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ORIGINAL ARTICLE

Evaluation of ultrasound-guided erector spinae plane block efficacy on post-operative pain in lumbar spine surgery: A randomized clinical trial

Lomber omurga cerrahisinde postoperatif ağrı üzerinde ultrason eşliğinde erektör spina plan bloğu etkinliğinin değerlendirilmesi: Bir randomize klinik çalışma

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Summary

Objectives: Patients suffer notable levels of pain after lumbar spine surgery. The primary objective of this randomized clinical trial is to investigate the efficacy of erector spinae plane block (ESPB) on 24-h post-operative pain score of patients undergoing lumbar spine surgery. Cumulative opioid consumption and intraoperative bleeding were assessed as well.

Methods: Adult patient candidates for elective lumbar spine surgery were randomly assigned to case (ESPB) and control (no ESPB) groups. The block was performed under ultrasound guidance in prone position after induction of general anesthesia. Both groups received the same anesthesia medication and technique. Post-operative pain score, number of patients requiring rescue analgesia (meperidine), total amount of post-operative rescue analgesic demand in the first 24 h, and intraoperative bleeding were recorded. To compare pain score variable in time span, the ANOVA repeated measure test was used. All the statistical tests were two tailed and $p<0.05$ considered as statistically significant.

Results: In all time intervals, pain score in case group was significantly lower than control group. In case group, eight patients demanded rescue analgesic (40%) which was significantly lower than that in control group (15 patients [75%]) (p=0.025). Total amount of meperidine consumption was 57.50±45.95 in control group and 22.50±32.34 in case group (p=0.01) which was higher in control group and statistically significant.

Conclusion: ESPB reduces post-operative pain score and opioid consumption, while it does not affect intraoperative bleeding in lumbar spine surgery.

Keywords: Erector spinae plane block; lumbar spine surgery; nerve block; post-operative analgesia.

Özet

Amaç: Hastalar lomber omurga cerrahisi sonrası kayda değer düzeyde ağrı çekerler. Bu randomize klinik araştırmanın primer amacı, lomber omurga cerrahisi geçiren hastaların postoperatif 24 saatlik ağrı skoru üzerinde erector spina plan bloğunun (ESPB) etkinliğini araştırmaktır. Kümülatif opioid tüketimi ve intraoperatif kanama da değerlendirilmiştir.

Gereç ve Yöntem: Elektif lomber omurga cerrahisi için yetişkin hasta adayları randomize olarak vaka (ESPB) ve kontrol (ESPB yok) gruplarına ayrıldı. Blok, genel anestezi indüksiyonu sonrası yüzüstü pozisyonda ultrason eşliğinde yapıldı. Her iki grup da aynı anestezi ilacını aldı ve aynı teknik uygulandı. Postoperatif ağrı skoru, kurtarıcı analjezi (meperidin) ihtiyacı olan hasta sayısı, postoperatif ilk 24 saatte toplam kurtarıcı analjezik ihtiyacı miktarı ve intraoperatif kanama kaydedildi. Ağrı skoru değişkenini zaman aralığında karşılaştırmak için tekrarlı ANOVA testi kullanıldı. Tüm istatistiksel testler çift kuyrukluydu ve 0.05'ten küçük P değeri istatistiksel olarak anlamlı kabul edildi.

Bulgular: Tüm zaman aralıklarında, vaka grubunun ağrı skoru kontrol grubuna göre anlamlı derecede düşüktü. Vaka grubunda 8 hastada kurtarma analjezik ihtiyacı oldu (%40), bu da kontrol grubuna göre anlamlı derecede düşüktü (15 hasta (%75)) (p=0.025). Toplam meperidin tüketim miktarı kontrol grubunda 57.50±45.95, vaka grubunda 22.50±32.34 (p=0.01) idi; kontrol grubunda daha yüksek ve istatistiksel olarak anlamlıydı.

Sonuç: Erektör spina plan bloğu lomber omurga cerrahisinde intraoperatif kanamayı etkilemezken, postoperatif ağrı skorunu ve opioid tüketimini azaltır.

Anahtar sözcükler: Erektör spina plan bloğu (ESPB); lomber omurga cerrahisi; postoperatif analjezi; sinir bloğu.

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Introduction

Spinal surgeries are among the most prevalent surgeries and may impose moderate-to-severe level of pain to patients. Various techniques and medications have been proposed for post-operative pain management among these patients, namely, epidural analgesia, opioids, and/or non-steroidal anti-inflammatory drugs (NSAIDs). Opioids could provide acceptable analgesia, but at the same time, it increases the risk of side effects such as respiratory depression, constipation, nausea and vomiting; moreover, they show a ceiling effect and have a limited efficacy.[1,2] Epidural catheter insertion before surgery limits surgical field in spine surgery; on the other hand, any probable dural damage during surgery could potentially lead to leak of anesthetics into subdural space, resulting in high spinal levels.[3] Erector spinae plane block (ESPB) first described by Forero in 2016.[4] Since then, this block has been reported by several anesthesiologists for post-operative pain management after different types of surgeries such as thoracic, breast and spine surgical procedures,[5–14] as well as for chronic pain management.[15,16]

Most of the literature concerning ESPB in spine surgery are case report,[10–15,17–20] and clinical trials are scars.[3,21] since case report and anecdotes are not strong documents, more clinical trials are needed to be able to judge the clinical efficacy of this block in different types of surgery.

Since our hospital is a referral center for spine surgeries, we are concerned about potential efficacy of different analgesic means, so we decided to study the effect of ESPB on post-operative pain after lumbar spine surgeries. The objectives of this study are to investigate the efficacy of ESPB on post-operative pain score and total opioid consumption in post-operative first 24 h.

Material and Methods

Ethical aspects

We conducted this single-centered and parallel randomized clinical trial study between October 2020 and December 2020. This study was performed in line with the principles of the Helsinki Declaration of 1975, as revised in 2000 and 2008. Approval was granted by the ethics committee (Institutional Review Board [ir.sbmu.retech.rec.1399.394] July 12, 2020) and received randomized clinical trial registration (IRCT20200628047936N1, registered at September 27, 2020, https://www.irct.ir/trial/49244). All patients (or their legal representatives) provided informed written consent before their recruitment into the study.

Sample size calculation

Based on the results of a pilot study on ten patients in each group, using pain score difference at 1st and 2nd post-operative h and using the formula mentioned below and considering alpha error of 0.05 with a statistical power of 80%, the minimum sample size was calculated to be 19 and 12 patients in each group for the 1st and 2nd post-operative h, respectively.

$$N \pm \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2}{\left(\mu_1 - \mu_2\right)^2}\left(\sigma_1^2 + \sigma_2^2\right)$$

α=Type 1 error (considered 0.05)
σ_1 and σ_2=Standard deviation (from the previous studies)
μ_1 and μ_2=Means (from the previous studies)
Z=Standard Normal Deviate, set at 1.96, which corresponds to 95% confidence level.

On the other hand, based on the results of a pilot study on ten patients in each group, analgesic requirement for control group and case group was 80% and 40%, respectively. Using the formula mentioned below and considering alpha error of 0.05 with a statistical power of 80%, the minimum sample size calculated as 20 patients for each group.

$$N \pm \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \left(P_1\left(1-P_1\right) + P_2\left(1-P_2\right)\right)}{\left(P_1 - P_2\right)^2}$$

α=Type 1 error (considered 0.05)
P_1 or P_2=Prevalence
Z (α)=Standard Normal Deviate, set at 1.96, which corresponds to 95% confidence level
1–β=Power of the study
Z (1–β)=is 0.84 for 80% power.

After sample size calculation, 20 patients were selected for each group of case and control. Randomization achieved using generated randomized numbers table using Microsoft Excel software 2013. Participants were randomly assigned to one of case (ESPB) or control (no ESPB) groups.

Participants

Inclusion criteria were American Society of Anesthesiologists (ASA) classification I and II, age between 18 and 75 years, candidates for one or two level lumbar laminectomy with body mass index (BMI) <35 kg/m^2, normal mental status, lack of allergy history to local anesthetics, no history of drug addiction, hematologic diseases, central or peripheral neurologic disorder, and no history of anticonvulsant medications. Exclusion criteria were surgery duration more than 4 h, blood loss more than 15% of patient's blood volume, and change of surgical approach to spine fusion. Written informed consent was obtained before surgery from every patient.

Anesthesia technique

Anesthesia technique was the same for both groups. All the patients received midazolam 0.03 mg.kg-1 and fentanyl 3 µg.kg-1 as premedication, followed by propofol 2.5 mg.kg-1, atracurium 0.5 mg.kg-1, and lidocaine 1 mg.kg-1 for induction; anesthesia maintained using propofol 100–300 µg.kg-1.min-1 to keep cerebral state index between 40 and 60 and atracurium repeated based on train of four. All the patients received intravenous morphine 0.1 mg.kg-1as the base analgesic at the beginning of surgery. Case group received bilateral single shot ESPB under ultrasound (US) guide after anesthesia induction in prone position, containing 20 ml of bupivacaine 0.25% on each side.

During surgery, blood loss was recorded by another anesthesiologist who was blinded to patient's group.

At the end of surgery, 1000 mg of paracetamol was infused intravenously before incision closure. Besides, the patients received intravenous ketorolac 30 mg every 8 h in the first 24 h after the surgery.

After the emergence and reversal of muscle relaxants (neostigmine 0.07 mg.kg-1, atropine 0.025 mg.kg-1), patients transferred to post anesthesia care unit (PACU) and pain score was recorded using numerical rating scale (NRS) (0=no pain, 10=the worst imaginable pain) by another anesthesiologist who was blinded to the study groups, NRS recorded in PACU and after discharge to ward in 1st, 2nd, 4th, 6th, 12th, and 24th h post-operative time.

In the PACU and next 24 h, if pain score was 4 or more, patients received 25 mg intravenous meperidine as rescue analgesic. The total amount of used meperidine in 24 h period was also recorded.

Blinding

Since ESPB was performed after induction of anesthesia, patients were blinded to the groups; on the other hand, the data-gathering anesthesiologist was different from the attending anesthesiologist who performed ESPB and maintained anesthesia.

Outcomes

The outcome of this study is post-operative pain score in predetermined time intervals as 1st, 2nd, 4th, 6th, 12th, and 24th h. The other outcomes are the number of patients requiring meperidine as rescue analgesic in mentioned time intervals and the total amount of injected meperidine in 24 h.

Distribution of variables was evaluated for normality using the Shapiro-Wilk test. The descriptive statistics are fully reported including frequencies, means, and standard deviation in percent. For comparison of quantitative variables, Student's t-test was used for normally distributed variables. Otherwise, non-parametric Mann-Whitney U-test was applied. We used Pearson Chi-square test for the analysis of qualitative variables and exact fisher test was used if necessary. To compare pain score variable in time span, the ANOVA repeated measure test was used. All the statistical tests were two-tailed and $p \leq 0.05$ considered as statistically significant.

Results

Forty-one patients were recruited in the study, one patient was excluded due to change of surgical plan, and 40 patients enrolled in the study: 20 patients randomly assigned to either control group or case (ESP) group (Fig. 1). Demographic data comprising age, sex, BMI, ASA classification, and laminectomy levels were not statistically different between the two groups (Table 1).

Pain scores in all time intervals were statistically lower in case group comparing with those in control group (Table 2). Intraoperative bleeding (p=0.550) and PONV incidence (p=0.451) were not statistically different between the groups (Table 3).

Number of patients who needed rescue analgesics was significantly higher in control group compar-

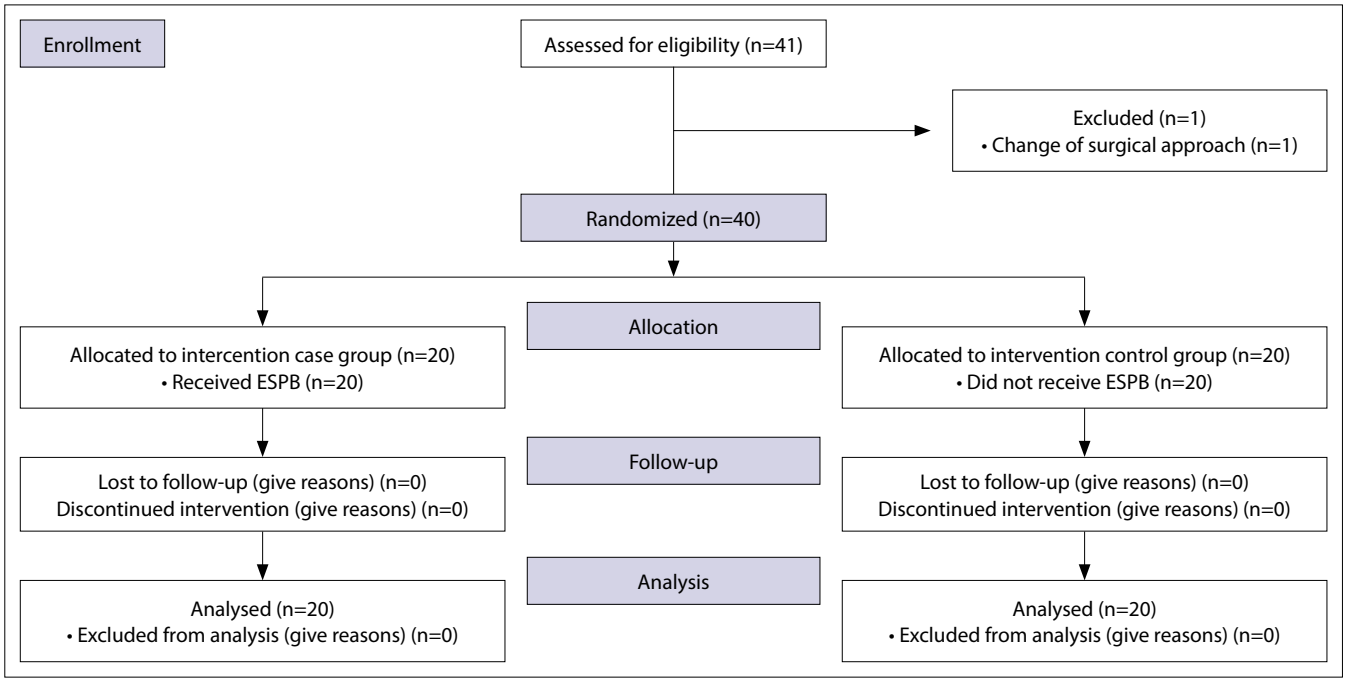

Figure 1. Study flow diagram, ESPB is acronym of erector spinae plane block.

ESPB: Erector spinae plane block.

ing with those in case group (15 [75%] vs. 8 [40%], p=0.025). Meperidine consumption was 57.50±45.95 in control group and 22.50±32.34 in case group which was statistically higher in control group (Table 4).

Discussion

In this study, ESPB resulted in less pain in first postoperative day among patients undergoing lumbar spine laminectomy; moreover, it reduced opioid demand as well.

Spine surgeries are among the most prevalent surgeries and impose high levels of pain inception on patients undergoing spine surgery. Therefore, pain management is an essential burden to ASA involved in these procedures. Optimal pain management could shorten hospital stay by the early mobilization and decrease morbidity and even mortality in vulnerable individuals.[22] To achieve these goals, opioids, NSAIDs and regional analgesia techniques have been widely applied. Although opioids are effective in pain reduction, they exert well-known side effects such as nausea, vomiting, constipation, and respiratory depression.[2] Concerning these side effects, any safe alternative technique which could provide efficient analgesia in parallel with less side effects and could help to use minimum dose of opioids, would be well accepted.

Table 1. Demographic data and clinical characteristics of the study groups

	Control n=20	Case n=20	p
Gender (M/F)	11/9	12/8	0.749
Age (year)	52.35±12.39	49.15±14.46	0.457
BMI (kg.m^{-2})	26.81±3.02	26.14±0.91	0.476
Surgery level (s) (one/two)	11/9	12/8	0.749
ASA classification (I/II)	10/10	11/9	0.752

Data are expressed as mean±SD or ratio. P<0.05 is considered as a statistically significant difference. M: Male; F: Female; BMI: Body mass index; ASA: American society of anesthesiologists.

In 2016, Forero first described and introduced ESPB to anesthesia practice.[4] This simple and easy-to-perform block consists of US-guided findings of transverse process of vertebrae about 3 cm lateral to spinous process, needle insertion too touch the transverse process with needle, and local anesthetic (LA) injection beneath erector spinae muscle which spreads cephalocaudally.[23] Although first suggestion was to perform in sitting position, it is now applied in all positions.[24] The simplicity and safety of this technique in addition to acceptable analgesia, has made it a desirable choice for pain management after various kinds of surgery as breast surgery,[8,25] thoracic surgery,[4,24] and shoulder pain, bariatric sur-

Table 2. Pain score assessed by numerical rating scale in first 24 h

Post-operative time (h)	Control n=20	Case n=20	p
1	3.65±1.63	1.65±1.14	<0.001
2	3.85±1.69	1.85±1.09	<0.001
4	3.65±1.27	2.20±1.15	0.001
6	3.55±1.64	2.20±1.00	0.004
12	2.75±0.97	1.75±0.79	0.002
24	2.60±1.05	1.50±0.76	0.001

Data are expressed as mean±SD.

Table 3. Intraoperative bleeding and PONV

	Control n=20	Case n=20	p
Intraoperative BLEEDIng (mL)	252.50±100.62	267.50±90.72	0.550
PONV, n (%)	6 (30.0)	3 (15.0)	0.451

Data are expressed as mean±SD or ratio. PONV: Post-operative nausea and vomiting.

Table 4. Patients who required rescue analgesic and opioid consumption

	Control n=20	Case n=20	p
Rescue analgesic, n (%)	15 (75.0)	8 (40.0)	0.025
Opioid consumption (mg of meperidine)	57.50±45.95	22.50±32.34	0.010

Data are expressed as mean±SD or ratio.

gery, abdominoplasty, nephrectomy, hip surgery, and lumbar spine surgery.[26–28]

Since it is a relatively novel technique, clinical trials dealing with its application and evaluating its effects in comparison with other techniques are scars.

Some of authorities perform ESPB before induction of anesthesia, while the patient is awake and cooperative,[3,21] but this imposes the discomfort of needle insertion and may require additional sedation. We performed ESPB after induction, while patient's position had been changed to prone and landmarks could be easily found. Applying the ESPB to anesthetized patient helps us to lower the bias by keeping the patients blind to the groups which is a valuable adding to the study.

Theoretically, LAs may cause local vasodilation and aggravate bleeding.[29] We had the same concerns but could not find any clue about the role of ESPB on potential intraoperative bleeding, so we decided to record the bleeding in both groups. Although it was higher in case group, the difference was not statistically significant. The incidence of post-operative nausea or vomiting was less among case group comparing to control group, although not statistically significant (3 [15%] and 6 [30%], p=0.451).

Limitations

Since ESPB is a relatively new technique, the optimal dose of LA and optimal level of injection are not well defined yet. Furthermore, the duration of analgesia is not well-known and further studies may be needed to answer these questions. In addition, limited laminectomy rarely is a cause of surgical significant bleeding and the perioperative bleeding may be more pronounced in other advanced spine surgeries. Therefore, to assess this item, we recommend further studies in complex and multilevel spinal surgeries, designed to measure bleeding as the primary outcome.

Conclusion

ESPB is a safe means of pain reduction for lumbar spine surgery that decreases both pain scores and opioid-demand among patients.

The datasets generated and/or analyzed during the present study are available from the corresponding author on reasonable request.

Ethical Approval: The study was approved by Shahid Beheshti University of Medical Sciences Institutional Review Board Ethics Committee (Date: 12/07/2020, No: IR.SBMU.RETECH.REC.1399.394).

Conflict-of-interest issues regarding the authorship or article: None declared.

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