# Prospective, randomized, double blind comparison of pain relief and physical function in patients with acute rib fracture after Erector Spinae Plane (ESP) block versus epidural block

**JF Asenjo, MF Arboleda, JC Pineda**

**Department of Anesthesia**

## INTRODUCTION

Rib fractures are the most common injury in blunt thoracic trauma, and it is present in 7 to 10% of patients admitted to trauma centers in the United States [1-5]. The age of the patient and severity of trauma are directly associated with high risk of mortality in individuals with rib fracture, estimated in some hospitals between 4-6%[6-8].

The most common symptom of rib fractures is pain. This is typically a nociceptive somatic type of pain, and in the majority of cases it is incidental; therefore, it may appear with deep inspiration or when coughing, among other possible triggers. Additionally, in patients with stable fractures, pain is frequently associated with more than two broken ribs. On the other hand, poor pain relief is usually related to a high risk of respiratory complications such as atelectasis or pneumonia, as well as a potential risk to transition from acute to chronic and/or neuropathic pain. If the fractures are complex, the patient may suffer from additional damage to underlying structures [9-10].

There is no specific treatment for pain management associated to rib fractures. Some patients with non-displaced fractures may show a positive response to nonsteroidal anti-inflammatory drugs (NSAIDs) [11]. Furthermore, some studies support the magnitude of a rib fracture displacement and the number of rib fractures is able to predict total opioid requirements. Hence, Bugaev N et al found that every 5mm of displacement predicted 6.3% increase of morphine equivalent doses (MED), and every additional rib fracture increased 11.2% of MED [12].

Moreover, adjuvant analgesics such as ketamine and pregabalin are other possible options to consider for pain control. These medications are able to decrease opioid consumption and therefore limit complications associated to opioid's usage[13].

In addition to pharmacological strategies suggested for pain control, interventional procedures can also be considered for patients with rib fractures. The most studied techniques are thoracic epidural blocks, thoracic paravertebral blocks

(TPVB), intercostal blocks, serratus anterior plane block, and recently described, erector spinae plane (ESP) block.

Epidural analgesia (EA) is considered a gold standard for pain relief in patients with multiple rib fractures and unstable thorax. This technique offers a superior pain control when compared to intravenous opioids and NSAIDs [14, 15]. According to the literature, thoracic epidural blocks are able to reduce plasma levels of interleukin-8 in patients with chest trauma, improve respiratory therapy and reduce length of hospital stay. Possible adverse effects related to this modality are hypotension and cardiovascular collapse (cardiac arrest). Additionally, the procedure is contraindicated in patients with current anticoagulation or coagulation impairment; therefore, this medication must stay on hold in order to perform the block [16, 17].

On the other hand, TPVB are safe and capable to provide relief for pain secondary to rib fractures. Single injection of local anesthetic is effective for simple fractures. However, for multiple broken ribs the evidence suggests the insertion of a catheter for continuous infusion after the local anesthetic bolus injection[18, 19]. Comparison of EA versus TPVB shows a clear advantage of TPVB to provide long duration of analgesia with early ambulation. The use of a ultrasound guidance for this procedure has shown to be safe and successful when compared to other techniques, allowing real-time visualization of the needle. [20,21].

A comparison of continuos epidural analgesia versus thoracic paravertebral infusion was done in elderly trauma patients. The results showed greater pain relief with TPVB continuous infusion, but no difference was observed for length of hospital stay or pain scores. The authors mentioned TPVB are safe, easily inserted and well tolerated in elderly patients with bleeding risk[22].

Furthermore, the ESP block is a new technique recently described by Forero et al. It consists in injecting 20 ml of local anesthetic (ropivacaine 0.5%), under ultrasound guidance, at the level of the T5 transverse process in the tissue plane deep to the erector spinae muscle. A study of the ESP block was conducted on fresh human cadavers; dye mixture was injected deep to erector spinae muscle, and the spread showed to be cranio-caudal from C7 to T8, lateral spread extended to the tips of the transverse processes at all levels, penetration of the dye was beyond the costotransverse junction and anteriorly into the intertransverse spaces. In addition, there was evidence of dye penetration deep to the intercostal muscles and into the immediate vicinity of the ventral and dorsal rami of the spinal nerve roots. The authors discussed the most significant advantage of the ESP block is its simplicity and safety. The sonoanatomy is easily recognizable, there are no structures at risk of needle injury in the immediate surroundings (lower risk of nerve damage and pneumothorax), and is probably safer for patients with coagulation disorders. The technique also allows the insertion of an indwelling catheter to extend the duration of analgesia as needed [23].

Therefore, this type of block has been used already for different type of surgeries and pain conditions. Currently the literature shows the ESP block may be considered for analgesia after thoracic surgery (thoracotomy), abdominal surgery (visceral

abdominal analgesia in bariatric surgery, ventral hernia repair), thoracic vertebra surgery, and for pain relief in rib fractures [24, 25, 26, 27].

The case report published by Hamilton et al in 2017 showed a successful ESP block using a continuous catheter technique for pain relief in a patient with multiple unilateral rib fractures. The infusion rate of the local anesthetic (bupivacaine 0.125%) was 10 ml/h, and was administered during 4 days. The patient was able to mobilize around the hospital ward during this time, and after discontinuation of the infusion he was discharged home [28]. Again, this author discussed the technically easier to perform procedure compared with neuroaxial or targeted nerve blocks, with the possibility of fewer adverse effects [29].

Taking in consideration previous facts mentioned above and the lack of strong and high-quality evidence supporting the use of ESP block for pain management in patients with acute rib fractures, there is a specific interest to develop a prospective study comparing the effect of ESP block versus epidural analgesia for pain control after unilateral rib fracture. Consequently, with a lower pain intensity, it will be possible to observe an improvement of physical and ventilatory function.

The ESP block could be a technique considered in the acute pain service as a possible treatment for patients with pain due to acute rib fractures. This strategy aims to decrease risks and side effects related to interventional procedures, and in the future could become first option for the management of this patients, or a possibility to consider in cases were epidural analgesia might be contraindicated.

Therefore, the purpose of this study is to compare pain relief and physical function improvement in patients with unilateral acute rib fractures after ESP block compared to the standard epidural analgesia protocol. Additionally, we hypothesize the ESP block is comparable to epidural analgesia for pain relief and improvement of physical and ventilatory function, with lower risks and/ or side effects.

### *Null Hypothesis*

There is no difference in pain relief and physical function in patients with acute rib fractures with ESP block compared to epidural catheter.

### *Outcomes, sample size and statistical analyses*

To test the null hypothesis, we consider as clinically relevant:

- A reduction of 30% in nociceptive somatic pain intensity over the rib fracture area after ESP block and continuous infusion of local anesthetic.

- Improvement of pulmonary function in 30%, by measuring the volume inspired through an incentive spirometer and measuring the range of motion of the thorax after ESP block and continuous infusion of local anesthetic.

There are no previous prospective studies comparing ESP block versus epidural block for the management of pain in acute rib fractures. However, based on the comparative study of epidural catheter versus thoracic paravertebral block for rib fractures, a total of 62 patients are required.

The primary outcome measures will be:

- Efficacy of ESP block versus epidural block to improve pain intensity. Pain level will be assessed using the 10 points Numerical Rating Scale (NRS) where zero= *no pain* and 10= *pain as bad as it can be.* The NRS is a validated tool to measure pain and discomfort, and it is also sensitive to pharmacological and non-pharmacological procedures that have an impact over experience of pain, and it correlates highly with pain levels.
  Pain intensity of rib fractures will be measured for static and dynamic pain with the NRS. This measurement will be performed before the procedure: ESP block or epidural block (basal), at the end of the procedure (NRS post-procedure), and in the follow-up after 24 and 48 hours.
- Improvement of physical function by measuring the range of movements of the thoracic wall (RMT). This is done by using measuring tape around the circumference of the chest wall in two levels: upper level at $4^{th}$ rib, and lower lever at the xiphoid process. Basal measurement will be done before the procedure, immediately after the block, and in the follow-up after 24 and 48 hours.
- Improvement in pulmonary function. This will be assessed using the incentive spirometer (IS), allowing the measurement of pulmonary capacity and inspirated volume. This measurement will be performed before the procedure (basal), immediately post block, 24 and 48hrs after.

Secondary outcomes will be:

- Total opioid consumption 24 and 48 hours after the block considering the Morphine Equivalent Daily Doses (MEDD). D
- Disability rating index for functionality assessment after the block and follow up 1 week after
- Side effects associated to opioid consumption or analgesic technique (ESP block or Epidural block) 24 hours after and 1 week after the procedure
- Length of hospital stay

To perform the study, we will prospectively randomize the patients, in a double-blind fashion, to two equal groups:

1. Experimental group: ESP block (technique as described by Forero et al) at the side and level of the rib fracture (s). Ultrasound -guided technique, done under sterile conditions, previous injection of local anesthetic to the skin (lidocaine 1%). Doses of local anesthetic Lidocaine 2% and epinephrine 1:100.000 (10ml) + Bupivacaine 0.5% (10ml), obtaining a total volume of 20ml, catheter insertion in plane view after administration of 20ml bolus, and continuous infusion between 10 and 12 ml per hour (high volume infusion rate recommended for interfascial plane blocks).
2. Control group: epidural block and catheter insertion with conventional sterile technique. Injection of local anesthetic to skin (lidocaine 1%) paramedial approach. Selection of level according to the rib fracture. Loss of resistance technique with NS and epidural space final position confirmed with waveform analysis. Testing dose with lidocaine 2% + epinephrine 1:100.00 (3ml) followed by standard infusion of bupivacaine + fentanyl as per hospital protocol for continuous epidural analgesia. Infusion rate between 4-10 ml per hour.

Student's T test and Chi-square test will be used to compare continuous and categorical variables between the two groups. Analysis of variance (ANOVA) will be used for the statistical analysis that evaluates the pain intensity and functional outcomes over time.

***Patients and Methods***

The study will be conducted at the Montreal General Hospital. Sixty-two consecutive patients, male and female, between 18 and 80 years old, with acute rib fracture (s), with acute pain and intensity higher than 4/10 (NRS) and with failure to conventional pharmacological management, will be prospectively recruited in the Acute Pain service (APS) for one of the two possible interventions (ESP block or epidural block).

Informed consent will be obtained by a Research Assistant.

Patients will be prospectively randomized in a double blind fashion, using a computer-generated number placed in a sealed brown envelope, to two groups: group 1, Erector spinae plane block (ESP block) and group 2, Continous Epidural Analgesia (control group).

After informed consent, general data of the patient will be collected. Afterwards, the investigator will measure static and dynamic pain intensity with the NRS, pulmonary function using incentive spirometer, and physical function by measuring the range of movements of the upper and lower thoracic wall (RMT).

***Exclusion Criteria***

The following will be considered as exclusion criteria:

- Patients younger than 18 years old
- ASA physical status >3
- Contraindication for local anesthetics, or anesthesia.
- Immunosuppression or high risk of infection
- Coagulation impairment for thoracic epidural.
- Patients with psychosis
- Patients with cognitive impairment
- Unstable thorax secondary to multiple rib fractures.
- Systemic illness, cardiovascular disease
- Patient with pacemaker
- Muscular dystrophy

Experimental group: patients will be in prone position with a previous marker of level and side of the rib fracture (s). The procedure will be performed under strict sterile conditions in the operating room. Ultrasound guidance will be used with a high-frequency linear transducer in a sagittal plane from the middle line to lateral with the objective to find the target transverse process before its union with the rib. The sonoanatomy will show: trapezius muscle, rhomboid major muscle, erector spinae muscle and transverse process. After the target has been identified, the needle will be inserted with the tip aiming to touch the transverse process. Once in the target, the local anesthetic will be injected (lidocaine 2% with Ephineprine 1:100000 10ml + Bupivacaine 0.5% 10ml) in the plane between the erector spinae muscle and the transverse process. After that, the catheter will be placed and final position verified under real time visualization with the ultrasound.

Control group: patients will be in sitting position. The procedure will be performed under strict sterile conditions in the operating room. After selection of thoracic level, the skin should be prepared and injected with local anesthetic Lidocaine 1% 5ml. A Touhy 18 G needle will be inserted by paramedial approach using a loss of resistance technique. When the epidural space is achieved, waveform analysis will be performed to confirm final position. An epidural catheter will be advanced and fixed. Continuous epidural infusion will be started as per hospital protocol.

Once the procedure has finished, a blinded researcher will assess the patient for the static and dynamic pain intensity, the functionality with the RMT, incentive spirometer and rating disability index. The same assessment will be done by the blinded researcher in the 24 and 48 hr of follow up and rating disability index after 1 week.

All patients in both groups will receive conventional co-analgesia with NSAID and acetaminophen. The doses will be recorded 24 and 48 hrs after the procedure, in order to measure secondary outcomes.

Neither the patient, neither the researcher who collect data in the follow-up will be informed about the study group.

***Risks associated with the procedure***

These risks will be the same as those directly associated with the therapeutic intervention, such as infection and bleeding secondary to accidental puncture vessels, local anesthetic allergy or toxicity, which are less likely when procedure is done under ultrasound guidance.

***Research vs standard of care***

The ESP block for the management of pain due to rib fractures represents a novel therapy that needs to be tested in a prospective double-blind randomized study. Pharmacological treatment and continuous epidural block represent a standard of care in this institution.

***Consent***

The study will be introduced by one of the researchers to the eligible patients at the first visit. The procedure, purpose of the study, and possible risks will be explained to the patient. The consent form will be signed and a copy inserted in the chart.

***Resources***

The study will not require any significant use of hospital resources beyond the routine.

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