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ORIGINAL RESEARCH REGIONAL ANESTHESIA

Evaluation of the effect of dexmedetomidine versus magnesium sulphate as an adjuvant to bupivacaine in ultrasound guided erector spinae block; a prospective randomized trial

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ABSTRACT

Background & Objectives: Since the introduction of erector spinae plane block (ESPB) in 2016 it has been used with success in various thoracic, abdominal, and spine surgeries. Spine surgeries result in significant postoperative pain. Postoperative opioids provide adequate pain control in most of the cases, but some patients continue to suffer from uncontrolled pain. Patients receiving multiple doses of opioids suffer from various side effects including postoperative nausea and vomiting, constipation, and delayed ambulation. We aimed to compare effect of dexmedetomidine and magnesium sulfate given as adjuvants with bupivacaine 0.25% for ESPB.

Methodology: It was a prospective randomized single-blinded study including 52 patients divided into 2 groups; one receiving ESPB with a combination of bupivacaine 0.25% plus magnesium sulfate and the other receiving the same block with a combination of bupivacaine 0.25% plus dexmedetomidine.

Results: The group receiving bupivacaine and dexmedetomidine had a prolonged postoperative analgesia duration as well as a decreased total opioid consumption ($P < 0.05$) compared to group receiving bupivacaine 0.25% plus magnesium sulfate, but had a significant decrease in intraoperative pulse rate and blood pressure compared to the group receiving bupivacaine 0.25% plus magnesium sulfate ($P < 0.05$).

Conclusion: Although dexmedetomidine results in prolonged postoperative analgesia duration compared to magnesium sulfate when combined with bupivacaine 0.25% in ESPB, its negative effects on hemodynamics should be considered.

Trial registration: This trial was registered on clinicaltrials.gov registry (NCT05694897) on 23/1/2023.

Abbreviations: ASA: American Society of Anesthesiologist; ESPB: Erector Spinae Block; ERAS: Enhanced recovery After Surgery; SPSS: Statistical Package for Social Sciences; VAS: Visual Analog Score

Key words: Erector Spinae Plane Block; Dexmedetomidine; Bupivacaine; Visual Analog Scale

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1. INTRODUCTION

Fascial plane blocks have gained exceeding interest in anesthesia and pain management in the recent years, including the erector spinae block (ESPB).[1] The ESPB was described by Forero et al., in 2016 to deal with thoracic neuropathic pain in patients resistant to treatment by regular pharmacologic methods.[2] Since its description, studies have been conducted on the technique to test its efficacy and to find out the adequate dose and concentration of anesthetics and the adjuvants to be used.

Although the first study published was to show the efficacy of the block in the treatment of thoracic neuropathic pain, many indications have been found for this block including thoracic, breast and abdominal surgeries.[3] The use of ESPB in lumbar spine surgeries has been a bit controversial. A meta-analysis study published in 2020 found the evidence insufficient to support the widespread use of ESPB for lumbar spine surgery and recommended high-quality RCTs to be done.[4] While a more recent study conducted in 2021 found that the block improved postoperative analgesic efficacy.[5]

Spine surgeries are usually elective and characterized by intense postoperative pain. So adequate management of postoperative pain allows early ambulation, decreases hospital stay, decreases the incidence of developing chronic neuropathic pain, with increased patient satisfaction and reduced overall cost.[6]

The erector spinae is the largest muscle mass of the back. It lies in the intermediate layer of intrinsic back muscles covered by the thoracolumbar fascia and arises from the erector spinae aponeurosis, which is a common aponeurosis connecting with the thoracolumbar fascia, having a proximal attachment on the sacrum and the spinous processes of the lumbar vertebrae.[7]

Although many studies have been conducted on various drugs to test their efficacy in combination with local anesthetics (LA) in locoregional anesthesia, studies on the effect of adjuvant drugs in ESPB are scarce. Hence, we aimed to compare the adjuvant effect of dexmedetomidine, and magnesium sulfate when added to bupivacaine 0.25% for ESPB. The primary outcome was to evaluate the effect on postoperative analgesia duration. While the secondary outcomes were to evaluate the time to first rescue analgesia, the total dose of postoperative opioids in 12 h, the effects on hemodynamic parameters, and any adverse effects.

2. METHODOLOGY

2.1. Study design

This study was a prospective, parallel-group, randomized, and single-blinded comparative study, carried out in anesthesiology departments of our University Hospitals from July 2021, and November 2022.

2.2. The participants

Fifty-seven patients undergoing lumbar spine surgeries were assessed for eligibility for the study, 5 of them declined to participate and 52 patients were enrolled for the study. Patients aged between 20-60 y, from both sexes, ASA-I and II, undergoing lumbar spine surgeries were enrolled. Patients with BMI > 35 or < 20 kg/m^2, pregnancy, infection at the site of injection, psychiatric illness affecting the patient's judgment, history of coagulopathies, or allergy to any of the drugs used were excluded. Patients with spine deformities (e.g. scoliosis) and patients who received massive blood transfusions were also excluded. Age, weight, sex, duration, and type of surgery were recorded.

All patients were randomly allocated using computer-generated block randomization made by the first generator of randomization.com prepared by an anesthesiologist not participating in the study, which divided them into two equal groups (26 patients each) as shown in Figure 1. Group BM received GA + ESPB with bupivacaine with magnesium sulphate; whereas, Group BD received GA + ESPB with bupivacaine with dexmedetomidine.

2.3. Sample size calculation

Based on the study done by Yesiltas et al.,[8] a sample size of 52 patients at a confidence interval of 95 percent was calculated. Assuming an effect size of 0.7 as regards the

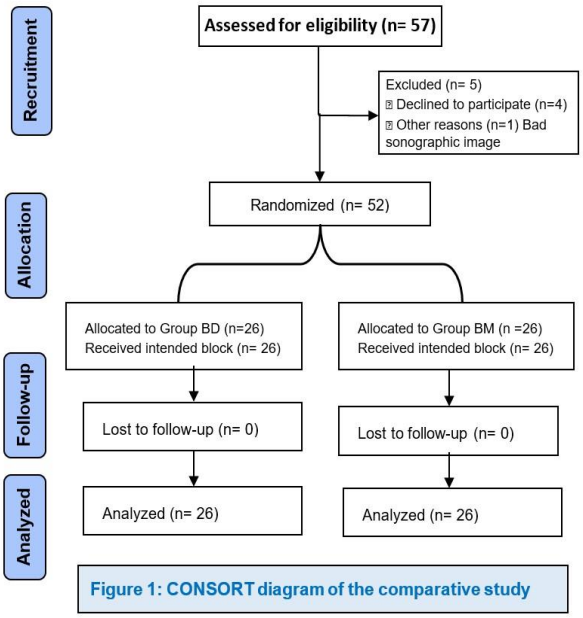

Figure 1: CONSORT diagram of the comparative study

duration of analgesia between the 2 groups, a sample of 26 patients in each group would be enough to detect such an effect.

2.4. The anesthetic procedure

The patients were instructed preoperatively to use a visual analog scale (VAS) for pain. General anesthesia was induced using 2 mg/kg propofol, fentanyl 2 µg/kg, and atracurium besylate 0.5 mg/kg in all patients, and it maintained using isoflurane 1.5-2%. The patients received no additional intraoperative opioids except the induction dose of fentanyl.

After induction, the patients were flipped to the prone position, and an ESPB was performed using, a high-frequency linear ultrasound probe placed longitudinally in the cephalocaudal orientation, 2 to 3 cm lateral to the 10th thoracic vertebrae. The transverse process was differentiated from the rib by being superficial and wider. After identifying the trapezius, and erector spinae muscles, an 18-G Tuohy needle was passed along the plane of the transducer with the bevel pointing superiorly until its tip hit the transverse process of T10, the needle was then withdrawn slightly, and a bolus of 2 mL of LA was injected. Once separation between the erector spinae muscle and the transverse process was visualized proper positioning of the needle was confirmed and a total volume of 25 mL was injected including 20 mL of 0.25% bupivacaine plus 3.75 mL NS and 125 mg $MgSO_4$ (1.25 mL) in the Group BM. The patients in Group BD received 20 mL of 0.25% bupivacaine plus 5 mL NS with 1 µg/kg dexmedetomidine. The anesthetic was injected deep to the erector spinae muscle, and the procedure was repeated on the other side. SonoSite M-Turbo C ® Ultrasound device with HFL – 38X Linear probe (USA) with high frequency (6 -13 MHz) was used in the imaging of the patient. A 22 G, 5 cm, and 10 cm nerve block needles were used.

The time needed to perform the block in each group was recorded. Hemodynamic changes were recorded following the bilateral blocks, adverse intraoperative events, and surgery time were documented.

After the surgery, all patients received diclofenac 0.5 mg/kg 8 hourly, and rescue analgesia was achieved with nalbuphine 10 mg IV as required. Postoperative pain was rated on Visual Analog Scale (VAS) every 2 h for 12 h.

The time to the first analgesic request was recorded. It was defined as the time from recovery until VAS score greater than 4. The total dose of nalbuphine used over 24 h postoperatively was recorded.

Any complications during and after the performance of the block, e.g., pneumothorax, Horner's syndrome, hoarseness, difficulty in breathing, weakness, and paresthesia in the arms were recorded. Postoperative nausea and vomiting and bradycardia were recorded.

2.5. Statistical analysis

SPSS for Windows (Statistical Package for the Social Sciences) version 26 (IBM, Armonk, NY, USA) was used for statistical analysis of the collected data. The Shapiro-Wilk test was used to check the normality of the data distribution. All tests were conducted with a 95% confidence interval. P (probability) value < 0.05 was considered statistically significant. Charts were generated using SPSS' chart builder and Microsoft Excel for Windows 2019.

Quantitative variables were expressed as mean and standard deviation, median, inter-quartile range, minimum, and maximum, as appropriate, while categorical variables were expressed as frequency and percentage.

Independent sample T and Mann-Whitney tests were used for inter-group (between subjects) comparison of parametric and non-parametric continuous data respectively.

For pair-wise comparison of data (within subjects), the follow-up values were compared to their corresponding basal value using paired samples T-test or Wilcoxon matched-pairs signed ranks test for parametric and non-parametric continuous data respectively. Fisher exact and Chi-square tests were used for inter-group comparison of nominal data using the crosstabs function anesthesia and the surgical procedure.

3. RESULTS

Demographic data including age, sex, and BMI showed no difference between both groups (Table 1).

Table 1: Demographic data of patients in both groups

Variables		Group BM (n = 26)	Group BD (n = 26)	P-value
Age in years		49.04 ± 8.426	48.31 ± 10.260	0.780
Gender n (%)	Male	14 (53.8)	9 (34.6)	0.264
	Female	12 (46.2%)	17 (65.4)	
BMI		30.913 ± 2.529	31.272 ± 3.606	0.680
ASA n (%)	I	16 (61.5)	12 (46.2)	0.404
	II	10 (38.5)	14 (53.8)	

Data presented as mean ± SD or n (%); P < 0.05 considered as significant

ASA status of patients in both groups showed no statistical difference (P > 0.05). The duration of surgeries showed no statistical difference in two groups; being 174.23 ± 36.26 min in Group BD vs. 183.46 ± 29.79 min in Group BM (P > 0.05).

Regarding complications, there was statistically no difference between the groups for postoperative nausea and vomiting; with Group BD showing an incidence of 15.4% and Group BM showing an incidence of 26.9% (P > 0.05). No other complication, including

pneumothorax, neurologic deficits and postoperative bleeding, was observed.

As for the intraoperative hemodynamic parameters, both blood pressure and heart rate decreased significantly in Group BD in comparison to the other group and this decrease continued throughout the whole operation time (Table 2) and (Table 3).

Regarding the postoperative analgesic duration, the patients in Group BD showed a significant lower VAS scores compared to Group BM at 4 and 8 h postoperatively (Table 4).

The number of patients who needed rescue analgesia didn't differ between the two groups, with 80.8% requiring opioid analgesics in Group BD and 84.6% requiring in Group BM (P > 0.05).

Although the time to the first analgesic request was slightly more in the Group BD, statistical analysis showed no difference between the groups. The total amount of nalbuphine consumed showed a significant difference between both groups, as it was less in Group BD (Table 5). Survival analysis using Kaplan Meier estimate showed no difference between the groups (Table 6 and Figure 2).

Table 2: Comparative intraoperative heart rate in two groups

HR recording time	No. of pts BD / BM	Group BD	Group BM	P- value
Baseline	26 / 26	78.50 ± 9.270	73.65 ± 8.546	0.056
15 min	26 / 26	71.77 ± 9.105	79.12 ± 9.872	0.007
30 min	26 / 26	67.96 ± 10.125	78.62 ± 10.940	0.001
45 min	26 / 26	66.38 ± 11.089	78.04 ± 11.014	< 0.001
60 min	26 / 26	68.35 ± 9.867	77.62 ± 10.782	0.002
75 min	26 / 26	66.50 ± 11.219	76.42 ± 11.914	0.003
90 min	26 / 26	66.92 ± 12.244	76.73 ± 12.052	0.005
120 min	26 / 26	67.65 ± 11.517	77.46 ± 11.455	0.003
150 min	21 / 23	65.52 ± 11.400	76.35 ± 11.142	0.003
180 min	10 / 18	69.10 ± 11.493	79.22 ± 10.724	0.028
210 min	7 / 8	71.14 ± 7.712	78.00 ± 12.282	0.226

Data presented as mean ± SD; P < 0.05 considered as significant

Table 3: Comparative intraoperative MAP in two groups

MAP recording time	No. of pts BD / BM	Group BD	Group BM	P-value
Baseline	26 / 26	99.31 ± 13.416	96.23 ± 8.608	0.330
15 min	26 / 26	82.31 ± 10.913	95.92 ± 8.831	< 0.001
30 min	26 / 26	83.19 ± 11.092	96.23 ± 9.227	< 0.001
45 min	26 / 26	83.23 ± 11.420	95.42 ± 9.052	< 0.001
60 min	26 / 26	82.58 ± 10.393	95.42 ± 9.131	< 0.001
75 min	26 / 26	82.54 ± 10.580	94.92 ± 9.570	< 0.001
90 min	26 / 26	81.38 ± 10.100	94.65 ± 9.875	< 0.001
120 min	26 / 26	81.15 ± 9.821	94.12 ± 9.881	< 0.001
150 min	21 / 23	81.62 ± 10.337	92.52 ± 10.103	0.001
180 min	10 / 18	82.10 ± 11.493	93.78 ± 9.771	0.009
210 min	7 / 8	85.29 ± 11.011	93.75 ± 9.438	0.133

Data presented as mean ± SD; P < 0.05 considered as significant

Table 4: Comparative postoperative VAS scores in two groups

VAS recording time	No. of pts BD / BM	Group BD	Group BM	P-value
2 h	26 / 26	2.69 ± 1.258	3.00 ± 1.095	0.351
4 h	26 / 26	3.04 ± .958	4.04 ± 1.076	< 0.001
6 h	26 / 26	3.62 ± 1.267	4.08 ± 1.324	0.001
8 h	26 / 26	3.69 ± .928	4.38 ± 1.098	< 0.001
10 h	26 / 26	4.38 ± .983	4.54 ± 1.240	0.205
12 h	26 / 26	4.23 ± 1.070	4.54 ± 1.208	< 0.001

Data presented as mean ± SD; P < 0.05 considered as significant

4. Discussion

In this randomized controlled study, we compared 2 adjuvant drugs each used in combination with bupivacaine 0.25% for ESPB. We found that the group receiving bupivacaine in combination with dexmedetomidine had a significantly prolonged postoperative pain-free period with decreased overall opioid consumption in comparison to the group receiving magnesium sulfate in combination with bupivacaine 0.25%.

Table 5: Comparison between both groups regarding time to first analgesic request and total dose of nalbuphine

Variable	Group BD (n = 21)	Group BM (n = 22)	P-value
Time to first analgesic request (min)	368.57 ± 195.02	265.91 ± 179.86	0.080
Total dose of nalbuphine (mg)	14.29 ± 6.76	20.27 ± 9.34	0.021

Data presented as mean ± SD; P < 0.05 considered as significant

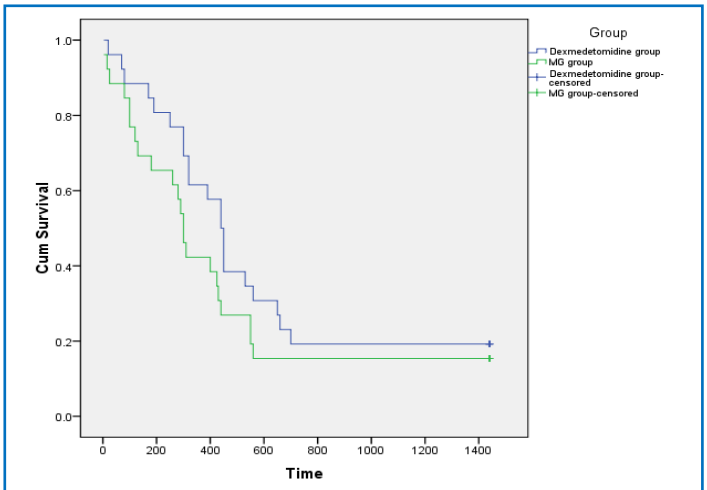

Figure 2: Shows analysis of pain-free time before the first analgesic request

ESPB has been used with relative success in thoracic surgeries as demonstrated by Fiorelli et al.,[9] and its efficacy in abdominal surgeries was demonstrated via clinical trials applying it in cesarean sections.[10] Its efficacy in posterior spine fusion surgeries was demonstrated in various clinical trials as well.[11,12] Although these studies have been challenged by meta-analysis done by Young Qui et al. who found that the effectiveness of ESPB was still controversial and that we needed more RCTs.[13] Finally, the meta-analysis done by Liang et al. demonstrated the efficacy of ESPB in lumbar spine surgeries.[14,15]

Numerous clinical trials have been conducted to study the effect of adjuvant drugs on the onset, duration, and quality of regional anesthesia blocks, among those adjuvants, was dexmedetomidine. Kathuria et al. demonstrated the beneficial effects of 50 µg dexmedetomidine on the onset and duration of supraclavicular block in 2015, and transversus abdominus plane blocks.[16,17]

Another adjuvant that was examined thoroughly in various blocks including supraclavicular, inter scalene, and transversus abdominus plane blocks is magnesium sulfate. Suresh and Emani studied the effect of 2 doses of magnesium sulfate, 125 mg and 250 mg, in interscalene block, and found that there was no significant difference between both, so we chose to go with the lower dose in our study.[18]

In our study, we intended to compare the effect of those adjuvants in ESPB specifically to enhance early recovery via decreasing the postoperative opioid consumption and to implement enhanced recovery after surgery (ERAS) protocols for lumbar spine surgeries in our hospitals in the future. We monitored postoperative pain in our patients using two parameters; the VAS score every 2 h for 12 h postoperatively, and the total amount of nalbuphine consumed during this period.

Although the time to the first analgesic requirement was increased in the group receiving dexmedetomidine in comparison to the other group, statistical analysis showed no significant difference between the two. But we found a significant decrease in the postoperative pain scores using the VAS at the 4th and 8th hour postoperatively in the group receiving dexmedetomidine in comparison to the group receiving magnesium sulfate, with a decrease in the total dose of nalbuphine

Table 6: Kaplan Meier analysis for pain-free time to first analgesia

Group	Median	
	Estimate	95% Confidence Interval
Group BD	440.000	380.036 - 499.964
Group BM	300.000	262.633 - 337.367
Overall	390.000	248.662 - 531.338
p-value (log-rank test)	0.209	

in the group receiving dexmedetomidine.

This could be attributed to the fact that dexmedetomidine inhibits pain via many mechanisms; centrally via acting as an alpha-2 adrenergic agonist inhibiting central sympathetic outflux affecting spinal, supraspinal, and interspinal nociception transmission, and peripherally via acting on the same receptors.[19,20] On the other hand, magnesium sulfate remains a good analgesic but acts via a single central effect through NMDA receptor inhibition.[21] And since this is an interfascial plane block so the prolonged analgesic effect could be attributed to the peripheral action of dexmedetomidine rather than the central effect, although absorption via epidural spread should still be considered.

There was significant bradycardia, and hypotension in the group receiving dexmedetomidine in comparison with the other group - an effect well known for intravenous and intrathecal dexmedetomidine, but not to facial plane blocks. This could be attributed to the relatively high dose we used in our block 1 µg/kg. We suggest doing clinical trials with lower doses

5. LIMITATIONS

Our study had some limitations first of all the small sample size, forced us to include surgical operations with various durations in our study. Postoperative hospital stay wasn't recorded. We used a relatively high dose of nalbuphine in the postoperative period because of adjusting the opioid rescue dose on a VAS > 4.

6. CONCLUSION

ESPB provides adequate postoperative analgesia for patients undergoing lumbar spine surgeries. Additives such as magnesium sulfate and dexmedetomidine have been suggested to increase the duration of postoperative analgesia, decrease postoperative opioid requirements and thus decrease the associated side effects. Dexmedetomidine showed a significant decrease in postoperative pain via VAS between the 4th and 8th h postoperative and showed a decrease in total nalbuphine consumption, but produced more bradycardia and hypotension.

7. Recommendations

We recommend studying the effect of smaller doses of dexmedetomidine on the duration and quality of the block to avoid bradycardia and hypotension resulting from the dose we used.

We recommend measuring plasma levels of dexmedetomidine in future studies to try to reach the level with the best analgesia and minimum hemodynamic effects.

Measuring CSF levels of the drugs used in the block should be considered in future studies as well.

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9. Presentation

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10. Consent to participate

Written informed consent was taken from all participants

11. Availability of Data

All data generated or analyzed during this study are are available for sharing from the corresponding author upon reasonable request.

12. Conflict of Interest

The authors declare no conflict of interest, financial, or otherwise.

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