

Does Erector Spinae Plane Block Decrease Analgesia Requirements After Minimal-Invasive Posterior Transpedicular Stabilization in Patients With Vertebral Body Fracture? A Prospective, Randomized, Double-Blind Controlled Study

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Abstract

Study design: Prospective randomized placebo controlled double blind trial.

Objective: To examine the effect of ESP block after minimally invasive posterior stabilization for vertebral fractures on opioid consumption, pain, blood loss, disability level, and wound healing complications.

Methodology: Patients indicated for minimal invasive posterior stabilisation were included to the study. Our primary outcome was the opioid consumption and Visual Analogue Scale (VAS) measured during the first 48 hours. Secondary outcomes used to measure the short-term outcome included Oswestry Disability Index (ODI) and Patient Reported Outcome Spine Trauma (PROST).

Results: In total, 60 patients were included with a 93.3% follow-up. Average morphine consumption during the PACU (Post Anaesthesia Care Unit) period was 5.357 mg in ESP group and 8.607 mg in placebo group (P = .004). Average VAS during first 24 hour was 3.944 in ESP group and 5.193 in placebo group (P = .046). Blood loss was 14.8 g per screw in ESP group and 15.4 g in placebo group (P = .387). The day2 PROST value was 33.9 in ESP group and 28.8 in placebo group (P = .008) and after 4 weeks 55.2 in ESP group and 49.9 in placebo group (P = .036). No significant differences in ODI were detected.

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Conclusion: The use of ESP block in minimally invasive spinal surgery for posterior fracture stabilization leads to a significant reduction of opioid consumption during PACU stay by 37.7%. Reduction of opioid consumption was accompanied with lower pain (VAS). We found positive effect of the ESP block on short term outcome scores, but no effect on perioperative blood loss and wound healing.

Keywords

regional anaesthesia, erector spinae plane block, minimal invasive spinal stabilisation, thoracic lumbar spine trauma

Introduction

Many studies show decrease of pain and blood loos with MIS stabilisation compared to classical approach.^{1–3} However, in spine surgery, postoperative pain control can often be challenging, especially in first 24 hours after surgery,⁴ and pain after surgery strongly influence early mobilisation and hospital stay.⁵

It is often difficult to achieve pain control if a onedimensional approach is used. There have been several studies that combined different modalities, like epidural catheters, spinal and epidural morphine, catheters placed at the lateral border extra thoracic paraspinous muscles and local infiltration for analgesia after spine surgery.^{6–8} Lately there are studies aiming to differentiate patients before surgery, that may be prone to higher pain scores after surgery. They study many different variables that can predict difficult pain control.^{9,10}

The erector spinae plane (ESP) block is a simple ultrasound guided block. Similar technique was first described in 2010 by surgeons as treatment option of pain associated with rib fractures.⁸ In 2016 was ESP block described by Forero et al. and since then used by anaesthesiologists for acute and chronic pain management.^{11,12} Many articles have been published on the use of this technique for pain treatment in the abdominal wall surgery,¹³ thoracic surgery,¹⁴ and breast surgery.¹⁵ There are only a few case reports published in the literature mentioned the use of ESP block in spinal surgery.^{16,17} They show that ESP block appears to be a promising technique that could be routinely used in spinal surgery.

In our study, we examined the effect of ESP block on opioid consumption in the first 48 hours after minimally invasive posterior stabilization for vertebral fracture treatment, as well as its effect on blood loss during surgery, on disability level, and wound healing complications.

Materials and Methods

The study was designed as a prospective randomized placebo controlled double blind single centre trial.

Adult patients with unstable vertebral body fracture in thoracic and lumbar region suitable for minimal invasive posterior stabilisation were included to the study. All patients were treated in a single level one trauma centre in Slovak

republic. After obtaining informed consent, randomisation was performed using online software https://www.graphpad. com/quickcalcs/randomize1/18 by hospital pharmacy department, which was also responsible for preparation of solutions for ESP block. All patients received general anaesthesia according to the protocol. After the induction of general anaesthesia and positioning to prone position, we marked under X-ray intensifier injured vertebral body and vertebral bodies chosen for screw insertion, then the local anaesthetic was administered under ultrasound guidance under erector spinae muscles group directly on transverse process of fractured vertebra bilaterally. The solution used for the block contained 20 ml of .25% levobupivacaine (ESP group) or saline solution (placebo group) per side. Surgery was performed in standard way, using established minimal invasive spine stabilisation systems. Choose of implant, vertebral bodies suitable for screw insertion, and length of fixation was determined by fracture type, and bone quality.

During the surgery blood loss was determined by weight of sterile gauze pads before and after surgery.

Postoperative analgesia was performed according to standardised protocol, was designed as patient demanded, and dosage of morphine was indicated according to actual VAS (Visual Analogue Scale) score (VAS > 3 – Morphine 5 mg, VAS > 4 – Morphine 6 mg). Opioid consumption and VAS were measured every 5 minutes after surgery on PACU (Post Anaesthesia Care Unit), at the moment of discharging from PACU, and then 3, 6, 12, 24, and 48 hours after surgery. Goal of pain management was to achieve VAS 3 or less.

The short-term outcome was measured using ODI (Oswestry Disability Index) version $2.1a^{19}$ and Slovak version of AOSpine PROST (Patient Reported Outcome for Spine Trauma)^{20,21} on 2nd day, 2nd week, and 4th week after surgery. Neither ODI nor PROST are designed to evaluate short term outcome, therefore we used the modified approach with only relevant questions about pain sleeping, walking etc. to lower the bias. For ODI, we used only questions 1,2,7 on 2nd day, and questions 1,2,4,6,7 on 2nd and 4th week, respectively. For PROST we scored questions 1-9 on 2nd day and questions 1, 2, 3, 4, 6, and 9 with value 0 on 2nd and 4th week, respectively.

Data were analysed in SPSS 28 software. The normality of the distribution was evaluated continue variables using the Shapiro-Wilk test. For comparison between 2 groups, we used a two-tailed t-test if the data met the Gaussian distribution, otherwise we used non-parametric Mann-Whitney test. Significance level was set to .05.

Results

In total, 60 patients were included in this study. Follow up finished 56 of them (93.3%), 28 in ESP group and 28 in placebo group. According to CONSORT 2010 Flow Diagram we had 81 patents eligible for enrolment. From this cohort 6 patients were not included due exclusion criteria, 5 declined to participate and 10 was not enrolled due to the lack of staff caused by the COVID pandemic.

Both groups were consistent in terms of age, gender, BMI, level of fracture, AO Spine classification of injured vertebra, length of fixation (number of screws used), and type of implant (Table 1).

Morphine consumption during the PACU (Post Anaesthesia Care Unit) period was 5.357 mg in ESP group and 8.607 mg in placebo group (P = .040), whereas median of morphine consumption was 3.0 mg in ESP group and 10.0 mg in placebo group. Total morphine consumption during 48 hours follow-up was slightly lower in ESP group 8.571 mg compared to placebo group 10.154 mg, but the difference was not statistically significant (P = .253) (Table 2).

An individual measurement of VAS according to the protocol of the study was not statistically significant. Average VAS for each patient during first 24 hour was in ESP group 3.944 and in placebo group 5.193 (P = .046) (Graph 1).

Blood loss per screw was 14.8 g in ESP group and 21.2 g in placebo group (P = .198). There were two higher values both in placebo group. After exclusion of these two higher values, due to the technical error during the weight measurement in the OR, blood loss per screw was 14.8 g in ESP group and 15.4 g in placebo group (P = .387).

The average value of the AO Spine PROST at 2^{nd} day after surgery was 34.2 in ESP group and 29.2 in placebo group (P = .029). At 2^{nd} week was 50.4 in ESP group and 49.5 in placebo

 Table 1. Sociodemographic and clinical characteristics by groups.

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		Placebo Group	ESP Group	Total	P value
Age		54.68 (+/-I3.56)	52.68 (+/-10.31)	53.68 (+/-11.98)	.333
Gender	Female	12 (42.9%)	11 (39.3%)	23 (41.1%)	
	Male	16 (57.1%)	17 (60.7%)	33 (58.9%)	.786
BMI		26.52 (+/-4.41)	26.48 (+/-4.62)	26.50 (+/-4.47)	.970
Injured vertebra	Th	12 (42.9%)	9 (32.1%)	21 (37.5%)	
	L	16 (57.1%)	19 (67.9%)	35 (62.5%)	.408
AOSpine classification	Α	21 (75%)	20 (71.4%)	41 (73.2%)	
	В	7 (25.0%)	8 (28.6%)	15 (26.8%)	
	С	0 (.0%)	0 (.0%)	0 (.0%)	.763
No. of screws		4.71 (+/-1.46)	4.93 (+/-I.39)	4.82 (+/-1.42)	.228
Type of implant	Top load	8 (28.6%)	11 (39.3%)	19 (33.9%)	
	Side load	20 (71.4%)	17 (60.7%)	37 (66.1%)	.391
		20 (71.170)		07 (00.170)	

Table 2. Morphine consumption.

		Placebo Group	ESP Group	Total	P value
Morphine during PACU	Ν	28	28	56	
	Mean	8.607	5.357	6.982	
	Std. Deviation	6.500	5.794	6.317	
	95% CI	2.520	2.247		
	Median	10.0	3.0	8.0	.040
	Minimum	0.0	0.0	0.0	
	Maximum	20.0	20.0	20.0	
Morphine in 48 hours	Ν	28	28	56	
	Mean	10.154	8.571	9.363	
	Std. Deviation	8.508	10.005	9.237	
	95% CI	2.520	2.247		
	Median	10.0	8.0	10.0	.253
	Minimum	0.0	0.0	0.0	
	Maximum	34.0	47.0	47.0	



Graph I. Visual Analogue scale.



Graph 2. Patient reported outcome for spinal trauma.

group (P = .550). At 4^{th} week was 55.2 in ESP group and 49.9 in placebo group (P = .036) (Graph 2).

The ODI score at 2^{nd} day after surgery was 39.1 in ESP group and 48.6 in placebo group (P = .071). At 2^{nd} week was 27.0 in ESP group and 34.3 in placebo group (P = .212). At 4^{th} week was 18.9 in ESP group and 27.9 in placebo group (P = .122) (Graph 3).

We had one deep surgical site infection which required surgical revision and negative pressure wound healing therapy in placebo group (1.79% of all patients) and we had 2 local haematomas with spontaneous resorption, one in each group (3.58% of all patients).

Discussion

The goal of this prospective, randomized, single-centre study was to examine the effect of ESP block after minimally invasive posterior stabilization for vertebral fractures on opioid consumption, blood loss during surgery, disability level, and wound healing complications. Sixty patients were included and the short-term follow-up rate after 4 weeks was 93%.

ESP block reduced the opioid consumption in first hours after surgery by 37.7%. This was similar to findings of systematic review and meta-analysis of analgesic efficacy of erector spinae plane block in lumbar spine surgery.²² However, after 24 and 48 hours there was no statistically significant opioid consumption difference.

In the literature minimal invasive spinal surgery reduce the pain after surgery compared to the classical approach.^{1–3}

However, the authors evaluated the pain only first day after surgery. In our study, average opioid consumption in both groups after fist 24 hours was .39 and only 3 patients needed any morphine at all.

Patients in ESP group had significantly lower average pain scores in first 24 hours compared to placebo group, however individual measurements of VAS on predefined time according to study protocol were slightly better in ESP group but were statistically insignificant. It is unclear how these findings can be interpreted in clinical practice.

There were two patients with higher blood losses both in the placebo group. After analysing these cases we found technical error during the weight measurement in the OR. After excluding these values of blood loss per screw were 14.8 g in ESP group and 15.4 g in placebo group (P = .387). We had expected higher blood loss in ESP group due to the vasodilatation effect of levobupivacaine, but this was not confirmed in our study.

One deep infection in placebo group (1.79% of all patients) occurred and 2 patients, one in each group, developed haematomas with spontaneous resorption (3.58% of all patients). This is comparable to wound healing complications reported in the literature.^{23,24}

To evaluate short term outcome we used two tools: ODI in all measurement showed no significant difference; PROST on 2nd day and 4th week after surgery showed significantly better results in ESP group. We can not compare our results with literature since PROST is a new tool and has not been widely used yet. However, PROST was designed to evaluate results after trauma to the spine

Mean ODI with 95 % CI 60.0 50.0 40.0 0.0 20.0 10.0 2nd day 2nd week 4th week

Graph 3. Oswestry disability index.

and therefore compares actual status to the status before trauma.

The limitations of our study are the relatively small sample size and the short-term follow-up regarding the opioid consumption. However, the results clearly point out that ESP block could be an important technique for postoperative pain management protocols. Similar studies with larger sample size are necessary to confirm this hypothesis.

Conclusion

The ESP block in minimal invasive spinal surgery after trauma leads to the reduction of opioid consumption in first hours after surgery by 37.7%., but not in 24 and 48 hours after surgery. This reduction of opioid consumption was accompanied with lower value of VAS. ESP block improves short term outcome but has no effect on perioperative blood loss and wound healing.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical Approval

This study was approved by the institutional ethics committee F. D. Roosevelt University General Hospital, Banska Bystrica, Slovakia (No. 5/2019; from 19. March 2019). The study was performed in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. All enrolled patients provided written and signed informed consent.

Data Availability

All data generated and analysed during this study are included in this published article (and its supplementary information files).

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