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Original Research Article

A Comparative, Randomized Controlled, Double Blind Trial of Extrafascial and Intrafascial Injection for Interscalene Brachial Plexux Block in Reduction of Hemidiphragmatic Paresis

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Abstract

Aim: comparative analysis of extrafascial and intrafascial injection for interscalene brachial plexux block in reduction of hemidiphragmatic paresis.

Methodology: This prospective Randomized Controlled, Double-Blind study was conducted in the Department of Anaesthesiology, MDM Hospital and MG hospital both affiliated to Dr. S.N. Medical College, Jodhpur, at Rajasthan after getting approval from ethical committee 50 patients 25 in each group. aged between 18 – 85 years of either sex belonging to ASA class I-III posted for elective surgeries of shoulder and upper humerus at our institute were randomly selected for the study. Study population (50 patients) were randomly divided by computer generated numbers into 2 groups with 25 patients in each group. **Group-E:** Extrafascial Injection Group. **Group-I:** Intrafascial Injection Group

Results: The rate of hemidiaphragmatic paresis was significantly reduced in the extrafascial injection group (28%) compared with the conventional injection group (100%]; P<0.0001) There was no significant difference in hemidiaphragmatic paresis and pulmonary function test at 30 minutes and at the end of surgery in both groups. All respiratory outcomes were significantly preserved in the extrafascial injection group. A conventional injection was associated with a faster onset and longer duration of post op analgesia.

Keywords: Extrafascial and Intrafascial Injection, Interscalene Brachial Plexux Block, Hemidiphragmatic Paresis.

Introduction

Regional anaesthesia or peripheral nerve block has grown in popularity and its use expanded from operation theater to postoperative recovery room, it decreases

the post operative pain, it also decreases the incidence of nausea, shorten the post anaesthesia care unit time, so patient satisfaction is more with regional anaesthesia.

Regional anaesthetic techniques have specific advantages both for standalone anaesthesia and as analgesic supplements for intra operative and post operative care. These techniques provide better quality acute pain control and subsequently less chronic pain[1]. Previously peripheral nerve block was used only in adults and selected group of patients, but now a days it can be used for all age groups with appropriate selection of patients and sedation.

Selection of regional anaesthesia technique depends on the surgical site, anticipated duration of surgery, post operative ambulation requirements and desired duration of postoperative pain control. Duration of surgery influences both selected technique and local anaesthetic agent used[2]. Ultrasound is a non-invasive technique which can show the relationship of nerves to surrounding structures in the living subject without morbidity. It is valuable anesthesiologist's modern armamentarium for ultrasound guided regional anaesthesia[3] because it illustrates individual anatomy in the living subjects and continually reinforces the anatomical relationship used when performing the nerve blocks which has revolutionized the regional anaesthesia field. The advent of ultrasound guidance for peripheral nerve blockade (PNB) has enabled providers to position the needle tip purposefully as close as possible to[4,5] and even inside[6,7] the target nerve. Ultrasound for interscalene brachial plexus block with excellent localization of the structure and drug spread, proper assessment of needle-tip position[8].·this increases the success rate, reduces the risk of complications and may also reduce the amount of local anaesthetics required.

If the surgical procedure is prolonged or postoperative analgesia is needed, continuous perineural infusion of the local anaesthetic agent can be used via a percutenious catheter. Regional anaesthesia has not only provided surgical anaesthesia and analgesia, but it also used to treat chronic pain syndromes involving the extremities and trunk[9] e.g. sympathetic ganglion blocked.

The aim of present study was to test the hypothesis that "USG guided extrafascial injection for interscalene brachial plexus block reduces hemidiaphrametic paresis compared with a conventional intrafascial injection" yet providing similar analgesia.

Materials and Methods

After approval from institutional ethical committee, the current study was conducted in the Department of Anaesthesiology, Dr. S. N. Medical College and Attached Group of Hospitals, Jodhpur. Fifty patients were selected from the patients posted for elective upper limb orthopedic surgery under interscalene block as per our institutional protocol, after confirming all inclusion and exclusion criteria. A written informed consent was obtained from all the patients for performance of block after complete explanation about the study protocol, anaesthetic technique, merits and demerits of the procedure in perioperative course of anaesthesia.

Design of study: A prospective, comparative, randomized controlled, double blind study.

Place of study: The study was conducted under the Department of anaesthesia, MDM Hospital and MG hospital both affiliated to Dr. S.N. Medical College, Jodhpur.

Sample size: 50 (25 in each group)

Participants: patients posted for shoulder and proximal humerus surgeries.

Inclusion criteria: Patients of both sexes aged 18 – 85 years of ASA class I- III posted for elective surgeries of shoulder and upper humerus.

Exclusion criteria:

1. Patient refusal
2. Localized sepsis
3. Allergy to local anesthetic drugs
4. History of bleeding disorder
5. Patients on anticoagulant therapy
6. Existing neurological deficit in the upper limb
7. Psychiatric illnesses
8. History of neck surgery or radiotherapy
9. Pregnancy
10. Moderate to severe pulmonary disease

Methodology

The study groups: A total of 50 patients were included in our study which was divided into two groups of 25 patients each using a computer-generated randomization table. The procedure of giving USG guided interscalene block was performed in operation theatre by an independent anesthesiologist experienced in regional anaesthesia who were included in the study. Group allocation was done in sealed opaque envelopes which were opened just before the procedure. The patient, the anaesthetist incharge of the patient in the operating room, PACU nurse, post-operative ward nurse and research assistant measuring the respiratory function, block related outcomes and other data were blinded to the group allocation.

- **Group-E**: EXTRAFASCIAL INJECTION GROUP- The needle tip was positioned 4 mm lateral to the brachial plexus sheath, at the level of C5 and C6 nerve roots. The distance of 4 mm is chosen according to the calculated success rate over 90% reported in previous study[10].
- **Group- I:** INTRAFASCIAL INJECTION GROUP- The needle tip was positioned within the brachial plexus sheath at the level of C5 and C6 nerve roots.

All patients undergone spirometry and hemidiaphragmatic assessment both pre and post procedure and onset of sensory and motor block was assessed before inducing GA.

All the selected patients were premedicated with injection Midazolam 0.03 mg/kg IV, 5 minutes before the procedure to reduce anxiety. All the baseline parameters including SPO2, NIBP, Pulse rate and respiratory rate were recorded. An 18 G IV cannula established, and the patient preloaded with 10-15 ml IV Fluid.

Drug administration

Under strict aseptic precautions and after local infiltration of 2ml (2%) lidocaine, the scalene muscles and interscalene brachial plexus was located by using USG (SonoSiteFUJIFILM M-Turbo) with high frequency linear probe (placed superior and parallel to clavicle), the C5, C6 and C7 roots was identified and then 20ml of inj. Ropivacaine (0.5%) drug solution was injected by using peripheral nerve stimulator needle (22G,5cm long) connected with peripheral nerve stimulator after negative aspiration for blood. Separation of the brachial plexus cords were seen on screen.

Interscalene block was performed according to types of blocks. In group-E the extrafascial interscalene block, the needle tip was placed outside the brachial plexus sheath. In this method, the needle tip will be advanced within the brachial plexus sheath and then motor responses (deltoid twitch) elicited with the help of a nerve stimulator, by using an on-screen calliper then the needle was slightly withdrawn about 4 mm from the brachial plexus sheath equidistant from C5 and C6 roots, While in group-I the intrafascial Interscalene block, the needle tip was

positioned within the brachial plexus sheath equidistant from C5 and C6 nerve roots.

Assessment of hemidiaphragm paresis

Hemidiaphragmatic paresis was assessed before the procedure (the interscalene block), 30 min after and after surgery by performing with a low-frequency curvilinear transducer (SonoSite-FUJIFILM M-Turbo) in a longitudinal semi-coronal plane using a subcostal approach. Briefly, the patients were examined in the lying position and the hemidiaphragm will be identified on USG as a 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 from the resting expiratory position to a deep and quiet inspiration position.

Assessment of block

Motor and sensory Assessment of sensory and motor blocks was assessed every 5 min after the interscalene nerve block performed, for the total duration of 30 min. Sensory block assessment was done in the C5 and C6 dermatomes using blunt tip pinprick test (0- no perception, 1-decreased sensation, 2-normal sensation). The motor block assessment was done by testing parameters such as arm abduction(C5), and forearm flexion (C6) (0-incapacity to overcome gravity,1-reduced force compared with contralateral arm, 2- no loss of force).

Respiratory function assessment

Respiratory functions such as FVC, FEV1 and PEFR were performed using bedside portable SPIROMETER SP10Bt assessed pre-procedure postprocedure at 30 min and after surgery**,**

Pain assessment

The numerical rating scale (NRS) is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line which contains 11-point numeric scale ranges from '0' representing one pain extreme (e.g. “no pain”) to '10' representing the other pain extreme (e.g. “pain as bad as you can imagine” or “worst pain imaginable”). NRS for pain will be assessed during rest (NRS-R) and movement (NRS-M) at predefined intervals at 2, 4, 6, 8, 10, 12, 16 and 24 h postoperatively. The data collected from all the patients in the study was subjected to appropriate statistical techniques to assess the level of significance and the difference between two groups.

Results

This study has been conducted at tertiary care centre and total 50 adults patients of either sex of ASA I-II, age between 18 -80 years scheduled for proximal humerus and shoulder surgery were enrolled and after completion of cases results of 50 patients devided in to two groups (25 in each group) statistically analysed. Statistical analysis was done by using descriptive and inferential statistics using chisquare test and Student’s unpaired t test and software used in the analysis were SPSS 24.0 version and GraphPad Prism 7.0 version and p value <0.05 is considered as level of significance.

Table 1: Assessment of block in Extrafascial group and Intrafascial group

Assessment of block	Extrafascial Group		Intrafascial Group		t-value	p-value
	Mean	SD	Mean	SD		
Onset of Sensory Block	15.44	2.08	13.12	1.61	4.40	0.0001, S
Onset of Motor Block	18.16	2.21	15.36	1.91	4.78	0.0001, S

Above table shows that the onset time of sensory block and onset time of motor block between extrafascial and intra fascial group were found as statistically significant (p <0.05).

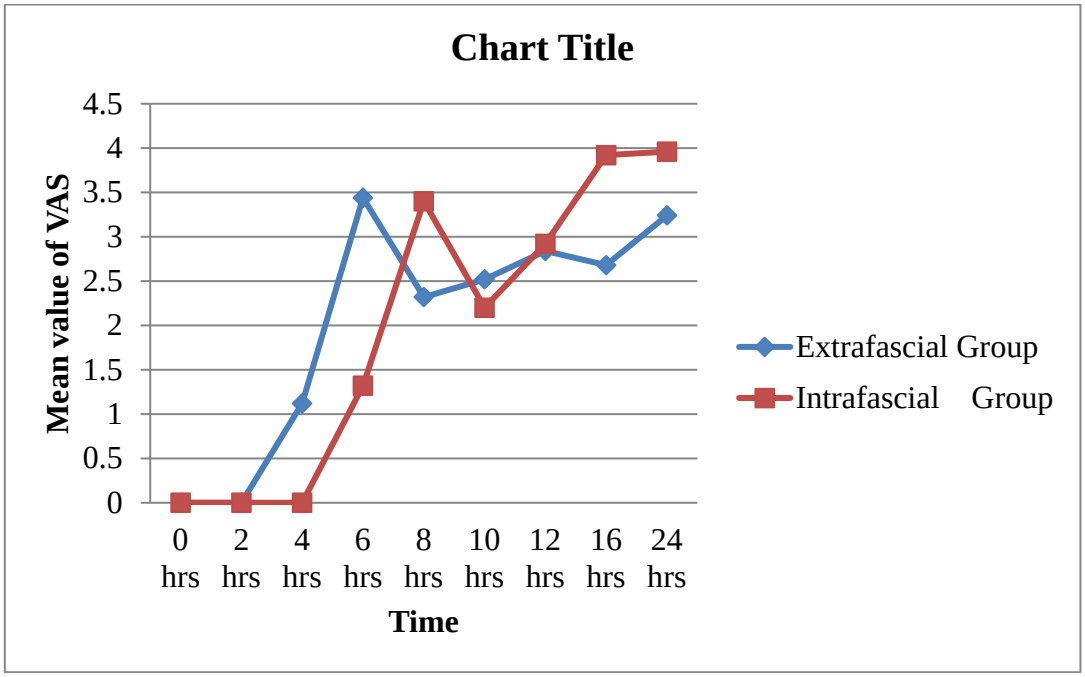

Figure 1: Comparison of VAS score during movement in Extrafascial group and Intrafascial group

Above graph shows that VAS score during movement in Extrafascial group and Intrafascial group was found as statistically significant (p<0.05) 4 hour after completion of surgery. But for first 4 hours it was found as statistically not significant (p>0.05).

Table 2: Comparison of mean time required for first resque analgesia in Extrafascial group and Intrafascial group

Time required for first resque analgesia	Extrafascial Group		Intrafascial Group		t-value	p-value
	Mean	SD	Mean	SD		
	6.56	1.22	8.48	1.04	5.95	0.0001, S

Above table shows that mean time required for first resque analgesia in Extrafascial group and Intrafascial group was found as statistically significant (p<0.05)

Table 3: Comparison of Diaphragmatic Movement of Extrafascial group and Intrafascial group

Time	Diaphragmatic Movement								P value
	Extra facial				Intra facial				
	Present		Absent		Present		Absent		
	N	%	N	%	N	%	N	%	
Pre Pro	25	100.00	0	0.00	25	100.00	0	0.00	-
O min	25	100.00	0	0.00	25	100.00	0	0.00	-
30 Min	18	72.00	7	28.00	0	0.00	25	100.00	<0.0001
End of Sur.	18	72.00	7	28.00	0	0.00	25	100.00	<0.0001

The above table shows that the Diaphragmatic Movement of the Extrafascial group and the Intrafascial group was found as statistically not significant (p>0.05) at pre-procedure and 0 min. while at 30 min and end of surgery it was found as statistically significant (p<0.05)

Table 4: Comparison of FEV1 both groups

Time	FEV1				t-value	p-value
	Extrafascial Group		Intrafascial Group			
	Mean	SD	Mean	SD		
Pre-Procedure	3.3	0.5	3.11	0.7	1.12	0.26**, NS**
Post-Procedure at 30 min	2.7	2.15	2.15	0.51	3.277	0.002, S
At the end of Surgery	2.65	0.56	2.1	0.49	3.64	0.001, S
% Reduction at 30 min	17.88	8.85	30.48	2.77	6.78	0.0001, S
% Reduction at the end of Sur.	19.48	8.75	31.28	2.8	6.41	0.0001, S

Discussion

Regional anesthesia has an established role in providing perioperative analgesia for shoulder surgery. However, phrenic nerve palsy is a significant complication that potentially limits the use of regional anesthesia, particularly in high-risk patients[11]. Patients who are operated for shoulder surgery, around 70% of these patients experiences severe post operative pain that is poorly controlled by opiods alone. Effect of severe pain last over 48 hours[12].

The ISB produce effective pain relief (analgesia) lasting 6-8 hours following shoulder surgery. It also reduces opioid analgesic requirement and decreases incidence of postoperative nausea and vomiting triggered by opioid analgesics in post-surgery period. ISB can also promote early recovery and improves arthroscopic shoulder surgery performance on an ambulatory (same day) basis[13]. Nowadays it is considered as gold standard for pain relief following shoulder surgery. The recent advances with use of ultrasound (US) imaging for ISB allowed the technique to be refined, by reducing the incidence of ISB complications (e.g. unintentional vascular puncture), the number of attempts (needle passes), the volume of local anesthetics required, and has increased ISB success rates.

In our study, the mean onset of sensory block in extrafascial ISB and intrafascial ISB group was 15.44 minutes (SD- 2.08) and 13.12 minutes (SD- 1.61) and the difference in onset of sensory blockade in both group was found as statistically significant (P<0.05).

In previous study Ayyanagouda B *et al* [14] found the mean onset of sensory block in extrafascial ISB and intrafascial ISB group was 19.25 minutes (SD- 2.24) and 12.35 minutes (SD- 1.84) and the difference in onset of sensory blockade in both group was found as statistically significant (P<0.05). This was comparable in both study.

In our study, the mean onset of motor block in extrafascial ISB and intrafascial ISB group was 18.16 minutes (SD- 2.21) and 15.36 minutes (SD- 1.91) and the difference in onset of motor blockade in both group was found as statistically significant (P<0.05).

In previous study Ayyanagouda B *et al*[14] found the mean onset of motor block in extrafascial ISB and intrafascial ISB group was 17.2 minutes(SD- 1.54) and 8.35 minutes (SD- 2.41) and the difference in onset of motor blockade in both group was found as statistically significant (P<0.05). The above data

shows delayed onset of sensory and motor blockade in extrafascial ISB group in comparison to intrafascial ISB group.

In previous study T. Sivashanmugam et al[15] also found similar results that local anaesthetic injected deep to the "brachial plexus sheath", under ultrasound-guidance, is associated with faster onset of surgical anesthesia and prolonged duration of postoperative analgesia than an injection superficial to the sheath.

In our study, the movement of diaphragm was absent in 7 patients (28%) and 25 patients (100%) in extrafascial ISB and intrafascial ISB group respectively and the difference in absent of diaphragmatic movements was found as statistically significant (P<0.05). In previous study they also found that an extrafascial injection reduces the rate of hemidiaphragmatic paresis. They found movement of diaphragm was absent in patients 5 (25%) and 19 patients (95%) in extrafascial ISB and intrafascial ISB group respectively.

In our study, the time required for first rescue analgesia between intrafascial ISB and extrafascial ISB was 6.56 hours (SD-1.22) and 8.48 hours (SD-1.04) respectively; t value was 5.95,which was found as statistically significant (P<0.05).

In our study, we found that FVC reduction at 30 minutes was 30.96% (SD-3.7) and 19.4% (SD-8.67) in intrafascial ISB and extrafascial ISB group respectively whereas FVC reduction at the end of surgery was 32.16 (SD-2.6) and 20.48% (SD-8.77) in intrafascial ISB and extrafascial ISB group respectively at end of surgery which was found as statistically significant (P<0.05).

In previous study. Ayyanagouda B *et al* [14] they also found similar results that an extrafascial injection hs reduced impact on respiratory function, They found that FVC reduction at 30 minutes was 33% (SD-3.62) and 15.86% (SD-2.35) in intrafascial ISB and extrafascial ISB group respectively which was found as statistically significant (P<0.05). Thus both study was comparable.

In our study, we found that FEV1% reduction at 30 minutes was 30.48% (SD-2.77) and 17.88% (SD-8.85) in intrafascial ISB and extrafascial ISB group respectively whereas FEV1% reduction at the end of surgery was 31.28 (SD-2.8) and 19.48% (SD-8.75) in intrafascial ISB and extrafascial ISB group respectively at end of surgery which was found as statistically significant (P<0.05).

In previous study. Ayyanagouda B *et al* [14] found smilar results that FEV1% reduction at 30 minutes was 28.6% (SD-3.11) and 15.75% (SD-2.26) in intrafascial ISB and extrafascial ISB group respectively which was found as statistically significant (P<0.05).Thus both study was comparable.

In our study, we found that PEFR reduction at 30 minutes was 23.92% (SD-2.37) and 13.22% (SD-7.37) in intrafascial ISB and extrafascial ISB group respectively whereas PEFR reduction at the end of surgery was 25.64 (SD-2.41) and 13.56% (SD-7.82) in intrafascial ISB and extrafascial ISB group respectively at end of surgery which was found as statistically significant (P<0.05).

In previous study. Ayyanagouda B *et al* [14] they also found similar results that an extrafascial injection, they found that PEFR reduction at 30 minutes was 23.7% (SD-1.95) and 8.65% (SD-1.75) in intrafascial ISB and extrafascial ISB group respectively which was found as statistically significant (P<0.05). Thus both study was comparable.

Conclusion

The rate of hemidiaphragmatic paresis was significantly reduced in the extrafascial injection group (28%) compared with the conventional injection group (100%]; P<0.0001) There was no significant

difference in hemidiaphragmatic paresis and pulmonary function test at 30 minutes and at the end of surgery in both groups. All respiratory outcomes were significantly preserved in the extrafascial injection group. A conventional injection was associated with a faster onset and longer duration of post op analgesia.

References

1. Wardhan, Richa, and Jacques Chelly. Recent advances in acute pain management: understanding the mechanisms of acute pain, the prescription of opioids, and the role of multimodal pain therapy. F1000 Research: 29 Nov. 2017: 6:2065.
2. Analgesia for day-case surgery N. Rawal *BJA*, June 2001: 87(1):73–87.
3. Suzanne Carty, Barry Nicholls: Ultrasound guided regional anaesthesia, oxford journals, medicine Br J Anesth; CEACCP; 2007; 7; 1:20-24.
4. Gray AT. Ultrasound-guided regional anesthesia: current state of the art. Anesthesiology. 2006; 104:368–373.
5. Franco CD. Reply to Dr Orebaugh et al. Reg Anesth Pain Med. 2013; 38:71.
6. Bigeleisen PE. Nerve puncture and apparent intraneural injection during ultrasound-guided axillary block does not invariably result in neurologic injury. Anesthesiology. 2006; 105:779–783.
7. Bigeleisen PE, Moayeri N, Groen GJ. Extra neural versus intraneural stimulation thresholds during ultrasound-guided supraclavicular block. Anesthesiology. 2009; 110:1235–1243.
8. Ootaki C, Hayashi H, Amano M: Ultrasound-guidedinfra-clavicular brachial plexus block, analternative technique to landmark-guided approaches. RegAnesth Pain Med. 2000; 25:600-604.
9. André P. Boezaart, David C. Warltier; Perineural Infusion of Local Anesthetics. Anesthesiology 2006; 104:872–880.
10. KopaczDJ, Allen HW, Thompson GE: A comparison of epidural levobupivacaine 0.75% with racemic bupivacaine for lower abdominal surgery. AnesthAnalg. 2000; 90: 642–648.
11. Kariem El-Boghdadly, Ki Jinn Chin, Vincent W. S. Chan; Phrenic Nerve Palsy and Regional Anesthesia for Shoulder Surgery: Anatomical, Physiologic, and Clinical Considerations. Anesthesiology 2017; 127:173–191.
12. Garimella, Veerabhadram, and Christina Cellini. Postoperative pain control. Clinics in colon and rectal surgery. 2013:26(3): 191-6.
13. Kalkman JC, Visser K, Moen J, Bonsel JG, Grobbee ED, Moons MKG. Preoperative prediction of severe postoperative pain. Pain. 2003 Oct;105(3):415-423.
14. Ayyanagouda B, Hosalli V, Kaur P, Ambi U, Hulkund S Y. Hemi-diaphragmatic paresis following extrafascial versus conventional intrafascial approach for interscalene brachial plexus block: A double-blind randomised, controlled trial. Indian J Anaesth 2019; 63:375-81.
15. Sivashanmugam T, Ray S, Ravishankar M, Jaya V, Selvam E, Karmakar MK. Randomized Comparison of Extrafascial Versus Subfascial Injection of Local Anesthetic During Ultrasound-Guided Supraclavicular Brachial Plexus Block. Reg Anesth Pain Med. Jul-Aug, 2015;40(4):337-43.