

Hemi-diaphragmatic paresis following extrafascial versus conventional intrafascial approach for interscalene brachial plexus block: A double-blind randomised, controlled trial

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ABSTRACT

Background and Aims: Hemidiaphragmatic paresis occurs in almost all patients undergoing interscalene block for proximal upper limb surgeries. This study tested hypothesis that ultrasound-guided extrafascial approach of interscalene block under nerve stimulator guidance reduces incidence of hemidiaphragmatic paresis in comparison to intrafascial approach by achieving same degree of anaesthesia and analgesia. **Methods:** Sixty patients undergoing proximal upper limb surgeries were randomised to receive an ultrasound-guided interscalene brachial plexus block (ISB) with the aid of nerve stimulator for surgical anaesthesia and analgesia using 20 mL 0.5% ropivacaine by extrafascial (Group E) or intrafascial (Group I) approach. The incidence of hemidiaphragmatic paresis was measured by M-mode ultrasound before and 30 min after the procedure. Secondary outcomes such as respiratory functions (forced vital capacity, forced expiratory volume in 1 s and peak expiratory flow rate) were measured, and complications were recorded and compared. The statistics was obtained using SPSS Version 19. Levene's test and paired and unpaired *t*-test were used. *P* value <0.05 was considered significant. **Results:** The incidence of hemidiaphragmatic paresis was 17% and 46% in Group E and Group I, respectively (*P* < 0.0001). All other respiratory outcomes were preserved in Group E compared with Group I. **Conclusion:** Ultrasound-guided ISB with the aid of nerve stimulator through extrafascial approach reduces the incidence of hemidiaphragmatic paresis and also reduces respiratory function impairment when compared with intrafascial approach.

Key words: Brachial plexus block, diaphragm, interscalene block, peripheral nerve stimulaor, ropivacaine, ultrasound

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INTRODUCTION

Interscalene brachial plexus block (ISB) technique is commonly adopted for intra- and postoperative regional anaesthesia of the upper extremity.^[1,2] Under the guidance of ultrasound, with or without nerve stimulator, successful block can be achieved by reducing the amount of local anaesthetic. This would reduce the complications of ISB. Also, this technique effectively provides surgical anaesthesia and analgesia for surgeries around shoulder, proximal humerus and acromioclavicular joint^[2] but causes hemidiaphragmatic paresis in almost all patients. The hemidiaphragmatic paresis is due to the spread of

local anaesthetic to the phrenic nerve and along the anteromedial surface of the anterior scalene muscle.^[3,4] This side effect is more among the patients suffering from severe respiratory problems, and the benefit

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of regional anaesthesia for such patients is clearly undermined.^[4,5] Attempts being made to reduce the side effects due to ISB have been inconsistent.^[6-8] The occurrence of increasing number of postoperative neurological deficits where ISB method is used to give local anaesthesia has been attributed to harmful needle–nerve contact.^[9] A cadaveric study concluded that difficulty with ultrasound discrimination of tissue layers may contribute to subepineurial injection in as many as 50% of intrafascial ISB procedures.^[10] To explore the important relationship of needle–nerve proximity in the setting of ISB, it is demonstrated that depositing local anaesthetic as far as 8 mm lateral to the brachial plexus sheath during ultrasound-guided ISB can produce excellent surgical anaesthesia and analgesia for various proximal upper limb surgeries.^[11] This extrafascial injection lateral to the nerve roots increases the distance to the phrenic nerve and may therefore reduce the likelihood of its block by the local anaesthetic spread.

In the present randomised, controlled double-blinded trial, we tried to test that ultrasound-guided extrafascial approach of interscalene block with the aid of nerve stimulator reduces incidence of hemidiaphragmatic paresis in comparison to conventional intrafascial approach, by achieving same degree of surgical anaesthesia and postoperative analgesia.

METHODS

This study was registered with Clinical Trials Registry – India (CTRI/2018/02/011651). After Institutional Ethical Clearance, a pilot study was conducted to know the feasibility and practical utility of ultrasound and peripheral nerve stimulator-guided technique. After getting convinced from pilot study in terms of patient safety and success rate of this new technique, the present study was conducted from January 2018 to December 2018. After obtaining informed consent from patients, a total of 60 patients between 18 and 70 years, American Society of Anesthesiologists (ASA) physical status I–III and undergoing elective proximal upper limb surgeries of shoulder, proximal humerus, clavicle and acromioclavicular joint were included. Patients who refused to participate in the study, allergic to local anaesthetics, with history of neck surgery or radiotherapy, existing neurological deficit in the upper limb, moderate to severe pulmonary disease, pregnancy and infection in the area were excluded from the study.

Sixty patients were divided into two groups, Group E (extrafascial injection) and Group I (intrafascial injection) with 30 patients in each group using a computer-generated randomisation. All ultrasound-guided ISB was performed before surgery in an operation theatre. These blocks were performed by an independent anaesthesiologist experienced in locoregional anaesthesia, who was not involved in the study protocol. Sealed opaque envelopes containing group allocation were opened before the blocks were performed. Both patient and research assistant (who assesses diaphragmatic excursion, respiratory function and block-related outcome) were blinded from the type of block injection technique.

All the patients were monitored continuously during the procedure for heart rate (HR), non-invasive blood pressure (NIBP) and oxygen saturation (SpO₂). Midazolam 0.05 mg/kg intravenously (IV) was administered for anxiolysis. Oxygen was started through nasal prongs at a rate of 2–3 L/min. Patients were positioned supine with the head turned 30°–45° towards non-operative side, and under all aseptic precautions, skin infiltration of 1–3 mL 1% lignocaine was administered.

The scalene muscles and interscalene brachial plexus were imaged using a 38-mm 13–6 MHz linear array ultrasound probe (LOGIQ e ultrasonography machine; GE Healthcare, California, USA). The C5, C6 and C7 roots were identified.^[12] A 22-gauge 50-mm insulated block needle (Stimuplex R; B Braun Medical AG, Melsungen, Germany) connected to peripheral nerve stimulator (Stimuplex-HNS II A; B. Braun Melsungen AG) was inserted in long axis. The needle was then advanced under ultrasound guidance through the middle scalene muscle towards the brachial plexus sheath which was identified as the linear hyperechoic layer surrounding the C5, C6 and C7 roots of the brachial plexus and block was performed according to group allocation.

In Group E, block needle was advanced with the aid of a nerve stimulator at an initial current of 0.7 mA and gradually reduced to 0.5 mA until it elicited motor responses (deltoid twitch). The needle was then slightly withdrawn for about 3–4 mm from the sheath. As per on-screen calliper measurement, the needle tip was placed 4 mm lateral to the brachial plexus sheath. It was ensured that the tip is equidistant from C5 and C6 roots. After stabilisation of needle, 20 mL of 0.5% ropivacaine was injected in 5 mL increments

with frequent aspiration so as to avoid intravascular injection [Figure 1].^[13] In Group I, the needle tip was positioned within the brachial plexus sheath equidistant from C5 and C6 nerve roots, and a similar block injection technique was used as in Group E. The needle tip was not repositioned except if patients complained of paraesthesia or deltoid muscle twitch with current of less than or equal 0.2 mA.

Hemidiaphragmatic excursion was assessed 30 min before and after the block procedure with a low-frequency 1–5 MHz curvilinear transducer in a longitudinal semi-coronal plane using a subcostal approach.^[14] The hemidiaphragmatic paresis was defined as hemidiaphragmatic excursion reduction of more than 75% compared with the preprocedure value.^[15,16] The patients were examined in the supine position, and using ultrasound probe hemidiaphragm was identified as an hyperechoic line with breathing-related movements using the liver or spleen as an acoustic window. The hemidiaphragmatic excursion was measured by real-time M-mode Ultrasonography, and the parameters recorded were excursion with quiet breathing, maximum excursion with deep inspiration and excursion with the sniff test (quick nasal inspiration with a closed mouth) [Figure 2].^[14]

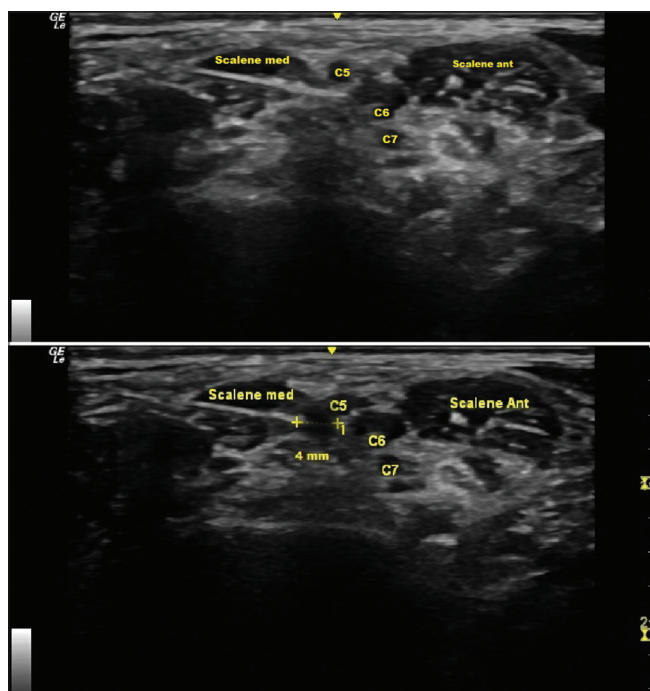


Figure 1: Ultrasound-guided interscalene brachial plexus block. Intrafascial approach (top) and extrafascial approach (bottom). In extrafascial approach, the needle tip placement is 4 mm lateral to brachial plexus sheath

Respiratory functions such as forced vital capacity (FVC), forced expiratory volume in 1 s (FEV₁) and peak expiratory flow rate (PEFR) were also assessed 30 min before and after the regional procedure, with a bedside spirometer (EasyOne Air PC mode spirometer; ndd Medical Technologies, Andover, Massachusetts, USA). The patient was instructed, as per the standard procedure, to sit straight and was told to inspire maximally and blow into the device as forcefully as possible. The test was repeated three times and the best values of respiratory parameters (FVC, FEV₁ and PEFR) were recorded.

In the duration of 30 min after local anaesthetic injection, the sensory and motor blocks' quality was assessed regularly at an interval of 5 min. Motor blocking was assessed by testing parameters such as forearm flexion (C6) and arm abduction (C5) (0 – incapacity to overcome gravity; 1 – reduced force compared with contralateral arm; 2 – no loss of force). The sensory

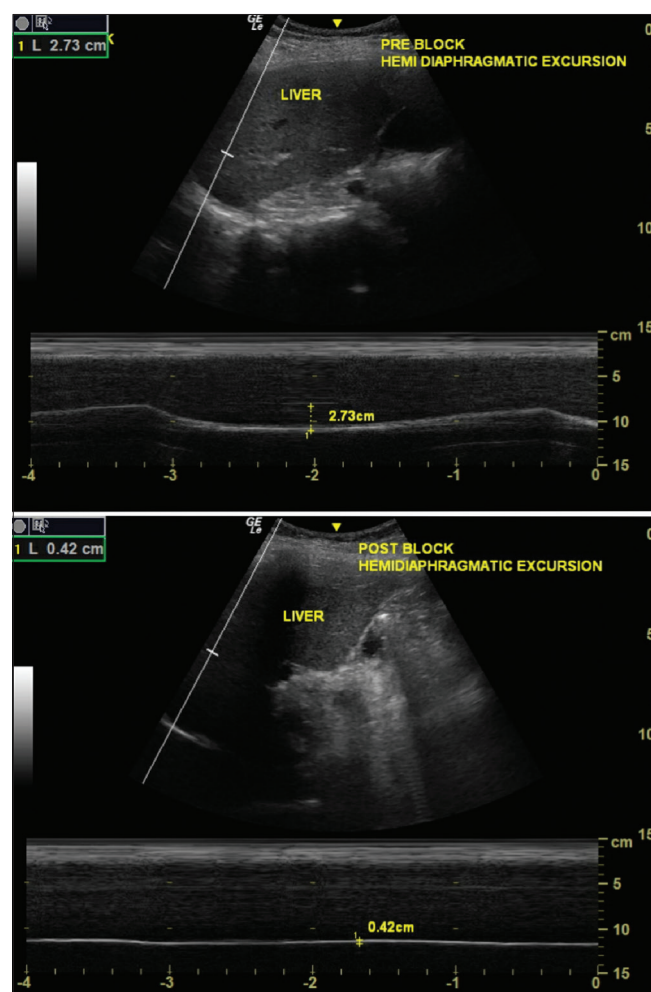


Figure 2: Hemidiaphragmatic excursion assessment by M-mode ultrasonography using subcostal approach during deep breathing before block and after block

block assessed in the dermatome supplied by C5 and C6 roots was tested by pinpricking using a blunt tip needle (0 – no perception; 1 – decreased sensation; 2 – normal sensation). A block is said to be successful when sensory and motor blocks' score is 0 in the C5 and C6 nerve root distribution. This should be achieved within 30 min of performing ISB. A 3-point scale, 0 = complete failure, 1 = inadequate block and 2 = successful block, was used for assessing overall quality of blocks. Intraoperative vital parameters (HR/rhythm/NIBP/SpO₂) were monitored every 5 min throughout the study after interscalene block procedure. All the patients were observed for side effects such as paraesthesia, Horner's syndrome (HS), hoarseness of voice, difficulty in swallowing and other complications such as pneumothorax, vascular injury, neuropathy/nerve injury, intraarterial injection and epidural/spinal injection. The primary outcome was to assess the rate of incidence of hemidiaphragmatic paresis. The secondary outcome was to assess the respiratory function impairment, alteration in block-related outcomes (onset and duration of sensory and motor blocks, pain score at recovery, satisfaction score) and also assessment of complications when injected both extradiscally and intradiscally. The diaphragmatic excursion, respiratory function (FVC, FEV₁ and PEFR), quality of block (onset and duration) and incidence of complications were assessed 30 min after block injection. The duration of analgesia was assessed and compared in both the groups.

OpenEpi software version 2.3.1 was used to calculate the sample size at a confidence level (CI) of 95% and 80% power. It has been reported that^[17] extradiscal needle tip placement has been found to reduce the absolute incidence of ipsilateral hemidiaphragmatic paresis to 50% corresponding to a relative reduction of 35%. Allowing for 10% dropout, the sample size in each group was calculated as $n = 27$ rounded off to 30. SPSS version 19 was used to generate statistics data. The continuous and categorical variables were presented as frequencies and mean values, respectively, at 95% CI. Using Levene's test, equality of variance was determined. Comparison of continuous parametric data between the two groups was done using unpaired *t*-test. Paired *t*-test was used within the group. $P < 0.05$ is considered significant.

RESULTS

The study included 60 patients. One patient was excluded from analytic list due to inadequate block

in Group E and general anaesthesia was administered for this patient. A total of 59 patients were included for statistical analysis, of which 29 and 30 belonged to Group E and Group I, respectively. Patients in both the groups were of comparable demographic variables such as gender, age, height, weight, ASA status and duration of surgery [Table 1].

The incidence of hemidiaphragmatic paresis was reduced in Group E which had 17% (95% CI) compared with Group I which had 46% (95% CI) having a significant *P* value of <0.0001 [Figure 3]. Reduction in percentage of respiratory outcomes such as FVC in Group E was 16.29% and in Group I was 27.80%, FEV₁ in Group E was 15.63% and in Group I was 26.13% and PEFR in Group E was 8.64% and in Group I was 25.05%. These respiratory outcomes were preserved in Group E when compared with Group I in reference to preprocedural values with significant *P* value of <0.0001 [Table 2]. Group I patients had faster onset of sensory and motor blocks when compared with Group E with significant *P* value of <0.0001 . But the duration of sensory and motor blocks almost remained the same, hence insignificant. It was also observed

Table 1: Demographic variables of extradiscal group and intradiscal group

	Extradiscal group	Intradiscal group	<i>P</i>
Gender (male/female)	20/9	20/10	0.08
Age (years) (mean±SD)	37.69±17.11	39.37±15.30	0.64
Height (cm) (mean±SD)	166.28±8.28	166.57±8.83	0.10
Weight (kg) (mean±SD)	69.21±7.20	70.03±6.05	0.19
ASA (I/II) (mean±SD)	20/9	16/14	0.19
Duration of surgery (min) (mean±SD)	84.83±24.65	90.83±25.38	0.36

SD – Standard deviation; ASA – American Society of Anaesthesiologists. Both groups were comparable with $P>0.005$

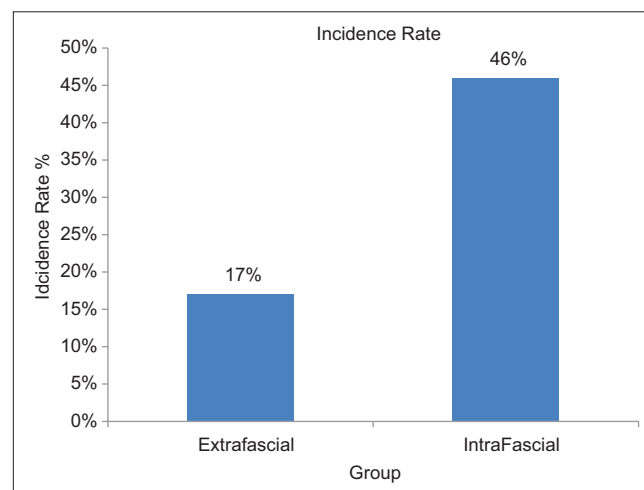


Figure 3: Incidence of hemidiaphragmatic paresis between two groups

that pain score and satisfaction score remained the same in both the groups with insignificant *P* value (0.334 and 0.001, respectively). In Group I, patients had paraesthesia in 31% of cases during the procedure and hoarseness was seen in 31% of cases 30 min after the procedure. Whereas in Group E, paraesthesia was not observed and hoarseness was observed in 3.4% of cases. HS was also seen in both the groups but observed relatively more in Group I with 27.4% [Table 3].

DISCUSSION

In the present study, we have demonstrated that the local anaesthetic drug injected extrafascially with the aid of ultrasound and peripheral nerve stimulator guidance for ISB reduces the rate of hemidiaphragmatic paresis and also reduces respiratory function impairment. The incidence of hemidiaphragmatic

paresis in our study yielded 17% in the extrafascial group and 46% in the intrafascial group which is less and consistent with a similar study done by Palhais *et al.* In this study, 40 patients were posted for shoulder and clavicle surgeries under general anaesthesia and ISB brachial plexus block was given for the purpose of analgesia only. They observed an incidence of 21% hemidiaphragmatic paresis following extrafascial injection of 20 mL of 0.5% bupivacaine with epinephrine 1:200,000 [Figure 3].^[13,18] In our study, block was administered for both surgical anaesthesia and analgesia. In the same study, they also observed that respiratory function was better preserved in the extrafascial group which was concordant with our study.

It is reported that the conventional intrafascial approach of ISB block accounts for nearly 100% of hemidiaphragmatic paresis.^[3] This is mainly attributed

Table 2: Respiratory-related outcomes

	Intrafascial injection	Extrafascial injection	<i>P</i>
Preprocedure	Mean±SD	Mean±SD	
Forced vital capacity (L)	4.4753±0.5140	4.5952±0.2081	
Forced expiratory volume in 1 s (L)	3.5307±0.3904	3.7093±0.2300	
Peak expiratory flow (L/s)	8.2020±0.8218	8.2128±0.5981	
Post procedure	Mean±SD	Mean±SD	
Forced vital capacity (L)	3.2310±0.4810	3.8466±0.2798	0.0001
Forced expiratory volume in 1s (L)	2.6080±0.3887	3.1293±0.2935	0.0001
Peak expiratory flow (L/s)	6.1470±0.7713	7.5003±0.6710	0.0001
Percentage reduction			
Forced vital capacity (%)	27.804	16.291	0.0001
Forced expiratory volume in 1 s (%)	26.132	15.636	0.0001
Peak expiratory flow (%)	25.054	8.674	0.0001

SD – Standard deviation. Data are presented as mean and at 95% confidence interval. Respiratory outcomes such as forced vital capacity, forced expiratory volume in 1 s, and peak expiratory flow rate better preserved in extrafascial group compared with intrafascial group

Table 3: Block-related outcomes and complications

	Intrafascial group	Extrafascial group	<i>P</i>
Block-related outcomes	Mean±SD	Mean±SD	
Onset of sensory block (min)	10.20±2.310	17.93±1.866	0.0001
Onset of motor block (min)	7.10±1.936	15.69±2.625	0.0001
Duration of sensory block (min)	957±136.991	934.14±80.761	0.442
Duration of motor block (min)	1078±149.260	995.17±71.948	0.009
Pain scores in recovery room (NRS 0-10)	0.00±0.00	0.00±0.00	
Pain scores at 6 h (NRS 0-10)	1.30±0.596	1.45±0.568	0.334
Satisfaction score (NRS 0-10)	9.477	9.186	0.001
Complications			
Paraesthesia (rate)	31%	0%	
Hoarseness (rate)	31%	3.4%	
Horner's syndrome (rate)	27.6%	20.7%	
Pneumothorax	0	0	
External Jugular Vein/intra arterial puncture	0	0	
Epidural or spinal injection	0	0	
Nerve injury	0	0	

SD – Standard deviation; NRS – Numerical Rating Scale for Pain. Data are presented as mean and at 95% confidence interval

to the involvement of phrenic nerve of C4 root with varying contributions from C3 and C5. As it courses downward between the ventral surface of the anterior scalene muscle and prevertebral fascia layer that covers this muscle and is separated from the brachial plexus only by a thin fascia layer. Its block in ISB can be explained by the proximity to the brachial plexus or to the cranial spread of local anaesthetic to the C3–5 roots of the cervical plexus before their formation of the phrenic nerve.^[4] Sinha *et al.* observed that decreasing the volume for interscalene block from 20 to 10 mL did not reduce the incidence of hemidiaphragmatic paresis or impairment in pulmonary function. No significant differences in quality or duration of analgesia were observed.^[8]

Another study done by Riazi *et al.* on 40 patients who were posted for shoulder surgery under general anaesthesia were administered reduced dose (5 mL) of 0.5% ropivacaine for ISB observed that there was reduction in incidence of diaphragmatic paresis to 45%.^[7] In our study, we were able to achieve lowest incidence of diaphragmatic paresis (17%) for extrafascial approach with 20 mL of 0.5% ropivacaine, without compromising analgesia.

It has been suggested based on the anatomic characteristics that lowering of incidence can be achieved by reducing the volume of local anaesthetics^[17,19,20] or by placing the tip of the needle away from C3–5 roots.^[18] The distance of 4 mm from the brachial plexus sheath has been observed to be effective.^[11,18] Albrecht *et al.* have observed 90% success rate by maintaining 4 mm needle to nerve sheath distance under the guidance of ultrasound. Whereas in our study, 97% (29 of 30 patients) of success rate has been achieved by maintaining the same 4-mm needle to nerve sheath distance under both ultrasound and peripheral nerve stimulator–guided ISB block.

On observation, effective surgical anaesthesia and analgesia was obtained in both the groups. It was seen that in Group E patients, the onset of both sensory and motor blocks took a substantially longer period of time to attain but was insignificant for surgical anaesthesia and analgesic purpose, while the duration of sensory and motor block was almost similar in both the groups. These results were comparable with a study conducted by Palhais *et al.*^[18] The prolonged onset of block when injected extrafascially is due to the time taken by the drug to diffuse through fascia to nerve root. The postoperative analgesia was effective and similar in both the groups.

Conventional intrafascial approach was associated with significant postoperative complications such as paraesthesia (31%), hoarseness (31%), and HS (27.6%) in comparison to extrafascial approach of ISB which were comparable to a study by Jadon *et al.*^[21]

The present study of extrafascial approach has the following limitations. First, it does not include the prediction of risk of developing hemidiaphragmatic paresis by the patients. Second, the duration of hemidiaphragmatic paresis and respiratory functions were not measured after surgery and third, our study was done in patients without any respiratory insufficiency. Therefore, to validate the results of extrafascial approach, future clinical trials on patients with respiratory compromise may be carried out.

CONCLUSION

When compared with conventional intrafascial approach, ultrasound and peripheral nerve stimulator–guided extrafascial approach of ISB is found to reduce the incidence of hemidiaphragmatic paresis and in turn respiratory function impairment.

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Conflicts of interest

There are no conflicts of interest.

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