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Comparison between epidural postoperative analgesia with Bupivacaine with 50mg Magnesium sulphate and of Bupivacaine with 50 mg Tramadol for patients undergoing lower limb surgeries

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Abstract. Background. *The comparative efficacy of epidural bupivacaine with Magnesium sulphate and bupivacaine combined with Tramadol in providing postoperative analgesia remains controversial. This study aims to assess the efficacy of epidural postoperative analgesia using a combination of 0.125 %of Bupivacaine with 50mg MgSO4, compared to 0.125 %of Bupivacaine with 50mg tramadol in patients undergoing surgeries for the lower limbs.*

Method. *60 patients classified as ASA grade I and II were randomly divided into two groups, Group I and Group II, each containing 30 patients. Group I received a total of 9 ml of 0.125 % bupivacaine (8 ml) combined with 50mg tramadol (1 ml), while Group II was given 9 ml of 0.125 % bupivacaine (8 ml) with 50mg MgSO4 (1 ml). The analgesic effectiveness was evaluated by the onset of analgesia, duration of analgesia, quality of analgesia, and the time taken to administer the first rescue analgesic.*

Results. *The onset of analgesia in Group I was recorded as 6.67±0.80 minutes, while Group II had an onset time of 7.67±0.80 minutes (p=0.001). The duration of analgesia for Group I was 5.16±0.72 hours, compared to 4.51±0.62 hours in Group II (p=0.001). The time until the first rescue analgesia was 5.260±0.716 hours for Group I, whereas Group II required 4.617±0.622 hours (p=0.001). Over a 24-hour period, Group I needed an average of 3.47±0.51 rescue doses, while Group II required 3.97±0.49 doses. The quality of analgesia was evaluated in both groups, showing no statistically significant differences. Adverse effects included nausea and vomiting in 4 patients and pruritus in 1 patient in Group I, while Group II experienced hypotension in 4 patients and bradycardia in 2 patients. Mean systolic and diastolic blood pressures were comparable across both groups, with significant differences only at 5, 10, and 15 minutes. The mean heart rates at 5, 10, and 15 minutes were 94.67±4.15, 89.73±3.85, and 85.40±4.40 in Group I, and 97.00±4.09, 92.20±3.46, and 87.53±3.27 in Group II, indicating statistical significance. The mean post-operative VAS scores recorded upto 24hrs. The mean VAS score was 0.40±0.498 and 0.47±0.507 at 2hrs, 2.87±0.730 and 2.93±0.691 at 4 hrs, 1.60±0.621 and 1.87±0.730 at 6hrs, 2.60±0.621 and 2.87±0.507 at 8hrs, 1.87±0.629 and 2.07±0.691 at 12hrs, 2.60±0.621 and 2.67±0.479 at 24hrs respectively.*

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Conclusion. *Tramadol proved to be more effective than magnesium when combined with bupivacaine, as it led to a faster onset of pain relief, prolonged the duration of analgesia, and decreased the requirement for extra rescue epidural top-up doses within a 24-hour timeframe.*

Keywords: *Bupivacaine, Tramadol, Magnesium sulphate, lower limb surgeries, postoperative analgesia*

Introduction

Pain is a complex and subjective experience that is difficult to measure consistently. Providing adequate pain relief for patients undergoing major surgical procedures is a daily challenge for clinical anaesthetists (1).

Epidural anaesthesia and analgesia is a dependable and cost-effective approach that reduces patient discomfort and promotes early mobilization and recovery by offering prolonged pain relief. Various methods have been used to manage postoperative pain, and numerous pharmacological agents have been studied for their effectiveness in epidural analgesia. In many research studies, epidural opioids have been employed to control postoperative pain (2).

Tramadol has been found to be effective when administered perioperatively; it functions as an opioid agonist and monoamine reuptake inhibitor without causing respiratory depression. Its analgesic strength is roughly 5–10 times less than that of morphine. However, it can lead to side effects such as vomiting, hypotension, urinary retention, and nausea (3).

Magnesium sulphate ($MgSO_4$) reduces the release of catecholamines and acts as a non-competitive antagonist of the voltage-gated N-methyl-D-aspartate (NMDA) receptor, inhibiting calcium entry into cells (4). Recent research has shown that it can extend the effects of epidural Bupivacaine without causing drowsiness, hyporeflexia, hemodynamic instability, or respiratory depression (5).

Due to the limited research comparing tramadol and magnesium sulphate as additives to bupivacaine for epidural postoperative analgesia, this study seeks to assess the effectiveness of epidural bupivacaine combined with tramadol versus epidural bupivacaine combined with magnesium sulphate at lower doses for postoperative pain relief, along with their respective side effect profiles.

The aim of this study is to compare the effectiveness of epidural postoperative analgesia using 0.125 % bupivacaine with 50mg $MgSO_4$.

Materials and Methods

Study type: A prospective, randomized control, double blind clinical study conducted over a period of one year to assess the effectiveness and reliability of epidural 0.125 % of bupivacaine with 50mg $MgSo_4$ versus 0.125 % of bupivacaine with 50mg tramadol for post-operative pain relief.

Patient randomization:

60 patients belonging to ASA-1 and ASA-II were randomly allotted into 2 groups, Group I and Group II, with 30 patients in each group.

Group I: 0.125 % bupivacaine(8ml) +50mg tramadol(1ml)

Group II: 0.125 % bupivacaine(8ml) +50mg $MgSO_4$ (1ml)

Sample size calculation:

We hypothesized that onset of analgesia with bupivacaine and tramadol was faster compared to bupivacaine and magnesium sulphate. Sample size was calculated keeping two sided alpha error at 5 % and power at 80 %, minimum of 23 patients in each group is required to detect difference in duration of analgesia between the groups. For better validation 30 patients were selected in each group.

Sample size formula:

$$\text{Sample size } (n) = \frac{2 \times (Z\alpha + Z\beta^2)\ \sigma^2}{(x_1 - x_2)^2}$$

n = Sample size

Zα = Level of significance Zβ = Required power

σ = Anticipated standard deviation

$X_1 - X_2$ = Meaningful difference between two means

Selection criteria:

Patients aged 18 to 60 years, regardless of gender, who were classified as ASA grade I and II, were selected for elective surgeries on the lower limbs. The criteria for exclusion was individuals who declined to participate, those classified as ASA grade 3 or 4, patients younger than 18 or older than 60, individuals with cardio-respiratory issues, renal or liver disorders, those who are physically depen-

dent on opioids, and pregnant women. Furthermore, all known contraindications for epidural anesthesia were taken into account, resulting in the exclusion of patients with high intracranial pressure, coagulation issues, those undergoing anticoagulant treatment, uncooperative or anxious individuals, patients suffering from severe hemorrhage or shock, local infections or inflammation, and those with a history of drug allergies.

Pre-Anaesthetic evaluation

The day before the surgery, a detailed medical history was collected, and a thorough examination was carried out. All patients underwent essential laboratory tests, which included measuring hemoglobin levels, fasting or random blood glucose, blood urea, and serum creatinine, along with routine urine tests. Those aged over 40 had an electrocardiogram (ECG) performed and, if necessary, a chest X-ray. On the evening before the procedure, patients were given 0.5 mg of Alprazolam and 150 mg of Rantac orally. They were advised to avoid solid food for 6 hours and liquids for 2 hours before the surgery.

Technique:

Hemodynamics were evaluated at the baseline. An intravenous line was then established using an 18 G cannula, and the infusion began. Following strict aseptic protocols, a skin wheal was created at the L2–L3 interspace with 2 cc of 1% lignocaine. The epidural space was identified using an 18G Tuohy needle and the loss of resistance to air technique. An 18G catheter was then threaded through the epidural needle and advanced approximately 3–4 cm into the target area. After withdrawing the needle, the catheter was secured to the patient's back. A test dose of 3 ml of 2% lignocaine with 1:200,000 adrenaline was administered through the catheter while monitoring for any signs of intravascular or intrathecal injection. Subsequently, under strict aseptic conditions, spinal anaesthesia was performed at the L2-L3 level using a 25G Quinkey's needle and an appropriate volume of heavy bupivacaine. Surgery commenced once sufficient anaesthesia was confirmed. Patients were given a Visual Analog Scale (VAS) to assess their pain intensity in the postoperative ward after the spinal effect had waned. If the VAS score exceeded 3, a single dose of Bupivacaine 0.125% (8ml) combined with 50mg tramadol (1ml) or Bupivacaine 0.125% (8ml) with 50mg $MgSO_4$ (1ml), totaling 9ml, was administered through the epidural catheter. Pain relief was evaluated at regular intervals for up to 24 hours.

Following observations recorded:

Onset of analgesia: Time from epidural topup with study drug till the patient has VAS score less than 3.

Duration of analgesia: Interval between epidural top up and VAS score fall less than 3.

Quality of analgesia: adequate/inadequate.

Time required for 1st rescue analgesia: Interval between 1st epidural top up to requirement of another top up i.e when VAS > 3.

Total number of rescue analgesic doses required in 24 hrs: The same study drug is given as bolus each time the VAS is > 3 & total amount is calculated.

Side effects: Nausea & Vomiting, Headache, Pruritis, Bradycardia, Hypotension.

Methods to assess pain was visual Analog Scale (VAS). Other scales such as Verbal Descriptor, Scales Numeric Rating Scale (NRS) and Oral Analog Scale (OAS) were also measured.

Statistical analysis

Descriptive statistics were calculated for both the explanatory and outcome variables, using mean and standard deviation for quantitative variables, and frequency and proportions for qualitative variables. The Chi-square test was applied to the qualitative variables. An independent sample t-test was conducted to compare the quantitative variables (Age, Onset of Analgesia, Duration of Analgesia, Time taken for the first rescue analgesia, Total number of rescue analgesia, SBP, DBP, PR, Oxygen saturation, VAS scores) across different groups. Data was analysed by using software Statistical Package for the Social Sciences (SPSS 26; IBM Corp., New York, NY, USA). A P value of <0.05 was considered statistically significant.

Results

66.7% in Group I and 63.3% in Group II were males, whereas 33.3% in Group I and 36.7% in Group II were females. The mean age of patients in Group I was 39.87±10.281 yrs and Group II was 36.87±8.504 yrs. There was no statistically significant difference between mean ages of both groups.

The mean onset of analgesia was 6.67±0.80 min in Group I and 7.67±0.80 min in Group II which was statistically significant. The mean duration of analgesia was 5.16 ± 0.72 hrs in Group I and 4.51 ± 0.62 hrs in Group II which was statistically significant. The mean time required for 1st rescue analgesia was 5.26 ± 0.716 hrs

Table 1. Comparison of the mean values between the groups using independent sample t test

	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
AGE	Group I	23	58	39.87	10.281	3.00	0.223
	Group II	24	52	36.87	8.504		
height	Group I	150.0	172.0	164.6	5.48	0.67	0.68
	Group II	150.0	176.0	164.0	6.99		
weight	Group I	56.0	78.0	69.36	6.53	1.03	0.60
	Group II	55.0	80.0	68.33	8.51		
Onset of Analgesia (min)	Group I	6	8	6.67	0.80	−1.00	0.001*
	Group II	7	9	7.67	0.80		
Duration of analgesia (hrs)	Group I	4.00	6.50	5.16	0.72	0.64	0.001*
	Group II	3.50	6.00	4.51	0.62		
Time required for 1st rescue analgesia(hrs)	Group I	4.1	6.6	5.260	0.716	0.64	0.001*
	Group II	3.6	6.1	4.617	0.622		
Total no of rescue analgesia	Group I	3	4	3.47	0.51	−0.50	0.001*
	Group II	3	5	3.97	0.49		

in Group I and 4.617 ± 0.622 hrs in Group II which was statistically significant difference between both groups. The mean total rescue analgesics in 24 hrs was 3.47±0.51 in Group I and 3.97±0.49 in Group II respectively which was statistically significant between both groups.

The mean ADEQUATE Quality of Analgesia was seen 96.7% in Group I and 86.7% in Group II, whereas INADEQUATE Quality of Analgesia was seen 3.3 %in Group I and 13.3 %in Group II. In Group I, Nausea &vomiting in 4 patients, pruritis in 1 patient was observed, whereas bradycardia in 2 patients, hypotension in 4 patients was observed in Group II which was statistically significant.

The mean systolic blood pressure was comparable in both groups, with no statistical significance except at 5 min, 10 min & 15 min.The mean systolic blood pressure was 119.60 ± 7.83,117.20 ± 6.84,116.53 ± 5.12 at 5min,10min,15min respectively in Group I, whereas mean systolic blood pressure was 124.20 ± 5.95, 121.47 ± 5.17, 119.80 ± 4.59 at 5min,10min,15min respectively in Group II which was statistically significant.

The mean diastolic blood pressure was comparable in both groups, with no statistical significance except at 5min,10min and 15min.The mean diastolic blood pressure was 77.60 ± 6.44, 73.00 ± 6.64, 69.73 ± 6.41at 5 min, 10 min, 15 min respectively in Group I, whereas mean diastolic blood pressure was 81.20 ± 5.84, 76.67 ± 5.88, 73.07 ± 6.10 at 5 min, 10 min, 15 min respectively in Group II which was statistically significant.

The mean heart rate was 94.67 ± 4.15, 89.73 ± 3.85, 85.40± 4.40 at 5 min, 10 min, 15 min respectively in Group I, whereas mean heart rate was 97.00 ± 4.09, 92.20 ± 3.46, 87.53± 3.27 at 5min,10min,15min respectively in Group II which was statistically significant.

The mean SPO_2 was comparable in both groups, with no statistical significance.

The average post-operative VAS scores were documented over a 24-hour period. At the 2-hour mark, the average VAS score for Group I was 0.40 ± 0.498, while for Group II it was 0.47 ± 0.507. At 4 hours, the average VAS score for Group I was 2.87 ± 0.730, compared to 2.93 ± 0.691 for Group II. At the 6-hour interval, Group

Table 2. Distribution of the subjects based on quality of analgesia and side effects

		Groups		Total	Chi-square	P value
		Group I	*Group II*			
Quality of Analgesia						
Adequate	Count	29	26	55	1.96	0.16
	%	96.7%	86.7%	91.7%		
Inadequate	Count	1	4	5		
	%	3.3%	13.3%	8.3%		
Side effects						
Bradycardia	Count	0	2	2	11.02	0.026
	%	0.0%	6.7%	3.3%		
Hypotension	Count	0	4	4		
	%	0.0%	13.3%	6.7%		
Nausea + vomiting	Count	4	0	4		
	%	13.3%	0.0%	6.7%		
No side effects	Count	25	24	49		
	%	83.3%	80.0%	81.7%		
Pruritis	Count	1	0	1		
	%	3.3%	0.0%	1.7%		

Table 3. Comparison of the mean systolic blood pressure between the groups using independent sample t test

Time intervals	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
Baseline	Group I	110	140	124.00	8.17	-3.40	0.092
	Group II	114	138	127.40	7.17		
5 min	Group I	106	132	119.60	7.83	-4.60	0.013*
	Group II	116	134	124.20	5.95		
10 min	Group I	106	130	117.20	6.84	-4.26	0.008*
	Group II	114	130	121.47	5.17		

Time intervals	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
15 min	Group I	110	128	116.53	5.12	−3.26	0.012*
	Group II	112	130	119.80	4.59		
30 min	Group I	112	126	117.13	4.38	0.4	0.736
	Group II	110	126	116.73	4.77		
60 min	Group I	110	124	116.27	5.50	0.80	0.53
	Group II	110	122	115.47	4.36		
90 min	Group I	110	122	115.33	4.01	−1.46	0.146
	Group II	112	124	116.80	3.70		
120 min	Group I	114	130	121.00	4.95	−1.66	0.15
	Group II	116	128	122.67	3.91		

Table 4. Comparison of the mean diastolic blood pressure between the groups using independent sample t test

Time intervalse	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
Baseline	Group I	70	92	81.40	6.75	−2.73	0.09
	Group II	74	94	84.13	5.85		
5 min	Group I	66	88	77.60	6.44	−3.6	0.027*
	Group II	70	92	81.20	5.84		
10 min	Group I	62	84	73.00	6.64	−3.66	0.027*
	Group II	66	86	76.67	5.88		
15 min	Group I	60	78	69.73	6.41	−3.33	0.043*
	Group II	62	82	73.07	6.10		
30 min	Group I	60	76	67.67	5.78	−2.66	0.063
	Group II	60	78	70.33	5.09		
60 min	Group I	62	72	66.60	3.07	−1.13	0.19
	Group II	60	72	67.73	3.55		

Time intervalse	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
90 min	Group I	68	76	70.93	2.27	−0.33	0.63
	Group II	66	76	71.27	3.08		
120 min	Group I	70	82	75.33	3.12	−0.93	0.23
	Group II	70	82	76.27	2.86		

Table 5. Comparison of the mean heart rate between the groups using independent sample t test

Time intervals	Groups	Minimum	Maximum	Mean	Standard deviatio n	Mean diff	P value
Baseline	Group I	96	112	102.93	4.12	0.73	0.49
	Group II	94	110	102.20	4.17		
5 min	Group I	90	104	94.67	4.15	−2.33	0.032*
	Group II	90	104	97.00	4.09		
10 min	Group I	82	96	89.73	3.85	−2.46	0.011*
	Group II	84	98	92.20	3.46		
15 min	Group I	78	92	85.40	4.40	−2.13	0.037*
	Group II	80	92	87.53	3.27		
30 min	Group I	76	88	81.73	4.32	−0.80	0.48
	Group II	76	90	82.53	4.49		
60 min	Group I	72	88	80.00	4.14	−2.00	0.09
	Group II	72	92	82.00	4.81		
90 min	Group I	68	86	80.53	4.17	−1.73	0.18
	Group II	68	88	82.27	5.65		
120 min	Group I	72	90	84.53	5.33	1.4	0.31
	Group II	72	90	83.13	5.40		

I recorded an average VAS score of 1.60 ± 0.621, whereas Group II had a score of 1.87 ± 0.730. At 8 hours, the average VAS score for Group I was 2.60 ± 0.621, and for Group II, it was 2.87±0.507. At the 12-hour mark, Group I's average VAS score was 1.87±0.629, in contrast to Group II's score of 2.07±0.691. Finally, at 24 hours, the average VAS score for Group I was 2.60±0.621, while Group II recorded a score of 2.67±0.479.

Table 6. Comparison of the mean oxygen saturation between the groups using independent sample t test

Time intervals	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
Baseline	Group I	96	99	97.37	0.81	0.10	0.609
	Group II	96	99	97.27	0.69		
5 min	Group I	97	99	98.03	0.49	0.067	0.57
	Group II	97	99	97.97	0.41		
10 min	Group I	98	99	98.26	0.44	−0.06	0.58
	Group II	98	99	98.33	0.47		
15 min	Group I	98	99	98.27	0.45	−0.20	0.112
	Group II	98	99	98.47	0.51		
30 min	Group I	98	99	98.47	0.51	−0.03	0.80
	Group II	98	99	98.50	0.51		
60 min	Group I	98	99	98.33	0.48	−0.167	0.197
	Group II	98	99	98.50	0.51		
90 min	Group I	98	99	98.50	0.51	−0.033	0.80
	Group II	98	99	98.53	0.51		
120 min	Group I	98	99	98.50	0.50	0.07	0.44
	Group II	98	99	98.43	0.50		

Discussion

The aim of this study was to evaluate the effectiveness and safety of epidural 0.125 % bupivacaine combined with 50mg $MgSO_4$, compared to 0.125 % bupivacaine with 50mg tramadol, for managing post-operative pain. A total of 60 patients classified as ASA-I and ASA-II were randomly divided into two groups, Group I and Group II, each containing 30 patients. Randomization was performed using computer-generated random numbers. Group I received an epidural injection of 0.125 % bupivacaine with 50mg tramadol (9 ml), while Group II was given an epidural injection of 0.125 % bupivacaine with 50mg MgSO4 (9ml).

After the epidural bolus, if the Visual Analog Scale (VAS) indicated a score above 3, a single 9 ml dose of 0.125 % bupivacaine (8ml) combined with 50mg tramadol (1ml) or 0.125 % bupivacaine (8 ml) with 50mg $MgSO_4$ (1ml) was administered through the epidural catheter as a rescue analgesic bolus. Pain relief was assessed at regular intervals over the next 24 hours in both groups. The analgesic effectiveness was evaluated using several criteria, including the onset of analgesia, duration of analgesia, quality of analgesia, and the time taken to administer the first rescue analgesic.

While previous studies have compared various local anesthetics and different opioids as additives for epidural analgesia, there is limited literature specifically addressing the

Table 7. Comparison of the mean vas scores between the groups using independent sample t test

Time intervals	Groups	Minimum	Maximum	Mean	Standard deviation	Mean diff	P value
2 hrs	Group I	0	1	0.40	0.498	−0.067	0.61
	Group II	0	1	0.47	0.507		
4 hrs	Group I	2	4	2.87	0.730	−0.067	0.718
	Group II	2	4	2.93	0.691		
6 hrs	Group I	1	3	1.60	0.621	−0.267	0.133
	Group II	1	3	1.87	0.730		
8 hrs	Group I	2	4	2.60	0.621	−0.267	0.074
	Group II	2	4	2.87	0.507		
12 hrs	Group I	1	3	1.87	0.629	−0.20	0.246
	Group II	1	3	2.07	0.691		
24 hrs	Group I	2	4	2.60	0.621	−0.067	0.64
	Group II	2	3	2.67	0.479		

comparison of tramadol and magnesium sulfate as additives to bupivacaine for postoperative pain relief.

Chowdary et al., compared the effects of MgSo4 and fentanyl when used alongside bupivacaine for lower abdominal surgeries. They randomly assigned 75 patients into three groups, each receiving a distinct treatment: one group was given 20ml of 0.5% bupivacaine alone, another group received 19ml of bupivacaine mixed with 500mg of MgSO4, and the final group was administered 19ml of bupivacaine with 50mcg of fentanyl. The results showed that the onset of sensory block at the T8 level was faster in Groups M and F, with times of 14.2±2.5 minutes and 13.8±2.2 minutes, respectively, compared to Group C, which took 18.5±3.1 minutes. In terms of sensory loss, 12 patients (48.0%) in Group M experienced it within 11–15 minutes, while 15 patients (60.0%) in Group F did so, in contrast to 12 patients (48.0%) in Group C who took 16–20 minutes. This difference was statistically significant ($p < 0.05$). Additionally, the duration of sensory block was longer in Group M than in Groups F and C. The time until the first request for analgesia was recorded as 479.5±48.1 minutes for Group M, 385.7±34.2 minutes for Group F, and 225.3±39.2 minutes for Group C. The total analgesic requirement (pethidine 1.5mg/kg) over 24 hours was 86.35±11.72 mg for Group M, 166.26±30.53 mg for Group F, and 220.86±31.61 mg for Group C (6).

In our research, Group I received an epidural injection of Bupivacaine 0.125% combined with 50mg of tramadol (9ml), while Group II was given an epidural injection of Bupivacaine 0.125% with 50mg of MgSO4 (9ml). The magnesium group recorded a duration of analgesia of 270.6±37.2 minutes. This difference in analgesia duration may be due to the higher concentration of bupivacaine, the increased dosage of magnesium, and the larger total volume administered in the previous study.

In their study on high tibial osteotomy orthopedic procedures, Salman et al. examined how epidural magnesium sulfate affects postoperative pain perception and serum B endorphin levels. They divided 60 patients into two groups of thirty. The control group received epidural bupivacaine 0.5%, lidocaine 2%, and saline, while the magnesium group was given epidural bupivacaine, lidocaine, and magnesium sulfate (50 mg/10 ml saline). The findings revealed that the magnesium group had a significantly longer time before their first request for pain relief compared to the control group ($P < 0.05$). Additionally, the magnesium group made fewer total analgesic requests than the control group ($P = 0.003$). Four hours after the epidural injection, B endor-

phin levels in the magnesium group were significantly lower than in the control group (P = 0.004). The authors concluded that adding magnesium sulfate 50 mg/10 ml saline to epidural bupivacaine/lidocaine improves postoperative pain relief and reduces serum B endorphin levels shortly after surgery without increasing complication risks in high knee osteotomy orthopedic procedures (8).

Consistent with this research, our study employed 50 mg of magnesium sulfate alongside 0.125% bupivacaine for postoperative epidural analgesia. Group I received an epidural injection of Bupivacaine 0.125% combined with 50 mg of tramadol (9 ml), while Group II was given an epidural injection of Bupivacaine 0.125% with 50 mg of $MgSO_4$ (9 ml). We observed effects similar to those found in the previous study, although they were less pronounced than those seen in the group that received 50 mg of tramadol for postoperative epidural analgesia.

In our study, Group I received an epidural injection of Bupivacaine 0.125% mixed with 50mg of tramadol (9ml), while Group II was given an epidural injection of Bupivacaine 0.125% combined with 50mg of $MgSO_4$ (9ml). As a result, Group I can be compared to group-B in the previously mentioned study. Both groups showed a reduction in VAS scores after surgery (0.125% bupivacaine + 50mg tramadol versus 0.125% bupivacaine + 50mg magnesium sulphate). The average VAS score recorded 12 hours after surgery in the tramadol group was 1.87±0.629, which is slightly higher than the score reported in the earlier study. This difference may be due to the smaller volume of medication used in our research (9ml compared to 30ml in the previous study), even though the concentration of bupivacaine was the same at 0.125% in both studies. Osama Helal Ahmed et al. compared Magnesium Sulphate and Fentanyl as adjuvants to Epidural Levobupivacaine in surgeries below the umbilicus. Magnesium sulphate is noted for its quicker onset of epidural block effects and a lower incidence of nausea, vomiting, and itching, while fentanyl, despite its longer half-life, is associated with a higher rate of these side effects. The study concluded that both magnesium sulphate and fentanyl are effective adjuvants when used epidurally with local anaesthetics. Although fentanyl offers a longer duration of pain relief compared to magnesium sulphate, it is also linked to a higher occurrence of nausea, vomiting, and itching, whereas magnesium sulphate may lead to more pain at the injection site. In this study, 14 ml of levobupivacaine 0.5% was combined with 50 mg of magnesium sulphate. The average time until the first rescue analgesia in group M was 294.98±21.67, and the mean VAS score at the 6th hour for this group was 3.85±0.33 (9).

Based on this research and considering the adverse effects linked to fentanyl, we categorized our patients into two groups: Group I received a mixture of 0.125% bupivacaine and 50mg tramadol, while Group II was treated with 0.125% bupivacaine combined with 50mg magnesium sulphate. In the tramadol group, 13.3% experienced postoperative nausea and vomiting, and 3.3% reported itching. Conversely, the magnesium group had 6.7% experiencing bradycardia and 13.3% showing hypotension. We administered 0.125% bupivacaine along with 50mg magnesium sulphate. The average time until the first rescue analgesia in the magnesium group was 300.0±0.62 minutes, and the mean VAS score at the sixth hour for this group was 1.87±0.73. The lower VAS observed in our study compared to previous research may be attributed to the bolus dose given during the fourth hour in response to a higher VAS. Agrawal et al. compared 50mg Tramadol and 5mg Nalbuphine as additives to 0.125% Bupivacaine for postoperative epidural analgesia, concluding that the addition of 5mg Nalbuphine to 0.125% Bupivacaine results in a quicker onset and longer duration of sensory blockade, enhanced pain relief with a lower VAS score, without causing motor blockade, while maintaining stable hemodynamic parameters and reducing the occurrence of side effects such as hypotension, bradycardia, nausea, and itching, compared to the use of 50mg Tramadol as an additive for postoperative analgesia via epidural catheter after TKR and THR surgeries. In the tramadol group, the mean VAS at the fourth hour was recorded at 2.8 (9).

Our findings indicated that the tramadol group offered a higher quality of analgesia, although this difference was not statistically significant. Participants in the tramadol group demonstrated better control of SBP, DBP, and HR at 5, 10, and 15 minutes post-surgery, but they were also more susceptible to postoperative nausea and vomiting. The mean VAS at the fourth hour was noted.

Shilpashri AM et al. compared the effects of 0.25% Ropivacaine with Tramadol against 0.25% Bupivacaine with Tramadol in lower limb and abdominal surgeries. The study aimed to assess postoperative epidural analgesia by evaluating the analgesic effectiveness of Bupivacaine and Ropivacaine in conjunction with Tramadol, focusing on analgesia quality, duration, and potential side effects. The mean onset times and quality of analgesia were similar in both groups. However, a significant drop in blood pressure was noted when comparing Group I to Group RT. The researchers concluded that Ropivacaine with Tramadol offered comparable and effective analgesia to Bupivacaine with Tramadol, but with a longer

duration, less cardiovascular depression, and no motor blockade. In Group I, the average duration of analgesia was 356.00 ± 49.03 minutes (10).

In our study, we evaluated the analgesic effectiveness of 0.125% Bupivacaine combined with 50mg Tramadol and 50mg Magnesium Sulphate, which produced similar results. Group I received an epidural injection of 0.125% Bupivacaine with 50mg Tramadol (9ml), while Group II was given an epidural injection of 0.125% Bupivacaine with 50mg $MgSO_4$ (9ml). The mean duration of analgesia in the Tramadol group was 309.6 ± 43.2 minutes. This variation in duration may be due to the lower concentration of Bupivacaine used in our study (0.125%) compared to the previous study (0.25%).

Sudhir Patil et al., compared the postoperative analgesic effectiveness of epidural Fentanyl-50 mcg (group A) against epidural Tramadol-50 mg (group B), both given as bolus doses with 0.125% Bupivacaine in a study involving 60 patients undergoing lower abdominal surgeries. The results showed that the average duration of analgesia after the epidural bolus in group A was significantly longer than in group B. Furthermore, the postoperative VAS score for group A was lower than that for group B, while hemodynamic parameters remained stable in both groups. The study concluded that patients undergoing lower abdominal surgeries had a better response to epidural fentanyl combined with bupivacaine, leading to a longer postoperative analgesic effect and fewer complications compared to tramadol with bupivacaine. In this study, the tramadol group received 50 mg of Tramadol and 8 ml of 0.125% Bupivacaine as a bolus, resulting in a mean VAS score of 2.26 at the fourth hour and an average analgesic duration of 378.64 minutes (11).

In our study, we replaced 50 mg of magnesium sulphate with 50 μg of fentanyl to assess the analgesic efficacy, side effects, and hemodynamic stability after surgery. Our findings revealed that the quality of analgesia was better in the tramadol group, although this difference was not statistically significant. The management of SBP, DBP, and HR was more effective in the tramadol group at 5, 10, and 15 minutes postoperatively, with these results being statistically significant. Consistent with the previous study, we administered 50 mg of Tramadol and 8 ml of 0.125% Bupivacaine in the tramadol group, yielding a mean VAS score of 2.87 at the fourth hour and an average analgesic duration of 309.6 minutes.

Dipti Saxena et al., performed a comparative study on in 40 patients, divided into two groups (Group A and Group B) to assess the effectiveness, safety, tolerability, and side effects of tramadol and bupivacaine when used together for managing post-operative pain after lower limb surgeries. Group A received epidural bupivacaine at a concentration of 0.5%, while Group B was given both epidural bupivacaine 0.5% and tramadol at a dose of 50 mg. Patients in the tramadol group experienced a significantly longer duration of pain relief. Additionally, those receiving tramadol reported better quality of pain relief and lower pain scores. The inclusion of tramadol notably decreased the total medication dosages required. The results indicate that tramadol is a safe and effective complement to epidural bupivacaine, extending the duration of analgesia during lower limb surgeries. In Group B, a combination of 20 ml of 0.5% bupivacaine and 50 mg of tramadol was administered. The average number of analgesic doses for Group A was 5.05±0.89, compared to 2.05±0.61 for Group B. A verbal rating scale was used to evaluate postoperative pain (12).

In our study, the magnesium group showed poorer results in terms of pain relief quality compared to the tramadol group. The tramadol group received a regimen of 50 mg of tramadol along with 8 ml of 0.125% bupivacaine. The total number of rescue analgesics used in the tramadol group was 3.47±0.51. This difference may be due to the lower concentration (0.125%) and smaller volume (8 ml) of the local anesthetic used. We employed a Visual Analog Scale (VAS) to evaluate postoperative pain relief, while the.

In our study, we compared the effects of 50 mg of magnesium sulfate against 50 mg of tramadol combined with 0.125% bupivacaine for managing postoperative pain. The tramadol group demonstrated superior analgesic quality but reported a higher incidence of nausea and vomiting, whereas the magnesium group experienced side effects like bradycardia and hypotension. The average duration of analgesia after the initial dose was 5.16± 0.72 hours, with variations likely due to the different tramadol dosages used.

Anurag Yadava et al. evaluated the effectiveness of bupivacaine, tramadol (100 mg), and magnesium sulfate (50 mg/kg) in managing pain following laparoscopic cholecystectomy. This study involved 180 patients divided into two groups of 90. The mean VAS pain score was significantly higher in the TB group than in the MB group at 1, 2, 4, 6, and 24 hours post-surgery ($P<0.05$). Additionally, the total amount of rescue analgesia consumed in the first 24 hours post-surgery was statistically significant ($P<0.05$), with the TB group averaging 2.4 g of paracetamol compared to 1.4 g in the MB group. The time to the first rescue analgesia in group TB was 4.94 hours, while it was 7.39 hours in group MB. Furthermore, the mean time interval for the first request for rescue analgesia (paracetamol)

was significantly longer in the MB group compared to the TB group (P<0.05) (13).

In our study, we assessed the pain-relieving efficacy of 0.125% bupivacaine in combination with 50mg tramadol and 50mg magnesium sulphate for postoperative pain management via epidural boluses. The results showed that the tramadol group had a higher quality of pain relief, although this difference was not statistically significant. At 5, 10, and 15 minutes after surgery, participants in the tramadol group exhibited better control over systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR), with these results being statistically significant. The average duration until the first rescue analgesia was 5.26±0.71 hours for Group I and 4.61±0.62 hours for Group II. The difference in the mean time to the first rescue analgesia observed in this study may be linked to the different methods of drug administration and the concentrations of the medications used.

In our investigation, we compared two groups: one received 50 mg tramadol with 0.125% bupivacaine, while the other was given 50mg magnesium sulphate with 0.125% bupivacaine. We evaluated the quality of analgesia and the side effects reported by participants in both groups. In the tramadol group, 13.3% of participants experienced nausea and vomiting, and 3.3% reported pruritus. As a result, the combination of 50 mg tramadol with 0.125% bupivacaine was found to be more effective.

Vaibhav Shahi et al. conducted a study to explore the effects of adding magnesium or dexmedetomidine as an adjunct to epidural bupivacaine in lower limb surgeries. A total of 120 patients were randomly assigned to Groups M, D, and C and received their treatments via the epidural route. Group M was administered Bupivacaine 0.5% (14ml) along with magnesium sulphate 50mg (diluted in 1ml of 0.9% saline), Group D received Bupivacaine 0.5% (14ml) plus dexmedetomidine 0.5 μcg/kg (in 1ml of 0.9% saline), and Group C was given Bupivacaine 0.5% (14ml) with saline 0.9% (1ml). In the magnesium group, hypotension occurred in 60% of patients, while bradycardia was noted in 15% of patients (14).

In our study, we investigated the effectiveness of epidural postoperative analgesia using a combination of 0.125% bupivacaine and 50mg $MgSO_4$, compared to 0.125% bupivacaine with 50mg tramadol for lower limb surgeries. The results showed that the tramadol group experienced better analgesic quality, although this difference was not statistically significant. In the magnesium group, hypotension occurred in 13.3% of patients, while bradycardia was observed in 6.7% of patients. Our research reported fewer side effects than the previous study, which may be due to the lower concentration of bupivacaine used in our investigation, even though the magnesium dosage was consistent across both studies.

Conclusion

Tramadol proved to be more effective than magnesium when combined with bupivacaine, as it led to a faster onset of pain relief, prolonged the duration of analgesia, and decreased the requirement for extra rescue epidural top-up doses within a 24-hour timeframe.

Ethics statement

Consent was obtained by all participants in this study.

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Порівняння післяопераційної епідуральної аналгезії бупівакаїном із додаванням 50 мг сульфату магнію та бупівакаїном із додаванням 50 мг трамадолу у пацієнтів, які перенесли операції на нижніх кінцівках

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Анотація

Передумови. *Ефективність комбінації епідурального бупівакаїну із сульфатом магнію порівняно з бупівакаїном у поєднанні з трамадолом у післяопераційному знеболенні залишається суперечливою. Метою цього дослідження було оцінити ефективність післяопераційної епідуральної аналгезії із застосуванням 0,125 % бупівакаїну з 50 мг $MgSO_4$ у порівнянні з 0,125 % бупівакаїном із 50 мг трамадолу в пацієнтів після операцій на нижніх кінцівках.*

Методи. *60 пацієнтів із класифікацією ASA I–II були випадковим чином розподілені на дві групи по 30 осіб. Група I отримувала 9 мл 0,125 % бупівакаїну (8 мл) у поєднанні з 50 мг трамадолу (1 мл). Група II отримувала 9 мл 0,125 % бупівакаїну (8 мл) із 50 мг $MgSO_4$ (1 мл). Ефективність аналгезії оцінювали за такими параметрами: час настання аналгезії, тривалість аналгезії, її якість та час до потреби в першій додатковій дозі аналгетика.*

Результати:
Час настання аналгезії: • Група I — 6,67 ± 0,80 хв, • Група II — 7,67 ± 0,80 хв (p = 0.001).
Тривалість аналгезії: • Група I — 5,16 ± 0,72 год, • Група II — 4,51 ± 0,62 год (p = 0.001).
Час до потреби в першій додатковій дозі: • Група I — 5,260 ± 0,716 год, • Група II — 4,617 ± 0,622 год (p = 0.001).
Потреба в рятівних дозах за 24 години: • Група I — 3,47 ± 0,51, • Група II — 3,97 ± 0,49.
Якість аналгезії не відрізнялася статистично значущо між групами.
Побічні ефекти: • Група I — нудота і блювання у 4 пацієнтів, свербіж у 1 пацієнта. • Група II — гіпотензія у 4 пацієнтів, брадикардія у 2 пацієнтів.
Гемодинамічні показники мали незначні статистично значущі відмінності на 5, 10 та 15 хвилинах. Показники VAS (0–10) у післяопераційний період до 24 годин були схожими між групами.

Висновок. *Трамадол виявився більш ефективним за магній при комбінуванні з бупівакаїном: він забезпечував швидший початок знеболення, тривалішу аналгезію та зменшував потребу в додаткових епідуральних дозах протягом 24 годин.*

Ключові слова: *бупівакаїн, трамадол, сульфат магнію, операції на нижніх кінцівках, післяопераційна аналгезія.*