# Study of Two Different Volumes of 0.75% Ropivacaine for Ultrasound Guided Supraclavicular Brachial Plexus Block on Successful Blockade and Diaphragmatic Motility

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## ABSTRACT

### Background

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Prasad JN, Adhikari S, Singh SN, Subedi A, Thapa P, Guddy KM, et al. Study of Two Different Volumes of 0.75% Ropivacaine for Ultrasound Guided Supraclavicular Brachial Plexus Block on Successful Blockade and Diaphragmatic Motility. *Kathmandu Univ Med J.* 2022;80(4):406-11. Use of ultrasound guidance during supraclavicular brachial plexus block allows the usage of a lower anesthetics dose and minimizing unwanted effects of the anesthesia.

#### Objective

To compare the success of sensory blockade and the incidence of hemidiaphragmatic dysfunction in patients receiving two different volume of 0.75% Ropivacaine for ultrasound guided supraclavicular brachial plexus block.

#### Method

A prospective randomized double-blinded comparative study was conducted. Group A patients (n=30) received 20 ml and Group B (n=30) received 25 ml of 0.75% Ropivacaine for ultrasound guided supraclavicular brachial plexus block. Hemodynamic parameters, oxygen saturation, diaphragmatic excursion, onset of sensory blockade and time for completion of blockade were measured. Independent t-test, Chi-square test and Mann-Whitney U test were used to analyze the data at p value of less than 0.05 using Statistical Package for Social sciences (version 11.5).

#### Result

At 30 minutes, 29 (96.67%) patients in group B and 27 (90.0%) patients in group A had no sensation in median, radial, ulnar, musculocutaneous and medial cutaneous nerves teritories; however, it was not significant statistically (p value > 0.05). At 30 minutes in Group A, 25 (83.33%) patients had no diaphragmatic hemiparesis and five (16.67%) patients had partial diaphragmatic hemiparesis. However, three (10%) patients had no diaphragmatic hemiparesis in Group B, 25 (83.33%) patients had partial and two (6.67%) patients had complete diaphragmatic hemiparesis and it was statistically significant (p < 0.05). Age and sex had no effect on diaphragmatic hemiparesis in both groups (p value > 0.05).

#### Conclusion

The patients receiving lower volume of Ropivacaine had less incidence of hemidiaphragmatic dysfunction with similar sensory blockade as compared to the patients receiving higher volume of Ropivacaine.

## **KEY WORDS**

Brachial plexus block, Diaphragmatic motility, Ropivacaine

## **INTRODUCTION**

Brachial plexus block (BPB) is a preferred alternative to general anesthesia for surgery of the arm, elbow, forearm and hand.<sup>1</sup> Supraclavicular BPB is usually the technique of choice because it offers dense anesthesia for surgical procedures at or distal to the elbow.<sup>2</sup> However, hoarseness of voice, Horner's syndrome and hemidiaphragmatic paresis occur due to the spread of injected anesthesia to the surrounding neural tissue.<sup>3</sup>

Use of ultrasound guidance during supraclavicular BPB has improved its safety. It also helps the operator to visualize needle placement in real time and its relation to the target nerves reducing the risk of intravascular and intraneural injections and pneumothorax.4-7 It allows the usage of a lower anesthetics dose minimizing unwanted effects of the anesthesia.8-12 Large volumes of local anesthetics (at least 30-40 ml) are generally used in landmark technique for BBB that leads to higher incidence of phrenic nerve involvement and diaphragmatic dysfunction. Injecting lowest possible volume of local anaesthetic at the site away from phrenic nerve in the brachial plexus would reduce the incidence of diaphragmatic dysfunction and with optimal quality of block. There is scarcity of data on effect of different volumes of anesthetics on success rate of sensory blockade and diaphragmatic motility. The objective of the study were to compare the success of sensory blockade and the incidence of hemidiaphragmatic dysfunction in patients receiving two different volume of 0.75% Ropivacaine for ultrasound guided supraclavicular BPB for distal arm surgery.

## **METHODS**

It was a prospective randomized double-blinded comparative study. Patients with distal arm surgery of either gender were enrolled. The study was conducted at operation theatre of B.P. Koirala Institute of Health Sciences (BPKIHS), Dharan, Nepal from April 2018 to March 2019.

## Inclusion criteria

i. Age between 18 and 60 years undergoing distal arm surgery (right side)

ii. American Society of Anesthesiologists Physical Status (ASA PS) I to III

iii. Body weight greater than 50 Kg

## **Exclusion criteria**

i. Contraindication to BPB: hemidiaphragmatic dysfunction, Coagulation disorders, Neuropathy, Pre-existing neurological diseases affecting upper extremities.

- ii. Pulmonary and cardiac disorders/conditions
- iii. Pregnancy
- iv. Allergy to local anaesthetics
- v. Chest or shoulder deformities

vi. Patient's refusal for the supraclavicular block

This study considered 95% confidence interval and 80% power to estimate the sample size. Using the formula  $N=(Z_{\beta}+Z_{\alpha/2})^2 * [p1(1-p1)*p2(1-p2)]/(p1-p2)^2$ , the sample size was calculated where  $Z_{\alpha/2}$  was 1.96 for a confidence level of 95%,  $Z_{\beta}$  was 0.842 for a power of 80%, p1 and p2 were the expected sample proportions of the two groups, that was 95% and 58.5%.<sup>12</sup> Adding 25% in the calculated sample size for any dropout, the sample size became 30 in each group.

Convenience sampling technique was used. i. Group A: Patients received 20 ml of 0.75% Ropivacaine for USGguided supraclavicular BPB. ii. Group B: Patients received 25 ml of 0.75% Ropivacaine for USG-guided supraclavicular BPB.

A total of 60 patients were assigned computer-generated random number sequence to either Group A or Group B. Patients and the anaesthesiologist who assessed the sensory nerve function were blinded to the study groups and volume of the drugs used.

The study was ethically approved from the Institutional Review Committee, BPKIHS (IRC/1091/017). A self-designed proforma was used to collect the relevant data that consisted of heart rate, respiratory rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure and oxygen saturation, diaphragmatic excursion, onset of sensory blockade and time for completion of blockade.

In the pre-operative patient holding area, informed written consent was taken from the patient or his/her relative only after giving full information regarding the study.

Patients were reassessed in the holding area and shifted to the operation theatre. Intravenous line was opened with intravenous cannula and the patients were under continuous standard monitoring. Patients were kept in supine position and the head turned 45 degrees to the nonoperative side. Skin preparation with povidone-iodine and spirit was done. A 7.5 MHz linear-array ultrasound probe was connected to a real-time ultrasound unit (Micromax sonosite), and focused at 6.5 cm depth and the brachial plexus was identified. After sterilization and injection of 1 ml of 2% Lidocaine to the skin, a 22-gauge insulated block needle (Stimuplex; B. Braun Medical, Bethlehem, USA) was inserted through the skin from lateral to medial toward the junction of subclavian artery and first rib or pleura and then 3 ml of 0.75% Ropivacaine was injected slowly after aspiration and spread of local anesthetics was observed. There after needle was withdrawn posterolateral to the brachial plexus and remaining volume of local anesthetics was injected slowly. Using multi-injection technique, the local anesthetic was injected in such a manner that it remained confined caudal and posterolateral to the brachial plexus. The patient received a total volume of either 20 ml (group A) or 25 ml (group B) of 0.75% Ropivacaine.

The extent of sensory blockade were tested using pinprick test with 26 gauge needle in all five nerve territory (Musculocutaneous, Radial, Ulnar, Median and Medial Cutaneous nerves) at baseline, 15 and 30 minutes after the injection of Ropivacaine. The sensory blockade was graded in three point scale: 0 (No perception, 1 (decreased sensation), 2 (normal sensation). Successful blockade was defined as a complete sensory blockade (sensory block score = 0) in the distribution of five terminal nerves 30 minutes after the injection of Ropivacaine. Any instances requiring unscheduled conversion to general anaesthesia intraoperatively or the need for supplementary or local infiltration by the surgeon were noted as failure of the blockade.

The diaphragmatic excursions was assessed at 15 and 30 minutes after the block using ultrasonography (micromax sonosite). Three measurements were made in centimeter using the digital calipers and the average of three was recorded. Diaphragmatic excursions were categorized in three category as follows: complete hemidiaphragmatic paralysis (> 75% reduction in diaphragmatic excursion in the deep breathing maneuver at 30 minutes), partial hemidiaphragmatic paralysis (25% to 75% reduction in diaphragmatic excursions in the deep breathing maneuver at 30 minutes), no hemidiaphragmatic paralysis (< 25% reduction in diaphragmatic excursions in the deep breathing maneuver at 30 minutes). Hemodynamic monitoring (Heart Rate, Respiratory Rate, Systolic and diastolic Blood Pressure, Mean Blood Pressure and SpO<sub>2</sub>) were monitored continuously and noted every five minutes till 30 minutes. Following the final (30 minutes) assessments, the patients were shifted to the operating room. Injections Paracetamol 15 mg/Kg, injections Ketorolac 30 mg and Fentanyl 0.5 mcg/Kg were given as a part of multimodal analgesia.

The data were entered in Microsoft Office Excel 2007. Descriptive statistics like mean, standard deviation, frequency and percentage were calculated. Independent t-test was used to compare the mean between two groups. For inferential statistics, Chi-square test was used for comparing the categorical data. Mann-Whitney U test was used to compare ordinal or non-discrete data between two groups. Statistical Package for Social Sciences (version 11.5) was used for statistical analysis at p value less than 0.05.

# RESULTS

The patients in Group A and B were similar with respect to age, gender, weight, ASA PS and diagnosis (p > 0.05) (Table 1).

Hemodynamic profile of the patient (heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, saturation of oxygen in blood and respiratory rate) were similar in groups A and B at baseline, 5, 10, 15, 20, 25 and 30 minutes after the block (p > 0.05) (Table 2 and 3).

Table 1. Socio-demographic data of the patients.

Variables		Group A (n=30)	Group B (n=30)	p value	
Age (Years)		27.93±12.52	33.57±14.40	0.23	
Gender	Male	21(53.84%)	18(46.15%)	0.41	
	Female	9(42.85%)	12(57.14%)	0.41	
Weight (Kg)		54.67±6.48	55.10±6.51	0.71	
	1	25(53.19%)	22(46.81)	0.34	
ASA PS	II	5(38.46%)	8(61.54%)		
Diagnosis	Implant Re- moval Forearm	9(56.25%)	7(43.75%)		
	Radius Fracture	7(46.66%)	8(53.33%)		
	Ulna Fracture	4(57.14%)	3(42.86%)	0.89	
	Both bone Fore- arm Fracture	5(45.45%)	6(54.55%)		
	Others	5(45.45%)	6(54.55%)		

# Table 2. Hemodynamic parameters in the patients after injection of the local anesthesia.

Hemodynamic variables		Group A (n=30)	Group B (n=30)	p value
Heart rate	Baseline	72.47±6.79	68.90 ± 5.42	0.27
	After 5 min	75.70±8.07	72.73 ± 6.52	0.21
	After 10 min	76.27±7.60	73.67 ± 6.96	0.79
	After 15 min	76.57±8.0	76.33 ± 7.66	0.84
	After 20 min	76.07±7.73	76.27 ± 7.13	0.97
	After 25 min	77.77±7.50	76.33 ± 6.63	0.58
	After 30 min	78.40±9.0	77.70 ± 7	0.77
	Baseline	121.30±12.31	121.17 ± 14.53	0.29
	After 5 min	125.63±11.82	124.87 ± 13.62	0.47
Systolic	After 10 min	124.33±10.73	124.43 ± 11.93	0.32
Blood	After 15 min	124.03±9.87	123.73 ± 12.00	0.20
Pressure	After 20 min	123.00±9.73	122.00 ± 11.89	0.13
	After 25 min	123.47±12.28	122.10 ± 10.83	0.61
	After 30 min	124.27±11.77	123.93 ± 11.30	0.91
	Baseline	73.90±8.16	73.47 ± 9.68	0.21
	After 5 min	76.73±7.67	75.93 ± 8.57	0.28
Diastolic	After 10 min	77.07±7.84	75.67 ± 9.58	0.15
Blood	After 15 min	76.00±7.85	75.10 ± 9.09	0.41
Pressure	After 20 min	75.13±6.68	75.07 ± 8.91	0.13
	After 25 min	74.97±7.77	74.70 ± 7.80	0.52
	After 30 min	73.90±8.16	73.47 ± 9.68	0.21
Mean arte-	Baseline	92.70±9.33	91.23 ± 12.27	0.10
	After 5 min	95.40±9.89	95.10 ± 11.16	0.36
	After 10 min	94.63±9.69	94.10 ± 10.69	0.48
rial blood	After 15 min	94.53±10.28	93.70 ± 11.24	0.24
pressure	After 20 min	93.47±9.35	92.00 ± 10.75	0.25
	After 25 min	93.77±11.70	91.20 ± 9.79	0.50
	After 30 min	93.17±11.50	92.33 ± 10.11	0.69

Table 3. Comparison of oxygen saturation of blood between groups A and B

Variables	Group A (n=30)	Group B (n=30)	p value
Baseline	98.07 ± 0.98	98.07 ± 1.01	0.97
After 5 min	98.33 ± 0.88	98.20 ± 0.88	0.92
After 10 min	98.53 ± 0.73	98.43 ± 0.77	0.81
After 15 min	98.57 ± 0.85	98.83 ± 0.91	0.89
After 20 min	98.53 ± 0.73	98.77 ± 0.62	0.14
After 25 min	98.47 ± 0.81	98.63 ± 0.71	0.43
After 30 min	98.50 ± 0.68	98.77 ± 0.67	0.66
Baseline	15.87 ± 1.25	15.77 ± 1.27	0.83
After 5 min	15.77 ± 1.00	15.67 ± 0.95	0.71
After 10 min	15.73 ± 0.98	15.80 ± 0.96	0.74
After 15 min	15.80 ± 1.27	$15.40 \pm 1.03$	0.26
After 20 min	15.63 ± 1.24	$15.30 \pm 0.91$	0.18
After 25 min	$15.50 \pm 0.97$	15.17 ± 1.08	0.60
After 30 min	15.73 ± 1.08	15.47 ± 1.07	0.97

Table 4 and 5 show the effect of the anesthetic drugs on sensory blockade. At 30 minutes, 29 (96.67%) patients in group B and 27 (90.0%) patients in group A had no sensation in median, radial, ulnar, musculocutaneous and medial cutaneous nerves; however, it was not significant statistically (p > 0.05) (Table 4 and 5).

# Table 4. Assessment of sensory blockade in median and radial nerve block

Time (minutes)	Characteristics	Group A (n=30)	Group B (n=30)	p value	
Median Nerve					
Baseline	Normal sensation	30 (100)	27 (90.0)	0.07	
	Decreased sensation	0 (0)	3 (10.0)		
	No perception	0 (0)	0 (0)		
	Normal sensation	2 (6.67)	1 (33.33)		
15	Decreased sensation	27 (90.0)	22 (73.33)	) 0.06	
	No sensation	1 (3.33)	7 (23.33)		
	Normal sensation	0 (0)	0 (0)		
30	Decreased sensation	3 (10.0)	1 (3.33%)	0.30	
	No sensation	27 (90.0)	29 (96.67)		
Radial Nerve	2				
	Normal sensation	28 (93.33)	26 (86.67)		
Baseline	Decreased sensation	2 (6.67)	) 4 (13.33) 0.		
	No sensation	0 (0)	0 (0)		
15	Normal sensation	3 (10.0)	1 (3.33)		
	Decreased sensation	24 (80.0)	22 (73.33)	73.33) 0.26	
	No sensation	3 (10.0)	7 (23.33)		
30	Normal sensation	0 (0)	0 (0)		
	Decreased sensation	3 (10.0)	1 (3.33)	0.30	
	No sensation	27 (90.0)	29 (96.67)		

Table 5. Assessment of sensory blockade in ulnar,musculocutaneous and Medial cutaneous nerves block.

Time (minutes)	Characteristics	Group A (n=30)	Group B (n=30)	p value	
Ulnar Nerve					
Baseline	Normal sensation	30 (100.0)	27 (90.0)		
	Decreased sensation	0 (0)	3 (10.0)	0.07	
	No perception	0 (0)	0 (0)		
	Normal sensation	4 (13.33)	1 (3.33)		
15	Decreased sensation	23 (76.67)	22 (73.33)	0.18	
	No perception	3 (10.0)	7 (23.33)		
	Normal sensation	0 (0)	0 (0)		
30	Decreased sensation	4 (13.33)	1 (3.33)	0.16	
	No perception	26 (86.67)	29 (96.67)		
Musculo-cu	itaneous Nerve				
	Normal sensation	30 (100.0)	27 (90.0)		
Baseline	Decreased sensation	0 (0)	3 (10.0)	0.07	
	No perception	0 (0)	0(0)		
	Normal sensation	4 (13.33)	1 (3.33)		
15	Decreased sensation	23 (76.67)	22 (73.33)	0.18	
	No perception	3 (10.0)	7 (23.33)		
	Normal sensation	0 (0)	0 (0)		
30	Decreased sensation	4 (13.33)	1 (3.33)	0.16	
	No perception	26 (86.67)	29 (96.67)		
Medial Cutaneous nerve					
	Normal sensation	28 (93.33)	26 (86.67)		
Baseline	Decreased sensation	2 (6.67)	4 (13.33)	0.38	
	No perception	0 (0)	0 (0)		
15	Normal sensation	2 (6.67)	1 (3.33)		
	Decreased sensation	25 (83.33)	22 (73.33)	0.34	
	No perception	3 (10.0)	7 (23.330)		
	Normal sensation	0 (0)	0 (0)		
30	Decreased sensation	3 (10.0)	1 (3.33)	0.30	
	No perception	27 (90.0)	29 (96.67)		

All 30 (100%) patients in Group A had no diaphragmatic hemiparesis 15 minutes after BPB. However, in Group B, three (10%) patients had no diaphragmatic hemiparesis and 27 (90%) patients had partial diaphragmatic hemiparesis and it was statistically significant (p < 0.05). Similarly at 30 minutes, in Group A, 25 (83.33%) patients had no diaphragmatic hemiparesis and five (16.67%) patients had partial diaphragmatic hemiparesis. However, in Group B three (10%) patients had no diaphragmatic hemiparesis, 25 (83.33%) patients had partial diaphragmatic hemiparesis and two (6.67%) patients had complete diaphragmatic hemiparesis and it was statistically significant (p < 0.05) (Table 6). Age and sex had no effect on diaphragmatic hemiparesis in both groups (p > 0.05). 
 Table 6. Comparison of diaphragmatic hemiparesis after USG 

 guided supraclavicular block between groups A and B

Time (minutes)	Diaphragmatic hemiparesis	Group A (n=30)	Group B (n=30)	p value
15	No	30 (100)	3 (10)	
	Partial	0 (0)	27 (90)	0.000
	Complete	0 (0)	0 (0)	
30	No	25 (83.33)	3 (10)	
	Partial	5 (16.67)	25 (83.33)	0.000
	Complete	0 (0)	2 (6.67)	

# DISCUSSION

In the present study, there were no differences in the demographic characteristics between the two groups reflecting proper randomization. However comparing sex, there were more male patients compared to female patients in the study. It could be due to the fact that male patients are more active in hard and difficult task and hence they are more susceptible to fracture and other injury. The patients in both groups after 30 minutes of the injection of 0.75% Ropivacaine showed 100% successful rate of sensory blockade without any rescue dose. These results were consistent with Renes et al in which the success rate of nerve blockade was 100% with no rescue dose.<sup>12</sup> Reason behind the similar finding could be due to same drug deposition technique and site of injection. Similarly success rate of nerve blockade in our study was comparable with Vazin et al.13 However, our result of successful nerve blockade was contradictory to Duggan et al. in which minimum volume required for USG guided supraclavicular block in 50% of patients was 23 ml and in 95% of patients it was 42 ml.<sup>14</sup> The discrepancy of result between the two studies could be due to site of drug deposition along with type of local anesthetics and adjuvant used in brachial plexus block. Similarly, our results of successful nerve blockade was contradictory to Jeon et al. in which the success rate was 66.7% with 20 ml, 90% with 30 ml and 96.7% with 35 ml of 1.5% Mepivacaine.15 Reasons behind the variations between the two studies could be due to different drug deposition site. They deposited local anesthetics only in corner pocket but in our study we deposited in caudal and posterolateral to brachial plexus.<sup>15</sup> Puspender et al. also had showed that 15 ml of 0.5% Ropivacaine led to success rate of 93.1% in peripheral nerve block without clinically apparent deterioration in block onset, duration and respiration and they had two cases of failure of the block.<sup>16</sup>

In the present study, incidence of hemidiaphragmatic paresis was more in the patients who received 25 ml of 0.75% Ropivacaine compared to those patients who received 20 ml of 0.75% Ropivacaine for USG-guided supraclavicular BPB. Incidence of diaphragmatic hemiparesis in our study with 20 ml of 0.75% Ropivacaine was more compared to a study conducted by Renes et al.<sup>12</sup> None of the 30 patients in Renes et al. study showed

complete or partial paresis of the hemidiaphragm, but in our study five patients (16.67%) had partial diaphragmatic hemiparesis.<sup>12</sup> These variations of hemidiaphragmatic paresis could be due to the individual observer variations regarding the drug deposition in caudal and posteriolateral to brachial plexus. Our results were also contradictory to Petrar et al. in which eleven (34%) of 32 patients showed complete paresis of the hemidiaphragm and they had used a higher volume of Ropivacaine, but in our study none of the patients had complete paresis who received 20 ml of 0.75% Ropivacaine.<sup>11</sup> However, two patients (6.67%) had complete diaphragmatic hemiparesis who received 25 ml of 0.75% Ropivacaine. The injection techniques, depositions site and the volume of the local anesthetic drugs used were different compared to our study. In the study conducted by Petrar et al. drug was injected via proximal approaches to brachial plexus structures and the phrenic nerve is in closer proximity to brachial plexus.<sup>11</sup>

In a study by William et al. incidence of diaphragmatic hemiparesis was more as compared to our study.<sup>2</sup> About 40-60% patients in their study showed paresis of hemidiaphragm after 30 minutes of drug injections, but in our study none of the patients had complete paresis who received 20 ml of 0.75% ropivacaine.<sup>2</sup> The reasons behind the variations of diaphragmatic hemiparesis between two study could be higher volume of local anesthetics deposited in brachial plexus in the study conducted by William et al. compared to our study.<sup>2</sup> Similarly a drug injections technique was also different compared to our study. Drug was deposited lateral to the subclavian artery and cephalad to the first rib in close proximity to the hypoechoic neural structures of the brachial plexus in their study.<sup>2</sup> Similarly, a study conducted by Jeon et al. showed that incidence of complete diaphragmatic hemiparesis was more compared to our study.15 About 6.67% patients in their study had complete paresis of the hemidiaphragm after 30 minutes of drug injection, but in our study, none of the patients had complete paresis of hemidiaphragm who received 20 ml of 0.75% Ropivacaine.<sup>15</sup> These variations in diaphragmatic hemiparesis using same volume of local anesthetics could be due to drug injections techniques, drugs deposition site, and drugs itself and concentrations.

Brachial plexus block associated phrenic nerve palsy may be well tolerated in patients who are not having significant respiratory disease. However, in patients with significant pulmonary or other comorbid conditions, inadvertent phrenic nerve palsy may be poorly tolerated and necessitate further testing and possibly a need for medical intervention. In our study two patients had complete diaphragmatic hemiparesis without hemodynamic deterioration with 25 ml of 0.75% Ropivacaine after 30 minutes of injection. In the study conducted by Petrar et al. 11 (34%) patients had complete diaphragmatic hemiparesis with 30 ml of 0.5% Ropivacaine after 30 minutes of injection. However any patients with complete diaphragmatic hemiparesis didn't had the features of respiratory compromise.<sup>11</sup> The reason behind the same result in both studies could be due to none of the patients in both studies have significant respiratory disease.

This study had some limitations. The local anesthetic drug was injected in such manner that it remained confined caudal and posterolateral to the brachial plexus. This study was conducted on right side, so the result of this study may not be applicable to the left sided block. This study was undertaken using 0.75% Ropivacaine; therefore, the findings of the present study cannot be extrapolated to other local anesthetics concentration with or without added adjuvants. As some studies have shown success with even lower volumes than 20 ml, minimizing the volume even further without a concomitant decrease in clinical success rate could be a possibility.

## CONCLUSION

The present study concludes that patient who received lower volume of local anaesthetics (20 ml of 0.75% Ropivacaine) had less incidence of hemidiaphragmatic dysfunction with similar successful rate of blockage (100%) as compared to the patients who received higher volume of local anaesthetics (25 ml of 0.75% Ropivacaine). Further studies with large sample sizes are warranted to validate these findings.

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