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ORIGINAL RESEARCH

REGIONAL ANESTHESIA

Analgesic efficacy of the erector spinae plane block using bupivacaine vs. bupivacaine/magnesium sulphate in patients undergoing lumbar spine surgery: a randomized, double-blinded comparative study

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Abstract

Background & Objectives: Postoperative pain is one of the most troublesome pains for the surgical patient, and is one of the causes of morbidity and prolonged hospital stay. Opiates and non-steroidal anti-inflammatory drugs have been routinely used across the world. Recent resurge of regional anesthetic techniques offer some advantages, especially reduced post-operative nausea and vomiting and less sedation.

We compared the efficacy of bupivacaine with a combination of bupivacaine/magnesium sulphate for the Erector Spinae Plane (ESP) block in patients for postoperative pain undergoing lumbar spinal fusion under general anesthesia.

Methodology: A total of 30 ASA-I and II patients, 20-60 y old, who undergoing lumbar spinal fusion were enrolled. They were randomly divided into two groups; Group B (n = 15) to receive bupivacaine 0.25 percent, 20 mL injected on each side to provide ESP block; and Group BMG (n = 15): to receive 20 mL of 0.25 percent bupivacaine plus 500 mg magnesium sulphate, injected on each side for ESP block.

The parameters measured included; the surgery time, non-invasive mean blood pressure during surgery, postoperative heart rate at 1, 6, 12, and 24 h, The time to first request for analgesics time after surgery referred to as the postoperative period (h). Postoperative total analgesic (pethidine needed per 24h) required and postoperative pain at rest and on moving, measured with VAS (Visual Analogue Scale) at the 1st, 6th, 12th, and 24th h.

Results: Both at rest and through moving the VAS (Visual Analogue Scale) among both groups. No significant difference could be seen at the first, sixth, twelfth, and twenty-fourth hours. The time to the first request for analgesics was significantly prolonged in the Group BMG than the Group B. The total analgesic need after surgery was significantly lower in Group BMG than the Group B.

Conclusion: The use of a combination of bupivacaine plus magnesium for bilateral erector spinae plane block after lumbar spinal fusion surgery is better in terms of prolonged postoperative analgesia and reducing the opioid use as compared to bupivacaine alone in patients undergoing lumbar spinal fusion under general anesthesia.

Abbreviations: ESP - Erector spinae plane; VAS - Visual Analogue Scale; NSAIDs - Non-steroidal antiinflammatory drugs;

Key words: Adult; Analgesia; Analgesics, Opioid / therapeutic use; Bupivacaine; Humans; Lumbar spine; Magnesium sulfate; Nerve Block; Pain, Postoperative / drug therapy; Pain, Postoperative / prevention & control; Paraspinal Muscles

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1. Introduction

Postoperative pain after spinal fusion surgery is one of the leading causes of high morbidity and prolonged hospital stay. The opioids have been the mainstay of management in this type of pain,¹ although nonsteroidal anti-inflammatory drugs (NSAIDs), either alone or in combination with opioids are also commonly used to treat postoperative pain. However, the adverse effects associated with opioids, including respiratory depression, constipation, and excessive sedation might be troublesome for the patients. To reduce the opioid use, regional anesthetic techniques offer a useful alternative.² The interfacial regional approach of erector spinae plane (ESP) block with ultrasound guidance was started to treat the neuropathic thoracic pain.³ As erector spinae fascia stretches from the nuchal fascia and ends at the sacrum, local anesthetic drugs can reach up to multiple levels and provide a broad block according to the volume of the drug.⁴ In the lumbar spinal fusion, the most effective analgesia (for the first 24 h postoperatively) can be obtained with the ESP block.⁵

Magnesium sulphate is an analgesic and exerts its effect by acting at the N-methyl, D-aspartate (NMDA) receptors antagonist. It's necessary for acetylcholine release from pre-synaptic terminals, and as a calcium channel blocker it could stop calcium from entering the cells.^{6,7} It is considered that magnesium serves multiple roles in nociception.⁸

We assessed the efficacy of bupivacaine compared to a combination of bupivacaine and magnesium sulphate in the bilateral ESP block for postoperative pain in patients undergoing lumbar spinal fusion under general anesthesia (GA).

2. Methodology

This randomized, double-blinded comparative study was carried out at the University Hospital of Beni-Suef between May and December 2020. Thirty patients, ASA-I and II, 20-60 y old, undergoing posterior lumbar spinal fusion under GA were enrolled in the study.

Exclusion criteria included, patient refusal, any contraindications to regional block, allergy to the study drugs, coagulopathy, chronic pain management, and BMI higher than 30 kg/m². Standard monitoring consisted of non-invasive arterial blood pressure,

pulse oxygen saturation, and electrocardiography in the preoperative room, and oxygen was supplied via a facemask. Two 22G intravenous cannulas were inserted. Preoperatively, all patients were infused lactated Ringer's solution at 3–5 ml/kg/h. Inj. midazolam 0.05 mg/kg IV was given to patients 3 min before induction.

The drugs were prepared in labeled syringes by the anesthetists, who were unaware of the work and did not participate in the study. Patients were divided into 2 groups via sealed opaque envelopes. They were given the study drug as follows: Group B (n = 15): received 20 ml of bupivacaine 0.25% on each side to provide ESP block; Group BMG (n = 15): received 20 ml of bupivacaine 0.25% plus magnesium sulphate 250 mg on each side.

While patients were in prone position, a highfrequency linear ultrasound transducer (6 -13 MHz) was positioned in the sagittal plane against the targeted vertebral level and moved about 3 cm on the spinous process's laterally.^{3,9} The transverse process and the erector spinae muscles were then recognized. The skin was infiltrated with 1 mL of lidocaine 2%. A needle was placed between the transverse process and erector spinae muscle through the interfacial plane between the two, and the drugs were administered slowly in divided doses into the space after negative aspiration. To avoid unintentional intravascular entry of the needle, the injectates in this research were given in increments following repeated aspiration. For induction of GA, fentanyl 2 µg/kg, propofol 2.5 mg/kg, and atracurium 0.5 mg/kg were injected intravenously. Patients were gently ventilated with isoflurane in 100% oxygen through a face mask, and intubation was performed. The anesthesia was maintained with isoflurane 1-2%. Inj. atracurium 0.1 mg/kg was given every 20 min. At the end of the surgery inhaled anesthetics were switched off. The usual reversants were given and extubation was performed.

The following parameters were noted: demographic data (age, sex, BMI); the duration of the surgery and anesthesia; non-invasive mean blood pressure in addition to postoperative heart rate at 1, 6, 12, and 24 h. Time to the first request for analgesics (TFA) *-the primary outcome*. The pain and discomfort at rest and during movement, was evaluated at 1, 6, 12, and 24 h using VAS, with 0 indicating no pain and 10 the most severe pain. Rescue analgesic (pethidine) needed



during 24 h postoperatively was compared - *the* secondary outcome.

Statistical analysis

Sample size was calculated by comparing TFA between Group B and Group BMG. In our pilot study, the results showed that the mean TFA was 7.6 ± 0.5 h and 9.5 ± 0.5 h, respectively. Student's t-test for independent variables, required about 15 individuals for 80% power in each group to reject the null hypothesis with a 0.05 significance level. The sample size was calculated by PS: Power and Sample Size Calculation (version 3.0.11) for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA). Data were presented by mean \pm standard deviation, median, range, as well as frequencies (the cases number) and percentages. To verify the data's normality, Shapiro Wilk test was conducted. Mann-Whitney U test for

independent samples was utilized to assess numerical variables among groups of the study. To compare categorical data, the chi-square (χ 2) test was employed. When the expected frequency was less than 5, the Fisher's exact test was utilized. The two-sided P-value of less than 0.05 was judged to be statistically significant. We utilized IBM SPSS (Statistical Package for the Social Sciences; NY, USA, IBM Corp, Armonk) for all statistical calculations.

3. Results

All individuals completed our study (Figure 1). According to demographic statistics, the two groups had no statistically significant differences. (Table 1). The Group BMG had a significantly longer TFA than the Group B (Table 2). Regarding VAS at rest and on movement, the two groups had no significant differences at the 1st, 6th, 12th, and 24th hours (Table 2). The requirements of postoperative rescue analgesic were significantly lower in the Group BMG than the Group B (Table 2). According to postoperative heart rate and mean blood pressure, the two groups had statistically no significant differences (Table 3).

4. Discussion

A large number of lumbar disorder patients need lumbar spinal surgery.¹⁰ This surgery causes severe postoperative pain, so multiple medications might be required. Epidural analgesia and intravenous drugs are routinely used for this purpose, but both have serious adverse effects.^{10,11} Postoperative opioids cause nausea and vomiting, which have negative impact on the patient satisfaction and recovery.¹² Neuraxial may cause headache, backache, procedures unintentional dural puncture, and bleeding on puncture site. Neuraxial ultrasonography has increased the safety of the procedure. Some of uncommon, but lifethreatening side effects include intracord injection, epidural hematoma, and epidural abscess formation.¹³ Other drawbacks include hypotension, urine retention,

Table 1: Demographic and operative data ^{ab}			
Parameter	Group B (n = 15)	Group BMG (n = 15)	P value
Age (y)	43.9 ± 6.9	46.1 ± 6.8	0.385
BMI (kg/m ²)	28.5 ± 1.9	27.3 ± 2.2	0.147
ASA (I/II)	9 (60)/6 (40)	8 (53.3)/7 (46.7)	0.713
Anesthesia time (min.)	188.6 ± 9.5	185.3 ± 7.2	0.288
Operative time (min.)	167.9 ± 5.7	166.3 ± 7	0.499
Sex (male: female)	8 (53.3): 7 (46.7)	9 (60): 6 (40)	0.713
^a Data displayed as mean \pm SD or N (%)			

^b The two groups had no statistically significant differences.

P < 0.05 considered statistically significant.

and permaine consumption per 24 n					
Parameter	Group B (n = 15)	Group BMG (n = 15)	P value ^b		
TFA (h)	7.6 ± 0.5	9.5 ± 0.5	< 0.001°		
VAS-rest					
1 h	1 (0-2)	1 (0-2)	1.000		
6 h	3 (2-4)	3 (2-4)	0.288		
12 h	4 (4-5)	4 (4-5)	1.000		
24 h	4 (4-5)	4 (4-5)	1.000		
VAS-movement					
1 h	3 (2-4)	3 (2-4)	1.000		
6 h	3 (2-4)	3 (2-4)	0.529		
12 h	4 (4-5)	4 (4-5)	0.473		
24 h	4 (4-5)	4 (4-5)	0.724		
Pethidine consumption (mg/24 h)	190 ± 12.8	153 ± 13.6	< 0.001°		
^a The data is displayed as mean , standard deviation or madian (range)					

Table 2: Comparative time to first request for analgesic (TFA). VAS scores at rest, on movement and pethidine consumption per 24 h

^a The data is displayed as mean \pm standard deviation or median (range).

^b A statistically significant P < 0.05.

^c Significant statistical difference.

Table 3: Postoperative heart rate, and MAP. Data presented as mean ± SD					
	Group B (n = 15)	Group BMG (n = 15)	P value*		
Postoperative heart rate (beat/min)					
1 h	79.5 ± 3.8	79.3 ± 4.5	0.862		
6 h	78.9 ± 5.0	79.7 ± 4.3	0.643		
12 h	78.9 ± 4.3	77.9 ± 4.0	0.512		
24 h	84.1 ± 5.8	85.1 ± 3.7	0.602		
Postoperative MAP (mmHg)					
1 h	98.5 ± 5.4	95.5 ± 4.1	0.091		
6 h	98.7 ± 3.7	96.4 ± 5.0	0.170		
12 h	98.5 ± 3.5	96.0 ± 4.6	0.108		
24 h	103.1 ± 4.9	104.3 ± 5.4	0.527		
The two groups had no statistically significant difference $* P < 0.05$ considered statistically significant	erences				

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and restricted use in patients with a spine fracture or surgery.

The ESP block might have a high analgesic efficacy and success rate than neuraxial nerve blocks.¹⁴ Several authors have employed ESP block for postoperative analgesia and demonstrated that local anesthetic solution diffusion is volume-dependent, and normally extends into the epidural area and neural foramina. When the laminae and ligaments are damaged, local anesthetics may have excessive epidural distribution, needing additional attention.^{15,16} The local anesthetics given through ESP, if widely diffused, may cause a para-spinal block; thus the block range is broad and it persists for a long time after the procedure.^{17,18,19}

As per our study's findings, ESP block with bupivacaine/magnesium had an efficient and prolonged postoperative analgesia in lumbar spine surgery in comparison with bupivacaine alone. The Group BMG's postoperative time to first request of analgesics was significantly prolonged than the Group B. At the 1st, 6th, 12th, and 24th hours, VAS at rest and on movement revealed no significant difference between the two groups. However, the requirement of postoperative analgesic (pethidine mg/24 h) was significantly lower in the Group BMG than in the Group B. When compared with previous similar studies on patients who underwent lumbar spine surgery and who got ESP block, the results differed from those of this research, owing to use of different local anesthetics, adjuvants, or concentrations; as well as the different timing of the blocks. Some researchers discovered a considerably lower fentanyl and morphine required at all times during the first 24 hours than the control groups.^{20,21} Tulgar et al. found that the ESP group received less fentanyl and tramadol than the control group, but there was no significant difference the twelve after first hours postoperatively.²² In contrast, other researchers discovered that the ESP block reduced pain corresponding to a lower numerical pain rating scale (NRS) score at every assessment point (every two hours for the first twelve hours).^{20,21} In terms of NRS scores, Gürkan²¹ discovered no statistical differences between the two groups. Tulgar et al. measured NRS score during the rest and on movement every three hours, for the first twenty-four hours, although NRS was statistically lower in the ESP group only for the 0-3 hour time frame.²² Nagaraja et al. measured pain for the first two days, recording comparable VAS levels for the first twelve hours, but considerably lower VAS scores in the TEA (thoracic epidural analgesia) group at 24, 36, and 48 h.23 It's worth noting, however, that the average VAS score in each group was ≤ 4 , both at rest and during cough. Only Krishna et al. provided information on the time to the first analgesic request (6 h in the control group vs. 10 h in the ESP group).²⁰ However, no statistical analysis was carried out. The rotator cuffs of 66 people were repaired arthroscopically, in a research by Lee AR et al.²² The interscalene nerve block consisted of 0.5 bupivacaine (20 mL), epinephrine percent (1:200,000), and either 10% of MgSO₄ (2 mL) (MgSO₄ Group) or normal saline (2 mL) (normal saline group). The magnesium group had less pain in comparison between the saline group ($664 \pm 188 \text{ min}$ vs 553 ± 155 min, respectively; P = 0.017). However, the fact that both groups consumed the same quantity of fentanyl, the magnesium group had significantly lower NRS scores at 12 h (P = 0.012). Postoperative fentanyl use was not statistically significant in the two groups.

5. Conclusion

Erector spinae plane block with a combination of bupivacaine and magnesium sulphate provides significantly more efficient postoperative analgesia and reduced postoperative discomfort when compared to bupivacaine alone, in lumbar spinal fusion surgery.

6. Clinical trial registration.

ClinicalTrials.gov ID: NCT04433624.

7. Conflict of Interests

Conflict of interest among authors was absent. No funding, either internal or external, was involved in this study.

8. Ethical Approval

All activities in our investigation, including those involving human participants, were conducted in compliance with all the following authorization, the ethical criteria of the institutional research committee, and the Helsinki Declaration of 1964 and its subsequent revisions or equivalent ethical standards. The ethics committee at Beni-Suef University's Faculty of Medicine in Egypt approved the study. (Approval number FMBSUREC/07062020/Abd EL Badie).

9. Informed Consent

Written notified consent was needed from all shared patients.

10. Data availability

The numerical data is available with the author and can be provided on request.

11. Authors' Contribution

The author is solely responsible for the concept, conduction of the study work , manuscript editing and statistical analysis

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