Original Research Article

Safety and Efficacy of Ultrasound Guided Costoclavicular Brachial Plexus Block versus Interscalene Block in Adult Patients Undergoing Shoulder Surgery. A Prospective Randomized Double Blinded Study

Abstract

Background: Adults who have shoulder surgery often experience acute postoperative pain; around 45% of individuals experience significant pain in the first few days after surgery. The aim of this work was to compare safety and efficacy of ultrasound guided costoclavicular brachial plexus block versus interscalene block in adult patients undergoing shoulder surgery.

Methods: This prospective randomized controlled double blinded study was carried out on 80 patients admitted for shoulder surgery. Patients were divided into two equal groups: Group I: Ultrasound guided Interscalene Block (ISB), in this group brachial plexus was blocked by 15 ml of levobupivacaine 0.5%, and group II: Ultrasound guided costoclavicular brachial plexus block (CCBPB), in this group brachial plexus was blocked by 20 ml of levobupivacaine 0.5%.

Results: The onset of sensory block was significantly shorter in ISB group ($P<0.001$). The incidence of hemidiaphragmatic paralysis was statistically significant higher in ISB group ($P<0.001$). At various measurement periods, there was no discernible difference in VAS between the two groups ($p > 0.05$). There was no statistically substantial difference between the two groups for the initial rescue analgesic need ($P=0.080$).

Conclusions: Although, ultrasound guided CCBPB and ISB has the same efficacy on providing postoperative analgesia for shoulder surgery, CCBPB is more safe than ISB because it decreases the incidence of postoperative complications as hemidiaphragmatic

paralysis (HDP), hoarseness of voice, pneumothorax, Horner's syndrome, and local anesthetic systemic toxicity.

Keywords: Ultrasound Guided, Interscalene Block, Costoclavicular Brachial Plexus Block, Adult Patients, Shoulder Surgery

Introduction:

Adults who have shoulder surgery often experience acute postoperative pain; around 45% of individuals experience significant pain in the first few days after surgery [1]. Even arthroscopic shoulder surgery may result in moderate to severe postsurgical pain, interfering with rehabilitation and recovery. [2].

The usage of opioids is often used to manage postoperative pain. But, they have several adverse effects, including vomiting, nausea, dysphoria, respiratory depression, and hormonal affection.[3, 4].

Therefore achieving postoperative analgesia with limiting opioid intake is essential, as inadequate pain control may contribute for more than 60% of prolonged unplanned hospitalizations. Furthermore, having effective pain management is a significant factor to determine postoperative patient satisfaction [5].

Presurgical local anesthetic (LA) blockade of brachial plexus minimizes postoperative pain and that may reduce consumption of opiate. Utilizing ultrasound to guide regional nerve blocks accelerates the process and raises rates of success.[6, 7].

The most often used block for reducing postoperative pain following surgeries in the shoulder is the inter-scalene block (ISB).[8]. Although it provides excellent postoperative analgesia but according to multiple publications, routine ISB after shoulder surgery result in a 100% chance of temporary diaphragmatic paralysis[9]. However, more recent findings indicate that this incidence may be decreased with adjusted local anaesthetic dose and ultrasound-guided insertion of a needle [10, 11]. Horner's syndrome, voice hoarseness, and arm weakness are other common side effects of ISB[8]. This calls for the search for alternative nerve blocks with analgesic effectiveness equivalent to that of the ISB but without the ISB's common side effects [12].

Karmakar MK published the first description of the costoclavicular brachial plexus block (CCBPB) in 2015. The costoclavicular region contains the brachial plexus, which is targeted by CCBPB because to the close proximity of its three cords. Clavicular head of pectoralis major and subclavius muscles border the costoclavicular area ventrally, while the anterior chest wall borders it dorsally [13].

The costoclavicular area has recently been proposed as a retrograde pathway to supraclavicular brachial plexus (SCBP)block [14]. Therefore, if local anaesthetic (LA) injected in the costoclavicular region can consistently reach the SCBP, it might provide analgesia as effective as ISB but with a lower risk of hemi-diaphragmatic paralysis (HDP) [15].

This study aims to compare safety and efficacy of ultrasound guided (CCBPB) versus (ISB) in adult patients undergoing shoulder surgery.

Patients and Methods:

This prospective randomised controlled double blinded research included 80 patients hospitalised for shoulder surgery aged 21-60 years of both genders, ASA physical status I & II. Tanta University Hospital hosted the study, which lasted a year, between November 2020 and December 2019.Tanta University's Ethical Committee granted permission for the study. The patients signed an informed written permission form.

Pre-existing (obstructive or restrictive) lung disease, patient refusal, neurological deficiency, bleeding disorders, recalcitrant patients, block injection site infection, and a history of allergy to local anaesthetics were all exclusion criteria.

Two equally groups of patients were formed: Group I: Ultrasound guided Interscalene Block (ISB), in this group brachial plexus was blocked by 15 ml levobupivacaine 0.5%, and group II: Costoclavicular brachial plexus block (CCBPB) Ultrasound guided, using 20 ml of levobupivacaine 0.5%.

All patients were subjected to: Medical, surgical histories were taken, clinical, routine laboratory investigations (CBC and INR), and standard ASA monitoring (heart rate (HR), non-invasive arterial blood pressure (NIBP), Electrocardiography (ECG).

All patients had an intravenous cannula (20 gauge) inserted into the upper limb contralateral to the surgery site and intravenous midazolam (0.02 mg/kg) was dispensed as a premedication. Supplemental oxygen (nasal cannula at 4 L/min) was applied throughout the procedure. Both groups utilised an ultrasound machine (Phillips Cx-50, Amsterdam, Netherlands) equipped with a linear probe (L12-3 MHz).

ISB group:

In the ISB group, patients were in supine position. The transducer of US was positioned aseptically on the neck's lateral side at the cricoid cartilage level to observe three hypoechoic structures representing the brachial plexus roots (C5, C6, and C7).

The skin was infiltrated with 3 mL of lidocaine 2%. The block needle was inserted using an in-plane approach and a lateral-to-medial direction until its tip was situated beneath the prevertebral fascia in between the two most superficial hypoechoic structures (C5 and C6 roots). Then, fifteen milliliters of levobupivacaine 0.5% were injected in this location. Then a sham CCBPB was performed (Description: A sham CCBPB was performed while looking for intended location of CCBPB placement. Skin was infiltrated with local anesthetics but CCBPB wasn't performed, instead 2 mL subcutaneous saline injection was applied).

CCBPB group:

Patients in the CCBPB group were lying supine with the operative limb abducted at a 90-degree angle. Initial placement of the US transducer was on top of the middle portion of the clavicle. The probe was then moved from the medial infraclavicular fossa to the inferior edge of the clavicle. The axillary artery is visible in the costoclavicular region under the subclavius muscle. The medial, lateral, and posterior brachial plexus cords may all be seen next to the

artery. Three millilitres of 2% lidocaine were injected into the skin. The block needle was moved in-plane and in a lateral-to-medial manner until its tip was situated in the centre of the three cords. Twenty milliliters of levobuivacaine 0.5% was incrementally injected. Then a sham ISB was performed (Description: A sham ISB was performed while looking for intended location of ISB placement. Skin was infiltrated with local anesthetics but ISB wasn't performed, instead 2 mL subcutaneous saline injection was applied).

Whether the sensorimotor blockage was successful or not, general anaesthesia with endotracheal intubation was administered to all patients after 30 minutes using intravenous 2 mg/kg of Propofol, 2 mic/kg of Fentanyl, and Cis-atracurium 0.15 mg/kg. Maintenance of anesthesia using isoflurane 1.2 MAC. To maintain end tidal carbon dioxide between 32 and 35 mmHg, mechanical ventilation was used on all patients. With a total flow of 2 litres, an anaesthetic was sustained by 80% oxygen and 20% air.

fentanyl (25 µg boluses) was administered intraoperatively if the patient's heart rate or blood pressure were 20% or higher than preoperative levels. Before being extubated at the conclusion of the procedure, all patients received 4 mg of ondansetron for prophylaxis from nausea and vomiting as well as intravenous acetaminophen 10 mg/kg. The time from skin incision to wound closure, or the surgical length, was noted.

The analgesic impact and pain intensity measured by Visual Analogue Score (VAS) in the first 24 hours following surgery served as the main outcome. The secondary outcomes were complications occurrence, total mepridine consumption in the first 24 hours postoperative and overall patient satisfaction

Sample Size Calculation:

The sample size was determined using William D. Dupont and Walton D. Plummer's Power and Sample Size (PS) Estimates, Version 3.0, 2009. Each group will have forty patients assigned to it. According to the following factors, N 36 samples were chosen for each group.

0.05 α error and 80% research power to show a 20% reduction in VAS (the main outcome) with CCBPB over ISB in accordance with a previous study. [16] To prevent dropout, four instances were assigned to each group.

Statistical analysis

SPSS version 23 was used for the statistical analysis. The unpaired Student's t-test was used to compare quantitative data between the two groups. Quantitative variables were provided as mean and standard deviation (SD). When applicable, qualitative variables were analysed using the Chi-square test or Fisher's exact test and provided as frequency and percentage (%). Statistical significance was defined as a two-tailed P value < 0.05.

Results:

Figure 1 displays the patient flowchart from the research protocol, which includes patient enrollment, allocation, follow-up, and analysis.

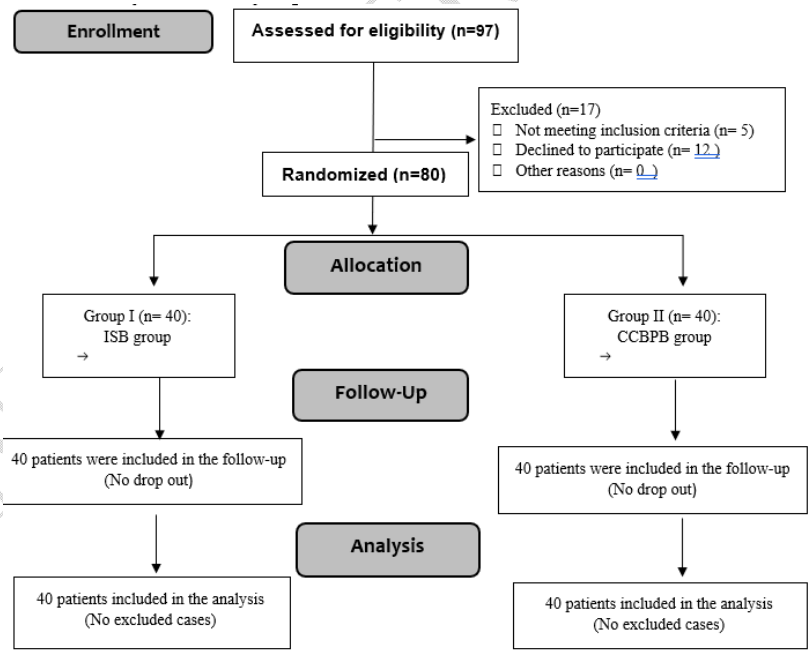


Figure 1: Patient flowchart including enrollment, allocation, follow-up and analysis in the study protocol.

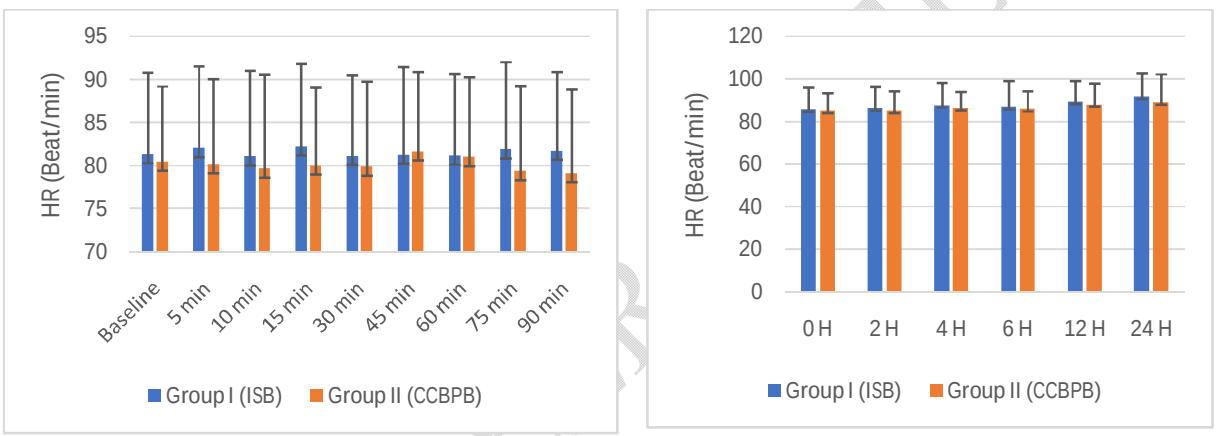
Age (years), sex, weight, BMI and duration of surgery were insignificantly different between two groups. Table 1

Table 1: Demographic data of the two groups

		Group I (n=40)	Group II (n=40)	P value
Age (years)		38.7 ±11.31	39.6 ±10.4	0.712
Sex	**Male**	23 (57.5%)	24 (60%)	0.820
	Female	17 (42.5%)	16 (40%)	
Weight (kg)		75.15 ± 9.23	76.17 ± 8.26	0.602
BMI (kg/m^2)		23.82 ± 4.09	25.11 ± 3.49	0.133
Duration of surgery (minutes)		103.37 ± 8.42	104.85 ± 9.06	0.453

Data are presented as mean ± SD or frequency (%). BMI: Body mass index,

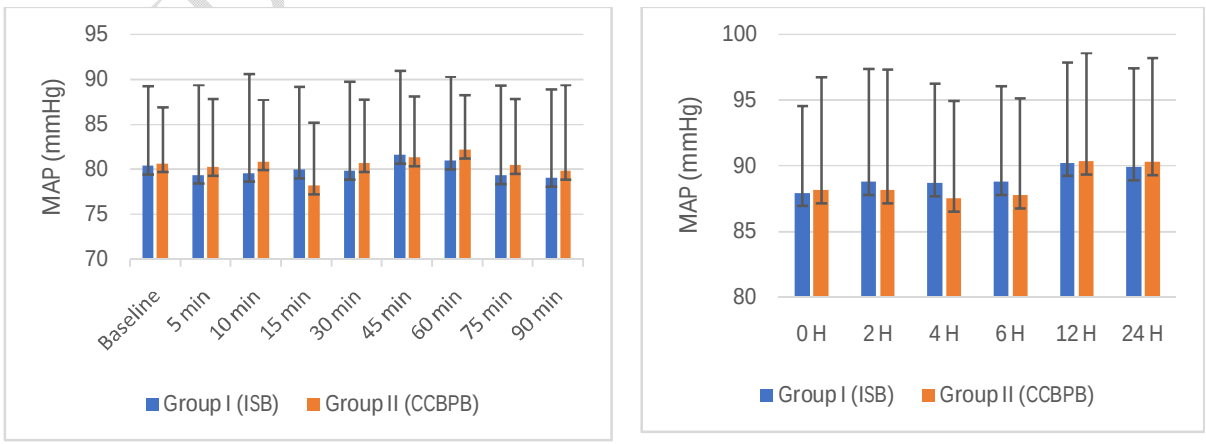
There was no significant difference of intraoperative and postoperative heart rate between both groups at different measurement times (p >0.05). Figure 2



(A) **(B)**

Figure 2: Comparison of (A) intraoperative and (B) postoperative heart rate changes between the two studied groups

There was no significant difference of intraoperative and postoperative MAP between both groups at different measurement times (p >0.05). Figure 3



(A) **(B)**

Figure 3: Comparison of (A) intraoperative and (B) postoperative MAP changes between the two studied groups

Between the two groups, there was a statistically significant distinction in the start of sensory block and the occurrence of hemidiaphragmatic paralysis (P 0.001). The incidence of Horner's syndrome and hoarseness of voice showed insignificant difference among the two groups. Table 2

Table 2: Comparison of the onset of sensory block, incidence of hemidiaphragmatic paralysis and adverse effects between the two studied groups

	Group I (n=40)	Group II (n=40)	P value
Onset of sensory block (min)	12.62 ± 3.20	17.75 ± 5.76	<0.001*
Incidence of hemidiaphragmatic paralysis	38 (95.0%)	0 (0.0%)	<0.001*
Adverse effects			
Horner's syndrome	3(7.5%)	0 (0.0%)	0.239
LAST	0 (0.0%)	0 (0.0%)	--
Pnemothorax	0 (0.0%)	0 (0.0%)	--
Hoarseness of voice	2(5.0%)	0 (0.0%)	0.47
Bradycardia and hypotension	0 (0.0%)	0 (0.0%)	--

Data are presented as mean ± SD or frequency (%), * significant as P value <0.05,

There was no significant difference of VAS between both groups at different measurement times (p >0.05). Table 3

Table 3: Comparison of visual analogue score (VAS) between the two studied groups

Time	Group I (n=40)	Group II (n=40)	P value
0 h	1.47 ± 0.93	1.40 ± 0.87	0.663
2 h	1.55 ± 0.90	1.42 ± 0.87	0.545
4 h	1.55 ± 0.87	1.42 ± 0.71	0.735
6 h	1.85 ± 0.76	1.62 ± 0.80	0.106
12 h	1.80 ± 0.64	1.70 ± 0.96	0.265
18 h	5.30 ± 1.48	5.37 ± 1.35	0.847
24 h	5.92 ± 0.94	6.15 ± 1.02	0.356

Data are presented as mean ± SD, * significant as P value <0.05

There was no statistically significant difference in first rescue analgesic requirement, total mepridine consumption and patients satisfaction among the two groups. Table 4

Table 4: Comparison of time to first rescue analgesic requirement, total mepridine consumption and patients satisfaction between the two studied groups

	Group I (n=40)	Group II (n=40)	P value
First rescue analgesic requirement(hours)	12.45 ± 3.31	11.05 ± 3.73	0.080
Total mepridine consumption (mg/24h)	93.0 ± 21.50	88.50 ± 20.07	0.336
Patients satisfaction			
Unsatisfied	7 (17.5%)	12 (30.0%)	0.413

Neither satisfied nor unsatisfied	9 (22.5%)	7 (17.5%)	
Satisfied	24 (60.0%)	21 (52.5%)	

Data are presented as mean ± SD or frequency (%), * significant as P value <0.05,

Discussion

In postsurgical period , 30-70% of individuals undergoing shoulder joint surgery complain of pain.[17] Postsurgical pain that ranges from moderate to severe after shoulder arthroscopic surgery might impede rehabilitation and recovery.[2]

Regarding VAS score changes in both groups, Our results revealed that the both blocks provide comparable postoperative analgesia since there was no discernible difference in VAS between the two groups at various periods of assessment.

The medial technique of the ultrasound-guided CCBPB is practically possible, with high clinical efficacy utilising 20 ml of 1.5 percent mepivacaine, and effective blocks were seen in 91 % of cases, according to Nieuwveld et al[18] In line with our research. Also, they concluded that CCBPB proved to be successful in producing upper extremity anaesthesia.

Also, Tran et al. [19] analysed diaphragm-sparing nerve blocks used for surgeries in the shoulder since January 2017 and reported that up to date, The CCBPB remains the only method that has been shown to provide analgesic equivalent with ISB.

Concerning the incidence of hemidiaphragmatic paralysis (HDP), it was (95%) in group I and (0%) in group II with significant difference among the two groups.

In accordance with our findings Aliste et al. [16] examined analgesic efficacy and safety of CCBPB against ISB in arthroscopic shoulder surgery and stated that ISB contributed to an increase in HDP incidence when compared with CCBPB 30 minutes after the blocks are performed and 30 minutes after the patients enter the PACU (100% with ISB across both time intervals against 0% when compared with CCB).

Also, Sivashanmugam et al. [20] examined the prevalence of ipsilateral HDP in patients having CCBPB and SCBPB. and they concluded that In comparison to SCBPB, CCBPB causes a reduced incidence of ipsilateral HDP.

In contrast with our results, Leurcharusmee et al. [21] examined paracoracoid and costoclavicular ultrasound-guided infraclavicular block(UGICB) for surgeries in upper limb and stated that, the incidence of HDP was 8.9% in both costoclavicular and paracoracoid UGICB. This may be described by the different LA mixture as they used (1% lidocaine and 0.25% bupivacaine, 5 μg·mL−1 of epinephrine) compared to 0.5% levobupivacaine used in our study. Also they used a larger volume of injectate (35 ml), compared to 20 ml of injectate in our study.

Regarding incidence of complications and side effects as (pneumothorax, bradycardia, hypotension, LAST, hoarseness of voice and Horner's syndrome) our results showed low incidence and insignificant difference among the two groups.

In line with our study, Aliste et al. [16] compared safety and efficacy of CCBPB vs ISB in arthroscopic shoulder surgery and No inter-group variations were discovered in terms of adverse events as Horner`s syndrome, hoarseness, puncture of a vessel, toxic effects of LA, parasthesia and postoperative nausea and vomiting occurred during the performance of the two blocks. Similarly, Nalini et al.[22] compared axillary brachial plexus block and costoclavicular block ultrasound-guided for mid arm surgeries and they postulated that There were no consequences such as pneumothorax, hematoma, or anesthetic toxicity.

Regarding patients satisfaction with analgesia, Between the two groups, there was no substantial distinction in patients' satisfaction.

In concordance with our findings, Aliste et al. [16] analysed analgesic effectiveness of CCBPB against ISB in arthroscopic shoulder surgery and they reported an equivalent patient satisfaction at 24 hours in both groups.

Concerning the onset of block, our study showed more rapid onset in group I (ISB) compared to group II (CCBPB).

On the other hand, Pradhan et al. [23] assessed CCBPB and ISB for pain relief in fifty adult patients scheduled for arthroscopic surgery of the shoulder by using 20 ml of 0.5% levobupivacaine and observed shorter onset of sensory block in CCBPB compared to ISB. This may be explained by the addition of dexamethasone to levobubivacaine in their study.

Regarding the timing of the initial analgesic requirement Between the ISB and CCBPB groups, there was no significant disparity. In line with the reported findings, Pradhan et al. [23] assessed CCBPB and ISB for pain relief in fifty adult patients scheduled for arthroscopic surgery of shoulder using 20 ml of 0.5% levobupivacaine and found that In terms of the timing of first painkiller demand, both groups had similar.

In contrast to our results, Kewlani et al. [24] studied the average beneficial volume of 0.5% Ropivacaine for CCBPB ultrasound-guided in 40 adult patients planned for hand and forearm surgeries and found that first request analgesia time was earlier in patients who received ultrasound guided CCBPB with mean time 6 hours versus 11 hours compared to our results. This might be described by the use of various LA agent (Ropivacaine) and also different site of surgery; forearm and hand.

Regarding comparison of consumption of total analgesic (mepridine) at the initial 24 hours following surgery between both groups that were analysed, The variation was not significant statistically between them

In accordance to our results, Kim et al. [25] assessed the efficacy of combined ultrasoundguided CCBPB and suprascapular nerve block for arthroscopic surgery of shoulder and noted that, supplemental analgesia was not significantly different in both groups at PACU and 24 hours postoperaive.

Concerning hemodynamic changes, In the two groups, there was no significant disparity in intraoperative HR and MAP from baseline at any of the measurement periods.

Also, at 12 and 24 hours postoperative, there was a significant statistically rise in MAP and HR as compared to 0 hour in the two groups. Moreover, our study revealed no substantial difference of HR and MAP between both groups at different measurement times.

In accordance with the present findings, Lee et al. [26] who studied on the effectiveness of ISB for postoperative pain and intraoperative hemodynamics for arthroscopic surgery of shoulder revealed substantially lower intraoperative systolic and diastolic blood pressures and heart rates in the ISB group.

Limitations of the study: One of our study's limitations was the small sample size.

As a result, large-scale trials are necessary to validate our results.

Our study did not consider at continuous analgesic blocks. This is a methodological constraint since continuous blocks provide considerable advantages than single injection counterparts. Moreover, although costoclavicular brachial plexus block may initially sparing the phrenic nerve, HDP resulting from LA accumulation may happen with continued infusion. Also, our study used 20 ml of levopubivacaine, further studies could compare other local anaesethic drug, volume, concentration or the addition of adjuvants.

Conclusions:

Although, ultrasound guided CCBPB and ISB has the same efficacy on providing post-operative analgesia for surgeries of the shoulder, CCBPB is more safe than ISB because it decreases the incidence of postoperative complications as hemidiaphragmatic paralysis (HDP), Horner's syndrome, hoarseness of voice, pneumothorax and LA systemic toxicity.

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