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CLINICAL TRIAL REPORT

Effect of Ropivacaine in Combined Costoclavicular Brachial Plexus - Cervical Plexus Blocks on Hemidiaphragmatic Paralysis for Humeral Fracture Surgery: A Prospective Single - Centre Cohort Study

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Background: The brachial plexus block is conducive to providing postoperative analgesia for patients with humeral fractures. The commonly used brachial plexus block techniques have a high incidence rate of hemidiaphragmatic paralysis (HDP), which may lead to respiratory problems. The combined costoclavicular brachial plexus - cervical plexus blocks (CCB-CPBs) had demonstrated favorable analgesic effects and had reduced the incidence of HDP in shoulder surgeries. However, the clinical experience regarding CCB-CPBs is rather limited. Consequently, our study aims to evaluate its various effects, such as the diaphragmatic and pulmonary functions, as well as the analgesia for humeral fracture surgeries.

Patients and Methods: We enrolled 30 patients who were slated to undergo surgery for humeral fractures under the combined use of nerve block and general anesthesia. All the patients underwent CCB-CPBs under the guidance of an ultrasound and a nerve simulator. The anesthetic dosage consisted of 20 ml and 10 ml of 0.5% ropivacaine respectively. Following the operation, all the patients were transferred to the Post-Anesthesia Care Unit (PACU). The diaphragmatic excursion, spirometry outcomes, pain score, along with the sensory and motor block, were evaluated.

Results: The diaphragmatic excursion was significantly reduced during the post-block period in contrast to the pre-block period. The mean change in diaphragmatic excursion (with the mean value [SD]) was −25.3 [48.6] %, accompanied by a *P*-value of 0.001. The forced vital capacity (FVC) during the post-block period was approximately 7% lower compared to that during the pre-block period, with a *P*-value of 0.032. The numerical rating scale (NRS) scores of the patients in the PACU were 0 (0–0).

Conclusion: CCB-CPBs can result in a reduction in hemidiaphragm excursion and may slightly affect lung function to some extent. Nevertheless, they can provide a favorable analgesic effect for humeral fracture surgery. Therefore, patients with poor respiratory reserve should exercise caution when using it.

Keywords: ropivacaine, costoclavicular, humeral fracture, nerve block, hemidiaphragmatic paralysis

Introduction

As a commonly utilized regional anesthesia technique, the brachial plexus block can offer effective postoperative analgesia to patients with humeral fractures.[1,2] thereby significantly reducing postoperative complications and the length of hospital stay.[3] Given that humeral fractures involve the shoulder and upper arm, the brachial plexus block typically necessitates the application of either the interscalene or supraclavicular block.[1] The interscalene block

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represents a standard technique for shoulder surgeries,[4] being particularly applicable to those involving proximal humeral fractures.[2] However, hemidiaphragmatic paralysis (HDP) exhibits a high prevalence, with the rate even capable of reaching 100% at its peak.[5] HDP is associated with a significant incidence of acute respiratory complications and augments the risk of postoperative complications.[6,7] The supraclavicular brachial plexus block is marginally less efficacious in providing shoulder block when compared to the interscalene block. Although the incidence of HDP is diminished, it can still attain a rate of 67%.[5] Consequently, it is worthy of note that reducing the incidence of HDP constitutes an urgent problem demanding solution when the brachial plexus block is applied to humeral fractures.

The costoclavicular brachial plexus block (CCB), a novel brachial plexus block technique, compared with the interscalene and supraclavicular approaches, not only ensures a definite analgesic effect but, more importantly, significantly reduces the incidence of HDP.[8] Recent studies have further confirmed the effective analgesic effect of CCB in shoulder surgeries.[4,9,10] Among them, the combination of costoclavicular brachial plexus-cervical plexus blocks (CCB-CPBs) appears to yield the best results.[4] Consequently, we speculate that together with a low incidence of HDP, CCB-CPBs could provide consistent analgesia for humeral fracture surgery.

To date, there has been limited clinical experience regarding the CCB-CPBs technique.[4] The objective of this prospective study is to evaluate the diaphragmatic function, spirometry outcomes, the characteristics of sensory and motor block, as well as the analgesic effect on humeral fracture surgeries of CCB-CPBs that are guided by ultrasound and nerve stimulator.

Materials and Methods

Design

The Ethics Committee of Ningbo No. 6 hospital, Zhejiang, China, approved the protocol of this study on April 25, 2024 (NO. 2024–20L). We registered this study at http://www.chictr.org.cn (ChiCTR2400083782; Miao Zhu; May 1, 2024). In accordance with the Helsinki Declaration, we obtained all participants informed written consent. This report was created using the principles outlined in Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).

Subjects and Setting

At Ningbo No. 6 hospital located in Ningbo, Zhejiang Province, China, our intention was to enroll 30 patients for the surgery of humeral fractures under general anesthesia. The following criteria were employed to determine the inclusion of patients: The physical status classified by the American Society of Anesthesiologists as I-III, a body mass index ranging from 18 to 28 kg/m^2, and an age range spanning from 18 to 80 years. The exclusion criteria were as follows: Patients who refused to participate in the study, those with pre-existing neuropathy of the operative limb, those with pre-existing moderate to severe lung diseases (either obstructive or restrictive), patients with coagulopathy, pregnant women, those with sepsis, patients with hepatic failure (with a Child-Turcotte-Pugh score of more than 9), or those with renal failure (with a creatinine level of 2 mg/dl or requiring peritoneal dialysis or hemodialysis), patients with an allergy to amide local anesthetics, those with a chronic pain condition, and patients who had undergone prior surgery in the neck or infraclavicular region.

Study Protocol

No premedication was administered to the patients, and they were required to observe an eight-hour fasting period. Upon entering the operating room, we established a peripheral intravenous access in the non-operative upper limb by using a 16-gauge catheter for fluid administration. We commenced a rapid peripheral intravenous preload of Ringer's lactate solution at a rate of 10 ml/kg and then maintained a low infusion rate throughout the procedure. Standard non-invasive monitoring techniques, including non-invasive blood pressure measurement, pulse oximetry, and electrocardiography, were implemented.

Baseline Spirometry Test and Diaphragmatic Excursion Measurement

The patient was placed in a semi-sitting position with their head elevated approximately 30 degrees. Through the anterior subcostal route, either the liver or the spleen was utilized as an acoustic window. Subsequently, the excursion of the hemidiaphragm was measured by us using the SONOSITE SII® (FUJIFILM SonoSite, Inc., Bothell, USA) M-mode equipped with a low-frequency (1 to 5 MHz) ultrasound probe. Stable waveforms were recorded during deep breathing, and the corresponding values were noted. The spirometry outcomes were tested using a CONTEC SP80B handheld spirometer (CONTEC Medical Systems Co., Ltd., Hebei, China). Three values each of forced expiratory volume in 1 second (FEV_1) and forced vital capacity (FVC) were recorded, and subsequently the average values were calculated.

Ultrasound and Nerve Stimulator Guided Costoclavicular Brachial Plexus Block

A soft pad was not placed under the patient's scapula as the patient with a humeral fracture would experience extreme pain when moving the injured arm. The patient's head was gently rotated to the non-operation side by us, and the SONOSITE SII equipped with a high-frequency (6–13 MHz) linear ultrasound probe was positioned parallel to and below the clavicle. The probe was gently tilted towards the cephalad in order to visualize the axillary artery and vein. Next, the image was adjusted until it showed all three cords of the brachial plexus, which were situated near the axillary artery. However, in contrast to other patients, our patients did not place a soft pad under their scapula and did not abduct their arm. Consequently, the three cords of the brachial plexus do not always display a triangular arrangement; at times, the medial cord is situated beneath the axillary artery, and at times, the three cords are not clearly visible. Accordingly, the Multistim Sensor nerve stimulator (PAJUNK, Geisingen, Germany) was used by us to confirm the target cord. The nerve stimulator was connected to the patient, along with a 21G 70mm disposable monopolar nerve block needle (Hakko Co., Ltd., Nagano, Japan). Initially, the nerve stimulator was set to a pulse width of 0.1 millisecond, a frequency of 2 Hz, and a current output of 0.4 mA. Then, the needle was inserted from the lateral to medial direction using the in-plane technique. The ideal electrical stimulator response for us was the deltoid twitch (posterior cord axillary nerve).[11] However, the deltoid twitch was not elicited every time as expected. Consequently, if any other responses were elicited, such as those of the biceps brachii (lateral cord musculocutaneous nerve), triceps brachii (posterior cord radial nerve), index finger (lateral cord median nerve), little finger (medial cord ulnar nerve), or pectoralis major muscle (lateral cord lateral pectoral nerve), the needle tip was regarded as having been positioned at the corresponding cord. 20 ml of 0.5% ropivacaine (Naropin; AstraZeneca Co., Ltd.; 10 mg/ml) was administered using the multiple injection technique until three cords were identified.

Ultrasound Cervical Plexus Block

All patients underwent a superficial cervical plexus block under the guidance of ultrasound. We are implementing the method previously mentioned.[12] This method offers enhanced coverage for skin incisions. A volume of ten milliliters of 0.5% ropivacaine was injected into the area between the sternocleidomastoid and scalene muscles at the fourth level of the cervical spine.

General Anesthesia

Upon completion of the nerve block, all the patients were readied for the induction of general anesthesia, and airway management was performed using a laryngeal mask airway. The induction agents consisted of intravenous propofol (at a dosage of 2–3 mg/kg) and atropine (in a dosage range of 0–0.5 mg). 1.5–3% sevoflurane was utilized to maintain the anesthesia. After the induction of anesthesia, the assisted ventilation mode was initially employed to assist patients with breathing.

When a skin incision was made, the ventilation mode was adjusted based on the patients' responses. For some patients, the pain stimulation during the skin incision elicited spontaneous breathing, and we promptly changed the ventilation mode to "spontaneous". If there was no response during the skin incision, the assisted ventilation mode was maintained until the patients exhibited sufficient spontaneous breathing, at which point we changed the ventilation mode again.

When a skin incision was made, the heart rate or blood pressure was allowed to rise by 20% of the preoperative value, and the sevoflurane concentration was adjusted to 3%. In the event that the heart rate and blood pressure did not show a decline within 15 minutes, intravenous boluses of 50 g fentanyl were administered, and the procedure would be repeated if deemed necessary. The surgical duration was defined to be the time interval stretching from skin incision to closure.

Each patient was transferred to the post-anesthesia care unit (PACU) subsequent to the completion of surgery. After the patients regained full consciousness, they reported their scores based on the numerical rating scale (NRS) score introduced by us, where 0 represents no pain and 10 indicates the greatest anguish imaginable. In cases where the patient's NRS score ≥ 3, an intravenous bolus of 50 μg of fentanyl was administered. The administration could be repeated as per the specific requirements.

Measurements

The primary outcome measures comprised the ipsilateral diaphragmatic function as well as the spirometry outcomes. The secondary outcome measures encompassed the patients' NRS score within the PACU, the characteristics of the sensory and motor block, the occurrence of complications, and the consumption of fentanyl.

Prior to the patients' departure from the PACU, we measured the diaphragmatic excursion and spirometry outcomes employing the same methodology utilized prior to the surgery. Complete HDP was defined as a 75–100% reduction in diaphragmatic excursion or the occurrence of paradoxical movement. Partial HDP was defined as a 25–75% reduction in diaphragmatic excursion.

Before leaving the PACU, we also assessed the sensory and motor block. Table 1 summarized the criteria. A cold test assessed sensory block on a 3-point scale (0 = no block; 1 = analgesia, allowing the patient to feel touch but not cold; 2 = anesthesia, preventing touch). We also assessed motor block on a 3-point scale (0 = normal movement, 1 = paresis, and 2 = no movement).[13]

During the first thirty minutes subsequent to the induction of general anesthesia, the systolic blood pressure was measured every three minutes; subsequently, it was measured every five minutes. A decrease in systolic blood pressure of more than 20% from the preoperative level was considered as hypotension. In patients with hypotension, 8 μg of norepinephrine could be injected intravenously once, and then the process was to be continued until the blood pressure returned to 80% of its preoperative systolic level. The total amount of norepinephrine administered was recorded.

Statistical Considerations

We tested the normality of continuous data using the Shapiro–Wilk test. We reported normally distributed data as the mean (SD), and nonnormally distributed data as the median (IQR). We used Friedman's two-way analysis of variance by rank to analyze the sensory and motor scores. The Bonferroni correction adjusted the significance values for multiple tests. We used a Wilcoxon-signed rank test to analyze the diaphragmatic excursion and spirometry outcomes. We used Pearson correlation analysis to find the association between changes in diaphragmatic excursion, changes in FEV_1, and changes in FVC.

All statistical analyses were conducted using Microsoft Excel 2010 and the SPSS 25.0 for Windows statistical application (SPSS, Inc., Chicago, IL). A statistically significant result was defined as $P < 0.05$.

Table 1 Sensory and motor Block Assessment

Nerve assessed	Sensory	Motor
Radial nerve	Dorsum of thumb	Thumb abduction
Median nerve	Palmar of thumb	Thumb opposition with the index finger
Ulnar nerve	Little finger	Thumb opposition with the little finger
Musculocutaneous nerve	Lateral aspect of distal forearm	Elbow flexion
Axillary nerve	Lower region of the deltoid muscle	Not allow to abduct the shoulder

Table 2 Characteristics of Subjects Who Completed the Study

Sample Size, n	30
Gender (male/female)	7/23
Side of surgery (left/right)	15/15
ASA (I/II)	1/29
Age (SD) in years	58 (11.2)
Weight (IQR) in kg	61 (54.8–75.5)
Height (SD) in cm	158 (7.6)
BMI (SD) in kg/m^2	24.4 (3.1)
Block performance time (IQR) in min	3 (3–3)
Surgical site	
Proximal humerus	22
Greater tuberosity of humerus	3
Middle humeral	7
Duration of surgery (SD) in min	80.6 (30.4)

Abbreviations: SD, standard deviation; BMI, body mass index; IQR, interquartile range.

Results

During the period from May 1, 2024, to July 1, 2024, the eligibility of 33 patients was assessed by us. One patient withdrew from the study after undergoing surgery due to severe vomiting. One patient withdrew from the study prior to surgery on account of anaphylaxis. One patient withdrew from the study as she was incapable of cooperating. The characteristics of the patients are summarized in Table 2. The age range of the included patients finally ranged from 35 to 77 years old.

Figure 1 shows the ipsilateral diaphragmatic and spirometry outcomes. The Hemidiaphragm excursion (median [IQR]) during deep breathing, in pre block, and in post block, were 3.78 [2.58–5.09] cm and 2.08 [1.36–3.14] cm respectively, and it was significantly lower in post block than in pre block ($P = 0.001$). The change of hemidiaphragm excursion (mean [SD]) was −25.3 [48.6] %.

The FVC (median [IQR]) in the post block was 2.19 [1.65–2.57] L and 1.93 [1.44–2.51] L respectively, and it was significantly lower in post block than in pre block ($P = 0.032$). The change of FVC (mean [SD]) was −7.31 [27.45] %.

The FEV_1 (mean [SD]) in pre block and in post block were 1.55 [0.74] L and 1.4 [0.68] L respectively. There was no significant difference between the values in the post block and those in the pre block.

Figure 2 shows that there was a significant relationship between changes in hemidiaphragm excursion and changes in FEV_1 (Pearson correlation coefficient = 0.417, $P = 0.022$). There was no significant correlation between changes in hemidiaphragm excursion and changes in FVC (Pearson correlation coefficient = 0.253, $P = 0.18$).

The NRS scores of patients in PACU were 0 (0–0). There were six patients whose NRS score was equal to or higher than 3. Figure 3 reveals the distribution of NRS scores before leaving PACU.

Figure 4 presents the nerve responses after combining the CCB with a nerve stimulator. Five individuals were not stimulated because the machine was broken.

Figure 5 summarizes the sensory and motor scores. The sensory axillary nerve had a significantly lower score compared with the motor radial nerve ($P = 0.015$) and motor musculocutaneous nerve ($P = 0.019$). There is no statistical difference between the scores of other nerves.

Table 3 indicate the adverse effects of anesthesia.

Discussion

We found that when CCB-CPBs were applied in the surgery of humeral fractures, around one hour after the surgery, patients experienced a loss of approximately 25% of the ipsilateral diaphragmatic excursion, and there was an

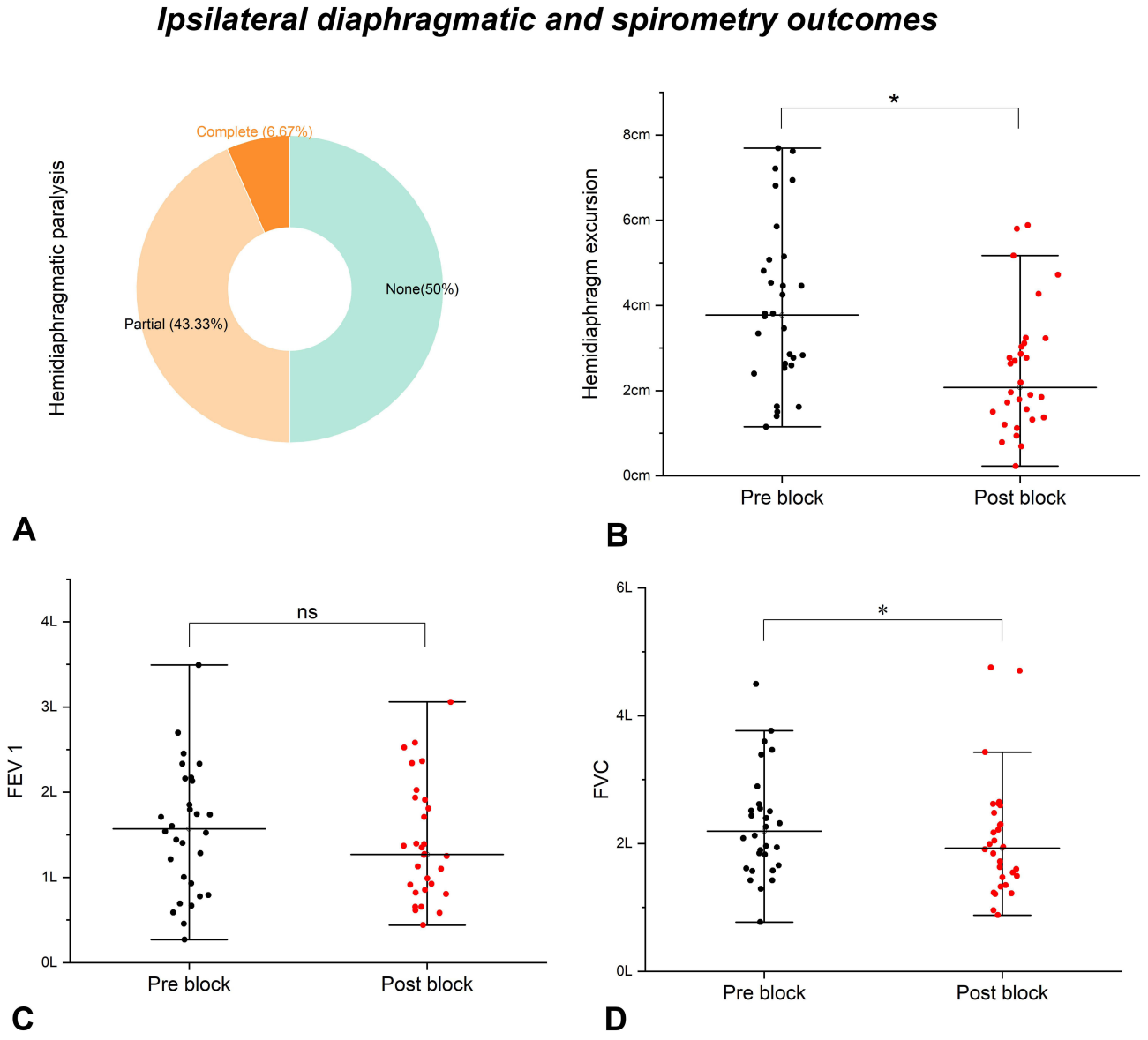

Figure 1 The diagram illustrates the hemidiaphragmatic and spirometry outcomes. (**A**) The percentage of patients with hemidiaphragmatic paralysis (HDP) categorized as complete, partial, or none prior to leaving the post-anesthesia care unit (PACU). (**B**) The scatter plot for hemidiaphragm excursion during deep breathing, in the pre-block stage, and in the post-block stage. (**C**) The scatter plot for spirometry FEV_1 (forced expiratory volume in one second) in the pre-block stage and in the post-block stage. (**D**) The scatter plot for spirometry FVC (forced vital capacity) in the pre-block stage and in the post-block stage. The whiskers represent the interquartile range, and the solid black line indicates the median. The black dots denote the data from the pre-block stage, while the red dots denote the data from the post-block stage. *p<0.05 by Wilcoxon-signed rank test and ns, not significant.

approximately 7% loss in FVC, with the FEV_1 being preserved, and furthermore, the pain of 80% of the patients was effectively controlled.

In our study, it was duly noted that the average reduction in hemidiaphragm excursion attained a value of 25.3%. Significantly, this figure surpassed that of the sole costoclavicular block, where the corresponding reductions were 6.63% and 12.5% respectively.[8,9] Similarly, in this study, the overall incidence of HDP, encompassing both partial and complete forms, was determined to be 50%. This incidence was markedly higher than the previously reported incidence of HDP associated with the sole CCB, which ranged from 7.5% to 20%.[9,14] We attribute the differences in the above data to the fact that the type of nerve block employed in this study is a combination of the CCB and the cervical plexus block. It has been reported that the cervical plexus block can indeed result in phrenic nerve block, potentially leading to a considerably high incidence of HDP,[12,15] Specifically, when combined with the cervical plexus block, the incidence of HDP can

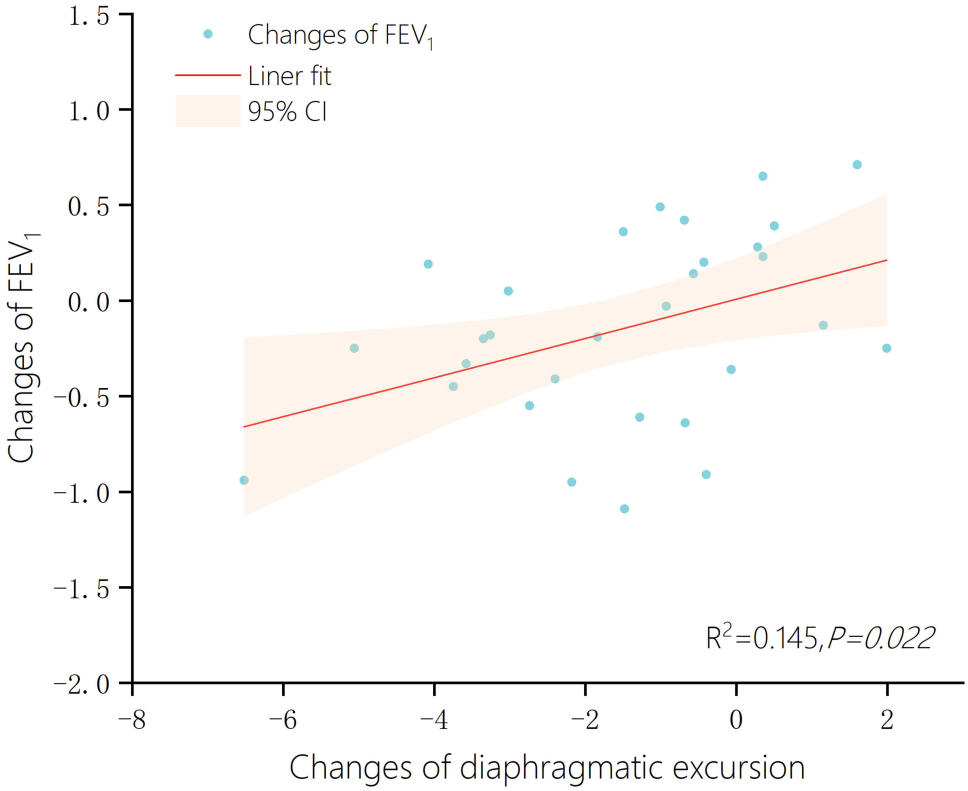

Figure 2 A significant correlation was observed between the changes in hemidiaphragm excursion and those in FEV_1, with a *P*-value of 0.022.

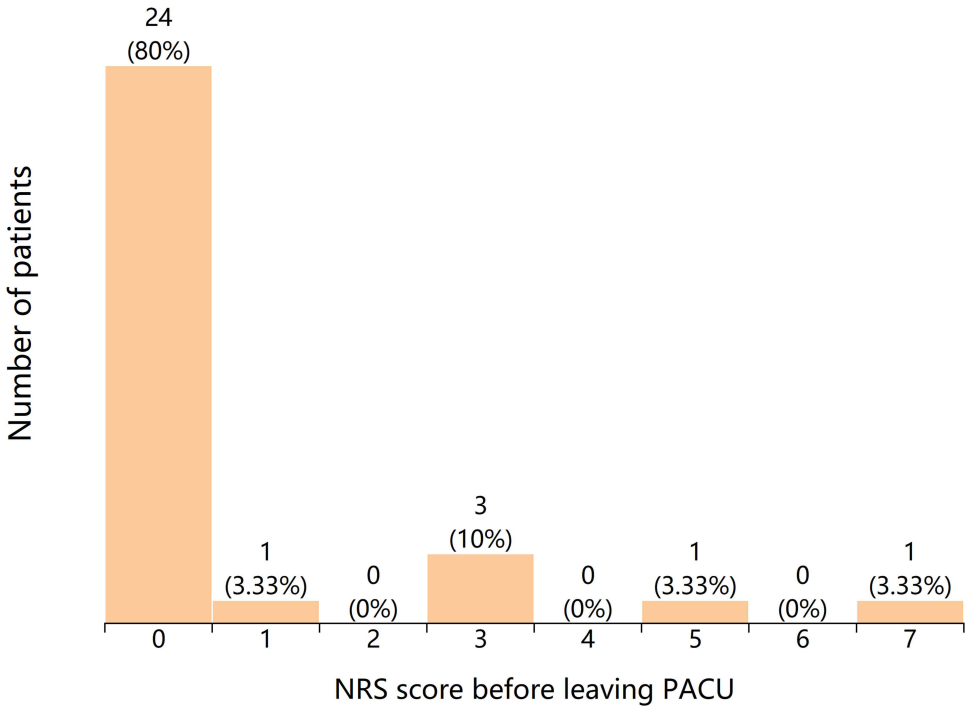

Figure 3 The Numerical Rating Scale (NRS) scores of all the patients prior to leaving the Post-Anesthesia Care Unit (PACU) are revealed.

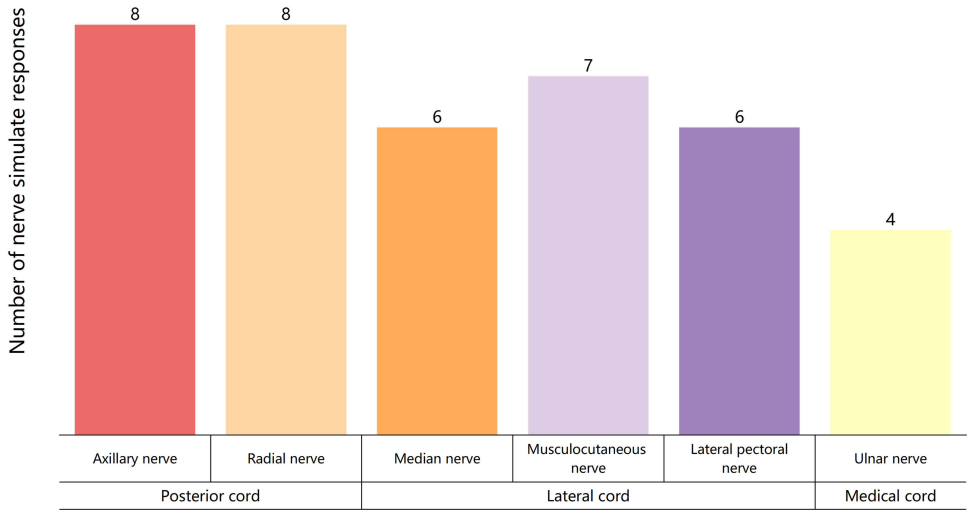

Figure 4 The sum is represented by the total of all patients' nerve-stimulated responses.

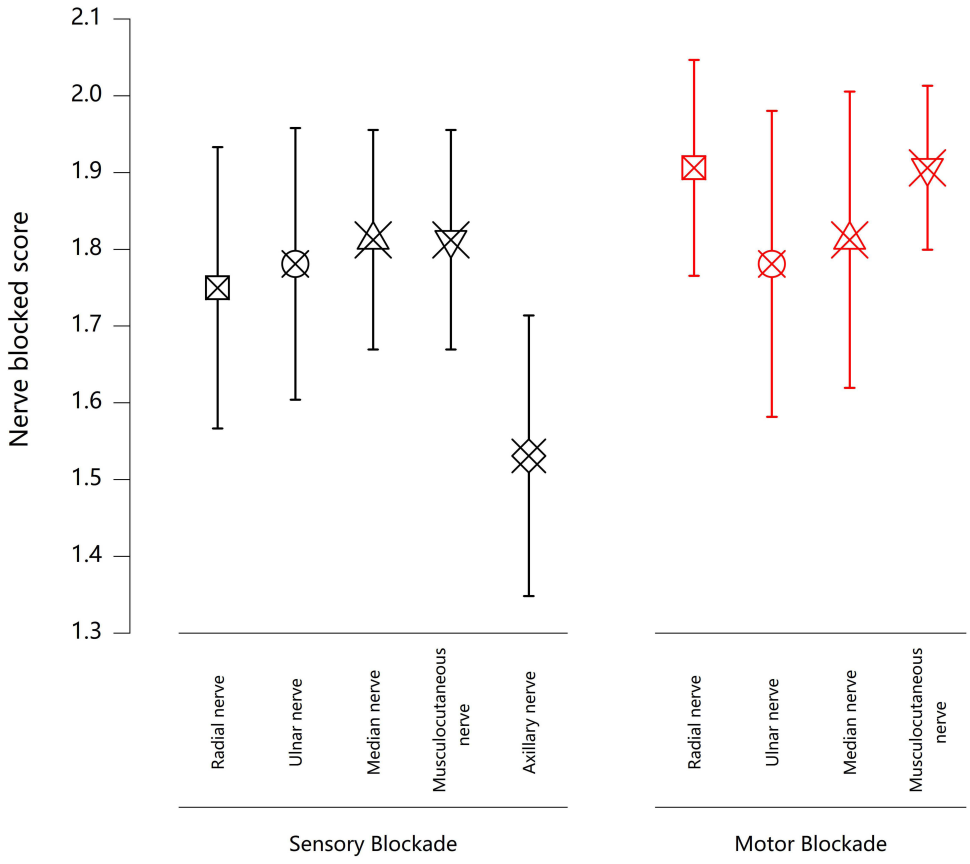

Figure 5 Individual nerves display both sensory and motor scores. The black lines denote the sensory nerve score, while the red lines denote the motor nerve score.

actually reach approximately 50%. It is our firmly held belief that the cervical plexus block holds the potential to induce diaphragmatic dysfunction on the ipsilateral side. The fundamental reason behind this lies in the fact that local anesthetics have the capacity to permeate through the prevertebral fascia and consequently block the phrenic nerve.[12,15]

In this study, it was observed that there was an approximately 7% loss in FVC, while FEV_1 remained preserved. Regarding the sole CCB, the loss in FVC was found to range from 1.9% to 7.5%,[16,17] and based on the data, these values

Table 3 Adverse Effects of Anesthesia

Sample size, n	30
Hypotension, n (%)	9 (30)
Norepinephrine requirement (IQR) in μg	0 (0–40)
Hoarseness n (%)	1 (3.33)
Intraoperative rescue fentanyl n (%)	3 (10)
Intraoperative fentanyl requirement (IQR) in μg	0 (0–0)

Abbreviation: IQR, interquartile range.

were approximately similar. It is worth noting that the reduction in FVC was not exacerbated due to the cervical plexus block. Overall, as reported in previous studies, a downward trend in the reduction of FVC was observed from the interscalene block to the infraclavicular block,[16–20] and a correlation was found between the reduction in FVC and diaphragmatic excursion.[21] However, anomalous situations did occur. For instance, in a highly esteemed research paper, when the decrease in diaphragmatic excursion reached 56%, the loss in FVC was 30%; yet, when the decrease in diaphragmatic excursion was 39%, the loss in FVC surprisingly increased to 39% instead.[22] The reduction in FVC did not decline in tandem with the decrease in diaphragmatic excursion; instead, it increased.

We attribute the aforementioned phenomena to two main reasons. Firstly, three-quarters of FVC depend on diaphragmatic excursion, while one-quarter relies on the expansion of the thoracic cage. Consequently, for the same degree of diaphragmatic excursion, different degrees of FVC may be measured due to this differential dependency.[21] Secondly, diaphragmatic excursion is highly susceptible to the influence of the subject's body position. Specifically, the amplitude of diaphragmatic excursion in the supine position is significantly greater than that in the standing and sitting positions.[23] In conclusion, the differences in thoracic cage compliance among different subject groups in various studies, along with the differences in the body position during testing, may lead to significant differences in FVC.

Our NRS scores, which were 0 [0–0] prior to leaving the PACU, were at least equivalent to those in a previous study, where the score was 0 [2] at 1 hour post-operation,[4] and might even be lower. When a similar nerve block technique was employed, the consumption of fentanyl in their case, which was 50 μg prior to surgery plus a median of 80 μg during the operation, was noticeably greater than ours, with a total of 50 μg. Moreover, compared to their arthroscopic shoulder surgeries, our open reduction and internal fixation surgeries were more traumatic.

The scores of the sensory axillary nerve in this study were significantly lower. In contrast to an anatomical study, it was reported that in all five injections, the axillary nerve was stained with methylene blue.[24] Although we attempted to confirm the axillary nerves using a nerve simulator, nearly two-thirds of the patients were unsuccessful. The possible reason for our failure might be that at the insertion level of the needle, the axillary nerve did not separate from the posterior cord, thereby preventing us from generating muscle contractions. Another potential explanation is that the axillary nerve could not be constantly blocked by the costoclavicular block. Moreover, the sample size of the anatomical study might be insufficient to identify those patients who remained unblocked. In conclusion, our investigation revealed that patients reported a reduced degree of blockage on the axillary sensory nerve.

Our current study had several limitations. Firstly, there was no control group in our observational study. Our aim was to preliminarily evaluate the impact of CCB-CPBs on the diaphragm and respiratory function in humeral fracture surgery. Subsequently, an appropriate control group would be selected based on the results for a comparative study. Secondly, our study included the greater tuberosity of the humerus and middle humeral surgery, and this reduced the ability to confirm the effectiveness of CCB-CPBs for shoulder pain. Further research could potentially address this issue.

Conclusion

In conclusion, CCB-CPBs can result in a reduction in hemidiaphragm excursion and may slightly affect lung function to some extent. Nevertheless, they can provide a favorable analgesic effect for humeral fracture surgery. Therefore, patients with poor respiratory reserve should exercise caution when using it.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no potential conflicts of interest for this work.

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