Acta Anaesth. Bel., 2024, 75 (2): *81-90*

Original study

Respiratory effects and analgesic efficacy of different local anesthetic volumes in ultrasound-guided interscalene brachial plexus block for shoulder arthroscopy: Prospective randomized study

S.A. Ahmed[1], M.A. Lotfy[1], M.A. Abduallah[1], A.A. Albadry[1]

[1]*Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine, Tanta University, Egypt.*

Corresponding author: Ahmed. S A. Saied st, Tanta, Al gharbia governate, Egypt.
E-mail: samehabdelkhalik1982@gmail.com

Abstract

Background: **The exact volume of local anesthetics that can be used in interscalene brachial plexus (ISBP) that produce adequate analgesia with minimal effect on phrenic nerve is a matter of debate.**
Objectives: **This study aimed to compare the effect of three different volumes of local anesthetics in (ISBP) on the incidence of diaphragmatic hemiparesis and the postoperative analgesia in patients scheduled for shoulder arthroscopy.**
Design: **Prospective Randomized Double-blind study.**
Setting: **Single-center study.**
Methods: **Seventy-five patients scheduled for shoulder arthroscopy were randomly distributed into three groups according to the volume of levobupivacaine 0.25% used in ISBP block; - (group I: 5 ml), (group II: 10 ml), and (group III: 15 ml).**
Main outcome measures: **The incidence of diaphragmatic hemiparesis (primary outcome) was assessed by ultrasound assessment of diaphragmatic excursion. Moreover, the postoperative pain score and the rescue analgesic consumption were measured (secondary outcomes).**
Results: **The incidence of diaphragmatic hemiparesis or paralysis was higher in group III in comparison to groups I and II (P = 0.019 and 0.037) with no statistically significant difference between groups I and II (P = 0.576). The postoperative pain score was significantly lowered in groups II and III as compared to group I (P < 0.05). The postoperative tramadol consumption was higher in group I in comparison to groups II and III (P = 0.0011 and 0.009) with a non-statistically significant difference between groups II and III (P = 0.577).**
Conclusion: **The use of 10 ml volume of levobupivacaine 0.25% in ISBP block had a lesser incidence of diaphragmatic hemiparesis or paralysis in comparison to the use of 15 ml volume and had a better postoperative analgesic profile in comparison to the use of 5 ml volume.**
Trial registration: **The study was registered at clinicaltrial.gov (I.D: NCT04549779)**

Keywords: **Interscalene, brachial plexus, shoulder arthroscope, diaphragm, excursion.**

This randomized clinical trial was approved by the institutional Ethical committee (Name: Ethical Committee of Faculty of Medicine, Tanta University - Address: Faculty of Medicine, Tanta, Gharbia Governate, Egypt - Protocol number :4017/8/20 – Chairperson: Prof Mona El-Gohary – Date of approval: August 2020) and registered prior to first patient enrolment on ClinicalTrials.gov (ID: NCT04549779).
All the enrolled patients signed an informed written consent to participate in the study after they had received a detailed explanation about the study. The study lasted from September 2020 to August 2022.

Introduction

The interscalene brachial plexus block (ISBP) is one of the most frequently used regional anesthesia techniques in upper extremity surgeries. It is capable of anesthetizing the 5th, 6th, and 7th cervical (C5, C6, and C7) roots of the brachial plexus. So, ISBP block can be used to provide analgesia to the shoulder and lateral aspect of the arm and the forearm[1,2]. However, the use of ISBP block with the standard volume of local anesthetics may be associated with potential complications as phrenic nerve palsy (up to 95%)[3]. Block of phrenic nerve with ISBP block may be explained by the cephalad spread of local anesthetics to C3-5 roots before they formed the phrenic nerve or by the proximity of the phrenic nerve to the brachial plexus[4]. The interscalene brachial plexus block represents the upper limb block which is associated with highest rate of incidence of complications[3].

Block of the phrenic nerve is associated with a considerable decline in the respiratory functions that includes 21–34% decrease in forced vital capacity (FVC), 17–37% decrease in forced expiratory volume in 1st second (FEV1), and 15.4% decrease in peak expiratory flow rate (PEFR). So, the use of ISBP block is restricted in patients with limited pulmonary reserve as those with bronchial asthma, chronic obstructive pulmonary disease (COPD), or elder patients. Unfortunately, patients with a limited respiratory reserve are highly susceptible to the respiratory depressant effects of opioids if the ISBP block cannot be performed[5,6].

Reducing the local anesthetic mixture volume in ISBP block may minimize the phrenic nerve affection and hence minimize the respiratory sequel without affecting the analgesic profile. This randomized clinical trial (RCT) aimed to evaluate the effect of the use of three different volumes of local anesthetic mixture (5 ml, 10 ml, or 15 ml) in ISBP block for patients scheduled for shoulder arthroscopy on the incidence of diaphragmatic hemiparesis (primary outcome), the postoperative pain scores, and postoperative opioid consumption.

Methods

This randomized clinical trial was approved by the institutional Ethical committee (Name: Ethical Committee of Faculty of Medicine, Tanta University - Address: Faculty of Medicine, Tanta, Gharbia Governate, Egypt - Protocol number :4017/8/20 – Chairperson: Prof Mona El-Gohary – Date of approval: August 2020) and registered prior to first patient enrolment on ClinicalTrials.gov (ID: NCT04549779). All the enrolled patients signed an informed written consent to participate in the study after they had received a detailed explanation about the study. The study lasted from September 2020 to August 2022. This study followed the applicable CONSORT guidelines.

Study Participants

Adult patients aged 21-70 years, of both genders, with American Society of Anaesthesiologists (ASA) physical status I-III and scheduled for shoulder arthroscopy were included in this study. Exclusion criteria were consisting of; - refusal of the patient to participate, severe respiratory co-morbidities (COPD or severe bronchial asthma), Body mass index (BMI) > 40 kg/m2, mental dysfunction, known or suspected allergy to the used medications, known or suspected coagulopathy, chronic use of opioids or gabapentoids, and major cardiac, renal, or hepatic disorders.

Study design

The patients were randomly distributed into three equal groups using computer-generated software of randomization introduced into sealed opaque envelopes.

- Group I: patients received Ultrasound-guided (US-guided) ISBP block with 5 ml levobupivacaine 0.25% before induction of anesthesia.
- Group II: patients received US-guided ISBP block with10 ml levobupivacaine 0.25% before induction of anesthesia.
- Group III: patients received US-guided ISBP block with 15 ml levobupivacaine 0.25% before induction of anesthesia.

Study interventions

Adequate preoperative assessment was carried out to all the enrolled patients through history taking, examination, and requesting the appropriate investigations. Moreover, pulmonary function tests (PEFR, FEV1, FVC, and FEV1/FVC) were performed to all patients preoperatively. Once the patient arrived at the operating room, intravenous access was established with starting fluid preload of 7 ml/kg lactated ringer solution. Also, the patient was connected to a monitor device consisting of a pulse oximeter, 5-leads electrocardiogram (ECG), and non-invasive blood pressure monitoring. A nasal cannula at a flow rate of 2-3 L/min was applied to the patient.

All the patients underwent a preoperative US-guided assessment of the diaphragmatic excursion during quiet breathing (3 readings) and deep breathing (3 readings) through the aid of an expert anesthesiologist who was not participating in the study and was blinded to its groups with obtaining

the mean value of the 6 readings. Then, all patients had received midazolam 2 mg i.v with starting US-guided ISBP block technique. An assistant anesthesia resident who was not participating in the study helped in the preparation of the medications and requirement of regional anesthesia technique and the resuscitation equipment. Local anesthetics in the form of 0.25% plain bupivacaine were prepared in different volumes according to the patient's group (5, 10, or 15 ml). The ultrasound machine (Philips CX 50 Compact- Xtreme ultrasound system, Philips; Amsterdam, the Netherlands) was prepared.

Technique of US-guided ISBP block

Under complete aseptic precautions and while the patient was in a supine position with the head turned to the contralateral side, a high-frequency linear probe of the ultrasound (6-12 MHz, Philips CX 50 Extreme edition, Philips) was placed transversely on the neck till the carotid artery can be visualized. Then, the probe was moved slightly lateral and caudal across the neck until the anterior and middle scaleni muscles can be visualized with the element of C5- C6 of brachial plexus located between them. Using the in-plane technique, the needle was directed from lateral to medial direction till it pierced the prevertebral fascia, then, the needle was advanced until its tip reached between the roots of C5-C6. After careful aspiration to exclude intravascular placement of the tip of the needle, the pre-prepared local anesthetic mixture (5, 10, or 15 ml) was injected slowly over 5- 10 minutes.

The patient was monitored closely for 30 minutes during which assessment of the sensory and motor block was carried out. The sensory block was assessed by exposure of the shoulder and the upper arm to a piece of ice (exposure to cold), while, the motor block was assessed by evaluation of the ability of the patient to abduct the shoulder and flex the elbow against gravity (0 = full strength (failed block), 1 = weak ability to abduct the shoulder and flex the elbow (partial block), 2 = inability to abduct the shoulder or flex the elbow (complete block). Preserved sensation to cold and/or absence of motor block after 30 minutes from performing the block was considered as failed block and the patient was excluded from the study. After 30 minutes, ultrasound assessment of the diaphragmatic excursion during both quiet breathing (3 readings) and deep breathing (3 readings) with obtaining the mean of the 6 readings.

Technique of US-guided assessment of diaphragmatic excursion

In a semi-recumbent position, a low-frequency curvilinear probe (2-5 MHz Philips CX50 Compact Xtreme®; Philips) was placed below the costal margin in a longitudinal parasagittal orientation and in the midclavicular line on the right side or in the anterior axillary line on the left side. Using the two-dimensional B-mode, the posterior third of the diaphragm was identified using the liver or the spleen as an acoustic window. The diaphragmatic lines were visualized hyperechoic and curved, then, M-mode was used to evaluate the degree of diaphragmatic excursion through the placement of the first caliper at the apex of the slope of the hyperechoic line and the second caliper at its foot[7]. (Fig. 1). Ultrasound assessment of diaphragmatic excursion was carried out by an operator who was not participating in the study and was blinded to its groups. It was carried out before admission to the operating room and after performing ISBP block and before induction of anesthesia. During each measurement, the mean of 6 readings was obtained (3 readings during quiet breathing and another 3 during deep breathing). The degree of the decrease in diaphragmatic excursion between preblock and after performing the block was calculated. Phrenic nerve paresis was diagnosed when the diagrammatic excursion distance was reduced by more than 25%, while phrenic nerve paralysis was considered when the reduction of the diaphragmatic excursion was more than 75%. Patients who were diagnosed to have diaphragmatic hemiparesis were observed closely with oxygen supplementation.

Induction of anesthesia was carried out after 3 minutes of pre-oxygenation through a well-fitted face mask using 80% oxygen by fentanyl 2 ug/kg, propofol 1-2 mg/kg, and atracurium 0.5 mg/kg. The airway was secured by a suitable sized endotracheal tube with connection of the patient to a mechanical ventilator with its parameters adjusted to maintain end-tidal carbon dioxide 34-38 mmHg. A nasopharyngeal temperature probe was applied, also, bispectral index (BIS) (Covidien, Mansfield, MA, USA) was applied. Anesthesia was maintained by isoflurane 1 MAC (minimum alveolar concentration) in a low flow gas mixture (1 ml/min) composed of oxygen: air 1:1, incremental doses of atracurium was administrated when required, and incremental doses of fentanyl 0.5 ug/kg was administrated when the BIS reading exceeded 60 or increase in heart rate or mean arterial blood pressure more than 20% of the baseline values. The isoflurane was switched off with the end of the surgery with reversal of muscle relaxation by a combination of neostigmine 0.05 mg/kg and atropine 0.01 mg/kg with full awake tracheal extubation. All the patients received dexamethasone 4 mg i.v after induction of anesthesia and ondansetron 4 mg i.v at the end of the surgery for prophylaxis against nausea and vomiting. The

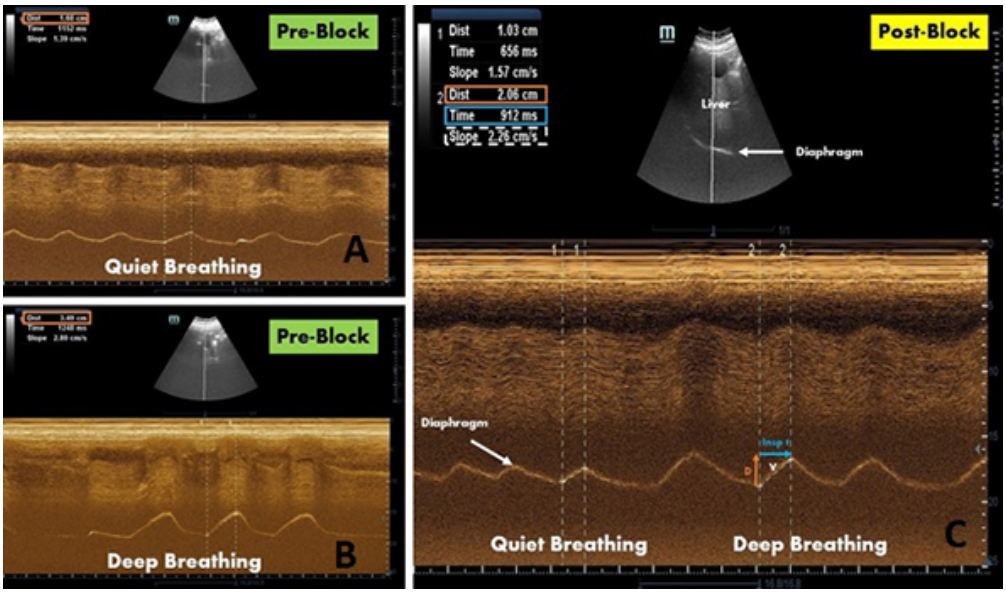

Fig. 1 — Ultrasound guided assessment of diaphragmatic excursion during quiet and deep breathing. Pre-block assessment of diaphragmatic excursion during quiet breathing. B) Pre-block assessment of diaphragmatic excursion during deep breathing. C) Post-block assessment of diaphragmatic excursion during quiet and deep breathing
The diaphragm is examined by M-mode and appears as hyperechoic line. Measurements extend from the baseline to the maximum height. (D) excursion, (Insp t) inspiratory time, and (V) velocity of contraction were recorded during quiet and deep breathing.

patients were transported to the post-anesthesia care unit (PACU) for adequate postoperative monitoring till their modified Aldrete's score reached 10 or more. All the patients had received paracetamol 1 gm i.v infusion /6 hours and ketorolac 30 mg i.v/12 h as routine postoperative analgesia. After discharge of the patients from the PACU, pulmonary function tests (PEFR, FEV1, FVC, and FEV1/FVC) were carried out after exclusion of the effect of sedation by the aid of modified observer's assessment of alertness[8].

Study outcomes

The degree of reduction of the diaphragmatic excursion was recorded by a blinded operator to the study groups who performed the ultrasound assessment of the diaphragm. All other measurements were obtained and recorded by an assistant nurse who did not participate in the study and was blinded to its groups.

The incidence of diaphragmatic hemiparesis or hemiparalysis (primary outcome) was recorded. Postoperative numerical rating score (NRS) (metric score 0-10 for assessment of the severity of pain where 0: no pain and 10: maximal pain) was assessed immediately postoperative, then every 2 h till 8 h, then, every 4 h till 24 h. patient who experienced NRS 4 or more had received rescue analgesia in the form of 30 mg tramadol i.v that can be repeated with calculating the time to the first request of rescue analgesia and the total tramadol consumption on the first day after surgery (secondary outcomes).

Furthermore, the preoperative and postoperative pulmonary function tests were recorded. Moreover, the incidence of perioperative complications as hypotension, bradycardia, hoarseness of voice, Horner syndrome, oxygen desaturation (in absence of oxygen supplementation), or pneumothorax was recorded in the first 24 hours after surgery by the aid of the assistant nurse. On the next day, the patients were asked to grade their degree of satisfaction as regards the postoperative analgesia using a 4-point scale where 4 = very satisfied, 3 = satisfied, 2 = dissatisfied, and 1 = very dissatisfied.

Sample size

The required sample size was calculated using the IBM[a] SPSS[a] Sample Power[a] version 3.0.1 (IBM[a] Corp., Armonk, NY, USA). Sample size calculation based upon the results of a previous study[9] that illustrated that diaphragmatic hemiparesis diagnosed by changes in diaphragmatic excursion occurred in 93% of patients who were presented for shoulder arthroscopy under general anaesthesia and interscalene block at the level of the cricoid cartilage (10 ml or 20 ml of ropivacaine 0.5%) So, at least 19 patients will be required in each group to detect a significant decrease in the incidence of diaphragmatic hemiparesis 30 minutes after performing the block detected by ultrasound assessment of diaphragmatic excursion from 93% to 46.5 % (50% reduction) at 0.05 alpha value, 90 % power of the study, and the ratio of cases to control 1:1:1. Twenty-five patients were included

in each group to overcome the possibility of dropout cases.

Statistics

Statistical analysis of the recorded data was done with the aid of SPSS computer program (SPSS Inc., Chicago, IL, USA). Categorical data were analyzed by Chi-square test and presented as number and frequency, and parametric data were analyzed by one-way ANOVA test and post-hoc Turkey's HSD Test and expressed as mean± standard deviation. The postoperative pain score was expressed as median and interquartile range after analysis by Kruskal-Wallis test with intergroup comparison carried out by Mann–Whitney test. The P value of comparing pain scores at multiple time points was corrected using Bonferroni correction (P value was adjusted by multiplication by the number of tests). The results were statistically significant when the P value is less than 0.05.

Results

Ninety-one patients were enrolled in the study from 19th September 2020, 16 of them were excluded from the study (7 patients declined to participate in the study and 9 patients were not meeting the inclusion criteria of the study), the other 75 patients were randomly distributed into three equal groups. Two patients in group 1and one patient in both group II and group III discontinued the intervention due to failed block. The data of the remaining patients were successfully obtained and analyzed (Fig. 2). The demographic data of the studied patients that included age, BMI, gender, and ASA class showed a statistically insignificant difference among the three studied groups (P = 0.36, 0.59, 0.76, and 0.94 respectively). Also, the surgical criteria including side and duration of surgery were comparable between the studied groups (P = 0.74 and 0.86 respectively) (Table I).

The incidence of diaphragmatic hemiparesis was 1 (4.35%) patient in group I, 2 (8.33%) patients

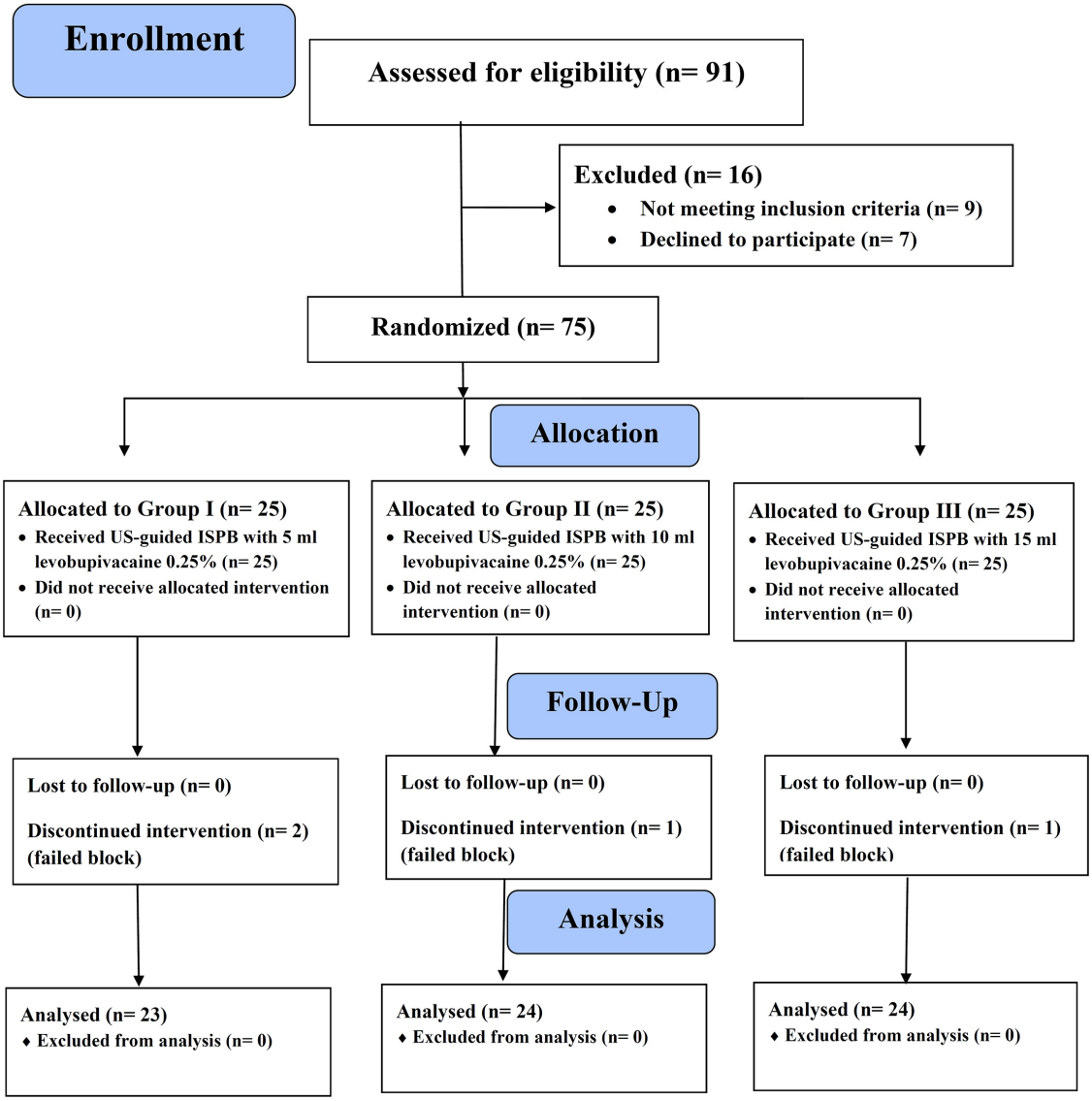

Fig. 2 — CONSORT flow chart of the study.

Table I. — Demographic data of the studied groups.

		Group I	Group II	Group III
Age (years)		42.17± 11.32	43.12± 10.83	39.04± 8.74
BMI (kg/m^2)		30.74± 4.13	31.96± 3.96	31.33± 4.06
Gender	M	10 (43.48%)	12 (50%)	13 (54.17%)
	F	13 (56.52%)	12 (50%)	11 (45.83%)
ASA class	I	9 (39.13%)	8 (33.33%)	10 (41.67%)
	II	11 (47.83%)	13 (54.17%)	10 (41.67%)
	III	3 (13.04%)	3 (12.5%)	4 (16.67%)
Side of surgery	Rt	10 (43.48%)	13 (54.17%)	11 (45.83%)
	Lt	13 (56.52%)	11 (45.83%)	13 (54.17%)
Duration of surgery (min)		137.39±26.58	132.92±28.13	135.42±27.89

Group I (US-guided ISBP block with 5 ml levobupivacaine 0.25% (23 patients)), Group II (US-guided ISBP block with 10 ml levobupivacaine 0.25% (24 patients)), Group III (US-guided ISBP block with 15 ml levobupivacaine 0.25% (24 patients)). Data were presented as mean ± Sd or number and %. BMI (body mass index).

in group II, and 5 (20.83%) patients in group III, on the other hand, the incidence of diaphragmatic hemiparalysis was 4 patients (16.67 %) in group III with no reported cases in groups I and II. The incidence of diaphragmatic hemiparalysis was significantly higher in group III as compared to group I (P = 0.019) and group II (P = 0.037) with a statistically insignificant difference between group I and II (P = 0.58). In addition, the degree of reduction of the diaphragmatic excursion was statistically significantly higher in group III (36.96± 21.10 %) as compared to group I (20.43± 6.22%, P = 0.0008) and II (21.29± 6.17 %, P = 0.001) with no statistically significant difference between groups I and II (P = 0.63). The pre-block diaphragmatic excursion was indifferent between the three studied groups (P = 0.86). However, the post-block diaphragmatic excursion was statistically significantly lower in groups III (2.64± 1.01 cm) in comparison to groups I (3.25± 0.52 cm, P = 0.013) and II (3.29± 0.45 cm, P = 0.006) with no statistically significant difference between groups I and II (P = 0.81). However, there was no statistically significant difference between the three groups in the incidence of hypotension, bradycardia, and Horner syndrome (P = 0.90, 0.89, and 0.60 respectively). No patients were recorded in the three groups to develop hoarseness of voice, oxygen desaturation, or pneumothorax (Table II).

The time to the first request of rescue analgesia was statistically significantly lowered in group I to 211.52± 100.84 min in comparison to 275.63± 85.56 min in groups II (P = 0.023) and 293.13± 98.93 min in group III (P = 0.007) with a statistically insignificant difference between groups II and III (P = 0.52). Furthermore, the total dose of tramadol consumed in the first 24 hours after surgery was statistically higher in group I (79.56± 29.46 mg) as compared to groups II (50.00± 28.89 mg, P = 0.001) and III (55.00± 32.70 mg, P = 0.009) with no statistically significant difference between groups II and III (P = 0.58). The NRS score of pain at 2, 4, and 6 hours after surgery was significantly lowered in groups II and III in comparison to group I (P = 0.009, 0.0009, and 0.005) with a non-statistically significant difference between groups II and III (P > 0.05). However, the NRS score was statistically insignificant between the three studied groups all over other time intervals (P > 0.05) (Table III).

There was no statistically significant difference between the three groups as regards the pulmonary function tests (PEFR, FEV1, FVC, and FEV1/FVC) either preoperatively or postoperatively (P > 0.05). However, there were statistically significant decreases in all parameters of pulmonary functions in the postoperative values in comparison to the preoperative values (P < 0.05). In addition, the patient's satisfaction was comparable between the three groups (P = 0.87) (Table IV).

Discussion

The results of this clinical trial revealed that the use of a local anesthetic volume of 10 or 5 ml in ISBP block in patients scheduled for shoulder arthroscopy was associated with a significant decrease in the incidence of diaphragmatic hemiparesis or paralysis than the use of a volume of 15 ml. On the other hand, the use of a volume of 5 ml was associated with a higher postoperative pain score, increased the postoperative rescue analgesia consumption, and decreased the duration of analgesia.

The ISBP block involves the block of the upper and middle trunk of brachial plexus. This results in satisfactory anesthesia to the shoulder[10, 11]. It carries a high risk for the development of diaphragmatic hemiparesis owing to the block of the ipsilateral phrenic nerve. This block may compromise respiratory function especially in patients with

Table II. — Changes in the diaphragmatic excursion and incidence of perioperative complications in the studied groups.

		Group I	Group II	Group III	P-value	P1	P2	P3
Pre-block diaphragmatic excursion (cm)		4.09± 0.56	4.18± 0.54	4.16± 0.59	0.86	-	-	-
Post-block diaphragmatic excursion (cm)		3.25± 0.52	3.29± 0.45	2.64± 1.01	0.003*	0.81	0.013*	0.006*
Degree of reduction in the diaphragmatic excursion (%)		20.43± 6.22	21.29± 6.17	36.96± 21.10	< 0.0001*	0.63	0.0008*	0.001*
Incidence of phrenic hemiparesis or paralysis	Phrenic nerve hemi-paresis	1 (4.35%)	2 (8.33%)	5 (20.83%)	0.012*	0.58	0.019*	0.037*
	Phrenic nerve hemi-paralysis	0 (0%)	0 (0 %)	4 (16.67 %)				
Incidence of perioperative complications	Hypoten-sion	3 (13.04%)	4 (16.67%)	3 (12.5%)	0.90			
	Brady-cardia	5 (21.74%)	4 (16.67%)	5 (20.83%)	0.89			
	Hoarse-ness of voice	-	-	-	-			
	Horner syndrome	1 (4.35%)	2 (8.33%)	3 (12.5%)	0.60			
	Oxygen desatu-ration	-	-	-	-			
	Pneumo-thorax	-	-	-	-			

Group I (US-guided ISBP block with 5 ml levobupivacaine 0.25% (23 patients)), Group II (US-guided ISBP block with 10 ml levobupivacaine 0.25% (24 patients)), Group III (US-guided ISBP block with 15 ml levobupivacaine 0.25% (24 patients)). Data were presented as mean ± Sd (analyzed by one-way ANOVA test and post-hoc Turkey's HSD Test) or number and % (analyzed by Chi-square test). P-value represents comparison between the three groups. P1 represents comparison between group I and II, P2 represents comparison between group I and III, P3 represents comparison between group II and III. * Denotes significant change.

respiratory diseases and make this block unsafe[12]. Ultrasonographic assessment of the degree of diaphragmatic excursion during quiet and deep breathing is a simple, non-invasive, and reliable method for diagnosis of phrenic nerve affection[13]. Phrenic nerve affection is diagnosed whenever the diaphragmatic excursion decreased by more than 25%[12]. The authors obtained the mean value of 6 readings of diaphragmatic excursion (3 readings during quiet breathing and another 3 during deep breathing) in order to increase the sensitivity of the readings. Furthermore, the ultrasound assessment of the diaphragm was carried out by experienced personnel. In addition, the study excluded the patients with respiratory co-morbidities and obese patients which may make the ultrasound assessment of diaphragm relatively difficult.

Many strategies may be used to decrease the incidence of phrenic nerve block in ISBP block. They include decreasing local anesthetic volume, ultrasonographic guidance, performing the ISBP block more caudally in the neck, or using supraclavicular nerve block[14]. This is in line with the results of Renes, et al, who studied 30 patients scheduled for shoulder surgery under general anesthesia and ISBP block. They compared the US-guided and the nerve stimulation-guided ISBP block using the same volume of local anesthetics (10 mL ropivacaine 0.75%). They revealed that the incidence of phrenic nerve block diagnosed by ultrasound assessment of diaphragm and spirometry was lower with the use of ultrasound guidance as compared to the nerve stimulation guidance despite obtaining comparable postoperative pain scores[1(].

Urmey, et al demonstrated that the decrease in the volume of the local anesthetic used in ISBP block from 45 ml to 20 ml had no effect on the incidence of diaphragmatic hemiparesis[16]. However, reduction of the local anesthetic volume and concentration to 10 ml of bupivacaine 0.25% was associated with a significant reduction in the phrenic nerve hemiparesis to 20% without consistent effect on the anesthesia at the level of C5 and C6. This may be explained by the effect of dilution of local anesthetics on sensory-

Table III. — Postoperative analgesia in the studied groups.

		Group I	Group II	Group III	P-value	P1	P2	P3
Time to first request of rescue analgesia (min)		211.52± 100.84	275.63± 85.56	293.13± 98.93	0.012*	0.023*	0.007*	0.52
Postoperative 24 h tramadol consumption (mg)		79.56± 29.46	50.00± 28.89	55.00± 32.70	0.003*	0.001*	0.009*	0.58
NRS	Immediately postoperative	0 (0-2)	0 (0-2)	0 (0-2)	0.968	-	-	-
	2 h	3 (1-5)	2 (0-4)	2 (0-4)	0.009*	0.007*	0.00007*	0.42
	4 h	5 (3-7)	4 (2-5)	4 (1-5)	0.0009*	0.009*	0.0002*	0.06
	6 h	5 (3-7)	4 (2-5)	4 (2-5)	0.005*	0.003*	0.0008*	0.55
	8 h	4 (2-5)	3 (2-6)	3(2-5)	0.096	-	-	-
	12 h	2 (1-5)	2 (1-4)	2 (2-4)	0.686	-	-	-
	16 h	2 (1-3)	2 (1-3)	2 (1-3)	0.936	-	-	-
	20 h	1 (1-2)	1 (0-2)	1 (0-2)	0.177	-	-	-
	24 h	1 (0-2)	1 (0-2)	0.5 (0-2)	0.467	-	-	-

Group I (US-guided ISBP block with 5 ml levobupivacaine 0.25% (23 patients)), Group II (US-guided ISBP block with 10 ml levobupivacaine 0.25% (24 patients)), Group III (US-guided ISBP block with 15 ml levobupivacaine 0.25% (24 patients)). Data were presented as mean ± Sd (analyzed by one-way ANOVA test and post-hoc Turkey's HSD Test) or Median and interquartile range (analyzed by Kruskal-Wallis test with intergroup comparison carried out by Mann–Whitney test). P-value represents comparison between the three groups. P values are corrected using Bonferroni correction (adjusted by multiplication by number of tests). P1 represents comparison between group I and II, P2 represents comparison between group I and III, P3 represents comparison between group II and III. * Denotes significant change.

motor separation[17]. Moreover, Riazi, et al evaluated the use of two different volumes of ropivacaine 0.5% (5 ml or 20 ml) in ISBP block in 40 patients undergoing shoulder surgery and revealed that the use of a volume of 5 ml was associated with significant reduction of diaphragmatic hemiparesis from 100% to 45% and less decrease in the pulmonary function tests 30 minutes after the block with no difference in the postoperative pain score between the two volumes. The indifference in the postoperative pain may be explained by the use of a different local anesthetic (ropivacaine 0.5%)[4]. In addition, Lee, et al studied 60 patients scheduled for shoulder arthroscopy under general anesthesia and ISBP block with either 5 or 10 ml of ropivacaine 0.75%. They found that the use of a lower volume of local anesthetics (5 ml) was associated with a significant decrease in the incidence of diaphragmatic hemiparesis from 60% to 33% without significant effect on the postoperative pain score or the duration of analgesia. The indifference in the postoperative pain score may be explained by the use of ropivacaine in a concentration of 0.75%[18]. On the other hand, the use of continuous ISBP block at a volume of 5-9 ml/hr for 24 hours was associated with a significant decrease in the diaphragmatic function. This may be attributed to the use of the initial bolus doses of local anesthetics with higher volume and concentration[19,20].

The effect of ISBP block on the phrenic nerve seems to be transient and short-timed and resolved over the duration of local anesthetics used[21]. Moreover, paresis or even paralysis of diaphragm in healthy people does not lead to respiratory failure as normal respiration depends upon coordination between diaphragm and other respiratory muscles. The activity of the accessory respiratory muscles may overcome the diaphragmatic paresis and paralysis[22,23]. This is in line with the results of this study that revealed that the postoperative pulmonary function tests were comparable between the three used volumes of local anesthetics[24].

This study is limited by being a single-center study with low sample size. Also, it was limited by the use of a single concentration of local anesthetic, the lack of the use of local anesthetic additives, the lack of scanning of the contralateral lung, and the lack of assessment of rebound effect of the regional block. Furthermore, the exclusion of patients with failed block, obese patients, and patients with respiratory co-morbidities added to the study limitations.

Conclusion

We can conclude that performing US-guided ISBP block in patients scheduled for shoulder arthroscopy with a volume of 10 or 5 ml levobupivacaine 0.25% was associated with a lesser incidence of diaphragmatic hemiparesis as compared to the use of a volume of 15 ml. Also, the use of volumes of 15 or 10 ml was associated with better postoperative analgesia in comparison to the use of a volume of 5 ml. A volume of 10 ml seems to be optimal as it is associated with lesser effect on the phrenic nerve and better postoperative analgesia. However, the diaphragmatic affection

Table IV. — Pulmonary function tests and patient satisfaction in the studied groups.

		Group I	Group II	Group III	P-value
Preoperative PFTS	PEFR (L/min)	308.70±21.81	310.42±26.62	306.25±26.99	0.85
	FEV1 (L)	3.09±0.79	3.00±0.78	3.04±0.75	0.93
	FVC (L)	3.80± 0.79	3.83±0.55	3.94± 0.70	0.74
	FEV1/FVC (%)	82.00±16.59	78.04±14.45	77.33±13.27	0.51
Postoperative PFTS	PEFR (L/min)	185.83± 13.70 *	187.50±16.22 #	183.33± 14.94 *#	0.63
	FEV1 (L)	1.65±0.65 *	1.67± 0.70 #	1.71± 0.69 *#	0.96
	FVC (L)	2.33±0.52 *	2.37± 0.72 #	2.31±0.70 *#	0.95
	FEV1/FVC (%)	70.07±18.26 *	69.49±14.86 #	67.94±11.62 *#	0.88
Patients Satisfaction	Very Dis-satisfied	4 (17.39%)	4 (16.67%)	5 (20.83%)	0.87
	Dis-satisfied	5 (21.74%)	5 (20.83%)	6 (25%)	
	Satisfied	8 (34.78%)	7 (29.17%)	6 (25%)	
	Very Satisfied	6 (26.09%)	8 (33.33%)	7 (29.17%)	

Group I (US-guided ISBP block with 5 ml levobupivacaine 0.25% (23 patients)), Group II I (US-guided ISBP block with 10 ml levobupivacaine 0.25% (24 patients)), Group III I (US-guided ISBP block with 15 ml levobupivacaine 0.25% (24 patients)). Data were presented as mean ± Sd (analyzed by one-way ANOVA test and post-hoc Turkey's HSD Test) or number and % (analyzed by Chi-square test). P-value represents comparison between the three groups. * Denotes significant changes between preoperative and postoperative values in the group I. # Denotes significant changes between preoperative and postoperative values in the group II. *# Denotes significant changes between preoperative and postoperative values in the group III. PFTs, Pulmonary Function Tests. PEFR, peak expiratory flow rate. FEV1, forced expiratory volume 1. FVC, forced vital capacity.

was not associated with significant clinical changes in the form of pulmonary function tests or the incidence of pulmonary complications.

Acknowledgments: We would express our great thanks to our colleagues in the Department of Anesthesia and Surgical Intensive Care, Faculty of Medicine, Tanta University, Egypt.

Authors agree to sharing the data reported in this study including the protocol of the study, the ethical committee approval, and the row data of primary outcome. The data can be obtained through contacting corresponding author.

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