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# Analgesic efficacy of erector spinae plane blocks for lumbar spine surgery: a randomized double-blind controlled clinical trial

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# **ABSTRACT**

**Introduction** Erector spinae plane block has been proposed to reduce opioid use and improve pain relief with controversial results. This randomized clinical study aimed to assess the efficacy of erector spinae plane block in major spine surgery including multimodal and 'Enhance Recovery After Surgery' programs.

**Method** After institutional review board approval, adult patients undergoing elective lumbar spine surgery with standardized general anesthesia, rehabilitation and multimodal analgesia protocols were randomly allocated to receive bilateral ultrasound-guided block with saline versus ropivacaine (3.75 mg/mL). Before surgery, a bilateral erector spinae plane block was performed at lumbar level (third vertebrae) with 20 mL of solution for each side. The primary outcome was morphine consumption after 24 hours. Secondary outcomes included pain scores and side effects, from postanesthesia care unit to discharge, and questionnaires at 3 months on pain and quality of life (EQ-5D).

**Results** From November 2019 to July 2021, 50 patients were enrolled with similar characteristics and surgery for each group. After the first 24 hours, there was no statistical difference regarding cumulative intravenous morphine consumption between ropivacaine and saline groups: 7.3 mg (3.7–19) vs 12.5 mg (3.5–26) (p=0.51). Over the five postoperative days, opioid sparing, pain scores and side effects were similar between groups. At 3 months, pain relief, incidence of chronic pain and EQ-5D were similar between groups.

**Discussion** Erector spinae plane block used in conjunction with 'Enhance Recovery After Surgery' and multimodal analgesia protocols provides limited reduction in opioid consumption and no long-term benefits.

**Trial registration number** EudraCT 2019-001678-26.

# Check for updates

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# INTRODUCTION

The number of annual spine surgery procedures worldwide has increased dramatically per year over the period 1999–2017, making spine surgery one of the fastest-growing categories of surgical procedure. Most of these procedures involve patients with intermediate to severe mechanical and neuropathic pain and psychological frailty. Moreover, in a large, observational, multicenter study, spine surgery induced severe postoperative pain and was ranked the second (spinal fusion one to two

# WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Erector spinae plane block for lumbar spine surgery remains debated regarding pain relief and opioid sparing when combined with 'Enhance Recovery After Surgery (ERAS)' programs and multiple drug therapies during the first two to three postoperative days.

# WHAT THIS STUDY ADDS

⇒ This randomized trial demonstrated that, in conjunction with the ERAS programs, erector spinae plane block (ESPB) provides limited reduction in intravenous opioid consumption (<5 mg vs placebo) and no long-term benefits (chronic pain, quality of life).

# HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Systematically performing an ESPB is unjustified and should be analyzed on a case-to-case basis according to the perioperative protocol.

segments) and third (dorsal spinal fusion, three or more segments) most painful surgical act among 179 procedures.<sup>5</sup> In this context, a multimodal analgesic approach has recently been recommended to enhance postoperative rehabilitation and pain relief after spine surgery.<sup>6–8</sup>

For lumbar spine surgery, various perioperative pharmacological and non-pharmacological interventions have been introduced to improve pain relief and outcomes and reduce the length of hospital stays. To enhance the multimodal approach and opioid sparing, several local anesthesia (LA) administration routes have been evaluated: intravenous, infiltration (wound), regional (paravertebral, **9** epidural and spinal).<sup>6-9</sup> Recently, lumbar erector spinae plane blocks (ESPB) have been proposed as an alternative to other regional techniques. 9-14 Previous cadaveric, CT scan imaging and randomized studies have inconsistently reported clinical efficacy (Numerical Rating Scale (NRS) pain score, opioid sparing) or effective dye diffusion due to the unpredictable injectate spread. 10-14 Furthermore, most studies published include various types of spinal surgery (laminectomy, decompression, fusion, discectomy), different levels of injection (thoracic, lumbar), absence of multimodal analgesia

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and 'Enhance Recovery After Surgey' (ERAS) protocols or short-term evaluation without any analysis of chronic pain. <sup>10–19</sup> Moreover, there are no randomized trials on the same levels of surgery. <sup>10–19</sup>

To assess the benefits of a single ESPB injection, we hypothesized that this technique would provide early opioid sparing, thus improving pain relief and quality of life at 3 months. We performed a prospective randomized study using LA (ropivacaine) versus saline on patients scheduled for major lumbar spinal surgery (>2 segments) as part of the ERAS program (multimodal analgesia protocol). The primary end point was opioid consumption at 24 hours. Secondary end points were pain levels, morphine consumption in the early postoperative days, quality of life and the occurrence of neuropathic and chronic pain at 3 months.

# **METHODS**

This was a prospective, single-center, randomized controlled, 1:1 allocation, parallel-armed, double-blinded, intention-to-treat superiority trial. The study was conducted at a single French tertiary hospital (Nîmes University Hospital, Carémeau, France). The Consolidated Standards of Reporting Trials recommendations were followed to report the trial. The analysis was made once patient enrollment had been completed.

# Study design and patients

Eligible patients were adults >18 years scheduled for major lumbar spinal surgery (posterior surgical approach, >2 segments) under standard general anesthesia combined with multimodal analgesia and an ERAS protocol as described by the Enhanced Recovery Spine Surgery committee (ERSS protocol that has been applied and implemented at our institution since its publication). For non-oncological surgery, the ERSS protocol was adapted as described in the 'General anesthesia, multimodal analgesia and ERAS protocol' section. 19 Exclusion criteria were: refusal to participate, age >80 years, weight <50 or >120 kg, emergency including fracture, any regional anesthesia or analgesia (including wound infiltration, epidural or spinal injection), cognitive disorders (delirium, dementia), pregnancy (betahuman chorionic gonadotropin test performed systematically for women <45 years), patients with alcohol or drug abuse (questionnaire), uncontrolled epilepsy, patients unlikely to be fully cooperative during the study and those who had participated in another study within the previous 30 days. Patients reporting any allergy or contraindication for the drug under study (ropivacaine, non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, nefopam, morphine), renal failure (creatinine clearance <50 mL/min, Cockroft formula), liver failure (transaminases and/or alkaline phosphatases > 3 times the normal upper value and/or prothrombin time <70% of control) and acute or chronic respiratory insufficiency (SpO2 <94% in ambient air) were not included.

# Drug under study, randomization and blinding

Patients were randomly assigned either to the saline group or the ropivacaine group using computer-generated random numbers created by the study statistician on a randomization ratio of 1:1. Group allocations were concealed in sequentially numbered opaque envelopes. Patients were randomized into blocks of six patients per block. The solution (saline, ropivacaine) vials were similar. Drug solutions (40 mL) were prepared using 40 mL of saline solution for the saline group and 150 mg of ropivacaine (3.75 mg/mL) for the ropivacaine group. Patients, surgeons,

anesthesia staff, surgical ward staff and investigators were blinded to group assignment until data analysis.

# Erector spinae plane block and treatment administration

Bilateral ESPB was performed at L3 level before surgery under general anesthesia in a ventral prone position by experienced practitioners (authors). For each procedure, an ultrasound examination of the lumbar area was performed using a low-frequency linear ultrasound probe (5 MHz, Vivid Q, GE Healthcare, USA) covered with a sterile sheath. Briefly, for all blocks, prescanning in both transverse and longitudinal views was performed to identify bone structures, including spinous processes, laminae, transverse processes and the fascial plane of the lumbar erector spinae muscle. This preview was performed from T8 to L5 spine level. Injection was performed through a 22-gage 80 mm needle (Pajunk Sonoplex, PAJUNK Medizintechnologie, Geisingen, Germany) using an in-plane ultrasound technique with the structures visualized in the sagittal plane. The needle was inserted at level L2 and translated in a cephalad-to-caudal direction to reach the transverse process of L3. The needle tip was translated to be placed with the bevel facing upward to reach the tip of the transverse process. Next, 2 mL of saline solution was injected under ultrasound vision to ensure the diffusion in the fascial plane without intramuscular injection. On each side, 20 mL of blinded solution was injected for a total of 40 mL per patient.

# General anesthesia, multimodal analgesia and ERAS protocol

The standardized intraoperative protocol was performed in both groups, including intubation and mechanical ventilation. Induction was performed with intravenous propofol (2–3 mg/kg), cisatracurium (0.6–1 mg/kg), sufentanil (0.25  $\mu$ g/kg) and maintained with sevoflurane 1%–2% and additional intravenous sufentanil (5  $\mu$ g) every hour or when variations in mean arterial pressure or heart rate >20% from baseline).

For the postoperative nausea and vomiting (PONV) prevention and analgesia protocol, all patients received intravenously:

- ► After induction: dexamethasone (8 mg), ketamine (0.5 mg/kg).
- At the end of surgery: paracetamol (1 g), ketoprofene (100 mg), nefopam (20 mg).
- From postanesthesia care unit (PACU) to day 2: paracetamol (1 g, at 6-hour intervals), ketoprofene (100 mg at 12-hour intervals and, if necessary, in the event of PONV, ondansetron (8 mg) or droperidol (1.25 mg).
- ► Morphine rescue from PACU to day 2 was the same for all patients:
  - In the PACU, patients experiencing pain with an NRS >3 (NRS 0-10; from 0=no pain to 10=the worst pain imaginable) were given an intravenous titration of 3 mg of the drug under study (2 mg if body weight <60 kg) at 5 min intervals until an NRS ≤3 was obtained according to the protocol.<sup>20</sup>
  - After PACU, for the first 24 hours, intravenous patient-controlled analgesia was given to the patient with morphine (1 mg/mL): postanesthesia care unit (PCA (Gemstar, Abbott Laboratories, Abbott Park, Illinois, USA), boluses of 1 mg, lockout interval of 7 min.
  - After 24 hours, intravenous PCA was stopped and oral morphine was used as rescue (10 mg of actiskenan every 4 hours if the NRS pain score >3).

The 'ERAS' protocol was based on the ERSS protocol, except for oncology-specific preparations. <sup>19</sup> This was the same for all patients and ran from the day before surgery up to hospital

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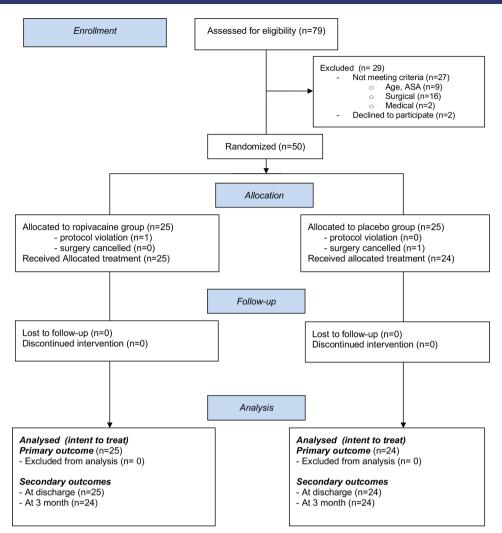


Figure 1 Study flow diagram. ASA, American Society of Anesthesiologists.

discharge: preoperative period (patient blood management program with oral iron or subcutaneous erythropoietin administration if hemoglobin (Hb) <13 g/L, no premedication, preoperative fasting: no food restrictions until H6 and no drinking restrictions until 2 hours prior to anesthesia, gabapentin or pregabalin were not introduced but continued if previously used), intraoperative period (intravenous fluid administration restriction <2 mL/kg/h, no intraoperative urinary catheter or gastric tube, central body temperature >36°C using hot air blankets, fluid warmers), postoperative period (early oral intake the day of surgery, no fluid administration, sitting up and walking on day 1). Transfusion was performed only if Hb level was <8 g/dL.

# Clinical evaluation

Patients were evaluated by the nurses and anesthesiology care team blinded to the allocated groups. Preoperative evaluations were performed 7 days before surgery including an NRS for pain at rest, a neuropathic pain diagnostic questionnaire (score 0-10) on medical diseases, physiological and biological parameters (Hb, creatinine). Pain intensity and adverse events were assessed at the PACU and every 6 hours throughout the study period on the ward until day 5 (or at home by phone when discharge before day 5). No attempt was made to waken sleeping patients. Total intravenous drug administration at the PACU and over the 48-hour period was recorded. Opioid-related adverse events arising from the analgesic protocol were systematically

assessed at the PACU and surgical ward by the nurses in charge of the patient (blinded to group assignment). Presence of nausea, vomiting, respiratory depression, pruritus, urinary retention requiring evacuation, allergy and hallucinations were recorded as binary (yes/no). Arterial oxygen saturation (pulse oximetry), heart and respiratory rates and blood pressure were also

recorded every 6 hours.

After 3 months, patients were contacted to record the NRS for pain, neuropathic pain using the DN4 score (0–10 points), satisfaction with postoperative analgesia (0–10), quality of life (EQ-5D health-related quality of life questionnaire) and adverse events (medical or surgical complications).

Objectives

The primary objective was to define morphine consumption at 24 hours (PACII+intravenous PCA period up to 24 hours).

24 hours (PACU+intravenous PCA period up to 24 hours).

Secondary objectives were to define pain scores, the total amount of morphine consumed during the study period, the number of patients requiring titration at the PACU, the duration of time spent at the PACU and in hospital and, at 3 months, pain relief and patient satisfaction regarding quality of life (EQ-5D).

# Sample size calculation

Previous studies had reported that mean morphine consumption was 30 mg (SD: 15 mg) and, using the ERAS program,

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	Saline	Ropivacaine	P value
Sample size, n	24	25	
Male, n (%)	18 (75)	19 (76)	0.99
Median age (IQR) in years	67 (59–70)	67 (60–72)	0.71
Median (IQR) body mass index (kg/m²)	26 (24–31)	28 (24–32)	0.66
ASA status (1/2/3), n	3/18/3	4/18/3	0.92
Median NRS pain score (IQR) at rest (0–10)	2 (0-6)	3 (2–6)	0.30
Median NRS pain score (IQR) on mobilization (0-10)	7 (4.8–8)	8 (6.3–9)	0.12
Personal treatment before surgery			
Paracetamol, n (%)	9 (38)	15 (60)	0.08
Tramadol, codeine n (%)	7 (28)	8 (32)	0.75
Opioids, n (%)	0	1 (4)	0.31
NSAIDs, n (%)	4 (17)	3 (12)	0.68
Gabapentinoids, n (%)	10 (40)	2 (8)	< 0.01
Median (IQR) pre-operative hemoglobin (g/dL)	14.4 (13.7–14.7)	14.2 (13.5–15)	0.58
Median (IQR) pre-operative hemoglobin (g/dL)	79 (60–90)	85 (62–95)	0.42
Surgery			
Type, n (%)			
Lumbar fusion without osteosynthesis	12 (50)	14 (56)	0.61
Lumbar recalibration without osteosynthesis	9 (37)	9 (36)	
Transforaminal circumferential arthrodesis	3 (13)	2 (8)	
Number of segments (=2, >2)	22 (90)/2 (10)	22 (88)/3 (12)	0.88
Median intraoperative drug and fluid (IQR) administration			
Ketamine (mg)	40 (30–49)	35 (30–50)	0.77
Sufentanil (µg)	27 (25–35)	25 (20–31)	0.12
NSAIDs, n (%)	22 (92)	22 (88)	0.55
Nefopam, n (%)	23 (96)	23 (92)	0.67
Dexamethasone, n (%)	23 (96)	25 (100)	0.14
Ondansetron, n (%)	23 (96)	24 (92)	0.24
Droperido, n (%)	6 (25)	16 (64)	<0.01
Intraoperative fluid (mL)	1100 (1000–2000)	1000 (625–1750)	0.56
Median time (IQR)			
Surgery (min)	124 (89–166)	112 (77–149)	0.37
Anesthesia (min)	178 (156–250)	161 (130–206)	0.19
Length of stay in PACU (min)	104 (72–154)	100 (89–120)	0.96
Length of stay in hospital (days)	3 (2–4.5)	4 (2-4.5)	0.60

\*P values compares saline versus ropivacaine procedure.

†Non-parametric test (Wilcoxon-Mann-Whitney test) to compare median (IQR) and  $\chi^2$  used to compare proportions.

ASA, American Society of Anesthesiologists; NRS, Numeric Rating Scale; NSAIDs, non-steroidal anti-inflammatory drugs; PACU, postanesthesia care unit.

ranged from 10 to 20 mg on postoperative day 1 including the PACU period: 50% opioid sparing. <sup>7 8 19</sup> The power calculation for an expected absolute difference of 50% morphine reduction between the two groups, with a two-tailed  $\alpha$  probability level of 0.05 and a power of 0.90 (1– $\beta$ ) yielded a sample size of 23 patients per group. This number was increased to 50 patients (25 per group) to account for 10% of patients lost to follow-up.

# Statistical analysis

Statistical analysis was performed using Prism V.9.1.0 software and SAS V.9.4 (SAS, Cary, North Carolina, USA). The analysis was made with no interim analysis and carried out with intention to treat. The Shapiro-Wilk test was used to test for a normal distribution of continuous variables. Statistical results were expressed with means, SD or medians (25–75 IQR) according to distribution. Numbers and associated percentages were given for categorical variables. Quantitative variables were compared between the two study groups using an independent sample t-test or the Wilcoxon-Mann-Whitney test according to variable distribution.

Categorical variables were compared using the  $\chi^2$  test or Fisher's exact test, as appropriate. The primary outcome (morphine consumption) was evaluated using the t-test due to the normal distribution of the variable. Secondary outcomes were evaluated using the Wilcoxon-Mann-Whitney test for quantitative variables with a non-normal distribution, by the  $\chi^2$  test or Fisher's exact test for qualitative variables when applicable. The numerical rating scale for pain was evaluated by a linear mixed model to take repeated measurements in the same patient into account. The NRS was the dependent variable. The randomization group and different measurement times were analyzed as fixed effects, and the patient was the random intercept. The slope, group and time interaction were tested. All statistical tests were conducted as 0.05 two-sided tests.

# RESULTS

# Study population

From November 2019 to July 2021, 79 patients were screened and 50 patients were randomized (figure 1). One operation was canceled after randomization (the surgical indication was

similar technologies

# Original research

				Saline	Ropivacaine	P value		
Sample size, n				24	25			
Median morphine titration at the	PACU (mg)			0 (0-8.5)	3 (0–6)	0.98		
Median PCA during the first 24 h	ours			12 (3–20)	6 (3–20)	0.08		
Patients requiring morphine at PA	ACU, n (%)			11 (46)	14 (58)	0.39		
Median total morphine (IQR) dur	ing the first 72 hou	ırs (mg)		15 (4–27)	10.5 (4.5–25)	0.65		
Median NRS pain score (IQR) at I	mobilization (0-10	)						
Baseline				7 (4.8–8)	8 (6.3–9)	0.15		
Day 0				3 (0-3)	3 (0–4)	0.34		
Day 1				3.5 (2-5)	3 (2–5)	0.42		
Day 2				3 (2-4)	4 (2–5)	0.08		
Day 3				3 (2-4)	3 (1–3)	0.35		
Day 4				3 (2–6)	3 (2–6)	0.35		
Day 5				3 (2-3)	4 (3–6)	0.07		
3 months				2 (0-6)	3.5 (0–7)	0.42		
Nausea, n (%)						0.51		
PACU				0	0			
Day 1				1 (2)	0			
Day 2				1 (2)	0			
Vomiting, n (%)						1		
PACU				0	0			
Day 1				0	0			
Day 2				0	0			
Urinary retention, n (%)						0.90		
PACU				0	0			
Day 1				1 (2)	0			
Day 2				0	0			
Confusion, n (%)				0	0	1		
Constipation after 3 days, n (%)				2 (4)	0	0.50		
*P values compares saline versus thon-parametric test (Wilcoxon-NRS, Numerical Rating Scale; PAGE evised to an anterior at 19 patients in the intended point and 49 for the figure 1).  Baseline characteristics the shown in the saline shown in the	Mann-Whitney tes CU, postanesthesia pproach). Th tion-to-treat ne secondary , preoperative	et) to compare media care unit; PCA, patie e final analysis analysis for th end points at	s included e primary discharge	Primary outo Total morph operatively the ropivaca 19) vs 12.5 s The numb PACU and m	come  ine consumption during the consumption during the consumption during the consumption of the consumption over	significantly lower in the group: 7.3 mg (3.7- p=0.51 (table 2). orphine titration in the r the first 72 postoper		
Table 3 Quality of life at	ative hours are given in table 2 with no difference groups. Morphine-related side effects are also given in with no difference between groups.							
	Saline	Ropivacaine	P value	with no diff	cremee between groups.			
Sample size, n	24	24						
Median NRS pain score (IQR) at mobilization (0–10)	2 (0–6)	3.5 (0–7)	0.42	Secondary outcomes  At baseline, pain scores at rest and during mobilization were				
Median DN4 (IQR) score	1 (0-3)	1 (0-3)	0.12	similar. No difference was observed between either group				
		/		similar. No difference was observed between either group over time in the PACU, from days 1 to 5, and at 3 months (table 2). Multiple comparison analysis by group and time				
	80 (52–90)	70 (50–80)	0.26	over time in	the PACU, from days 1	to 5, and at 3 month		
Median VAS (IQR) "Your health today on 100?" Median (IQR) EQ-5D	80 (52–90) 8.5 (5–10.5)	70 (50–80) 10 (5–13.5)	0.26		the PACU, from days 1 if Interest and the PACU, from days 1 if Interest and Interes			

<sup>\*</sup>P values compares saline versus ropivacaine procedure.

Table 3 Quality of life at 3 months

	Saline	Ropivacaine	P value
Sample size, n	24	24	
Median NRS pain score (IQR) at mobilization (0–10)	2 (0–6)	3.5 (0–7)	0.42
Median DN4 (IQR) score	1 (0–3)	1 (0-3)	0.12
Median VAS (IQR) "Your health today on 100?"	80 (52–90)	70 (50–80)	0.26
Median (IQR) EQ-5D	8.5 (5–10.5)	10 (5–13.5)	0.24
Median NRS patients (IQR) satisfaction (0–10)	9 (8–10)	9 (8–9.8)	0.81

<sup>\*</sup>P values compares saline versus ropivacaine procedure.

(table 2). Multiple comparison analysis by group and time (fixed model) did not reveal any difference. There was no significant difference between the two groups regarding time spent in the PACU or length of hospital stay (table 1).

At 3 months, there were no serious adverse events apart from one re-intervention on day 7 for hematoma. No surgical site infection was recorded and there was no difference between the two groups in terms of pain, quality of life or satisfaction scores. Details of the scores are given in table 3.

<sup>†</sup>Non-parametric test (Wilcoxon-Mann-Whitney test) to compare median (IQR) and  $\chi^2$  used to compare proportions.

NRS, Numerical Rating Scale; PACU, postanesthesia care unit; PCA, patient controlled analgesia.

<sup>†</sup>Non-parametric test (Wilcoxon-Mann-Whitney test) to compare median (IQR) and  $\chi^2$  used to compare proportions.

DN4, evaluation of probability of neuropathic pain 0-10 (neuropathic > or =4); EQ-5D, standardized measure of health-related quality 5-25; NRS, Numeric Rate Scale; VAS, Visual Analog Scale.

At 3 months, the DN4 score was not different between groups. For all patients, the NRS scores for pain at rest or on mobilization were lower than preoperatively (tables 2 and 3).

# DISCUSSION

This prospective trial found that lumbar ESPB combined with the ERAS program (ERSS protocol) including multimodal analgesia did not lead to less opioid consumption than with saline within the first 24 hours after major spine surgery. Postoperative pain relief and patient quality of life at 3 months were similar for both groups, clearly demonstrating the limited benefits of this block in an ERAS program.

In this study, using an erector block brought few benefits, both on pain scores and additional morphine consumption. There may be several reasons for this lack of benefits. First, we performed very diversified multimodal analgesia which may have led to clear postoperative morphine sparing. 19 This way, several recent reports have highlighted the postive impact of the ERAS program on opioid sparing to significantly reduce intravenous morphine consumption on the first postoperative days. 6 19 In a recent network meta-analysis, the authors reported a mean reduction in morphine consumption and a 24-hour postoperative pain score of -26 (95% CI -39 to -12) mg and -2.3(95% CI - 3 to - 1) using triple drug therapy.<sup>6</sup> In our study, we used multiple drug therapy in the control group (see protocol). Thus, our control group was impacted by this program and consumed a median of only 12.5 mg, which is half the expected dose for calculating the initial sample size. Postoperatively, several patients in the control group did not use any opiates. The high dose of ketamine used (0.5 mg/kg) combined with dexamethasone, NSAIDs and nefopam, probably contributed to this effect. Moreover, this lack of benefit after spine surgery with ESPB was noted in two recently published studies. 12 21 22 In a first study, Zhang et al found no difference on morphine rescue consumption in multimodal analgesia without ketamine but had associated dexmedetomidine. 22 Later, in a single blind, randomized controlled study with NSAIDs without ketamine, Zhang et al, only found a decrease in morphine consumption and NRS scores at rest in the first 12 hours, with no difference at 24 hours (puncture in L3). 12 All in all, the data in the current literature are similar to our results and tend to demonstrate only slight benefits in terms of morphine sparing or pain scores in favor of ESPB at lumbar level. <sup>10–18</sup> In our study, we evaluated the long-term benefits in favor of ESPB (at 3 months), because no data were available for this major end point for patients (chronic pain, opioid abuse). Although the number of patients included was limited, we clearly demonstrated the absence of any benefits for these secondary end points. These data now need to be confirmed by a large cohort.

Regarding the efficacy of the erector block, the level of injection and volume injected have been debated. In our study, we performed the block opposite the surgical site (L2 or L3), whereas other authors injected local anesthetics into the low thoracic vertebrae (T10–T12) for lumbar surgery.<sup>22</sup> In this study, the advantage of this higher-level injection was not demonstrated. Regarding the volume administered, the anatomical studies seem to favor large volumes so in our study we administered a volume of 40 mL.

Several limitations and biases should be discussed. First, this was a single-center study with patients that received lower consumption of morphine in controls than expected (see above). This strategy (ERAS) leads to an underpowered study due to the drastic reduction of morphine in both groups. <sup>19</sup> Underestimated

in the recent spinal surgery literature, this rescue reduction will require future studies to include a larger number of patients (large SD). This opioid saving by ERAS should be taken into account in future studies to calculate a number of patients. It should also be noted that saline injection throughout muscle plays a role in the analgesic component. A control group without any injection could have been proposed but we wanted to carry out a study against a real placebo. Second, the heterogeneity of the lumbar surgeries performed should be noted. The number of segments operated on varied from 2 to 4 and the duration of operations ranged from 55 to 371 min, which probably resulted in different degrees of postoperative pain, limited by the randomization. Concerning the site and volume of injection, these are debatable as previously mentioned. Concerning the risk of infection at the surgical site, the administration of LA in contact with surgery deserves discussion between anesthesia and surgical teams to limit the risk of sepsis related to contamination by the block.

To conclude, this study highlighted the absence of any benefits with ESPB when ERAS and multimodal analgesia were used in

To conclude, this study highlighted the absence of any benefits with ESPB when ERAS and multimodal analgesia were used in major lumbar spine surgery. However, the morphine savings in the ropivacaine group may be of interest in situations with a higher risk of morphine consumption. This clinical impact should be evaluated on a large cohort.

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

Ethics approval In accordance with French legislation, this randomized study was approved by the institutional human investigation committee (Comité de Protection des Personnes, Kremlin Bicêtre, Paris, France, on September 11, 2019 with corresponding identification number: 19.051) and registered prior to enrollment on EudraCT (number: 2019-001678-26 on 2019-09-16, URL: https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-001678-26/FR). Before inclusion, the investigator had obtained written informed consent from each subject in accordance with the Declaration of Helsinki.

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# Original research

Data availability statement Data are available on reasonable request.

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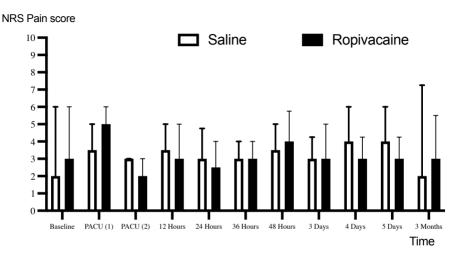
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Abbreviations: 1, first evaluation; 2, after morphine titration; NRS, Numerical Rating Scale
Bar represent median and Lines represent IQR
Comparisons by analysis of repeated measures revealed that pain scores during the first postoperative 5 days
were statistically similar between groups (*Saline vs Ropivacaine*, *comparisons by repeated measures: P* = 0.47).