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Ultrasound guided erector spinae plane block for percutaneous radiofrequency ablation of liver tumors

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ABSTRACT

Background: Percutaneous radiofrequency ablation (PRFA) of hepatic tumors is a painful procedure. Regional anesthesia is currently considered one of the fundamental elements for managing both intra and postoperative pain. We aimed to compare the analgesic efficacy of ultrasound-guided erector spinae plane block (ESPB) versus local anesthetic infiltration for pain relief in patients undergoing PRFA of liver tumors.

Methods: Sixty adult patients undergoing PRFA of primary or secondary liver malignancies were randomized into: Group I (local anesthetic infiltration group) or Group II (right ultrasound-guided ESPB group). Postoperative pain score as a primary outcome, rescue analgesic consumption, number of subjects requiring general anesthesia and incidence of complications were recorded.

Results: Postoperative pain score was significantly lower in Group II during the first 4 hours postoperatively (P = 0.000*, 0.000*, 0.001*, 0.001* and 0.002*, respectively) as compared to Group I, whereas comparable pain scores were recorded among the study groups at 8, 12, 16, and 24 hours postoperative (P = 0.492, 0.075, 0.893, and 0.094, respectively). Intra and postoperative rescue analgesic requirement was significantly less in Group II than Group I (P = 0.031*, and 0.000*, respectively). Nine patients in Group I and two patients in Group II were converted to general anesthesia. The incidence of adverse events was comparable between the two groups.

Conclusions: Ultrasound-guided ESPB provided efficient analgesia during intraoperative and early postoperative periods with reduced analgesic requirements and fewer patients needing general anesthesia as compared to local infiltration technique.

Trial registry: Pan African Clinical Trials Registry (PACTR201705002296409).

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Liver neoplasms; radiofrequency ablation; nerve block; pain; postoperative

1. Introduction

Percutaneous radiofrequency ablation (PRFA) has been gaining importance in recent years as the mainstay of management, at most centers, for patients with primary and secondary malignant liver tumors [1,2]. Anesthesia for PRFA of liver tumors usually involves local anesthesia and intravenous sedation [1,3]. However, intraoperative and early postoperative pain is frequently reported by the majority of patients undergoing such procedures [4,5].

The ultrasound-guided erector spinae plane block (ESPB) initially described by Forero et al. [6], is an interfascial plane block with deposition of local anesthetic solution at the tip of the transverse process deep to the erector spinae (ES) muscle [7]. In cadavers, injecting 20-mL solution at the level of the T5 transverse process has been associated with spread of the injectate between the C7 and T8 vertebral levels. ESPB can thus provide thoracic analgesia. Since the ES muscle extends inferiorly to the lumbar spine, performing ESPB at a lower vertebral level (e.g., T7 or T8) should result in local anesthetic spread to the lower thoracoabdominal nerves that innervate the abdomen [6]. The analgesic efficacy of the ESPB has been proven in various thoracic [8] and abdominal procedures [9,10]. To the best of our knowledge, our study is the first prospective randomized study that assesses the analgesic effect of ESPB during procedures performed under conscious sedation.

The aim of the current study was to compare the effectiveness of right-sided ultrasound-guided ESPB versus local anesthetic infiltration for pain relief in patients undergoing PRFA of liver tumors.

2. Methods

The current prospective randomized study was approved by Ethics Committee of the Faculty of Medicine, Tanta University (32215/03/18), and registered in Pan African Clinical Trials Registry (PACTR201705002296409). After a written informed consent was provided from all participants, sixty adult patients, of either gender, aged between 50 and 80 years with a Child-Pugh score not more than B6 and scheduled for ultrasound-guided PRFA of

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primary or secondary hepatic tumors were enrolled during the period from May 2018 to December 2019. Only those with a single focal hepatic lesion not exceeding 5 cm in diameter or with a maximum of two lesions (each of them ≤3 cm) were involved.

Exclusion criteria comprised patients with an INR value exceeding 1.5, platelet count less than 50,000/mm^3, body mass index (BMI)>35, history of mental disorders or psychiatric illness, allergy to local anesthetics and spine deformity. In addition, those with chronic pain or on regular remedies of analgesics were also excluded.

The procedure of PRFA as well as the regional anesthetic techniques to be used were explained to the patients during their visit to the anesthesia clinic, besides, they were acquainted to the use of the Numeric Rating Scale (NRS) for assessment of pain where zero is equivalent to no pain and 10 represents the worst pain.

Patients were randomized into two equal groups of 30 patients each to receive either local anesthetic infiltration (Group I) or right-sided ultrasound-guided ESPB (Group II). The process of randomization was implemented using computer-generated random sequence concealed in sealed opaque envelopes.

The interventional radiology procedures were accomplished in the operating theater. A peripheral intravenous (IV) line was secured and basic monitoring including electrocardiography, pulse oximetry, and noninvasive arterial blood pressure were applied to all patients. In addition, oxygen supplementation via nasal cannula was administered at a low flow rate (2 L/min).

All patients were given IV 1–2 mg midazolam as well as 0.5 µg/kg fentanyl before performing the blocks. Both regional techniques were implemented under aseptic conditions, patients were initially placed in the sitting position and the spinous process of T7 was located. A high-frequency linear array probe (6–-12 MHz – SonoSite Edge, Bothell, Washington) was placed in a longitudinal orientation adjacent to the spinous process, then the probe was slid laterally to visualize the anatomical landmarks including the T7 transverse process with the overlying trapezius and erector spinae muscles. The skin was then infiltrated with 3 ml lidocaine 2% and a 50 mm, 22 G needle (B. Braun Medical Inc., Bethlehem, PA) was subsequently introduced in plane through the skin and subcutaneous tissue and advanced with the aid of ultrasound guidance till it came in contact with T7 transverse process. Accurate placement of the needle tip deep to the erector spinae muscles was verified by injecting 0.5–1 ml saline 0.9% while observing the injectate separating the erector spinae muscles from the transverse process with a satisfactory caudal and cephalic extension. Negative aspiration of blood was assured, followed by injection of 20 ml of an equal mixture of 10 ml lidocaine 2% and 10 ml bupivacaine 0.5% solution in Group II and injection of 2 ml of normal saline 0.9% solution in Group I.

Thirty minutes after application of ESPB, patients were instructed to rest in a supine position to allow percutaneous infiltration of either 10 ml of a local anesthetic solution (1:1 mixture of lidocaine 2% and bupivacaine 0.5%) or 2 ml of normal saline 0.9% solution along the track of insertion of the ablative device in Group II and Group I, respectively.

All patients were given propofol 0.5 mg/kg as a bolus dose. This was followed by infusion of propofol at a rate of 25–50 µg/kg/min which was adjusted to attain moderate sedation during the PRFA procedure (Ramsay sedation score (RSS) ≥3).

The PRFA procedures were done by the same experienced radiologist who was unaware of group allocation. The regional anesthetic techniques were performed by one anesthesiologist who had no subsequent role in the study while intra and postoperative data collection was accomplished by another anesthesiologist blinded to group assignments.

During the course of the procedure, intraoperative pain was assessed at 5 min interval using Critical Care Pain Observation Tool (CPOT) [11]. Four components were evaluated and rated from 0 to 2: facial expressions, movements, muscle tension, and vocalization. Scores ≤2 indicated absence of pain while those ranging from 3 to 8 correlated with significant pain. Whenever the patient was uncomfortable or CPOT score ≥3, rescue analgesia was administered in the form of IV fentanyl 50 µg to be repeated only once for the same event and the total dose of rescue fentanyl was recorded. If the patient experienced pain following the 2nd dose of fentanyl, general anesthesia was induced with propofol along with laryngeal mask airway insertion and anesthesia was maintained with isoflurane (2–3%) till the end of the procedure. Furthermore, the number of patients who required conversion to general anesthesia was documented.

After completion of the procedure, the anesthetic drugs were discontinued and the patients were transferred to the recovery room. All the patients received standard analgesia in the form of IV paracetamol 1 g every 8 h. Post-procedural pain was evaluated and recorded using the NRS for pain at the following intervals: immediately on arrival to the recovery room (T0) then at 30 min, 1, 2, 4, 8, 12, 18 and 24 h(T1, T2, T3, T4, T5, T6, T7 and T8, respectively). Morphine 2 mg IV was administered in case of NRS ≥4, and the total postoperative morphine consumption was recorded.

Adverse events occurring throughout the study (including but not restricted to, hypotension, airway obstruction, nausea, vomiting and local anesthetic toxicity) were noted and recorded. Hypotension, defined as a reduction in mean arterial pressure >20% of the baseline value, was treated with IV fluid

and vasopressors if necessary whereas Patients suffering from episodes of nausea and/or vomiting were prescribed IV ondansetron 4 mg. Moreover, oxygen desaturation ($Spo_2 \leq 92\%$) warranted the use of face mask in conjunction with assistant airway maneuvers to restore oxygenation. Patients and radiologist were requested to rate their degree of satisfaction regarding the anesthetic techniques on a 4 point scale (1 = very satisfied, 2 = satisfied, 3 = dissatisfied, 4 = very dissatisfied).

2.1. Sample size calculation

Our primary outcome variable was the first 24-hour postoperative pain scores. Based on the findings of a previously published literature [12] that reported a standard deviation of 1.5, and assuming a significant difference of 1.5 in the postoperative NRS, a sample size of 27 participants was needed at α error of 0.05 and 95% power of the study. So, we included 30 patients in each group for possible dropouts. The sample size calculation was based on a two-sample independent t-test (2-sided) of the NRS. The sample size was estimated using the G*Power© software (Institutfür Experimentelle Psychologie, Heinrich Heine Universität, Düsseldorf, Germany) version 3.1.9.2.

2.2. Statistical analysis

Data were analyzed using computer statistical software system SPSS version 16.0 (SPSS Inc., Chicago, IL, USA). The Shapiro–Wilk test was performed to check the assumption of normality. The continuous data were presented as mean ± standard deviation (SD) or median with interquartile range (IQR), and were compared by using Student's *t*-test or the Mann–Whitney U-test as appropriate. The categorical data were expressed as number (*n*) or percentage (%) and compared using the chi-square or fisher exact test as appropriate. The level of significance was adapted at P-value < 0.05.

3. Results

An overall 74 patients with either primary or metastatic liver malignancies were evaluated for eligibility. Of those, six patients did not meet our inclusion criteria (four patients had coagulopathy and two were omitted for BMI>35) and eight patients declined to participate. Hence, 60 participants were recruited and randomized into two equal groups (30 each) (Figure 1).

The studied groups were equivalent in terms of demographic data including age, gender and BMI. Moreover, no significant differences were noticed regarding their illness' characteristics, their co-morbidities, or the total duration of the ablation procedures (Table 1).

Patients in the control group demonstrated significantly higher pain scores during the PREA procedures as well as the first four post procedural hours as compared to those who received ESPB. Whereas comparable pain scores were recorded among the study groups at 8, 12, 16, and 24 hours postoperative (*P* = 0.492, 0.075, 0.893, and 0.094, respectively) (Figure 2).

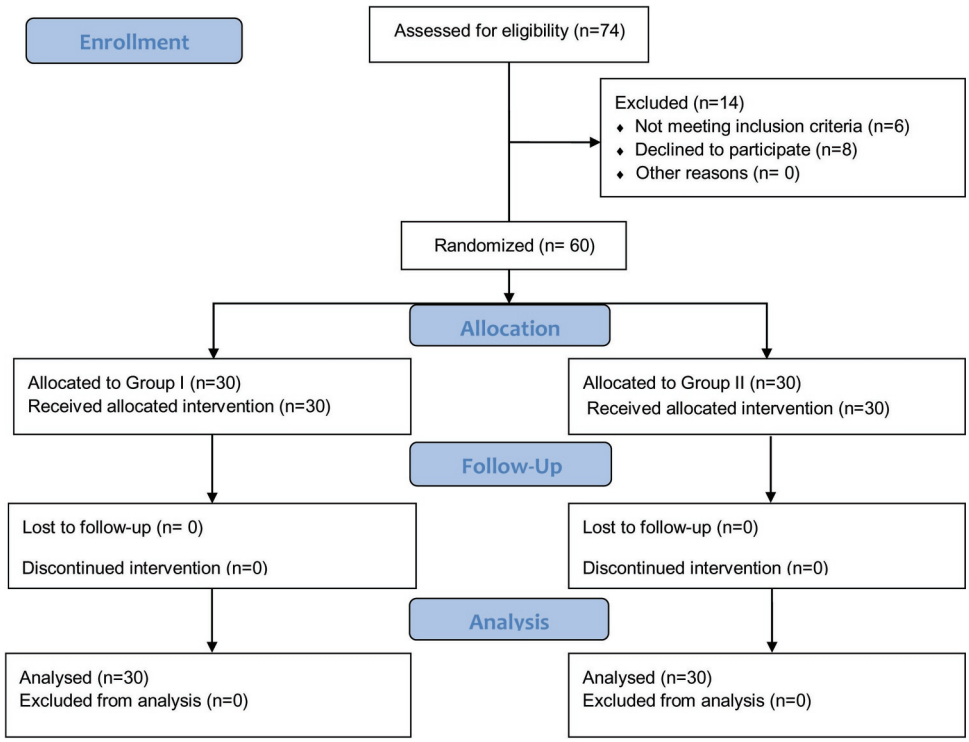

Figure 1. Consort flow chart demonstrating patients' enrollement, allocation and analysis of the results throughout the study.

Table 1. Patients 'characteristics in both of the study groups.

Variable		Group I	Group II	P value	95% CI
Age (year)		56.63 ± 5.48	58.37 ± 6.46	0.267	(−4.83; 1.37)
Gender (M/F)		20(66.6%)/10(33.3%)	18(60%)/12(40%)	0.789	
BMI (kg/m^2)		26.48 ± 3.7	27.26 ± 4.19	0.450	(−2.82; 1.27)
Child- -Pugh classification	Class A	22(73.3%)	24(80%)	0.761	
	Class B	8(26.6%)	6(20%)		
Liver tumor	Primary	25(83.3%)	27(90%)	0.706	
	Secondary	5(16.6%)	3(10%)		
Number of tumor nodules	Single	23(76.7%)	21(70%)	0.771	
	2 nodules	7(23.3%)	9(30%)		
Co-morbidities	Hypertension	17(56.6%)	14(46.6%)	0.876	
	Diabetes	7(23.3%)	6(20%)		
	Cardiovascular	8(26.6%)	10(33.3%)		
	Respiratory	4(13.3%)	5(16.6%)		
Duration of procedure		27.42 ± 6.98	25.1 ± 4.43	0.131	(−0.71; 5.35)

Data presented as mean ± SD or patient's number (%). BMI: Body mass index. P < 0.05 is significant.

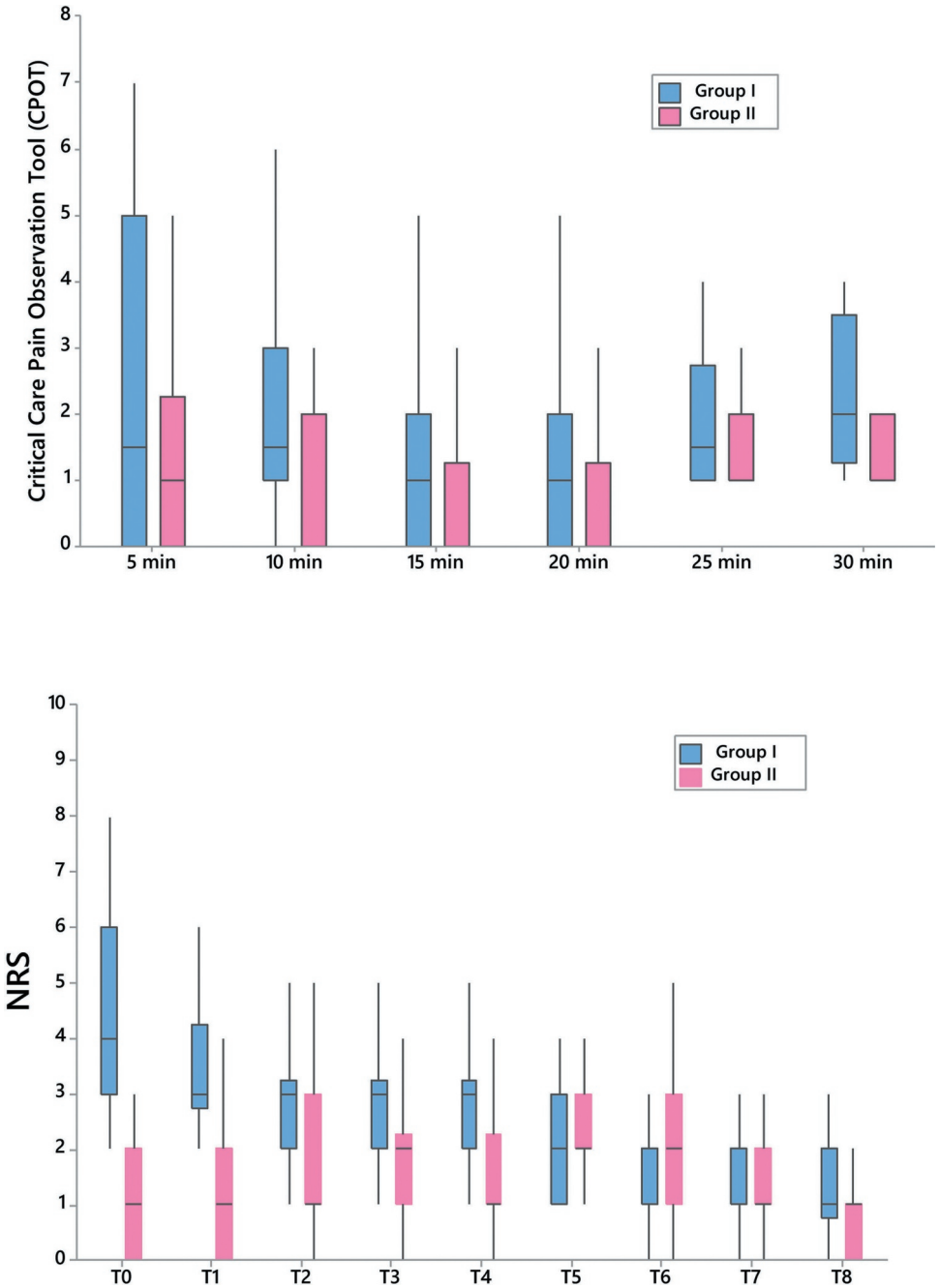

Figure 2. Intra and postoperative pain scores in the studied groups. NRS: Numeric Rating Scale.

A notable difference in the analgesic consumption was observed among the two groups with significantly less consumption of intra and postoperative rescue analgesia in Group II as compared to Group I ($P = 0.031$*, and 0.000*, respectively). Conversion to general anesthesia was required in nine subjects in Group I, while only two patients in Group II were subjected to general anesthesia administration. The incidence of adverse events did not differ significantly among the studied groups. As a final point, there was a significantly higher degree of satisfaction among both the interventional radiologist and the patients in Group II as compared to Group I (Table 2).

4. Discussion

Our results showed that right-sided ultrasound-guided ESPB with sedation produced better intraoperative and postoperative analgesia in patients undergoing PRFA with decreased postoperative rescue analgesic consumption compared to local infiltration alone. The number of patients that required conversion to general anesthesia was significantly lower in the ESPB. The decreased intraoperative analgesic consumption caused better preserved conscious level and hence the respiratory drive during the procedure with better patients and interventional radiologist satisfaction.

PRFA is a minimally invasive procedure during which the liver tumor is thermally ablated and associated with intense pain during and after the procedure [13,14], especially during PRFA for superficial tumors or tumors located in close proximity to large hepatic vessels [15].

The liver is innervated by the hepatic nerve plexus. Pain during hepatic procedures is mediated from afferent somatic and autonomic innervations; sympathetic nerve (T6-11) and parasympathetic fibers (the vagus nerve) [16,17].

Local anesthetic infiltration with conscious sedation is being the widely used anesthetic technique for PRFA [3]. Conscious sedation has been defined by the American DentalSociety of Anaesthesiology as "a minimally depressed level of consciousness, that retains the patients' ability to maintain the airway independently and continuously, and to respond appropriately to physical stimulation and verbal command; produced by pharmacologic and nonpharmacologic methods, alone or in combination" [18].

However, this anesthetic technique often associates with pain during and after PRFA procedure [5,18–20]. In addition, the intravenous sedative agents must be titrated meticulously during PRFA procedure to keep a balance between maximum patients comfort and patient cooperation (to do Valsalva maneuvers at the request of the radiologist) [3].

ESPB is a novel technique that involves local anesthetic injection into the fascial plane deep to the erector spinae muscle. ESPB involves penetration of local anesthetics into the thoracic paravertebral space. It blocks not only the ventral rami of spinal nerves but also the rami communicants that contain sympathetic nerve fibers. The ESPB thus has the potential to provide both somatic and visceral sensory blockade, which would make it an ideal regional anesthetic technique for abdominal surgery [21,22].

The ESP block thus resembles thoracic paravertebral blockade and thoracic epidural analgesia. Previous studies reported that TPVB is an effective anesthetic technique for management of PRFA for hepatic tumors [23,24] and for control of hepatic pain in cases of blunt abdominal trauma [25]or percutaneous transhepatic biliary drainage [26]. TPVB causes sympathetic and spinal nerve fibers block in the paravertebral space but it does not affect the parasympathetic fibers (vagus) and this is considered the main drawback of this technique [27]. Moreover, thoracic paravertebral block is also associated with more serious complications such as pneumothorax [28]. Thoracic epidural analgesia as well is not an ideal choice in such procedures where early discharge is mandatory [29].

In our study, we hypothesized that single injection ESPB at the level of the T7 transverse process would

Table 2. Analgesic consumption, complications and satisfaction in both groups.

Variable		Group I	Group II	P value
Total intra-operative consumption of rescue fentanyl (μg)		50(0–100)	0(0–50)	0.031*
General anesthesia administration		9(30%)	2(6.6%)	0.042*
Total post-operative consumption of rescue morphine(mg)		4(2–4)	1(0–2)	0.000*
Complications	Hypotension	2(6.6)	4(13.3%)	0.671
	Airway obstruction	5(16.6%)	3(10%)	0.706
	Nausea and vomiting	7(23.3%)	3(10%)	0.299
Radiologist's satisfaction	Very satisfied	16(53.3%)	26(86.6%)	0.015*
	Satisfied	12(40%)	4(13.3%)	
	Dissatisfied	2(6.6%)	0	
	Very dissatisfied	0	0	
Patient's satisfaction	Very satisfied	12(40%)	22(73.3%)	0.029*
	Satisfied	14(46.6%)	7(23.3%)	
	Dissatisfied	4(13.3%)	1(3.3%)	
	Very dissatisfied	0	0	

Data are presented as median (interquartile range) or patient number (%). P < 0.05 is significant. *Denotes statistically significant difference.

provide extensive sensory blockade over the abdomen, which could completely cover pain area after PRFA with a better safety profile.

However, the pain in our study may be attributed to the inability of ESPB to block the parasympathetic nerve fibers (vagus) as well as the contralateral sympathetic fibers. In addition, the referred shoulder pain experienced during PRFAof the peripheral hepatic tumors located adjacent to the diaphragm may be explained by the fact that the phrenic nerve is not blocked by either ESPB or local anesthesia infiltration.

No major complications were reported in either groups. The relative safety of ESPB was attributed to the easily identifiable landmarks as well as the fact that the injection is distant from pleura, major blood vessels and nerves.

Our study has some limitations. Besides the relatively small number of patients included in the trial, we did not assess the dermatomal sensory loss obtained by the ESPB to maintain the double blinding of the study.

5. Conclusion

Right-sided ESPB with sedation is more effective than local anesthetic infiltration with sedation in relieving pain during and after PRFA of hepatic tumors along with lower rate of conversion to general anesthesia and less analgesic needs.

Disclosure statement

No potential conflict of interest was reported by the authors.

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