blockade through measurement of reduction in FEV1 and PEF caused by equipotent doses of Bupivacaine and Ropivacaine for ISB. (Group B and group R) using bedside spirometry.

Methods

After the institutional ethics committee approval and registration in the clinical trials registry, this prospective randomised interventional trial was conducted in 50 American Society of Anesthesiologists (ASA) grades 1 and 2, adult (18-65 years) patients of either sex undergoing elective unilateral proximal humerus or shoulder surgery requiring an ISB. The study was conducted in the Orthopaedic operating theatres of KPC Medical College and Hospital. Exclusion criteria included patients refusing to give consent, refusing regional blocks, local infection at the puncture site, coagulopathy, pregnant females, history of allergy to local anaesthetics used, psychiatric and neurological disease and patients with

severe obstructive or restrictive lung disease pre-existing COPD, unstable asthma, BMI more than 30.

After written informed consent, patients were randomly allocated into 2 groups of 25 each using block- computerised randomisation technique (blocks of 10) and allocation concealment was achieved using the sealed envelope technique. Spirometric findings were recorded by different anaesthetists from those performing the ISB.

Group B (n=25): ISB using 20 ml of 0.25% Bupivacaine.

Group R(n=25): ISB using 20 ml of 0.375% Ropivacaine.

Pre-anaesthetic check was done on the day before surgery with a detailed history and physical examination. Routine investigations such as complete hemogram, fasting blood sugar, blood urea and creatinine , electrocardiography and chest X- ray were done in all cases. Written informed consent was taken from each patient after explaining the procedure in the language the patient understood.

The patients were kept fasting from midnight. An intravenous (IV) access was secured using 18-G cannula on the side opposite to the fracture site. Routine monitors, e.g peripheral O2 saturation (SpO2), non-invasive blood pressure and ECG were connected to patients before performing the block.

The patients performed a forced expiration into the spirometer (Microlife, USA, Inc, Clearwater, FL 33755) in a sitting up position as directed by the investigator with disposable mouthpieces. The best of three readings for FEV1 and PEFR were taken.

Keeping the patients in supine position and turning the head away from the side to be blocked, the landmarks were identified as follows; clavicular head of sternomastoid, interscalene groove and clavicle were identified and marked. The patients were asked to sniff to make recognition of the interscalene groove easier. After antiseptic dressing and draping, the ISB was done using a low approach. The point of entry was two fingers above the clavicle in the interscalene groove. Skin was anaesthetized with 2% lignocaine, 2 ml. A 5 cm, short bevel 22 G insulated needle (Stimuplex HNS12, Braun, Melsungen, Germany) was inserted perpendicular to the skin directed slightly caudad. The nerve stimulator, PNS (Stimuplex HNS12, B.Braun Melsungen AG, Germany) was initially set to deliver 1.2 mA (2 Hz,100µsec). The needle was then advanced slowly and once motor response of the brachial plexus was elicited (pectoralis, deltoid, triceps or biceps response) was accepted as a successful localization of the brachial plexus. The response disappeared at 0.48 mA. 20 ml of 0.375% Ropivacaine or 0.25% Bupivacaine was injected depending on the group in which the patient was randomly allotted into, Group R or Group B. The injection was made very slowly, after careful and frequent aspirations, in divided doses, 3 ml at a time, by and experienced operator making sure not to inject if there were high injection pressures. Onset of anaesthesia was noted as loss of sensation to pinprick over C5-C7 dermatomes (C5-skin over deltoid, C6- thumb tip, C7-middle fingertip). Motor block was assessed as restriction of shoulder abduction and elbow flexion.

FEV1 and PEFR were subsequently recorded at 5 minutes, 10 minutes, and 15 minutes after ISB was done as best of three attempts, with the patient in the sitting up position. Suitability for surgery in terms of motor and sensory block was confirmed and surgery was allowed to commence. Side effects like Horner's syndrome and hoarseness of the voice were noted, all medications given intraoperatively were recorded. Intraoperative fentanyl or other drugs administered and hemodynamic parameters were noted.At the end of surgery, the patients were shifted to a recovery area where FEV1 and PEFR were

recorded once more(best of three attempts). The VAS score was recorded 4 hourly and time of request for analgesia and drugs given were noted. In a previous study by Altintas et al[7], the mean PEFR dropped 31% from the baseline in the Bupivacaine group and 5% in the Ropivacaine group. Considering these values as reference with a clinically important difference of 2% decline and SD of 1.9 we needed 21 patients per group with 90% power and 5% two-sided level of significance. To allow for loss to follow-up and drop outs we inflated the sample size and enrolled 25 patients per group.

Statistical analyses: were done using Statistical Package for the Social Sciences (SPSS) version 26.0 (Armonk, NY: IBM) The categorical data were expressed as numbers (percentages) while continuous data were presented as mean±□standard deviation (SD) and median values. The data normality was checked using the Kolmogorov-Smirnov test.The comparison of the variables, which were quantitative and normally distributed, was analysed using the independent t-test [e.g., weight, BMI, baseline FEV1 and PEFR values.]

Mann-Whitney test was used to analyse non-parametric data (age, height and onset of block). The comparisons of qualitative variables (gender and ASA) were analysed using Chi-square test/ Fisher's exact test. One-way analysis of variance was used for comparing pulmonary function within groups with post hoc Bonferroni's tests. The statistically significant difference was considered as a P value of < 0.05.

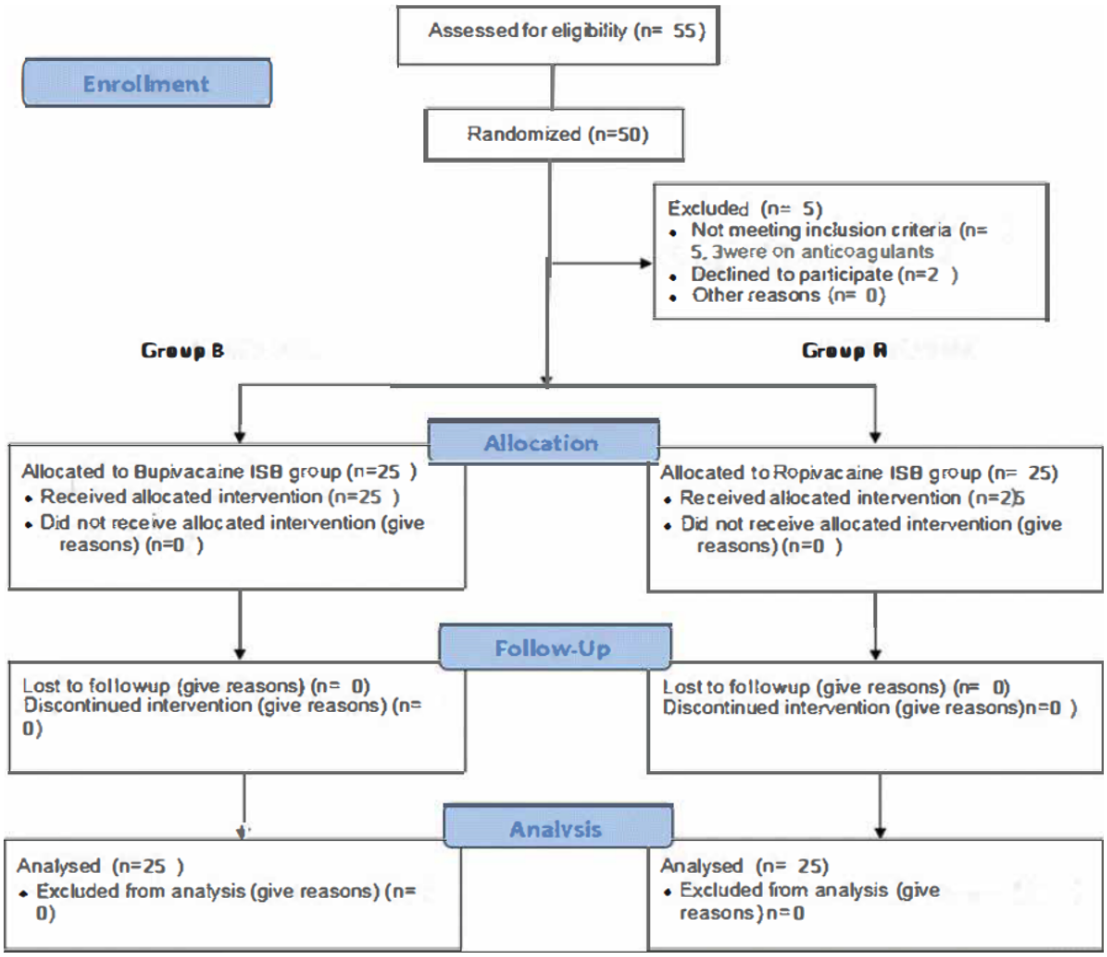


Figure 1

Table 1: Demographic Characteristics of the Patients

Group	Bupivacaine(n=25)	Ropivacaine(n=25)	P
Age(years)	42.75(15.70)	42.08(14.10)	0.393
Gender(male/female)	20/5	19/6	1.000
Weight(kg)	65.87(12.13)	67.33(10.14)	0.687
Height(cm)	169.34(8.7)	170.03(7.96)	0.768
BMI (kg/m2)	23.53(2.87)	23.87(2.63)	0.911
ASA PS*(1/2)	20/5	21/4	0.981
Duration surgery(min)	55.34(10.99)	53.6(10.98)	0.485
Baseline PEFR(L/min)	408.36(62.29)	403.44(71.25)	0.796
BaselineFEV1(L)	2.83(0.55)	2.84(0.53)	0.953
Onset time(min)	6.7(2.3)	6.4(1.9)	0.302

The data are presented as number or mean (Standard deviation). *ASA PS: American Society of Anesthesiologists physical status , BMI: Body mass indexBetween November 2022 and April 2023, fifty-five patients between 18 and 65 years of age, posted for elective orthopaedic surgery of the clavicle, shoulder or proximal humerus requiring an ISB were assessed for eligibility and after screening for exclusion criteria, the remaining 50 patients were included [Figure 1].

The demographic profile including age, gender, BMI and baseline spirometry was not significantly different between the two study groups as shown in Table 1. Successful performance of the ISB was confirmed by loss of sensory and motor function of the arm and shoulder in all patients. The spirometric values of both groups declined from baselines values at 5 min, 10 min, 15 minutes significantly from pre-block levels. ($p< 0.001$ compared with baseline values within groups for FEV1 and PEFR) However, between groups this difference was significant at 15 minutes ($p<0.05$, see Figure 1). Both PEFR and FEV1 at 15 minutes dropped significantly more in Group B than in Group R.

There were no oxygen desaturations in any group (although all patients were given 2-4l of oxygen through nasal cannula in the operation theatre). Two patients needed block supplementation and one of them required a conversion to a general anaesthetic. Hemodynamic parameters were not significantly different between the two groups.

Delta FEV1 and Delta PEFR were calculated as the difference between the variable at a time point and its baseline values, expressed as a percentage of the baseline values. (e.g, Delta PEFR at 5 min=(PEFR at 5 min- baseline PEFR)/baseline PEFR*100).Delta FEV1 at 15 minutes and end of surgery were significantly lower in Group B (28% and 29%) as compared to Group R (19% and 21% respectively), [p=0.001, p=0.005]. Delta PEFR at 15 minutes and end of surgery were also significantly lower in Group B (26% and 30%) as compared to Group R (18% and 23%) respectively, [p=0.001 and p=0.024], see Figure 3.Block duration, estimated by the time from giving the ISB to when the patients no longer felt their arm was numb, was not significantly different between groups.

Table 2: Complications

Variable	Group B	Group R
Horner's syndrome	4/25	3/25
Hoarseness	1/25	0/25

P>0.05 between groups

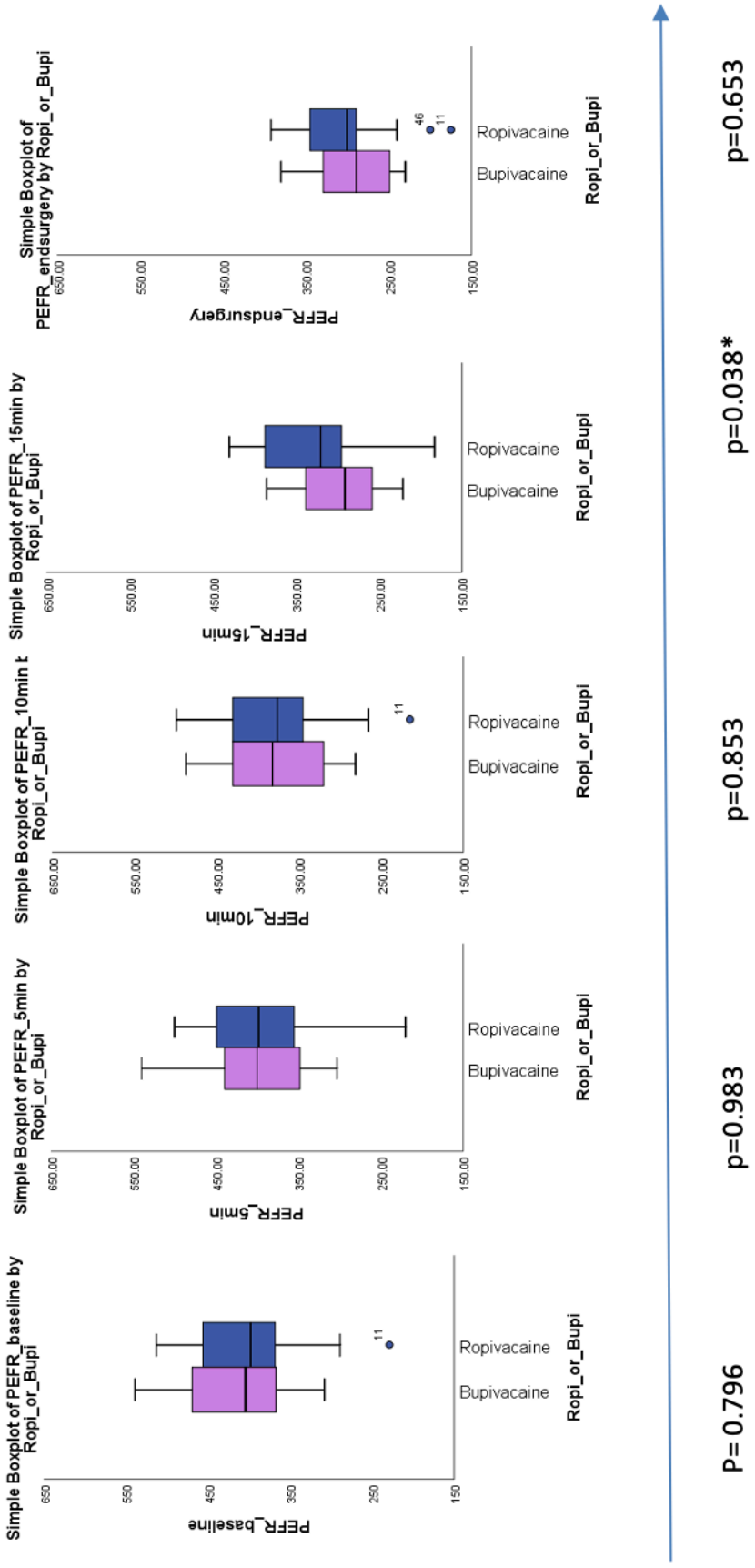
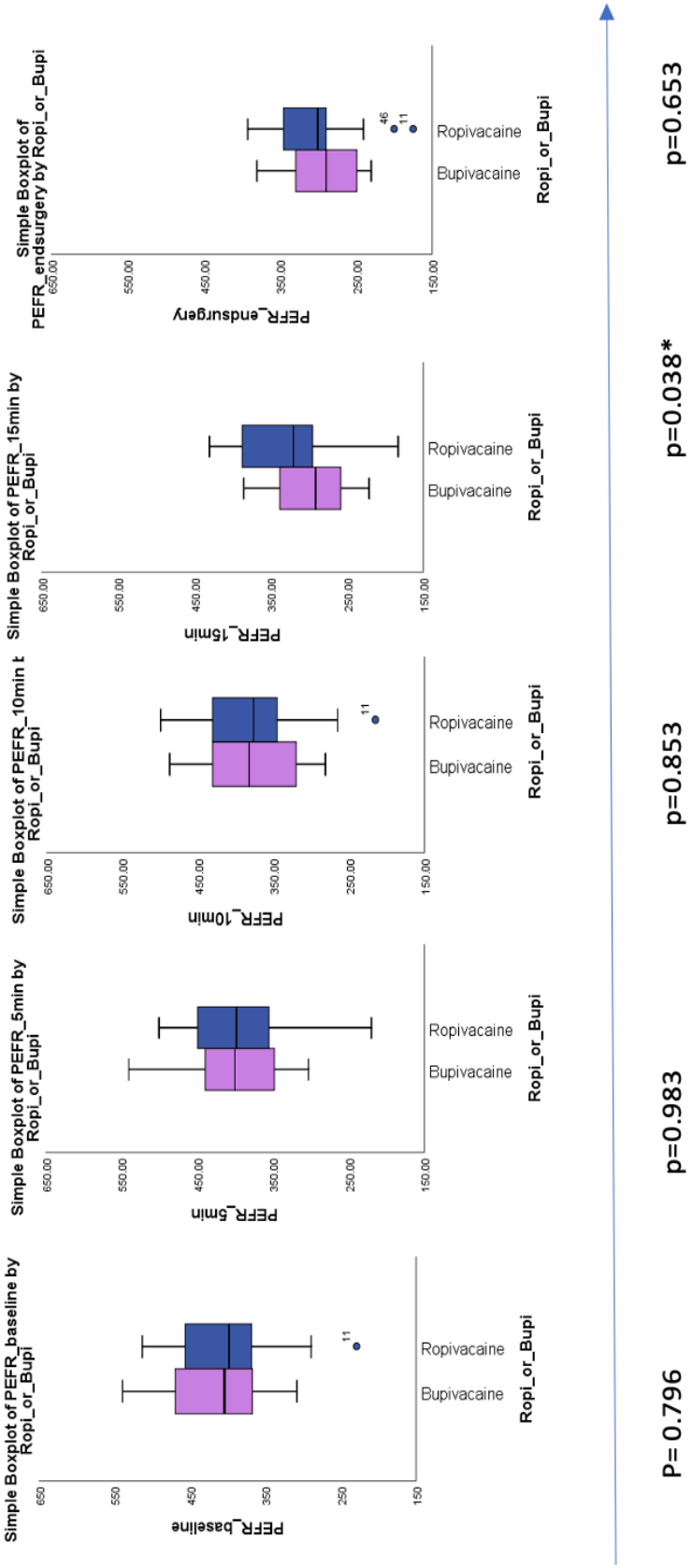


Figure 2: *Variation of PEFR over time in both the groups (p value between interscalene block(IBP) with 20 ml of either 0.25% Bupivacaine or 0.375% Ropivacaine.)*



Variation of PEFR over time in both the groups (p value between interscalene block(IBP) with 20 ml of either 0.25% Bupivacaine or 0.375% Ropivacaine.) **FIGURE 2**

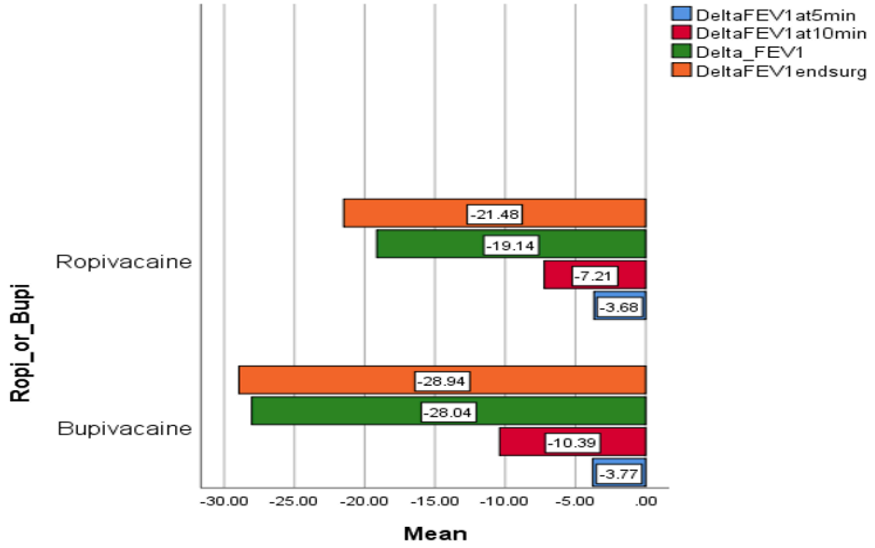


Figure 4:

Delta FEV1 and Delta PEFR as calculated as the drops in the values of FEV1 and PEFR expressed as a percentage of the baseline values.

As seen in the figures there is significant difference in Delta FEV1 and Delta PEFR between the two groups at 15 minutes and at the end of surgery (p=0.001 and p=0.005 for FEV1, and p=0.001 and p=0.024 for PEFR)

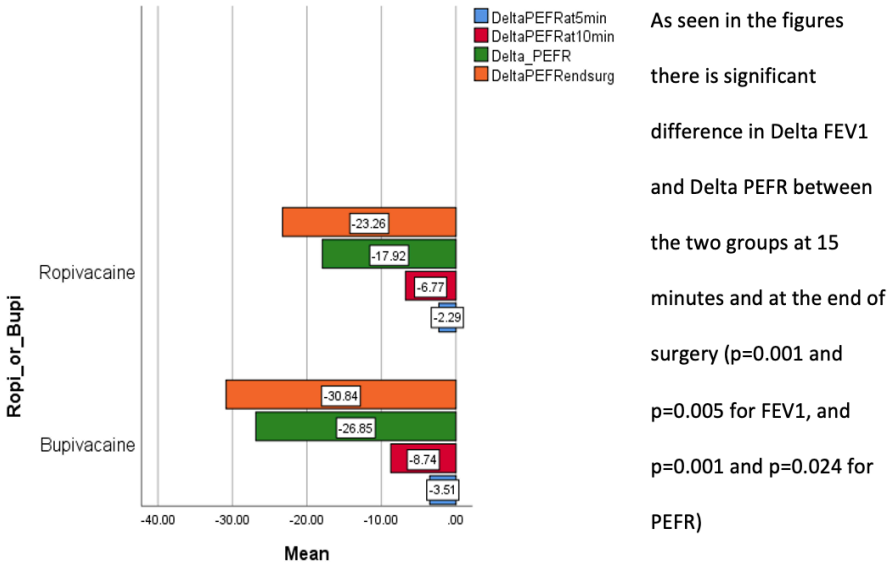


Figure 5:

Discussion

Interscalene brachial plexus block (ISB) is an extensively used regional block for surgical procedures on the shoulder girdle and proximal humerus. Hemidia-pragmatic paresis almost invariably ensues following an ISB.[1]

The results of this study demonstrate that 20 ml of both 0.25% Bupivacaine and 0.375% Ropivacaine used for ISB cause diaphragmatic dysfunction as reflected by a drop in spirometric values.

Our endeavour was to compare the relative pulmonary effects of 20 ml of 0.25%

Bupivacaine and 0.375% Ropivacaine used for ISB. Both were seen to cause diaphragmatic dysfunction as reflected by a drop in spirometric values. Diaphragmatic paralysis was estimated using spirometric values of FEV1 and PEFR as surrogate measures. We further sought to compare an equipotent dose of these two drugs for ISB using a fixed volume (20 ml).

In our study, complete sensorimotor block (C5 to T1) was achieved in 48 out of 50 patients. The overall success rate for IBP in our study was 96%. We defined onset time as sensory block to pinprick over C6, C7, C8 and loss of shoulder abduction. It was similar in both groups ($p>.05$)

Significant decreases in all measured pulmonary function variables were observed in every patient after ISB. (Figure 2 and 3) ISB depresses pulmonary function due to unilateral hemidiaphragmatic paresis. [1]. It has been shown that ISB causes diaphragmatic paralysis in up to 100% of cases and causes a considerable reduction (41% in FVC and 30% in FEV1) in pulmonary function.[2] Our study corroborates this as we have a 100% incidence of decline in measured pulmonary variables from baseline in both Group B and in Group R from baseline till the end of surgery. ($p <0.001$ compared with baseline values within groups) (Figures 2 and 3)

The drop in the parameters of FEV1 and PEFR was noted throughout, after the blocks, more in Group B (Bupivacaine) but the differences between the two groups became significant at the time point of 15 minutes. ($p=0.038$ for FEV1 and $p=0.044$ for PEFR) This supports our hypothesis that Bupivacaine group causes a much larger drop whereas those in Group R had their pulmonary function affected less by ISB block.

The 30% decrease in FEV1 and PEFR confirms similarities with previously published results in healthy patients. [3] (Figure 3)

This time point of 15 minutes is important as surgery is about to commence around that time, with cleaning and draping going on before this. We do not know when the peak fall in spirometric variables occurs as we are unable to get further measurements after 15 minutes, but pulmonary function is likely to worsen to a lowest point when surgery is going on. It makes sense therefore to avoid 0.25%Bupivacaine in favour of 0.375% Ropivacaine in a susceptible population such as the obese or those with sleep apnea or ASA III patients ie, patients who poorly tolerate a 25% reduction in pulmonary function.[3]

Group R may be less affected by ISB as the drug Ropivacaine has a marked differential effect in sensory/ motor blockade. [4]. Casati et al [5] performed ISB and compared the pulmonary effects of 20 ml of 0.5% Ropivacaine, 0.75% Ropivacaine and 2% Mepivacaine for shoulder capsuloplasty and acromioplastic procedures. Pulmonary variables fell in all three groups but differences were less noticeable at 30minutes. We, however found a significantly greater fall in percentage of FEV1 and PEFR as compared to baseline in Group B (Figure 4) at the end of surgery.

Altintas et al [7] used 0.33% Bupivacaine and 0.33% Ropivacaine in ISB in forty two patients undergoing ISB for creation of arterio-venous fistulas in chronic renal failure. They found that pulmonary function decreased more with 0.33% Bupivacaine than with 0.33% Ropivacaine. They used equal rather than equipotent doses of the two drugs.

They have used higher volumes (30 ml) as compared to our study (20ml).Equipotent doses of Ropivacaine and Bupivacaine are approximately 1.3:1. [10]. The relative analgesic potency ratios were 0.65 (0.56-0.76) for Ropivacaine:Bupivacaine[11,12] and various studies have stated the potency ratios for these two as somewhere between 1.4 and 1.68. [13] We used the concentrations of 0.375% of Ropivacaine and 0.25% of Bupivacaine as these are

easily prepared or available and lead to a potency ratio of 1.5 as required.

We have conducted our study on relatively healthy patients, ASA I and II patients, whereas Altintas et al[7] studied patients in chronic renal failure, for fistula formation. Perhaps that could explain why we did not observe dyspnea in any of our patients. This is similar to the study performed by Casati et al, in 60 healthy patients,[4] in which they used 20 ml of 0.5%,0.75%, and 1% Ropivacaine versus 2% Mepivacaine for ISB and do not report any incidence of dyspnea. O2 supplementation given to all. There were no oxygen desaturations recorded for any patients suggesting that statistically significant differences in spirometry values do not necessarily translate into clinical outcomes for our relatively healthy population of ASA I and ASA II patients only. However, avoidance of diaphragm dysfunction is more important in patients with a limited pulmonary reserve. [3]Horner's syndrome was seen in 7 patients and hoarseness in only one patient as shown in Table 2. No significant difference was found between groups with regard to these complications ($p > 0.05$).To our knowledge, this is the first study comparing the pulmonary effects of equipotent doses of Bupivacaine and Ropivacaine for ISB. These are the most readily available drugs to us and Ropivacaine has a demonstrable superiority in this study.

Apart from this Ropivacaine also has an improved safety profile when contrasted with Bupivacaine in terms of cardiac depression and neurological toxicity. [14,15]

Limitations-

1. We are unable to comment on just how much these pulmonary variables may actually decline after 15 minutes as it was not possible to gather measurements intraoperatively.
2. All our blocks were done by skilled operators so the results may not be the same in inexperienced hands.
3. We did not perform ultrasonography to visualise and quantify hemi diaphragmatic paresis.
4. US guided nerve stimulator was not used.

Conclusion

In conclusion, our study showed that 20 ml of equipotent doses of Ropivacaine (0.375%) and Bupivacaine (0.25%) both cause a drop in FEV1 and PEFR when used for ISB. The drop in these variables is significantly more in the Bupivacaine group, after 15 minutes. These results suggest that 0.375% Ropivacaine is a better local anaesthetic than 0.25% Bupivacaine for ISB , especially in high- risk patients with respiratory compromise. Ropivacaine also has an added advantage of an improved safety profile over Bupivacaine.

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