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The effect of clavipectoral fascia plane block or interscalene brachial block on the postoperative analgesia after clavicle surgery: Randomized controlled study

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Abstract
Background: Fractures of the clavicle are prevalent in young boys and older persons, frequently arising from direct trauma to the shoulder.
Aim and objectives: To assess the analgesic effectiveness of the US-guided clavipectoral fascia plane block vs US-guided inter scalene brachial plexus block in patients having clavicle surgery.
Materials and methods: Our prospective randomized controlled research involved sixty cases who had clavicle surgery at Tanta University Hospitals' Anesthesia Department for 18 months, from March 2022 to September 2023. Subjects underwent a random and equal categorization to 3 groups, with twenty cases each. Group I got simply the normal analgesic treatment, Group II received a unilateral US-guided CPB block, and Group III received a unilateral US-guided ISB block. All subjects underwent assessment as regards total morphine consumption, NRS, total intraoperative fentanyl consumption, duration till 1st rescue analgesia, adverse events, and diaphragmatic excursion preoperatively and postoperatively using ultrasound. The primary goal was postoperative morphine usage within the initial twenty-four h following surgical procedure, with secondary outcomes including the Numeric Rating Scale (NRS), duration till 1st rescue analgesia as well as complications' occurrence.
Results: A significant variance was documented in total morphine uptake across three groups (p<0.001), with group one consuming more than groups two and III. Group II did not significantly increase morphine intake in comparison with group III. Group III and II had considerably longer wait times for their first analgesic than group I (P2 < 0.001 as well as P1 < 0.001). A significant variance was documented in NRS at rest among the three groups within PACU for two hours, four hours, twelve hours, eighteen hours, as well as twenty-four hours (p<0.05). Nevertheless, no statistically significant change was documented at 6 h (p>0.05). A significant variance was documented in NRS while traveling among all groups at PACU at 2h, 4h, 6h, 12h, 18h, as well as 24h (p<0.05). No statistically significant variance was documented as regards complications' occurrence among all groups (p>0.05). However, a statistically significant variance was documented among all groups in diaphragmatic hemiparesis (p<0.001).
Conclusion: Preoperative US-guided CPB as well as interscalene brachial plexus block are efficient instruments in analgesia during and after surgery in patients undergoing clavicle surgery because they improve the time to first protect analgesia, reduce postoperative total morphine usage, reduce pain after surgery scores, and improve patient satisfaction.

Keywords: Clavicle surgery, postoperative analgesia, fractures

Introduction
Clavicle fractures represent 2.6 to 4% of all fractures, being most prevalent among young men and older people. They are frequently caused by direct trauma to the shoulder [1].
Displaced fractures are typically treated surgically for improved functional outcomes. Traditionally, general anesthesia (GA) is preferred because it offers adequate surgical conditions. The advantages of GA being entirely calm and unconscious patient, there are certain downsides such as multi-drug use, postoperative nausea, vomiting, headache, dangers of the higher hemodynamic stress response, and airway difficulties, which makes regional anesthesia procedures more preferred [2, 3].

The ultrasound-guided approach is more favorable than the landmark-based technique because we can visualize the LA distribution within the right plane, boosting success rate [4, 5]. Valdés-Vilches described the clavipectoral fascial plane block (CPB) as a novel as well as safe regional anesthesia approach in 2017 [6]. They reported injecting around ten to fifteen mL of the LA agent utilizing ultrasonographic-guidance into the gap between the clavipectoral fascia as well as the clavicle periosteum, in both the fracture site medial along with lateral parts [7, 8].

This work was aimed at assessing the analgesic effect of the US-guided clavipectoral fascia plane block versus the US-guided interscalene brachial plexus block among cases undergoing clavicle surgical procedure. The main aim was total morphine usage during the first day after surgery, with the pain after surgery score, the initial call for emergency analgesia, and the occurrence of complications as additional goals.

Materials and Methods

Our prospective randomized controlled trial involved sixty cases who had clavicle surgery at Tanta University Hospitals' Anesthesia Department for 18 months (March 2022–September 2023). It was authorized by the Faculty of Medicine's Institutional Ethical Committee (approval code: 35234.1.22).

This research comprised cases whose ages fell between twenty-one and sixty-five years old, classified as I-III by the ASA, and scheduled for clavicle surgery under general anesthesia.

Patients were removed from the research if they refused, were taking pain relief for a long-term medical condition or have a history of abuse of drugs, were unable to describe their pain after surgery (e.g., language barrier or neuropsychiatric disorder), had a history of hemorrhaging diathesis, received anticoagulant therapy, had a known local anesthetic and opioid allergy, had an infection at the needle puncture site, pregnant or lactating women, and those who have heart, lung, kidney, or liver diseases.

Study design

Patients who satisfied the aforementioned criteria participated in the trial. Participants underwent a random (randomised number) categorization into three equal groups: Group I (Group C = control group) (n=20): Patients in this group were solely administered the normal analgesic treatment. Group II (Group CPB = Clavipectoral fascia plane block group) (n=20): subjects within this group went through a unilateral US-guided CPB block on ipsilateral side of the procedure following GA induction as well as prior to surgical repair. Group III (Group ISB = Interscalene brachial plexus block group) (n=20): Patients in this group were given a unilateral US-guided ISB block on the ipsilateral side of the surgery after general anesthesia was administered and before surgical repair began.

Anesthetic Technique

Preoperative assessment was done by

Adequate preoperative evaluation was carried out by collecting the patient's medical and surgical histories; during the pre-anesthetic examination, all patients were familiarized with the numeric rating scale (NRS) score. Prior to surgery, all patients had their diaphragmatic excursion assessed using ultrasound.

Intraoperative

On entering operating room

All patients were connected to standard ASA monitoring, which included: HR, ECG, NIBP, involving systolic, diastolic, as well as MAP, oxygen saturation (SPO2) utilizing pulse oximetry, capnogram, along with a temperature probe applied after induction. An intravenous cannula (18 gauge) is inserted into the upper limb contralateral to the surgery location. Anesthesia was induced by intravenous fentanyl (2ug/kg lean BW), propofol 1.5 mg/kg lean BW, as well as atracurium 0.5 mg/kg lean BW. A tracheal tube of appropriate size was inserted three minutes after atracurium administration, and anesthesia maintenance was accomplished through isoflurane 1.2 MAC in some oxygen: air ratio of 1:1. Fentanyl was given at a dose of 0.5ug/kg lean body weight if HR or MAP increased by more than 20% from baseline or if BSI exceeded 60. The ventilator settings were modified to maintain normocapnia (ETCO2 = 32-35 mmHg). The allocated block was done in all patients following the introduction of general anesthesia, and surgery began 20 minutes later. A standardized analgesic protocol was used for all patients in all groups, consisting of 1g acetaminophen every 6 hours and 30mg ketorolac every 8 hours. The rescue analgesia is 3mg IV morphine when NRS>3 and can be repeated as needed if the total day consumption does not exceed 20mg.

Ultrasound clavipectoral fascia plane block technique

The procedure was carried out completely aseptically, with a high frequency (12 MHz) linear ultrasound probe (ALPINION E-CUBE 8) and a 10% povidine iodine disinfection solution. It was positioned at anterior superior border of the clavicle medial third on both the fracture medial as well as lateral sides. Additionally, inserting a 22-G needle was accomplished caudally-cranially. After visualizing and aspirating the clavicle and clavipectoral fascia, two ml of saline was administered for checking proper alignment, followed by 20 ml of 0.5% bupivacaine administered between the periosteum as well as clavipectoral fascia (ten ml for each fracture side).

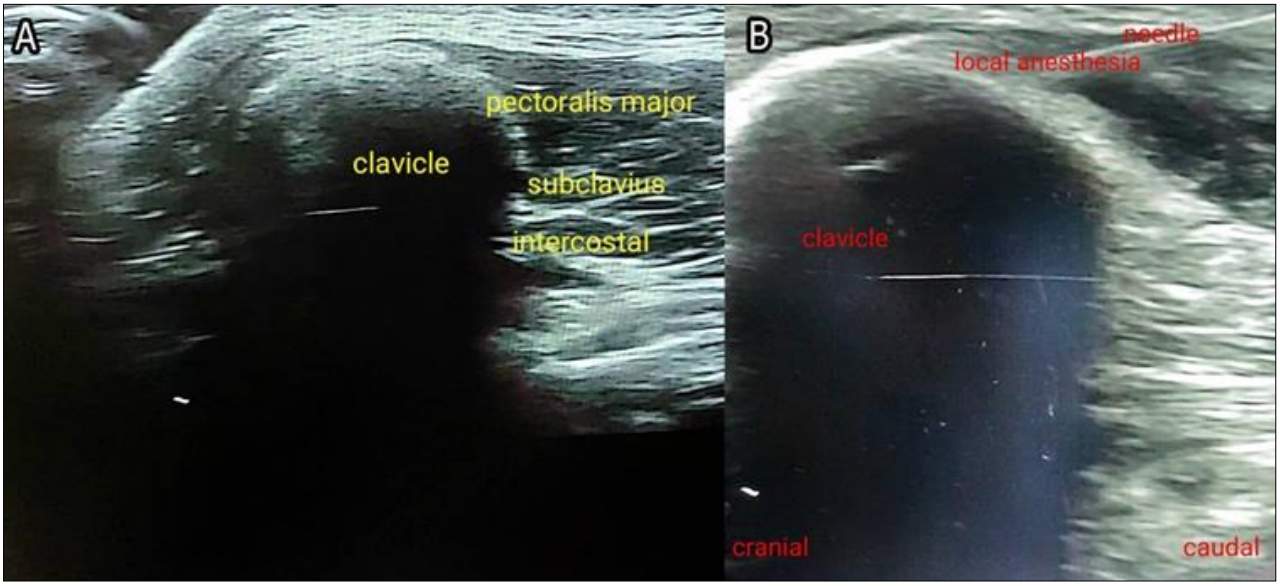

Fig 1: Ultrasound-guided Clavipectoral Fascia Plane Block Technique: A) Ultrasound landmarks for identifying the clavipectoral fascia; B) An ultrasound picture of the in-plane needle method for CPB.

Ultrasound Interscalene brachial plexus block technique

The technique was performed totally aseptically, utilizing a high frequency (12 MHz) linear ultrasonic probe (ALPINION E-CUBE 8) and a 10% povidine iodine disinfectant solution. Subjects were in supine posture with heads rotated to the other side. Additionally, positioning the transducer is accomplished over the cervical area till relevant landmarks in addition to identifying structures. To find the subclavian artery and brachial plexus, the ultrasound device was put just above the clavicle (see image for a supraclavicular block).

Then, ultrasound transducer was advanced cephalad to cases' neck when ensuring brachial plexus nerves were visible, till a "stop-light" image emerged. At this point, the brachial plexus consists of from three to five hypoechoic bands. Inserting needle was accomplished within a plane with the transducer, lateral to medial, and a snap was heard when it entered the prevertebral fascia. Once in the interscalene groove, the block needle moved till tip reached below prevertebral fascia, between the two most superficial hypoechoic structures. Following cautious aspiration, 15 mL of 0.5% bupivacaine was given.

Measurements

The patients' data were gathered by an anesthesiologist who was not involved in the trial and was blinded to their group. The total morphine intake within 1st 24 h following surgery underwent assessment in milligrams (1ry outcome).The postoperative NRS score was reported at (PACU, 2, 4, 6, 12, 18, and 24 hours), as well as the duration of surgery, total intraoperative fentanyl consumption in mic, duration for 1st rescue analgesia required (in hours), adverse events, hemodynamic parameters (MAP and HR), degree of patient satisfaction assessed on a 3-point scale, and mean diaphragmatic excursion in cm.

Statistical analysis

Categorical data underwent analysis utilizing the Chi-square test and reported as numbers as well as percentages, whereas parametric data underwent analysis utilizing the F-test (ANOVA) for normally distributed quantitative variables and the Kruskal Wallis test. To evaluate abnormally distributed quantitative variables among more than 2 examined groups, nonparametric data underwent analysis using the Mann-Whitney test. P-values ≤0.05 were deemed statistically significant.

Sample size: The sample size underwent calculation using Open-epi, addressing a 95% confidence level, a power of 95%, a ratio of exposed to unexposed of 1:1, a percentage of exposed with outcome (opioid consumption) of 20%, and a percentage of unexposed with outcome of 100%, so the sample size will be 10 for each group, with a 20% loss during follow-up, so each group will be 12 patients, which we will increase to 20 patients.

Results

No statistically significant variance was documented among all groups as regards LBW, operation length, or ASA (p>0.05), as shown in Table 1. Morphine rescue analgesia was shown to be more effective within group I in comparison with groups II as well as III (p1&p2 < 0.001) after 24 hours after surgery. No significant rise was documented as regards morphine intake in group II in comparison with group III (p3>0.001), as shown in Table 2. Table 3 exhibits a significant variance as regards NRS among all groups at PACU after two h, four h, six h, twelve h, eighteen h, as well as twenty-four h (p<0.05).

Group I had significantly higher intraoperative fentanyl consumption than group II (p<0.001), while no significant variance was documented among groups II as well as III (p=0.687), as shown on Table 4. Groups III and II had considerably longer wait times for their first analgesic than group I (P2 <0.001 and P1 <0.001). No significant delay was documented among groups III as well as II (p3 > 0.05), as demonstrated on Table 5.

No significant variance was documented among all groups as regards hypotension, bradycardia, pneumothorax, or LAST (p>0.05). However, a significant variance was documented among all groups in diaphragmatic hemiparesis (p<0.001), as shown on Table 6. a statistically significant variance was documented as regards patient satisfaction across all groups (p<0.001), with group I at 0.0%, group II at 100%, and group III at 90%, demonstrated on table 7.

Table 1: Comparison among all groups according to LBW, ASA as well as duration of surgery

	Group I (n = 20)	Group II (n = 20)	Group III (n = 20)	Test of sig.	p
LBW					
Min. – Max.	53.0 – 80.0	54.0 – 65.0	55.0 – 67.0	H=0.977	0.614
Mean ± SD.	59.20 ± 6.14	59.20 ± 2.78	59.05 ± 3.25		
ASA					
ASA I	16 (80.00%)	17 (85.00%)	18 (90.00%)	χ^2=0.784	0.676
ASA II	4 (20.00%)	3 (15.00%)	2 (10.00%)		
Duration of surgery					
Min. – Max.	95.0 – 120.0	95.0 – 120.0	99.0 – 120.0	F=0.154	0.857
Mean ± SD.	111.60 ± 7.76	112.80 ± 7.88	112.70 ± 7.08		

SD: Standard deviation, F: F for One way ANOVA test H: H for Kruskal Wallis test, χ2: Chi square test, p: p value for performing a comparison among all groups, Group I: Control, Group II: Clavipectoral fascia plane block (CPB), Group III: Interscalene brachial plexus block (ISB)

Table 2: Comparison among all groups based on morphine up take (mg)

Morphine consumption	Group I (n = 20)	Group II (n = 20)	Group III (n = 20)	H	p
Min. – Max.	9.0 – 12.0	3.0 – 6.0	3.0 – 9.0	43.082*	<0.001*
Mean ± SD.	9.90 ± 1.41	3.90 ± 1.41	5.40 ± 1.85		
Sig. bet. Grps.	p_1<0.001*, p_2<0.001*,p_3=0.079				

SD: Standard deviation, H: H for Kruskal Wallis test, Pairwise comparison among each two groups were accomplished utilizing Post Hoc Test (Dunn's for multiple comparisons test), p: p value for perfornming a comparison among all groups, p1: p value for performing a comparison among group I as well as group II, p2: p value for performing a comparison among group I as well as group III, p3: p value for performing a comparison among group II as well as group III, *: Statistically significant at $p \leq 0.05$,

Table 3: Comparison among all groups based on NRS on moving

NRS	Group I (n = 20)	p_0	Group II (n = 20)	p_0	Group III (n = 20)	p_0	H	p	p_1	p_2	p_3
2hrs (Moving)											
Min. – Max.	2.0 – 4.0	<0.001*	0.0 – 2.0	0.320	0.0 – 2.0	0.123	42.216*	<0.001*	<0.001*	<0.001*	0.306
Median (IQR)	3.0 (3.0–4.0)		1.0 (0.0–1.0)		1.0 (1.0–1.5)						
4hrs (Moving)											
Min. – Max.	2.0 – 6.0	<0.001*	0.0 – 2.0	0.011*	1.0 – 3.0	0.003*	32.709*	<0.001*	<0.001*	<0.001*	0.188
Median (IQR)	3.5 (2.0–5.0)		1.0 (1.0–2.0)		2.0 (1.0–2.0)						
6hrs (Moving)											
Min. – Max.	2.0 – 5.0	<0.001*	1.0 – 3.0	<0.001*	2.0 – 3.0	<0.001*	10.936*	0.004*	0.001*	0.357	0.022*
Median (IQR)	2.5 (2.0–4.0)		2.0 (2.0–2.0)		2.0 (2.0–3.0)						
12hrs (Moving)											
Min. – Max.	3.0 – 6.0	<0.001*	2.0 – 4.0	<0.001*	2.0 – 4.0	<0.001*	23.379*	<0.001*	<0.001*	<0.001*	0.403
Median (IQR)	4.5 (4.0–5.0)		3.0 (2.5–4.0)		4.0 (3.0–4.0)						
18hrs (Moving)											
Min. – Max.	4.0 – 6.0	<0.001*	1.0 – 4.0	<0.001*	2.0 – 5.0	<0.001*	24.649*	<0.001*	<0.001*	0.001*	0.092
Median (IQR)	4.0 (4.0–5.0)		3.0 (2.0–4.0)		4.0 (3.0–4.00)						
24hrs (Moving)											
Min. – Max.	2.0 – 4.0	<0.001*	2.0 – 5.0	<0.001*	3.0 – 5.0	<0.001*	12.736*	0.002*	0.032*	<0.001*	0.161
Median (IQR)	3.0 (3.0–3.0)		3.5 (3.0–4.0)		4.0 (3.0–4.0)						

IQR: Inter quartile range, H: H for Kruskal Wallis test, pairwise comparison bet. each 2 groups was done using Post Hoc Test (Dunn's for multiple comparisons test).

Table 4: Comparison among all groups based on Fentanyl Consumption (mic)

Fentanyl consumption	Group I (n = 20)	Group II (n = 20)	Group III (n = 20)	H	P
Min. – Max.	160.0 – 240.0	110.0 – 130.0	110.0 – 134.0	40.325*	<0.001*
Mean ± SD.	184.25 ± 21.04	119.50 ± 5.60	118.70 ± 6.54		
Sig. bet. GRPS.	p_1<0.001*,p_2<0.001*,p_3=0.687				

Table 5: Comparison among all groups based on time to first rescue analgesia in hours

T. RA	Group I (n = 20)	Group II (n = 20)	Group III (n = 20)	H	P
Min. – Max.	2.0 – 6.0	12.0 – 24.0	12.0 – 24.0	42.042*	<0.001*
Mean ± SD.	3.20 ± 1.20	16.50 ± 4.72	15.30 ± 4.12		
Sig. bet .Grps.	p_1<0.001*, p_2<0.001*, p_3=0.614				

Table 6: Comparison among all groups based on undesirable negative events

	Group I (n = 20)		Group II (n = 20)		Group III (n = 20)		χ^2	P
	No.	%	No.	%	No.	%		
Hypotension	0	0.0	0	0.0	3	15.0	4.329	^{MC}p=0.097
Bradycardia	0	0.0	0	0.0	2	10.0	2.765	^{MC}p=0.329
Pneumothorax	0	0.0	0	0.0	0	0.0	–	–
Dia hemiparesis	0	0.0	0	0.0	20	100.0	60.0*	<0.001*
LAST	0	0.0	0	0.0	0	0.0	–	–

χ2: Chi square test, MC: Monte Carlo, p: p value for comparing between the three studied groups, *: Statistically significant at p ≤ 0.05

Table 7: Comparison among all groups based on patient satisfaction

Patient satisfaction	Group I (n = 20)		Group II (n = 20)		Group III (n = 20)		χ^2	^{MC}p
	No.	%	No.	%	No.	%		
Unsatisfied=1	11	55.0	0	0.0	0	0.0	57.316*	<0.001*
Neither satisfied nor unsatisfied=2	9	45.0	0	0.0	2	10.0		
Satisfied=3	0	0.0	20	100.0	18	90.0		

Discussion

Our study proved that the CPB group and ISB group provided long-lasting and more efficient postoperative analgesia than the control group, duration till 1st rescue analgesic requirement exhibited significantly increased within CPB group as well as ISB one as opposed to controls, the total dose of morphine consumed in the 1st twenty-four h exhibited significantly decreased within CPB one and ISB group as opposed to controls, but complications occurred in the ISB group, particularly diaphragmatic hemiparesis.

Furthermore, patients were more satisfied within CPB as well as ISB groups as opposed to controls; there was no significant variance among all groups in hypotension, bradycardia, pneumothorax, or LAST, but there was a significant difference in diaphragmatic hemiparesis.

The CPB represents an enticing substitute to the aforementioned due to a single-injection approach, easy to administer, along with being safe, particularly among individuals developing respiratory issues. In comparison with brachial plexus blocks like the interscalene block that stop transmitting pain in a more proximal direction, thus lying near the cervical spine as well as neck neurovascular stucture, the CPB is more likely safe since it is injected more laterally as well as superficially. Additionally, the clavicle exhibits a natural barrier.

In agreement with our findings, Abu Sabaa *et al* examined US-guided clavipectoral block for pain relief after clavicular surgical procedure. A prospective randomized research was carried out on forty participants split into two groups: group 1 involved twenty subjects undergoing clavipectoral block while group 2 involved twenty subjects who were placebo. A thirty mL of the LA mixture (1:1 bupivacaine 0.5% in addition to lidocaine 2%) administered into the clavipectoral fascia as well as the clavicle periosteum on the fracture lateral and medial sides [9].

Their findings addressed, CPB was linked to a significantly reduced VAS within PACU as well as twelve-h following surgery, as well as a substantial decrease as regards total opioids' intake among cases receiving the block. Furthermore, the analgesia duration was considerably extended within the same group, resulting in increased satisfaction. No issues existed with the injection technique.

Rosales *et al*. examined a case report including clavipectoral plane block to be a single anaesthetic method as regards clavicle surgical procedure. Preoperatively, administering a peripheral nerve block was accomplished utilizing sedation with midazolam at a dosage of two to five mg along with an IV fentanyl dosage of fifty to one-hundred µg.

The local anesthetic combination employed consisted of thirty ml (1:1 ratio) of 0.25% levobupivacaine in addition to 1% lidocaine, divided into fifteen ml for the medial as well as fifteen ml for the lateral side. The case underwent monitoring for pain control within PACU till 2h, with their NRS score being 0 out of 10. 12-h following the nerve block, they were comfortably seated on the bed wearing an arm sling, addressing a pain score of 0.10 on the NRS. However, 16 hours after the block, the cases reported an NRS level of pain reaching 7/10 at the surgical location. A dosage of intravenous tramadol (50 mg) provided instant relief, lowering the pain level to NRS 0/10 [10].

The second example is a lady with COPD. The case's forced expiratory volume within one second was less than 1 L, as shown by a respiratory examination. To avoid phrenic nerve paralysis, a CPB with superficial cervical plexus block was scheduled rather than an interscalene brachial nerve block. Her HR as well as BP exhibited constant values, in addition to experiencing minor discomfort (VAS score indicating one to two out of ten) during surgery, without any painkiller consumed till thirteen hours later.

Furthermore, Atalay *et al*. investigated a case of good treatment of pain following the surgical procedure utilizing superficial cervical plexus-clavipectoral fascia plane block within a patient having right-clavicle fracture surgical

procedure utilizing GA. After surgery, they carried out an US-guided superficial cervical plexus-clavipectoral fascia plane block. They administered twenty mL of 0.25% bupivacaine into periosteum as well as clavipectoral fascia. In the PACU, the pain was assessed by a VAS. With pain rated as zero, addressing no administered analgesic. The patient addressed 2 as maximum VAS score at rest due to a headache. She didn't notice any pain at the site of the operation until a day after the surgical procedure, while having a pain level reaching 3 based on VAS that was managed utilizing multiple analgesics (NSAIDs along with tramadol) [11].

The reduced VAS as well as total opioids' usage postoperatively withn the research could be attributed to: CPB must offer efficient pain management since all sensory nerves supporting clavicle transmit via clavipectoral plane with an exception for the suprascapular nerve supplying skin around clavicle. But Kukreja *et al* discovered a sensory obstruction within such a region. The findings were ascribed to many causes, including the penetrating anesthetic agent utilized within block, the previous LA infiltration diffusion, and some branches' obstruction passing probably via such a plane, inducing sensation loss [12].

Conclusion

Preoperative US-guided CPB as well as interscalene block of the brachial plexus are useful instruments for during and after surgery operation analgesia in patients having clavicle surgery as increase the time to first rescue analgesia, reduce after surgery total morphine usage, reduce pain after surgery scores, and improve patient satisfaction. However, ultrasound-guided clavipectoral fascia plane block is preferred since it does not result in diaphragmatic hemiparesis.

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