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ORIGINAL RESEARCH **REGIONAL ANESTHESIA**

Clavipectoral fascial plane block versus superficial cervical plexus block for fracture clavicle surgery: a randomized clinical trial

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ABSTRACT

Background & objective: Both, the clavipectoral fascial plane block as well as superficial cervical plane block have been utilized as a regional anesthesia technique for clavicular fracture surgery. We compared the efficacy and safety of clavipectoral plane block with superficial cervical plexus block for intraoperative and postoperative pain relief in clavicular fracture surgery under general anesthesia (GA).

Methodology: This double-blinded randomized controlled trial included 84 patients, aged between 21 and 60 y, ASA classification I and II, with fracture clavicle, either isolated or part of other trauma, undergoing fracture clavicle fixation. The patients were divided into two groups. The first group received a clavipectoral fascial plane block and the other received a superficial cervical plane block. The visual analogue scale (VAS) scores were recorded as primary outcome, while the patients' hemodynamics, time to first rescue analgesic, and total morphine consumption were the secondary outcomes at post-anesthesia care unit (PACU) then every 2 h in the ward till 8 h.

Results: Compared to the superficial cervical plexus block the clavipectoral plane block was superior in analgesia and more effective during surgical dissection and intraoperative manipulations with a clinically and statistically significant difference all the time from PACU to 8 h postoperatively. The heart rate and arterial blood pressure were much more stable in the clavipectoral group. Also, time to first rescue analgesic was more in the clavipectoral group than in the superficial cervical block. Total morphine consumption was significantly less in the clavipectoral group than in the superficial cervical group.

Conclusion: Clavipectoral plane bock is superior to superficial cervical block in fracture clavicle surgeries regarding efficacy and safety. Postoperative pain, measured by VAS, was less with clavipectoral plane block, with more hemodynamic stability and less opioid consumption postoperatively.

Abbreviations: PACU - post-anesthesia care unit; CFP - Clavipectoral fascial plane; SCP - Superficial cervical plexus

Keywords: Clavipectoral Plane Bock; Fracture Clavicle; Pain, Postoperative; Superficial Cervical Plexus Block

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1. INTRODUCTION

Clavipectoral fascial plane (CFP) block has been utilized as a novel technique for clavicular fracture surgery, that accounts for 2.6% of all fractures and is frequently seen in both the emergency department and operating room settings.[1,2]

The CFP block technique for clavicular surgery has been hypothesized to be an effective regional anesthesia technique for perioperative pain control since the sensory nerve terminal branches (suprascapular, subclavian, lateral pectoral, and long thoracic nerves) pass through the plane between the clavipectoral fascia and the clavicle itself.[3]

Superficial cervical plexus (SCP) block may be of beneficial in emergency for patients with injuries to the ear, neck, and clavicular region, including fracture clavicle and acromioclavicular dislocations. The SCP originates from the anterior rami of the C1-C4 spinal nerves and gives rise to the 4 terminal branches (greater auricular, lesser occipital, transverse cervical, and suprascapular nerves) that give sensory innervation to the skin and superficial structures of the anterolateral neck and sections of the ear and shoulder.[4]

The study assessed the efficacy and safety of CFP block compared to SCP block regarding control of pain intraoperatively and postoperatively during fracture clavicle surgery under general anesthesia (GA).

2. METHODOLOGY

The double-blinded, parallel-group, randomized trial was approved by the Ethics Committee of the Faculty of Medicine, Ain Shams University, Egypt (FMASU R 57/2023), and was registered at ClinicalTrials.gov (ID: NCT05881473; Date: May 19, 2023). After the explanation of the aim and procedures of the study, written informed consent was acquired from the participants' parents or guardians. The participant's data were kept confidential.

The study was conducted at the orthopedic operating room (OR) of Ain Shams University Hospitals, between March 2023 and September 2023. We included 84 patients of both genders aged from 21 to 60 y with ASA classification 1-2 with fracture clavicle either isolated or part of other trauma, undergoing surgical fixation. While, hemodynamically unstable traumatized patients, patients with infection at the site of injection, patients with a known history of allergy to any type of local anesthetics, and/or patient refusal at any time, were excluded from the study.

Randomization and allocation concealment were performed using the computer-generated random number table and sequentially numbered, opaque, sealed envelopes**.** The patients and the outcome evaluators were blinded to the group allocation.

2.1. Sample size calculation

Using the PASS 15 program for sample size calculation, setting power at 80% and alpha error at 0.05, and according to a study by Xu et al., the expected median VAS score 6 h post-operative among study groups was 0 (0-2) and 1 (0-2). A sample size of 40 patients per group was needed to detect the difference between the two groups.

2.2. Interventions

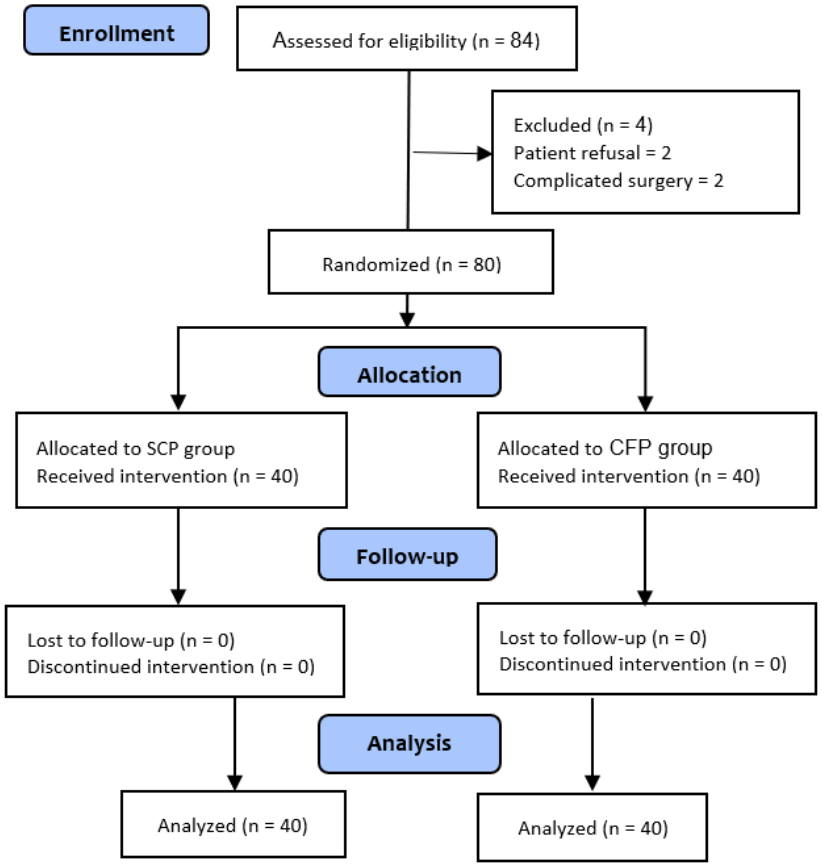

Figure 1: The CONSORT flow diagram

Table 1: Comparative demographic data and characteristics

Parameters		CFP group (n = 40)	SCP group (n = 40)	Test value	P-value
Age (y)		39.72 ± 11.66	39.5 ± 11.59	0.087•	0.931
Sex	Females	13 (32.5)	13 (32.5)	0.000*	1.000
	Males	27 (67.5)	27 (67.5)		
Weight (kg)		69.0 ± 7.54	67.5 ± 8.85	0.816•	0.417
ASA	I	32 (80.0)	31 (77.5)	0.075*	0.785
	II	8 (20.0)	9 (22.5)		

*Data presented as mean ± SD or n (%); •: Independent t-test; *: Chi-square test*

Eighty patients were randomly divided into two groups, 40 patients in each group, either the clavipectoral group (CFP group) or the cervical plexus group (SCP group).

For all enrolled patients, full history, clinical examination, and routine laboratory investigations were ensured. Before induction of anesthesia, all patients had IV access (20-gauge IV cannula). Standard monitoring, including ECG, pulse oximetry, and non-invasive blood pressure, were applied to all patients.

GA was induced with propofol 2 mg/kg, fentanyl 1µg/kg, and atracurium 0.5 mg/kg. An endotracheal tube was inserted and connected to the anesthesia machine. Anesthesia was maintained by inhalational anesthetic sevoflurane 1 to 2% in 60% oxygen. After induction of anesthesia, either CFP block or SCP block, were executed under ultrasound guidance.

2.2.1. SCP Group: (control group)

Patients in this group had ultrasound-guided SCP block, in the supine position, with the head turned to the contralateral side, a linear high-frequency ultrasound probe (6–13 MHz, Sonosite) used at a midpoint on the sternocleidomastoid muscle at the level of the transverse process of C6. A 5 cm block needle, Ultraplex® 22G a.x 2 in. (50 mm) non-stimulating echogenic needle with 30° bevel and extension set (UPLEX2250/30®, was introduced from lateral to medial using the posterior-in-plan technique to identify the interscalene groove between the anterior and middle scalene muscles. Then, the SCP was visualized just superficial to the prevertebral fascia overlying the interscalene groove; 10 ml of 0.25% bupivacaine were deposited after careful negative aspiration (Figure 1).

2.2.2. CFP Group: (study group)

The patients in this group had medial and lateral CFP block under ultrasound guidance. The patient's head was turned to the contralateral side while being in a supine position, after padding a small pillow under the shoulder. A linear high-frequency ultrasound probe (6–13 MHz, Sonosite®) was placed over both the inner and outer one-third of the anterior surface of the clavicle, A 5 cm block needle, Ultraplex® 22G a.x 2 in. (50 mm) non-stimulating echogenic needle with 30° bevel and extension set (UPLEX2250/30®, was introduced using the in-plan technique and advanced into the space between the periosteum of the clavicle and clavipectoral fascia in a caudal to cephalad direction; a total of 20 mL of 0.25% bupivacaine was equally injected medially and laterally.

2.3. Outcomes

The primary outcome was VAS pain scores, recorded preoperatively, in the PACU and then every 2 h for 8 h. Secondary outcomes included hemodynamic monitoring (heart rate, non-invasive mean arterial blood pressure) intraoperative and in the PACU and every 2 h post-operative for 8 h. Time to first rescue analgesia demand post-operatively, total dose of morphine used postoperatively, and complications either related to the block or the surgery e.g., inadvertent intravascular injection, nerve injury, infection, and hematoma were recorded.

2.4. Statistical analysis

Data were analyzed using Statistical Package for Social Science (SPSS) version 26 for Windows (IBM© Corp., Armonk, N.Y., USA), Quantitative data were expressed as mean ± SD or median (IQR) when indicated. Qualitative data were expressed as frequency and percentage. The Independent-samples t-test, Chi-square (χ^2) test, and Mann-Whitney U test were used as appropriate. Categorical data were summarized as counts and percentages, and the associations between the studied groups were tested using Pearson's Chi-square test or Fisher's exact test as appropriate. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the $P < 0.05$ was considered significant.

3. RESULTS

As shown in Figure 3, 84 patients were assessed for eligibility, 4 of them excluded (2 due to refusal to share in the study before the start of it and 2 due to complicated and lengthy surgery). 80 patients were divided into 2 groups (40 in each group), all allocated patients received the intervention and completed the study to the end of it.

Both groups were comparable as regards demographic data and ASA classification and, there were no differences between the groups (Table 1).

Table 2 shows the visual analogue scale postoperatively, there was significant differences between the two groups from 0 h (in the PACU) to 8 h postoperatively.

While Table 3 shows the comparison between the 2 groups as regards the mean arterial block pressure it was significantly lower in the group clavipectoral than the superficial cervical group all the measured time postoperatively and highly significant during surgical dissection, but there was no significance during skin incision.

Table 4 shows the comparison between both groups as regards heart rate that was significant at 0,2,4,6 postoperatively and during surgical dissection but there was no significance at 8 h postoperatively.

The first request for rescue analgesia of morphine and total dose of morphine were comparable with significance between the 2 groups as shown in Table 5.

Table 2: Comparative VAS pain scores in the two studied groups

Time		VAS pain score		Test value≠	P-value
		CFP group (n = 40)	SCP group (n = 40)		
Pre	Median (IQR)	6 (6–7)	6 (6–7)	–0.348	0.728
	Range	5–9	5–9		
0 h	Median (IQR)	1 (1–2)	2 (2–3)	–4.647	< 0.0001*
	Range	0–4	1–4		
2 h	Median (IQR)	1 (1–2)	3 (2–4)	–5.703	< 0.0001*
	Range	0–5	2–5		
4 h	Median (IQR)	2 (1–2)	4 (3–4)	–6.954	< 0.0001*
	Range	1–5	3–6		
6 h	Median (IQR)	3 (2–4)	5 (4–5)	–6.543	< 0.0001*
	Range	1–6	4–7		
8 h	Median (IQR)	4 (3–5)	6 (5–6.5)	–5.898	< 0.0001*
	Range	2–7	4–8		

P < 0.05: Significant; IQR: inter–quartile range; ≠: Mann-Whitney test

Table 3: Comparative mean arterial blood pressure in the studied patients

Time	MAP (mmHg)		Test value•	P-value
	CFP group (n = 40)	SCP group (n = 40)		
Pre	78.65 ± 8.61	79.13 ± 8.27	–0.252	0.802
After OA block	75.63 ± 8.02	75.65 ± 7.55	–0.014	0.989
After skin incision	73.4 ± 7.1	75.4 ± 7.38	–1.235	0.220
During dissection	72.8 ± 7.24	77.98 ± 8.02	–3.030	0.003*
0 h	73.48 ± 7.09	77.8 ± 7.92	–2.574	0.012*
2 h	73.53 ± 7.37	77.63 ± 7.08	–2.537	0.013*
4 h	74.07 ± 7.19	77.98 ± 7.42	–2.387	0.019*
6 h	74.42 ± 7.3	78.0 ± 7.34	–2.184	0.032*
8 h	74.7 ± 7.48	78.1 ± 7.4	–2.044	0.044*

P < 0.05 considered as significant; •: Independent t-test

4. DISCUSSION

While the sensory innervation of the clavicle is controversial, the cutaneous innervation of the skin above it is supplied mainly by the supraclavicular nerve of the superficial cervical plexus (SCP). While some reports say that the clavicle itself may be supplied by the supraclavicular nerve, other authors state that the subclavian, long thoracic, and suprascapular nerves (branches of the brachial plexus) also share sensory supply to the clavicle and skin above it. That is why, multiple techniques for regional anesthesia have been used in fracture clavicle surgery like SCP block, brachial plexus block as interscalene, and the new technique CFP block.[3] Most of the anesthetists still use GA. including muscle relaxation an endotracheal intubation; anesthesia is maintained by sevoflurane 1 to 2%. Regional techniques are used to augment intraoperative analgesia as well as for prolonged postoperative analgesia. In the present study, we compared the analgesic efficacy and safety of CFP block versus the most commonly done SCP block.

As regards the analgesic effect of both blocks results of this study showed that at the time to shifting to PACU, in both groups pain scores decreased dramatically from the 6 to 1 in CFP group compared to 2 in the SCP group

Table 4: Comparative heart rates at different times in the two groups

Time	Heart rate (beat/min)		Test value•	P-value
	CFP group (n = 40)	SCP group (n = 40)		
Pre	89.3 ± 10.42	86.6 ± 14.78	0.944	0.348
After OA block	82.0 ± 10.11	78.83 ± 12.66	1.239	0.219
After skin incision	77.73 ± 10.89	76.85 ± 12.28	0.337	0.737
During dissection	77.43 ± 10.07	82.93 ± 11.61	–2.264	0.026*
0 h	77.45 ± 8.35	82.98 ± 11.13	–2.512	0.014*
2 h	77.25 ± 8.68	82.93 ± 11.06	–2.553	0.013*
4 h	77.65 ± 8.49	83.1 ± 10.67	–2.528	0.013*
6 h	78.43 ± 8.22	83.32 ± 11.08	–2.246	0.028
8 h	79.25 ± 8.53	83.25 ± 10.8	–1.838	0.070

P < 0.05 considered as significant

Table 5: Comparative use of rescue analgesia and morphine consumption

Rescue analgesia & Morphine		CFP group (n = 40)	SCP group (n = 40)	Test value	P-value
1st time of rescue analgesia (h)	Mean ± SD	15.95 ± 5.07	6.25 ± 1.3	11.716•	< 0.001*
	Range	6–24	4–8		
Dose of morphine given	2	37 (92.5)	9 (22.5)	40.758*	< 0.001*
	4	3 (7.5)	18 (45.0)		
	6	0 (0.0)	11 (27.5)		
	8	0 (0.0)	2 (5.0)		

*P < 0.05 considered as significant; •: Independent t-test; *: Chi-square test*

and these results were statistically highly significant, but clinically non-significant as patients in both groups were comfortable, not experiencing severe pain and did not ask for analgesics; possibly pain may have been masked by residuals of general anesthetics used.

In a case series by Kukreja et al. on three patients with fractured clavicles received CFP block. Their results were in agreement with the results of the present study as two of their patients had pain scores of 0 and were fully satisfied and discharged without any need of analgesia, only one patient had pain score of 5 at PACU and the main complaint was not the site of surgery but the complaint was related to others injuries.[3,8]

A study done by Yoshimura et al. involved two case reports with fractured clavicles received CFP block showed that the BP and HR were stable in the two patients and the VAS score was 0/10 in the first patient and he did not require any analgesia till the next day and in the other patient the VAS score was 1-2/10 and did not require any analgesia till 13 h, the results of the present study were also in accordance with these case reports.[9]

Sonawane et al. managed a patient with a clavicular fracture with CFP block only, without deep sedation or GA for a surgery that lasted for 3.5 h and all the time the patient remained comfortable, communicating and pain scores were 0 and it persisted also in the recovery room which proves the strong analgesic efficacy of the block in accordance with the results of the present study.[10]

Baran et al. performed a combined supraclavicular and superficial cervical plexus block for a female patient with a fractured clavicle who refused to have GA the surgery passed pain-free without any complications but they pointed out that superficial cervical plexus alone would be not effective, as it will give anesthesia only to supraclavicular nerves which innervates the skin over the clavicle only and should be combined with either interscalene brachial plexus block or supraclavicular plexus block which will add to the risk of the procedure due to the high possibility of vascular injury, phrenic nerve affection and the large dose of local anesthetics which will be used in two blocks rather than a single block.[11]

The results of the present study were in accordance with the study done by Atalay et al. in which they managed a 47-year-old female patient with midshaft clavicle fracture with combined superficial cervical and clavipectoral plane block; the analgesia maintained for more than 24 h which is not common with superficial cervical plexus block alone.[12]

In a study done by Arjun et al. comparing combined interscalene and intermediate cervical plexus block and interscalene and superficial cervical plexus blocks, observed that analgesia and outcome were better in the group of intermediate cervical plexus block as local anesthetic was infiltrated deeper and they rendered that

superficial or intermediate cervical plexus blocks alone are not effective and should be combined with another block such as interscalene block.[13]

As regards the use of morphine as rescue analgesia there was a statistical difference between both groups as the group SCP groups needed 1st dose of rescue analgesia (morphine) early than the group CFP group. Total morphine used postoperatively was significantly more in group SCP than in CFP group.

It looks that CFP block is the sole effective and strong anesthetic technique, so that it can be used alone even without GA or sedation. The CFP can avoid any possible complications of the interscalene block, like phrenic nerve palsy, vocal cord paralysis, vascular injury, total spinal anesthesia, and pneumothorax, besides its ease of performance.[14]

5. LIMITATIONS

The study included a limited number of patients with isolated fracture clavicle cases only.

6. CONCLUSION

Clavipectoral plan bock is superior to superficial cervical block in fracture clavicle repair surgeries regarding efficacy and safety. The pain post-operatively is less with clavipectoral plan block than with superficial cervical plexus block, with more hemodynamic stability and less opioid consumption post-operatively.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

9. Authors' contribution

AG: concept and revision

WA: analysis and editing

OM: statistical analysis

AE: collecting data and conduction of study

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