Critical Review Form
Therapy

Ramesh S, Ayyan SM, Rath DP, Sadanandan DM. Efficacy and safety of ultrasound-guided erector spinae plane block compared to sham procedure in adult patients with rib fractures presenting to the emergency department: A randomized controlled trial. Acad Emerg Med. 2024 Apr;31(4):316-325.

Objectives: **"The primary objective was to compare the analgesic efficacy of ultrasound-guided erector spinae plane block (ESPB) with a sham procedure in adult patients presenting with rib fractures to the emergency department (ED)." (p. 316)**

Methods: **This was a prospective, randomized controlled trial conducted at an academic tertiary care ED in southern India between March 2022 and July 2023. Consecutive adults over 18 years of age with a traumatic rib fracture and a pain score ≥ 4 on the numeric rating score (NRS) despite routine analgesia (IV tramadol 100 mg, IV paracetamol 1 g) were enrolled. Exclusion criteria were allergy to amide-type local anesthetics, NSAIDs, tramadol, or fentanyl; penetrating thoracic trauma; pregnancy; signs of infection or laceration at the injection site; systolic BP < 100 mmHg; subcutaneous emphysema at the block site; chronic pain or analgesic use; substance abuse; institutionalization/incarceration; need for immediate surgery; and inability to consent.**

Patients were randomized 1:1 via block randomization with variable block sizes. The ESPB group received an ultrasound-guided injection of 0.5% bupivacaine (2.5 mg/kg, max 150 mg, diluted to 30 mL) at the transverse process corresponding to the fractured rib level. The sham group underwent identical positioning, skin prep, and a blunt-tip pressure sensation at the injection site without actual needle insertion (Grade 1 sham). Rescue analgesia (IV tramadol, then IV fentanyl) was given for NRS ≥ 4 in both groups and quantified in morphine equivalents. The primary outcome was pain intensity (11-point NRS) at rest and during deep inspiration across six time points over 12 hours. Secondary outcomes were total rescue analgesia, chest expansion, and adverse events.

Of 153 patients screened, 46 were randomized (23 per group) with no loss to follow-up. Mean age was 49.5 years in the ESPB group and 51.5 years in the sham group. Males comprised 91.3% of the ESPB group and 82.6% of the sham group. Road traffic accidents accounted for the majority of rib fractures (56.5% ESPB, 65.2% sham), and lateral rib fractures were most common (63% overall).

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Guide	Comments
Are the results valid?	

Did experimental and control groups being the study with a similar prognosis?	
Were patients randomized?	Yes. Participants were randomized in a 1:1 fashion by block randomization with variable block sizes.
Was allocation concealed? Was it possible to subvert the randomization to ensure a patient would be "randomized" to a particular group?	Yes. Random allocation software was used for sequence generation, and "The sequentially numbered, sealed, opaque envelope method was used for allocation concealment." (p. 318) This should be adequate to maintain allocation concealment.
Were patients analyzed in the groups to which they were randomized?	Yes. All patients appear to have been treated according to group allocation and were analyzed as such.
Were patients in the treatment and control groups similar with respect to known prognostic factors?	Uncertain. Patients in each group were similar with respect to age, gender, mechanism of injury, presence of bilateral fractures, location of fracture, baseline vital signs. The authors provide no information on medical comorbidities (particularly history of pulmonary disease), number of fractures, or the presence of additional injuries.
Did experimental and control groups retain a similar prognosis after the study started?	
Were patients aware of group allocation?	Uncertain. The authors used a sham procedure for the placebo group that did not involve skin penetration with the needle. It seems likely that patients would be able to tell whether they received the block or not, and there is some risk of performance bias on the part of the patients.
Were clinicians aware of group allocation?	Yes. Clinicians were not blinded to group allocation; there is some risk of performance bias on the part of the cliinicians.
Were outcome assessors aware of group allocation?	No. "Changes in the NRS at rest and on deep breathing were recorded at each of these time points by emergency medicine residents who were blinded to the allocated group.
Was follow-up complete?	Yes. Outcome data was available for all patients at all outcomes.
What are the results?	
How large was the treatment effect?	• NRS scores at rest and during deep inspiration were significantly lower in the ESPB group at 30, 60, and 120 minutes postintervention ($p < 0.001$); the difference at 360 minutes was not statistically significant. • No significant difference in chest expansion between groups at any time point. • Rescue analgesia (morphine equivalents) was significantly lower in the ESPB group (median 10 mg, IQR 2.5) than the sham group (median 20 mg, IQR 5) ($p \leq 0.01/p < 0.001$). • Adverse events did not differ significantly between groups ($p > 0.23$); 3 ESPB patients had transient, self-limited dizziness. No serious adverse events occurred in either group.
How precise was the estimate of the treatment effect? (i.e. what 95% CIs were associated with the results?)	The authors report 95% confidence intervals for differences in resting and deep breathing pain at various time points; these intervals favor the ESPB group and do not cross 0 at 30, 60, and 120 minutes, but do cross 0 at 360 and 720 minutes.
How can I apply the results to patient care?	
Were the study patients similar to my patient?	Uncertain. This study was conducted at a tertiary care center in India, where differences in ethnicity, healthcare provision, and baseline medical conditions differ from our institutions. In addition, the primary opioid used for analgesia was IV tramadol, which we do not typically use and which is less efficacious than opioids we use (external validity).
Were all clinically important outcomes considered?	Authors did not assess patient satisfaction, ED or hospital length of stay, development of hypoxia, or incidence of pneumonia.

Are the likely treatment benefits worth the potential harm and costs?	Likely yes. This study found that ultrasound-guided ESPB produced significantly lower pain scores (both at rest and during deep inspiration) at 30, 60, and 120 minutes post-intervention compared to sham, along with roughly half the rescue analgesia requirement (10 mg vs. 20 mg morphine equivalents). There was no significant difference between groups in chest expansion or adverse events, and no serious adverse events.

Limitations:

1. **Patients with other injuries, besides rib fractures, were not excluded. The existence of other injuries would confound pain scores and need for rescue analgesia.**

2. **The authors provide no information on medical comorbidities (particularly history of pulmonary disease), number of fractures, or the presence of additional injuries. It is therefore unclear if the two groups were balanced with respect to important prognostic factors.**

3. **Authors did not evaluate several key patient-centered outcomes, including patient satisfaction, ED or hospital length of stay, development of hypoxia, or incidence of pneumonia.**

4. **This study was conducted at a tertiary care center in India, where differences in ethnicity, healthcare provision, and baseline medical conditions differ from our institutions. In addition, the primary opioid used for analgesia was IV tramadol, which we do not typically use and which is less efficacious than opioids we use (external validity).**

Bottom Line:

In this single-center randomized controlled trial from India, ultrasound-guided ESPB produced significantly lower pain scores (both at rest and during deep inspiration) at 30, 60, and 120 minutes post-intervention compared to sham, along with roughly half the rescue analgesia requirement (10 mg vs. 20 mg morphine equivalents). There was no significant difference between groups in chest expansion or adverse events, and no serious adverse events occurred in either group. Lack of true blinding and issues with external validity limit the applicability of these results.