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The Analgesic Efficacy of Erector Spinae Plane Block in Ankle and Foot Surgery: A Randomized Controlled Study

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ABSTRACT

Background: *During ankle and foot surgeries, we often use different regional analgesic modalities to reduce patient pain during and after orthopaedic and surgical operations. The purpose of this research was to examine the effectiveness of erector spinae plane (ESP) block for postoperative pain management after ankle and foot surgeries.*

Methods: *Sixty patients, aged 18 to 65, with ASA physical status I, participated in a randomized controlled clinical experiment. Patients were divided into two groups (E and C) at random, with group (E) receiving ESP block and group (C) receiving a placebo. The patients' medical histories were evaluated, and they were all examined and tested.*

Results: *Observations At 2, 4, 12 & 24 hours postoperatively, the ESP group had substantially lower visual analogue scale (VAS) ratings in contrast to the control group. The total quantity of fentanyl and pethidine given during, and after surgeries were both considerably lower in the Erector group in comparison with the control group. Total nonsteroidal anti-inflammatory medication usage did not vary significantly among the 2 groups, however.*

Conclusions: *ESP is safe & effective technique in decreasing pain and providing adequate analgesic effect in ankle and foot ssurgeries.*

Trial Registration: *This study was prospectively registered on https://clinicaltrials.gov/ under the NCT05708742 number (principal investigator: Mohamed Ahmed Hamed), registration date: 24/01/ 2023.*

Keywords

Analgesic Efficacy, Regional anaesthesia, Erector Spinae Plane Block, Ankle, Foot Surgeries.

List of Abbreviations

ESP: erector spinae plane, ESPB: erector spinae plane block, ICU: Intensive Care Unit, IQR: Interquartile Range, PCA: patient controlled analgesia, SICU: Surgical Intensive Care Unit, RCT: Randomised Controlled Trial, SD: Standard deviation, VAS: Visual Analog Scale.

Introduction

Regional anesthesia is frequently employed to manage pain in ankle and foot surgeries throughout orthopedic and surgical procedures [1]. Ultrasound-guided nerve blocks are excellent approach of regional anesthesia for pain treatment that also reduces the need for opioids [2].

The treatment of pain after surgery may be challenging and calls for an interdisciplinary approach [3]. Regional anesthetic techniques are often used for the purpose of postoperative pain management in the pediatric and adult populations after ankle and foot surgeries [4,5]. This is mostly attributable to the increased availability of ultrasonography as well as improved levels of clinical experience.

Analgesia is provided to the dorsal and ventral rami of spinal neurons using a procedure known as the ESP block, which is a kind of targeted anesthesia. Despite the enormous future potential of ESP block for lower limb surgery, the medical literature only contains a small number of descriptions of actual instances involving its use [6,7]. Since it was first described, the ESP has shown to be a dependable form of regional anesthesia, and its use in perioperative pain management has been growing [8].

We suspected that bilateral ESP block would reduce postoperative pain following ankle and foot surgeries.

Methods

This prospective randomized clinical study was registered at ClinicalTrials.gov under the NCT05708742 number (principal investigator: Mohamed Ahmed Hamed), registration date: 24/01/2023.

The study was performed from January 2023 through September 2023, Sixty individuals between the ages of 18 and 65 with physical statuses I according to the ASA scheduled for ankle and foot surgeries were enrolled in this randomized controlled clinical trial. All patients provided written informed consents. The Ethical Committee at Fayoum University Hospitals approved the study before it was carried out with registration number D295.

Exclusion criteria were Major hepatic, renal, or cardiovascular diseases; local infection; any ESP contraindications as bleeding tendency and patient refusal; or known drug allergy utilized for the research.

Randomization and blinding

Cases were split at random into two equal groups (30 patients each) using opaque, sealed envelopes and a computer-generated sequence. Cases were divided to two groups, group (E): received ultrasound guided ESP block & group (C): received placebo only.

Every individual had a thorough history taken, clinical examination, and set of lab tests performed.

The study was double-blind, with the participant, clinical care team, and assessor were blinded.

Anaesthetic Technique

In this investigation, an ultrasound-guided ESP block was conducted at the L4 level using a solution of bupivacaine containing 0.25 percent and a volume of 20 millilitres. As a placebo, an equal amount of saline solution was given to the group that served as the control. Participants in the study were given instructions on how to use the patient-controlled analgesia (PCA) device as well as information on the visual analog scale (VAS) before they had surgery. Preoperative checks and procedures were carried out as usual the day before the operation. We used non-invasive blood pressure monitors, pulse oximeters, and electrocardiograms to monitor our patients in both study groups. After accessing a vein, all patients were mildly sedated with intravenous (IV) administration of 0.01-0.02 mg/kg of midazolam.

The patient was seated for the administration of the ESP block, which was performed at the L4 level after the skin had been well-cleaned. a linear ultrasonic transducer made in Italy by Phillips-Saronno was positioned vertically three centimeters to the side of the midline. After that, two milliliters of a lidocaine solution that was two percent concentration were administered as local infiltration to the skin and subcutaneous tissues. Using an ultrasonic transducer, a 22-gauge short bevel needle (Spinocan, B. Braun Melsungen AG, Germany) was inserted in a cranial-caudal orientation, in-plane with the TP, until it crossed all three muscles and reached the TP. After the needle had made contact with the TP, the full length of the needle was visually inspected, and then one milliliter of anesthetic was injected to check that the needle had been inserted correctly. Verification of hydro dissection of the interfascial plane between the erector spinae muscle and TP was achieved by examining the linear distribution of local anesthetic solution among the muscle and the bone acoustic shadows of the TP, this provided evidence that the interfascial plane had been successfully hydro-dissected. After that, up to 20 milliliters of bupivacaine at a concentration of 0.25 percent were administered. The treatment was carried out on the control group as well; however, they were given a 20-milliliters injection of saline 0.9% instead.

Induction of general anesthesia was then performed by intravenous administration of 2 mcg/kg of fentanyl, 2 mg/kg of propofol and 0.5 mg/kg of atracurium to all patients. After the patient had been intubated, a maintenance dosage of isoflurane (1 MAC) and atracurium 0.1 mg/kg was given every thirty minutes until the surgery was completed. After recovering from general anesthesia, participants were sent to the post-anesthetic care unit (PACU) for a period of observation lasting two hours. As soon as the patients' adjusted Aldrete scores dropped to a level lower than 9.10, they were moved out of the PACU.

Both groups were given immediate postoperative analgesia in the form of a PCA fentanyl infusion, and they were also given 1 gram of oral acetaminophen four times a day. The fentanyl titration technique was terminated when the following conditions were met satisfactory pain management; increasing sedation (Ramsay sedation scale >2); and reduced breathing rate.

Statistical Analysis

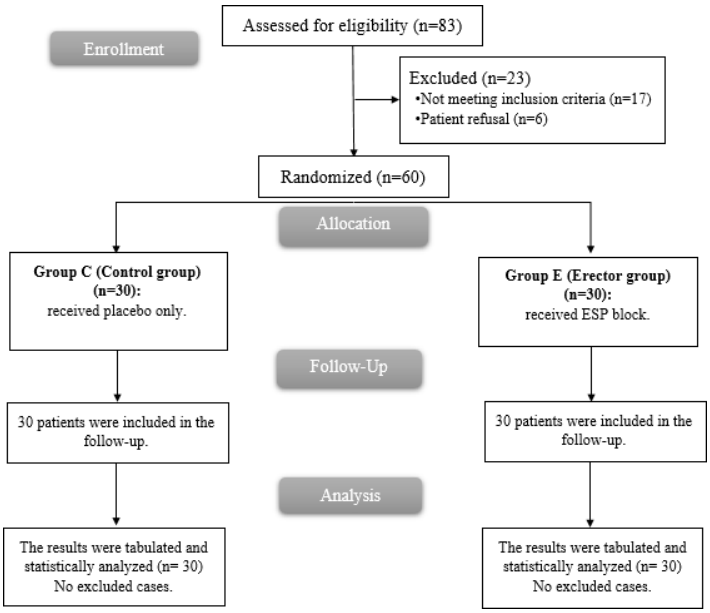
The statistical analysis was conducted using IBM SPSS v27 software. To assess data normality, the Shapiro-Wilks test and histograms were employed. Quantitative data, such as sample mean and standard deviation, were analyzed utilizing an unpaired

Student's t-test. Non-parametric quantitative data, represented by median and interquartile range (IQR), were analyzed using the Mann-Whitney test. The Chi-square test was utilized to analyze qualitative data, which was presented as frequency counts and percentages (%). Statistical significance was determined by a two-tailed P value of fewer than 0.05.

Results

In this research, eighty-three people were screened for qualification, seventeen did not match the requirements, and Six declined to participate. The remaining sixty individuals were randomly split into two distinct groups of Thirty each. All assigned patients (30) were tracked and statistically assessed (Figure 1).

Figure 1: Consort flow diagram of the study population.



There was an insignificant difference among both groups as regard sex, ASA, age & BMI Table 1.

Table 1: Demographic data comparison between the three study groups

	Control group (n=30)	Erector group (n=30)	*p-value*
Sex			
Male	15 (50%)	14 (47%)	0.796
Female	15 (50%)	16 (53%)	
ASA			
I	9 (30 %)	9 (30 %)	> 0.99
II	21 (70 %)	21 (70 %)	
			p-value
Age (years)	44.7 ± 11.5	43.8 ± 11.4	0.762
Body mass index (Kg/m²)	35.2 ± 3.2	35.1 ± 3.2	0.969

Abbreviations: n, number; Data presents as mean ± SD or frequency (%), ; Chi-squared test, ; independent sample t-test

There was an insignificant difference among 2 groups as regard Heart rate **preoperatively, Intraoperatively, immediately postoperative, 2 hours postoperative Table 2.**

Table 2: Heart rate comparison among the two study groups.

Heart rate (beat/minute)	Control group (n=30)	Erector group (n=30)	*p-value*
Preoperative	76 ± 8	76 ± 7	0.945
Intraoperative	72 ±7	72 ±7	0.970
Immediately postoperative	71 ± 7	71 ±8	0.917
2 hours postoperative	69 ± 6	69 ±6	0.984

Abbreviations: IQR: Interquartile range (25th percentile-75th percentile); n, number.

VAS was significantly lower in ESP group in contrast to Control group Immediately postoperative,2h, 4 h, 12 h, and 24 h (P<0.001) Table 3.

Table 3: Postoperative VAS pain score comparison between the 2 study groups.

VAS score	Control group (n=30)		Erector group (n=30)		p-value ‡
	Median	IQR	Median	IQR	
Immediately postoperative	8	6-8	4	3-5	**< 0.001***
2 hours	7	6-8	0	0-1	**< 0.001***
4 hours	6	6-7	1	0-1	**< 0.001***
12 hours	7	7-8	2	0-1	**< 0.001***
24 hours	7	7-8	3	2-4	**< 0.001***

Abbreviations: n, number; *, statistically significant; IQR: Interquartile range (25th percentile-75th percentile).

There was an insignificant difference between both groups as regard MAP preoperatively, Intraoperatively, immediately postoperative, 2 hours postoperative Table 4.

Table 4: Mean arterial blood pressure comparison between the two study groups.

+++Mean arterial blood pressure (mmHg)	Control group (n=30)		Erector group (n=30)		p-value
	Median	IQR	Median	IQR	
Preoperative	97.5	(95-101.5)	98	(95-101.5)	> 0.99
Intraoperative	95	0	95	1 (94-95)	0.785
Immediately postoperative	99.5	1 (99-100)	99.5	1 (99-100)	0.902
2 hours postoperative	93	(83-95)	93	(83-95)	0.964

Abbreviations: IQR: Interquartile range (25th percentile-75th percentile); n: number.

When comparing the Erector group to the control group, the latter has considerably reduced total intraoperative fentanyl consumption (g) and total postoperative pethidine consumption (g). There was no statistically significant variation in the daily dose of NSAIDs (mg) consumed by either group Table 5.

Table 5: Opioid consumption comparison between the two study groups.

	Control group (n=30)		Erector group (n=30)		p-value ‡
	Median	IQR	Median	IQR	
Total intraoperative fentanyl consumption (µg)	50	12.5 (50-62.5)	0	50 (0-50)	**< 0.001***
Total postoperative pethidine consumption (mg)	25	6.25 (25-31.25)	0	25 (0-25)	**< 0.001***
Total NSAID consumption (mg)	50	12.5 (50-62.5)	50	50 (50-100)	0.252

Abbreviations: n, number; *, statistically significant; NSAID; non-steroidal anti-inflammatory drugs.

Discussion

In this randomized clinical trial, we demonstrated that analgesia with erector spinae plane block (ESPB) reduced VAS ratings. Also, the total quantity of fentanyl and pethidine given before, during, and after surgery were both considerably lower in the erector group in comparison with the control group. Total NSAID consumption, postoperative heart rate and mean arterial blood pressure were similar in both groups. Our results suggest that ESPB may be effective and a promising analgesic block in ankle and foot surgery to decrease use and complications of narcotic usage.

There are many advantages of using regional anesthesia techniques in ankle and foot surgery. First, it leads to perioperative and postoperative analgesia, therefore reducing opioid requirement and the incidence of postoperative delirium [9]. Second, regional anesthesia techniques can be used as the main anesthetic method in patients where general or neuraxial anesthesia should be avoided due to comorbidities. It also allows surgical procedures such as ankle surgery to be completed under sedation [10].

The mechanism of these results and this good analgesia in erector spinae block can be explained by spread of local anesthetic injection in low level erector spinae plane block at L4. This explanation is augmented by Diwan and Nair in their case reports reporting two patients who presented with absent knee reflexes and one patient with absent ankle reflex following continuous ESPB at the level of L3 and referred this to spread of local anesthetic to lumbar plexus blocking the lower thoracolumbar outflow as ESPB is a large volume block especially with infusion that increases with a chance of local anesthetics spread to the lumbar plexus. This was confirmed by CT contrast study injected through the ESP catheter [11]. Another study explained these results, Ahiskalioglu et al. who used Lumbar-ESPB as the surgical anesthetic method in hip surgery. Local anesthetics differs in L-ESPB when compared to ESPB from the thoracic levels in that its spread cephalad and caudally is not so extensive. In a previous study, we demonstrated the LA spread for L-ESPB on computerized tomography from the dorsal of the transverse process from T12 to S1 and between L1 and L5 to the anterior of the transverse process and to the L2–L4 foraminae, spreading around the psoas muscle with significant contrasting around the lumbar plexus [10].

Since ESP is considered a muscle or fascial planar block, it may be a safer alternative for patients with cardiac problems in whom pain increases stress on heart without any effect on heart rate or arterial blood pressure as there was no statistical significance between erector group and control group both intraoperatively and postoperatively. Pirsaharkhiz et al. in their study reported safety of erector spinae over both epidural and paravertebral blocks, as injection and catheter placement rarely are associated with adverse events such as urinary retention, or hypotension that can result from medication administration to the neuroaxis [12].

Several studies demonstrated and reported that that ESPB significantly decreases pain in the first 24 hours which appeared in our study with statistical significance between the two groups regarding VAS score in all postoperative periods until 24 hours [13-15]. The mechanism of action can be shown by the anterior spread through the paravertebral space, resulting in blockage of not only ventral and dorsal rami but also rami communicantes as reported by the study by Forero et al who was the first to describe ESPB block in the literature in 2016 when it was used t treat chronic neuropathic thoracic pain [16]. Regarding opioid consumption, our study revealed that ESPB is associated with lower opioid consumption compared with the control group both intraoperatively and postoperatively avoiding their complications. These results are consistent with several studies comparing ESPB with other nerve block as paravertebral, retrolaminar, or epidural in adults and pediatrics [17-19]. The most similar study to our results and surgical field was performed by Ahiskalioglu et al., who demonstrated that injection of 40 ml of a local anesthetic mixture between the erector spinae and *L*4 transverse process for both hip and femoral surgeries resulted in adequate analgesia [10]. This is consistent to our findings of decreased opioid requirements both intraoperatively and postoperatively.

To date, this is the first study to evaluate the analgesic efficacy of ESP block for postoperative analgesia after ankle and foot surgery. Its prospective randomized design, complete follow-up of study population and proper use of protocol to avoid bias are some strengths of our study. Our study results could become a basis for future studies.

Our study had some limitations. First, we only observed the analgesic effect within 24 hours after surgery, and the long-term effects of this regional block technique need to be further explored. Second, anatomic studies to further confirm the spread of local anesthetics and the nerves targeted are required. Comparisons with other regional anesthesia techniques as well as larger controlled studies will be useful.

Conclusions

ESP is safe and effective technique in decreasing pain and providing adequate analgesic effect in ankle and foot Surgery. More prospective, randomized clinical trials are needed to demonstrate the clinical role of US-guided ESP block for various types of surgery.

Declarations

Ethics approval and consent to participate:

The ethical review board of Fayoum University Hospital approved the study design before the start of the study (D295) according to the relevant guidelines and regulations. Written informed consent was obtained from all patients.

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