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EASIER trial (Erector-spinAe analgeSia for hepatopancreaticobiliary pain In the Emergency Room): a single-centre open-label cohort-based randomised controlled trial analysing the efficacy of the ultrasound-guided erector-spinae plane block compared with intravenous morphine in the treatment of acute hepatopancreaticobiliary pain in the emergency department

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ABSTRACT

Background Ultrasound-guided (USG) erector-spinae plane block (ESPB) may be better than intravenous opioids in treating acute hepatopancreaticobiliary (HPB) pain in the ED.

Methods This open-label randomised controlled trial was conducted in the ED of a tertiary-care hospital between March and August 2023. All adult patients with severe HPB pain were recruited during times that a primary investigator was present. Unconsenting patients, numeric rating scale (NRS) ≤6, age ≤18 and ≥80 years, pregnant, unstable or with allergies to local anaesthetics or opioids were excluded. Patients in the intervention arm received bilateral USG ESPB with 0.2% ropivacaine at T7 level, by a trained ED consultant, and those in the control arm received 0.1 mg/kg intravenous morphine. Pain on a 10-point NRS was assessed by the investigators at presentation and at 1, 3, 5 and 10 hours after intervention by the treatment team, along with rescue analgesia requirements and patient satisfaction. Difference in NRS was analysed using analysis of co-variance (ANCOVA) and t-tests.

Results 70 participants were enrolled, 35 in each arm. Mean age was 40.4±13.2 years, mean NRS at presentation in the intervention arm was 8.0±0.9 and 7.6±0.6 in the control arm. NRS at 1 hour was significantly lower in the ESPB group (ANCOVA p<0.001). At 1, 3, 5 and 10 hours, reduction of NRS in the intervention arm (7±1.6, 6.7±1.9, 6.6±1.8, 6.1±1.9) was significantly greater than the control arm (4.4±2, 4.6±1.8, 3.7±2.2, 3.8±1.8) (t-test, p<0.001). Fewer patients receiving ESPB required rescue analgesia at 5 (t-test, p=0.031) and 10 hours (t-test, p=0.04). More patients were 'very satisfied' with ESPB compared with receiving only morphine at each time period (p<0.001).

Conclusion ESPB is a promising alternative to morphine in those with HPB pain.

Trial registration number CTRI/2023/03/050595.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Pain from pancreatitis and other hepatopancreaticobiliary (HPB) diseases can be challenging to treat in the ED.

⇒ Erector-spinae plane block (ESPB) is a relatively new and versatile technique for visceral and somatic anaesthesia in the peri-operative setting; however, more robust data on its application in the ED setting are needed, especially when compared with standard medical care like opioids.

WHAT THIS STUDY ADDS

⇒ This randomised, open-label trial found that in patients with acute severe (numeric rating scale ≥7) pain from HPB disease, the ESPB resulted in significantly better reduction of pain, lower requirement for rescue analgesia and greater patient satisfaction.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ ESPB is a potential alternative to opioids in the management of severe acute HPB pain in the ED.

⇒ Further large comparative studies using different operators to perform ESPB are needed before this can be considered as a standard practice.

INTRODUCTION

Acute hepatopancreaticobiliary (HPB) pain is a common and debilitating condition that brings many patients to the ED.[1 2] The mainstay of pain relief from HPB pathology in the ED has been opioids,[3] the usage of which increases the risk of vomiting, sedation, respiratory depression as well

as dependence with long-term use.[4 5] Thus, managing acute HPB pain is a challenge in the ED and a better, safer alternative is required. The ultrasound-guided (USG) erector-spinae plane block (ESPB) is a relatively new regional anaesthetic technique for thoraco-abdominal postoperative analgesia,[6] and has been explored in ED settings for the treatment of rib fractures[7] and pancreatitis.[8] However, to date, there have been no studies comparing USG ESPB with intravenous opioids in the management of acute HPB pain. Recognising this as an area of need, the authors undertook this study hypothesising that USG ESPB is more effective than intravenous morphine in treating acute HPB pain.

The aim of our study was to compare the reduction in pain score for ED patients receiving USG ESPB performed by an emergency physician versus intravenous morphine for management of pain in HPB disorders. Our objectives were to analyse the reduction in pain score by the numerical rating scale (NRS) between those receiving the ESPB and those receiving morphine, to analyse the requirement for rescue analgesia between the groups for the duration of the study (10 hours), to determine the success rate of the ESPB when done in the ED and to compare patient satisfaction between the two patient groups.

METHODS

Study design

This was a single-centre open-label randomised controlled trial comparing two methods of acute pain management in patients presenting with severe HPB pain. Clinical trial registration was obtained before initiation of the study (CTRI/2023/03/050595).

Setting

The study was performed in the ED of a major tertiary-care medical college and hospital in southern India between the months of March and August 2023.

Selection of participants

Eligible patients were those between the ages of 18 and 70 years with newly diagnosed or previously known HPB disease presenting to our ED with NRS ≥7 (on a scale of 1–10) when one of the primary investigators was present. Patients were eligible regardless of whether analgesia had been administered prior to arrival. Patients excluded were those younger than 17 years or older than 71 years of age, pregnant, those who were haemodynamically unstable, those not consenting to be part of the study or who had known adverse reactions to opioids or local anaesthesia.

Study procedures

After recording demographic details, taking a history and performing a complete physical examination, informed written consent was obtained from eligible patients. Patients were then randomly assigned (1:1) to USG ESPB and intravenous morphine for acute pain management. The randomisation scheme was developed with the assistance of a statistician and assigned patients to one of the two arms in blocks of 6 or 8 to assure balance. Allocations were sequentially distributed in sealed envelopes after recruitment and initial NRS assessment by the investigating team. Those allocated to the intervention arm underwent a bilateral USG ESPB at T7 level by an experienced ED consultant with regional anaesthesia training and certification. Those randomised to the control group were given 0.1 mg/kg morphine (Verve Human Care Laboratories, Selaqui, Dehradun, India) intravenously for analgesia.

Procedure

The ESPB was performed by one of two emergency consultants (SND or PDK) using the previously published Single-operAtor Nerve block under Direct ultrasound visualisation in emergencY (SANDY) technique, developed for performing bedside regional anaesthesia in the ED using non-specialised equipment by a single doctor.[9] This differs from traditional regional anaesthesia techniques, which require a separate area to perform the nerve block, at least two practitioners to administer it and specialised needles that can be visualised under ultrasound. Preparation for the procedure involved drawing up two 20 mL syringes (BD Discardit II, Becton Dickinson India, Madhavaram, Chennai, India) with 0.2% ropivacaine (manufactured by Abbot Healthcare, distributed by Miraculous Pharma, Navsari, India) and attaching the hollow stylet of an 18 g intravascular cannula (Vasofix Luer Lock, B. Braun Medical Industries, Penang, Malaysia) to each. Those were used to administer the ESPB, one on each side. The patient was placed in a sitting position and asked to bend forward. Using a linear high-frequency vascular probe (6–13 Hz HFL38, SN 04QGNX, FUJIFILM SonoSite, Washington, USA), a check scan was performed to localise the transverse process of T7. This was done by confirming the position of the first rib posteriorly lateral to the midline, then sliding medially just off the midline to identify the transverse process of T1. The probe was then moved caudally counting to T7, visualised under the erector-spinae muscle complex. The check scan was performed bilaterally to confirm the landmarks, following which, using aseptic technique and under direct vision, the needle was advanced in a cephalo-caudal direction through the muscle until contact was made with the bone. After aspiration to confirm absence of vascular transgress, the drug was injected looking for free flowing spread of liquid separating the transverse process and the muscle plane. This was repeated on the opposite side, 20 mL of each side for a total of 40 mL of 0.2% ropivacaine. The patient was asked to lie supine 5–10 min after the procedure was completed.

Patients in both groups could request additional analgesia if they complained of pain during the study period. This rescue analgesia was delivered in additional titrated doses of intravenous morphine. All participants were continuously monitored for side effects such as injection site infection or bleeding, rapidly expanding haematoma, pneumothorax and adverse drug reactions to either bupivacaine or morphine by the treating team who were not study personnel. At 1, 3, 5 and 10 hours after the intervention, the patient's NRS, need for rescue analgesia and satisfaction levels were noted and communicated to the investigators by the treatment team, minimising assessor bias. For satisfaction, patients were asked to choose among three levels: not satisfied, somewhat satisfied and very satisfied.

Outcome measures

The primary outcome of our study was the difference in NRS scores between the patients receiving the USG ESPB and those receiving intravenous morphine after 1 hour. Secondary outcomes were the reduction in NRS scores at 3, 5 and 10 hours, the need for rescue analgesia between the two groups, the overall satisfaction rates of the participants with the therapy and the success rate of the ESPB. We defined a block as successful if there was 50% or more reduction in NRS 1 hour after the procedure, or if the absolute value of postintervention NRS was 4 or less.

Statistical analysis

Our sample size was calculated based on a previous study by Gürkan *et al*,[10] which compared ESPB and paraverterbal blocks with intravenous morphine for postoperative analgesia following breast surgery. The study had reported SD value for ESPB and control group as 3 and considered the mean difference as 2. With 80% power, alpha 5% and two-sided tests, the sample size for our study was estimated to be 70, with 35 participants in each arm.

Continuous variables were expressed as mean±SD and categorical variables were expressed as frequency or percentages. The t-test and Mann-Whitney U test (for skewed variables) were used for comparison of continuous variables at 1, 3, 5 and 10 hours. Analysis of co-variance (ANCOVA) was also conducted to assess the primary outcome of difference in NRS at 1 hour between the two groups while controlling for the NRS baseline. An incidence of adverse events was compared between two groups using χ^2 test. Fisher's exact test or χ^2 test was used to analyse the categorical variables. A subgroup analysis was done analysing the need for rescue analgesia across the various HPB pathologies. All tests were two-sided at $\alpha=0.05$ level of significance. Intention-to-treat analysis was carried out to compare the outcomes across both groups. All analyses were done using SPSS software V.21.0 (IBM, Armonk, New York, USA).

Patient and public involvement

No patients or members of the public were involved.

RESULTS

We enrolled 284 participants across the study period, out of which 184 were excluded and 70 patients were randomised (figure 1). 35 patients were allocated to each arm with adequate matching (table 1). The majority of patients were male (72.9%). The overall mean age was 40.4 (SD±13.2) years. The mean NRS at presentation in the intervention (ESPB) arm was 8.0 (SD±0.9) and 7.6 (SD±0.6) in the control (intravenous morphine) group. According to the revised Atlanta severity criteria, the severity of pancreatitis cases was relatively evenly distributed among the study groups.

The mean reduction from baseline in NRS at 1 hour was 7.0 (±1.6) in the ESPB group and 4.4 (±2.0) in the morphine group, demonstrating a significant difference (p<0.001). ANCOVA while adjusting for NRS also showed significant difference within 1 hour of intervention from the baseline (p<0.001) (online supplemental table 1). Reductions in the NRS at 3, 5 and 10 hours were all significantly greater in the ESPB group compared with the intravenous group (table 2, figure 2).

No patient who received the ESPB needed rescue analgesia in the first hour, thus success rate of the ESPB was deemed to be 100%. Significant differences in the need for rescue analgesia for all diagnoses were noted in the intervention arm compared with the control arm at 5 and 10 hours. In the acute pancreatitis group, at 1, 5 and 10 hours, the number of patients who needed rescue analgesia in the intervention and control arms were 0 and 4 (p=0.045), 1 and 7 (p=0.026) and 2 and 16 (p=0.010), respectively (online supplemental table 2). Satisfaction rates were significantly higher in the ESPB arm compared with the intravenous treatment arm across all the time intervals (p<0.01) (figure 3).

There were no adverse effects or drug reactions noted in either of the patient arms.

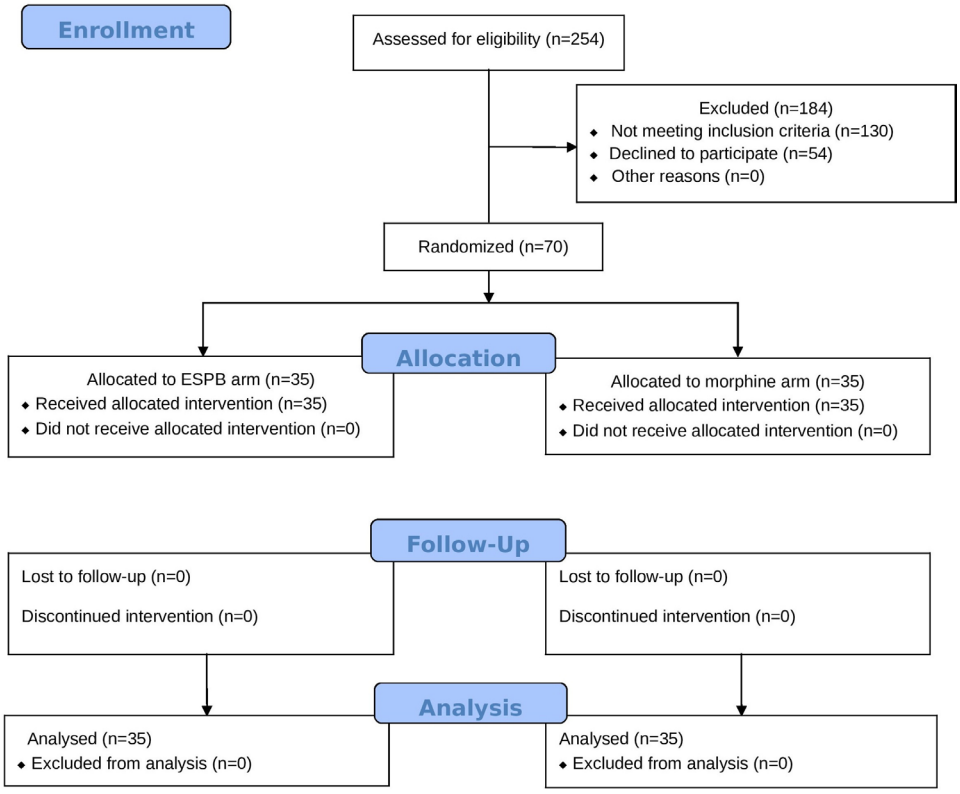

Figure 1 Consolidated Standards of Reporting Trials flow chart of the Erector-spinAe analgeSia for hepatopancreaticobiliary pain In the Emergency Room trial. ESPB, erector-spinae plane block.

Table 1 Baseline characteristics of participants

Patient characteristics (n=70)	Total (%) N=70	ESPB (%) N=35	Intravenous morphine (%) N=35	P value
Sex				0.179
Male	51 (72.9%)	28 (54.9%)	23 (45.1%)	
Female	19 (27.1%)	7 (36.8%)	12 (63.2%)	
Age (years)				0.950
18–30	19 (27.1%)	11 (31.4%)	8 (22.9%)	
31–40	19 (27.1%)	7 (20%)	12 (34.3%)	
41–50	14 (20%)	8 (22.9%)	6 (17.1%)	
51–60	13 (18.6%)	6 (17.1%)	7 (20%)	
61–70	5 (7.2%)	3 (8.6%)	2 (5.7%)	
Comorbidities				
Diabetes	23 (32.9%)	10 (28.6%)	13 (37.1%)	0.445
Hypertension	16 (45.7%)	8 (22.6%)	8 (22.9%)	1.000
Chronic liver disease	1 (1.4%)	1 (2.9%)	0	1.000
Coronary artery disease	2 (2.9%)	1 (2.9%)	1 (2.9%)	1.000
Reactive airway disease	2 (2.9%)	1 (2.9%)	1 (2.9%)	1.000
Chronic smoking	11 (15.7%)	8 (22.9%)	3 (8.6%)	0.188
Chronic alcohol consumption	26 (37.1%)	15 (42.9%)	11 (31.4%)	0.322
Diagnoses				
Acute pancreatitis	38 (54.3%)	18 (51.4%)	20 (57.1%)	0.952
Acute on chronic pancreatitis	19 (27.1%)	11 (31.4%)	8 (22.9%)	
Chronic pancreatitis	7 (10%)	3 (8.6%)	4 (11.4%)	
Cholangiocarcinoma	4 (5.7%)	2 (5.7%)	2 (5.7%)	
Cholecystitis	2 (2.9)	1 (2.9%)	1 (2.9%)	
Severity of pancreatitis (Atlanta)				
Mild	28 (40%)	13 (37.1%)	15 (42.9%)	0.636
Moderate	21 (30%)	13 (37.1%)	8 (22.9%)	
Severe	8 (11.4%)	3 (8.6%)	5 (14.3%)	
Not applicable	13 (18.6%)	6 (17.2%)	7 (20%)	

ESPB, erector-spinae plane block.

DISCUSSION

The Erector-spinAe analgeSia for hepatopancreaticobiliary pain In the Emergency Room (EASIER) trial showed significantly greater reduction of HPB pain in those who received USG ESPB compared with those who received morphine for analgesia. Furthermore, the requirement for rescue analgesia was lower in the group receiving ESPB and these patients also reported higher satisfaction. Importantly, all ESPB procedures were successful in providing analgesia.

Pain from acute pancreatitis is secondary to inflammation and destruction of pancreatic architecture.[11] Chronic pancreatitis pain however is incompletely understood, and a neural mechanism has been suggested.[12] Opioids such as morphine are ubiquitous in EDs and are commonly used as the mainstay of pain relief in the treatment of HPB diseases such as pancreatitis, with varying degrees of success.[13–15] They are not without their own problems, notably side effects such as nausea and vomiting at standard doses and respiratory depression with higher doses. Long-term use of morphine can potentially result in dependence and desensitisation, making treatment even more challenging in the long term or on repeat visits.

The ESPB is a well-described technique for thoraco-abdominal regional anaesthesia, having been used for intra-operative and postoperative analgesia for a variety of conditions. It is done under USG by visualising the transverse process at the desired level and injecting long-acting local anaesthetic such as ropivacaine or bupivacaine between the transverse process and the erector-spinae muscle complex. This acts on the dorsal and ventral branches of the spinal nerves as they leave the spinal cord, providing localised visceral and somatic analgesia at the level given. It can be performed unilaterally or bilaterally at either the thoracic or lumbar levels depending on the desired location of analgesia, with an expected spread of 2–4 spinal levels cephalad and caudad. Unlike the paravertebral block, the pleura is not encroached on, thus there is markedly reduced risk of causing a pneumothorax under USG. Therefore, the ESPB is fast becoming a mainstream method of regional anaesthesia for its versatility and good safety profile. A randomised controlled trial by Gürkan *et al* showed a statistically significant benefit in postoperative analgesia for patients who underwent breast surgery with intravenous morphine compared with those who did not.[10] A recent meta-analysis by Oh *et al* looking at 12 randomised controlled trials comparing ESPB with control (no block/sham block) for lumbar spine surgery concluded that ESPB provided better postoperative analgesia, better patient satisfaction rates and less overall opioid consumption in the first 24 hours compared with the control arm.[16] Another meta-analysis by Viderman *et al* comparing ESPB with standard medical care in seven randomised controlled trials for various abdominal surgeries found significantly less opioid use and time to first analgesia in the ESPB group, but had insignificant differences with regard to pain score, nausea and vomiting.[17] It is imperative that the operator be familiar with the sono-anatomy and required landmarks to perform the ESPB instead of an intertransverse or

Table 2 Postintervention assessment

	ESPB (n=35)	Intravenous (n=35)	P value
Mean reduction in NRS (±SD)			
<1 hour	7.0 (±1.6)	4.4 (±2.0)	<0.001
1–3 hours	6.7 (±1.9)	4.6 (±1.8)	<0.001
3–5 hours	6.6 (±1.8)	3.7 (±2.2)	<0.001
5–10 hours	6.1 (±1.9)	3.8 (±1.8)	<0.001
Satisfaction rates (%)			
<1 hour			
Not satisfied	0	4 (11.5%)	<0.001
Somewhat satisfied	1 (2.9%)	18 (51.4%)	
Very satisfied	34 (97.1%)	13 (37.1%)	
1–3 hours			
Not satisfied	1 (2.9%)	4 (11.4%)	<0.001
Somewhat satisfied	4 (11.4%)	22 (62.9%)	
Very satisfied	30 (85.7%)	9 (25.7%)	
3–5 hours			
Not satisfied	0	8 (22.8%)	<0.001
Somewhat satisfied	7 (20%)	22 (62.9%)	
Very satisfied	28 (80%)	5 (14.3%)	
5–10 hours			
Not satisfied	0	11 (31.4%)	<0.001
Somewhat satisfied	11 (31.4%)	21 (60%)	
Very satisfied	24 (68.6%)	3 (8.6%)	
Number of patients needing rescue analgesia			
<1 hour	0	4 (11.4%)	0.114
1–3 hours	3 (8.6%)	9 (25.7%)	0.053
3–5 hours	3 (8.6%)	10 (28.6%)	0.031
5–10 hours	5 (14.3%)	16 (45.7%)	0.004

ESPB, erector-spinae plane block; NRS, numerical rating scale.

paravertebral block, as these may have different drug spreads and more chance of causing pneumothorax.[18]

From an ED setting, several case reports document the efficacy of ESPB in the acute analgesic treatment of rib fractures,[8 19] back pain,[20] abdominal pain[21 22] and pancreatitis.[9 23 24] A literature review by Abdelhamid *et al* stated that the ESPB was an anaesthetic modality quickly gaining popularity in the ED due to its long action, excellent safety profile and overall decrease in patient opioid consumption.[25] A recently published randomised

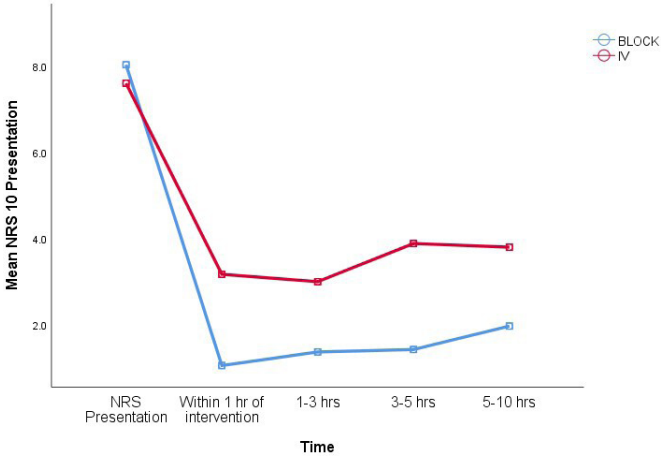

Figure 2 Mean reduction in numeric rating scale (NRS) between the patients who received ESPB against those who received intravenous morphine. ESPB, erector-spinae plane block.

Figure 3 Graphical representation of patient satisfaction rates from both study groups across the study period. The majority of patients in the block arm reported being very satisfied with the erector-spinae plane block as compared with morphine.

controlled trial by Ramesh *et al*, comparing ESPB with a placebo procedure in 46 patients presenting with rib fractures, showed significantly better pain scores in those who received the ESPB compared with those who did not, along with reduced rescue opioid consumption.[26] In our study, we noted that although the mean reduction in NRS was significantly greater in the ESPB arm compared with the intravenous arm, the difference in overall requirements for rescue analgesia became significant only after 3 hours in the ESPB arm, especially in cases involving acute pancreatitis. This could be explained by the fact that morphine has an average duration of action lasting 3–5 hours.[27 28] Therefore, as the drug wore off within the 10-hour study period, rescue analgesia was required. This is in contrast with one-time ESPBs using 0.2% ropivacaine, which are reported to act anywhere between 4 and 24 hours, depending on the site injected.[7 29] This wide range of action could be explained by the variable spread of drug away from the desired site over time. The toxic dose of ropivacaine is 2 mg/kg, thus up to 70 mL of 0.2% preparation could be given for a 70 kg adult. With that in mind, we divided the dose into 20 mL injections bilaterally totalling 40 mL, allowing us to avoid the toxic limit while providing adequate analgesia.

As of the time of penning this manuscript, there have been no published comparative studies showing the benefit of ESPB over standard analgesic modalities in the ED for HPB pain. Our EASIER trial showed that bedside USG ESPB resulted in significantly lower pain scores in the patient cohort compared with morphine. It also showed a significantly lower usage of rescue opioid overall and greater patient satisfaction scores as well. Importantly, all ESPBs were performed with 100% success rate by a single operator at the bedside. This study used the SANDY technique, developed for performing bedside regional anaesthesia in a high-volume or low-resource ED without the need for specialised needles, equipment such as high-pressure extension lines, multiple personnel or a separate room.[10] Additionally, ESPB using the SANDY technique can be performed with the patient sitting up and bending forward, which is a comfortable position for those suffering from pancreatitis (figure 4).

Strengths of the study

This study used a randomised design with an active control, including a well-defined patient population, intervention, comparison arm, outcomes and a specific observation period that allowed for sufficient assessment of pain control after the procedure. There was no participant attrition. Although the ESPB in our study was performed by one of two experienced consultants and executed by a single operator, it is a procedure that is relatively easy to perform in the ED setting without requiring specialised equipment. Therefore, training more emergency physicians and implementing the procedure could be considered in the acute management of these painful conditions.

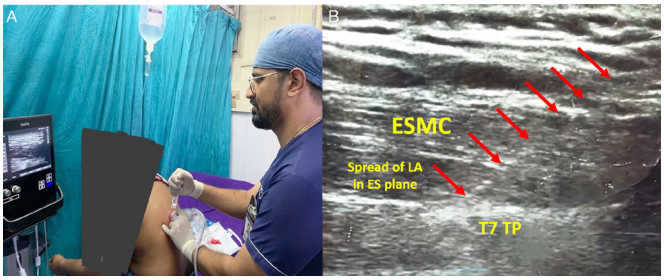

Figure 4 (A) Bedside erector-spinae plane block (ESPB) using the Single-operAtor Nerve block under Direct ultrasound visualisation in emergencY technique. (B) Sonoanatomy of the ESPB. The needle path is marked by red arrows contacting the transverse process (TP) of T7 with spread of local anaesthetic below the erector-spinae muscle complex (ESMC).

Limitations of the study

This was an open-label single-centre study. Due to differences between the treatment modalities and logistic difficulties, proper blinding could not be done leading to potential bias in patient-reported outcomes. As patients were recruited for the study only when the designated consultants were on shift, many were excluded at presentation. The ESPB was only administered by consultants trained and certified in regional anaesthesia, which limited generalisability in performing the procedure. The 10-hour follow-up period was provisionally chosen, considering that the duration of action of the single-shot ESPB with 0.2% ropivacaine varies from 4 to 24 hours. Therefore, a longer follow-up period could provide more insight into patient satisfaction and long-term complication rates.

In conclusion, the EASIER trial found that USG ESPB in the ED provided more effective and long-lasting pain relief compared with intravenous morphine, without adverse events. Further studies with longer follow-up periods are warranted to assess the incidence of delayed side effects and to confirm or refute the findings of this trial.

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Contributors SND is guarantor. SND and VM conceived the presented idea and developed the study model. SND and PDK performed the interventions. RK, VM and AT verified the analytical methods and performed the data analysis. KPPA and SDC encouraged AT and VM to investigate and supervised the findings of this work. Manuscript preparation and write-up was done by SND. All authors discussed the results and contributed to the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval Ethical and scientific approval was obtained by the Institutional Review Board of Christian Medical College, Vellore (Ethics Committee registration no: ECR/326/INST/TN/2013/RR-2019; IRB number: 15004). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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