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The role of low dose ketamine plus magnesium sulfate infusion versus dexmedetomidine infusion on postoperative pain in posterior spinal fusion surgery: Prospective randomized study

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Abstract

Background: The fusion technique is often used to preserve the lumbar spine, reduce spinal cord injury, stabilize the spine, and relieve pain. The study compared the pain after posterior spinal fusion (PSF) surgery with small dosages of ketamine and magnesium sulfate ($MgSO_4$) with dexmedetomidine infusion.

Methods: This prospective randomized double-blind trial included 90 patients aged 21–60, both sexes, who were eligible for nontraumatic elective posterior spinal fixation surgery with two to five levels. Two equal groups of patients were formed: Group Ketamine and magnesium (KM): patients received low-dose KM sulfate (0.2 mg/kg bolus over 10 minutes, 0.12 mg/kg/hr. + Mg sulfate: 30 mg/kg bolus, 10 minutes, 8 mg/kg/hr) and Group Dexmedetomidine (D): patients received 0.5 μ g/kg bolus over 10 minutes, 0.2 μ g/kg/hr.

Results: Numerical rating scale was insignificantly different at any time 24 hrs postoperatively between the two groups ($p > 0.05$). The 1st time to rescue analgesia and total dose of opioid were insignificant difference between the two groups. Group D had a significant elevation in sedation levels (as measured by the Ramsey scale) in comparison to group KM.

Conclusions: The use of ketamine plus magnesium sulphate or Dexmedetomidine as intraoperative infusion in PSF surgeries is effective in controlling pain, delaying 1st time of rescue analgesia, decreasing opioid consumption without any significant difference between the two groups as regard demographic data, level of pain control, 1st time to rescue analgesia or total dose of opioids except postoperative sedation which was more in group D than group KM.

Keywords: Ketamine, magnesium sulfate, dexmedetomidine, postoperative, pain, spinal fusion surgery

Introduction

Pain management not only diminishes the amount of pain that a patient experiences, but it also lowers the risk of death, facilitates a patient's fast discharge from the hospital, enhances the patient's quality of life, and lowers the costs that the hospital incurs [1]. In order to effectively control postoperative pain, a multimodal approach that incorporates a number of medications with distinct mechanisms of action is required [2].

Following spine surgery, a wide range of therapeutic alternatives are available to reduce postoperative pain, and each option has particular benefits. One of those options is the injection of opioids either before to or during the surgical procedure [3]. When it comes to alleviating postoperative pain, medications like dexmedetomidine and ketamine are among those that can be utilized after surgical procedures [4].

As a non-competitive NMDA receptor blocker, ketamine is able to exert its effects. It accomplishes this by lowering the activation of NMDA receptors in both the CNS and the peripheral nervous system. Ketamine is capable to exercise its effects [5]. It is possible to administer intraoperative subanesthetic dosages of ketamine in order to reduce hyperalgesia as well as postoperative acute and chronic pain from the procedure. Inhibiting the wind-up effect, which takes place when NMDA receptors are blocked, is the means by which this is accomplished [6].

A number of different mechanisms of action are exhibited by magnesium sulfate (MgSO₄) when it is employed as an adjuvant to general anesthesia. These mechanisms include the reduction of central excitability through the blockade of NMDA receptors, the delay of the formation of opioid tolerance, and the effects on the balance of neurotransmitters [7, 8].

As a consequence of its action on alpha 2 receptors in the CNS and its blocking effect on the posterior spinal cord, dexmedetomidine is capable of producing analgesic effects. These outcomes are a result of the drug's ability to induce analgesic effects simultaneously [9]. The fusion procedure is commonly performed because of its ability to provide various benefits, including pain relief, prevention of potential degeneration of the lumbar spine, protection of the spinal cord from stress, and stabilization of the spine [10].

A wide range of benefits, such as the treatment of pain, the avoidance of future degeneration of the lumbar spine, the avoidance of stress to the spinal cord, and the stabilization of the spine, are among the many reasons why the fusion procedure is widely performed [11].

The goal of the study was to explore the impact of low-dose ketamine and magnesium sulfate (MgSO₄) infusions on postoperative pain in PSF surgery in contrast to the impacts of dexmedetomidine infusion pertaining to pain following surgical procedures.

Patients and Methods

This study was carried out on 90 patients, aged 21 to 60 years old, of both sexes, who were suitable for nontraumatic elective posterior spinal fixation surgery. The patients belonged to the American Society of Anesthesia (ASA) class I-II and required a minimum of two and a maximum of five levels of surgery. The study was conducted between November 2022 and April 2023, following approval from the Ethical Committee of Tanta University Hospitals in Tanta, Egypt. The patients provided their informed written permission. The patient data was securely stored with encrypted codes and individual private files for each participant, ensuring confidentiality. The provided data was exclusively utilized for this research.

All unknown dangers encountered throughout the research were promptly communicated to both the participants and the Ethical Committee. For the purpose of protecting the patients' privacy and maintaining the confidentiality of their data, a unique code number was assigned to each individual patient, and they were given an explanation on the purpose of the study. The exclusion criteria encompassed patients who had undergone posterior spinal fixation surgery for traumatic fractures, individuals with a history of chronic mental disorders, seizures, or raised intracranial tension, and those with systemic diseases affecting the cardiovascular system, liver, kidneys, lungs, infectious conditions, neuromuscular disorders, addiction, and patients receiving chronic opioid therapy for pain management.

Drugs preparation

- **Ketamine:** 50 mg of ketamine completed to 50 cc with normal saline so each ml contains 1 mg of ketamine.
- **Magnesium sulphate:** 1 gm of Mg completed to 50 cc with normal saline so each ml contains 20 mg of Mg.
- **Dexmedetomidine:** 100 µg of Dexmedetomidine completed to 50 cc with normal saline so each ml contains 2 µg of Dexmedetomidine.

Randomization and Blindness

Following the completion of the registration process, the patients were distributed in a random manner to opaque envelopes that were sealed and then separated into two equal groups using computer-generated tables. The patients were separated into two groups of equal sizes, as follows: Patients were allocated to the KM group, comprising individuals who were administered a small dosage of ketamine and magnesium sulfate. Both general anesthesia and a bolus of 0.2 mg/kg of ketamine given over a period of ten minutes were included in the administration process. Subsequently, a constant infusion of 0.12 mg/kg/hr was administered. A bolus dose of 30 mg/kg of magnesium sulfate was administered during a 10-minute period, followed by a continuous infusion of 8 mg/kg/hr. On the other hand, Group D consisted of patients who were administered Dexmedetomidine. General anesthesia was administered along with a Dexmedetomidine bolus of 0.5 µg/kg over 10 minutes, and then a continuous infusion of 0.2 µg/kg/hr was started. A blinded anesthesia resident, who was not participating in the study groups, assisted in collecting the postoperative measured data.

Anesthetic Management

Prior to surgery, all patients underwent an extensive assessment including a detailed medical history, general and local examination, and standard laboratory tests. The patients avoided from consuming sedatives or narcotics on the evening before the surgical procedure. All necessary preparations for intubation, resuscitation, and medication were made in the operating room. Standard monitoring was initiated upon the patients' arrival in the surgery room. This included the use of electrocardiography, pulse oximetry, a temperature probe, and non-invasive blood pressure monitoring to assess the systolic, diastolic, and mean arterial blood pressure. An 18-gauge needle was used to introduce a cannula intravenously. The lactated Ringer's solution was administered at a starting dose of 0.5 ml/kg and thereafter infusion was maintained at a rate of 4 ml/kg/hour. Preoxygenation was performed for a duration of 5 minutes prior to the administration of anesthesia. Anesthesia protocol in the two groups was identical, induction was done by IV 25 µg/kg midazolam, 1 µg/kg fentanyl, 2 mg/kg propofol, 0.5 mg/kg atracurium and then endotracheal intubation was done. Temperature probes and capnography were applied to the patient. Another IV cannula was inserted for drug infusion. Anesthesia was maintained using isoflurane at 1-2 MAC (with a target BIS range of 40-60) and 0.1 mg/kg atracurium bolus every 20-30 minutes. To keep the end tidal CO₂ between 32 and 36 mmHg and the tidal volume between 6 and 8 ml/kg, the mechanical ventilation was customized. The bolus dose of the study drugs was given just after intubation followed by the maintenance dose infusion. Any event of hypotension (30% reduction in BP compared to baseline or MAP <50 mmHg) was treated with bolus of IV fluid, and/or bolus doses of ephedrine 5 to 10 mg IV repeated in 5 to 10 minutes if needed. Bradycardia, defined as a heart rate decrease of more than 30% relative to the baseline or a heart rate lower than 50 beats per minute, was managed by administering an intravenous bolus of atropine at a dose of 0.01 mg/kg. This treatment was repeated as necessary for patients who did not respond to the initial dose. If there was an occurrence of tachycardia or hypertension during the surgery that resulted

in a greater than 30% rise relative to the baseline, it was addressed by administering a single dose of 50 µg fentanyl. Following the surgery, all patients were administered 10 mg/kg of paracetamol and 4 mg of ondansetron intravenously. This dosage was repeated every 6 hours after the operation.

Before skin closure, discontinuation of ketamine, Mg and dexmedetomidine infusions. By the end of surgery, closure of the inhaled anaesthetic and reversal of action of muscle relaxant using IV neostigmine (0.05mg/kg) + IV atropine (0.01mg/kg). Extubation was done after fulfillment of its criteria and then patient was transferred to PACU.

Measurements

The postoperative pain was the primary outcome and it was assessed and recorded by numerical rating scale (NRS) ^[11] [0: no pain, (0-3) mild pain, (4-6) moderate pain and (>6) severe pain]. In postoperative period, NRS was recorded at 30 min after recovery, 2hrs, 6hrs, 12hrs, 18hrs and 24 hours postoperatively. The secondary outcomes were the first time when the patient needs rescue analgesia, the entire morphine dose in the 1st 24 hours, level of sedation evaluated by Ramsey scale, patient satisfaction, intraoperative and postoperative complication (hypotension, bradycardia, delirium, agitation, nausea or vomiting).

The sedation level was evaluated using the Ramsey scale ^[12] 30 minutes after recovery, 2hrs, 6hrs, 12hrs, 18hrs, and 24 hours postoperatively from 1 to 6; [The patient displays symptoms of anxiety and agitation. The patient is cooperative and aware of their surroundings. The patient only responds to commands. The patient shows a quick response to a light tap on the glabella or a loud auditory stimulus. The patient shows a slow response to a light tap on the glabella or a loud auditory stimulus. The patient does not exhibit any response.

If the NRS is more than 4, intravenous morphine titration is provided as a bolus of 2mg (for individuals with a body weight of 60 kg or less) or 3 mg (for individuals with a body weight greater than 60 kg), with a 5-minute gap between each bolus. ^[13]. The average morphine demand in the first 24 hours is calculated by subtracting the age of the patient from 100 and expressing the result in mg ^[14]. Pain relief was defined as NRS<4.

Sample Size Calculation

The Epi-Info software statistical program, which was developed by the WHO and the Center for Disease Control and Prevention, that is founded in Atlanta, Georgia, in the United States of America, was utilized in order to determine the sample size and conduct the power analysis. It was the year 2002 that was used. The following are the criteria that were applied in the process of computing the sample size: The extent of the study's power is 80%, and its confidence level is 95%. The anticipated efficacy of pain management in the favorable treatment group was 90%, while it was 65% in the least favorable treatment groups.

It was found that the sample size for each group must be equal to N=44, based on the previously described parameters. To address the issue of incomplete results, the researcher augmented the sample size to 45 cases. The patients that were registered were systematically divided into two equal groups (45 patients in each group) using a computer-generated table and then randomly assigned to sealed opaque envelopes.

Statistical analysis

Utilizing the SPSS v26 program (IBM Inc., Chicago, Illinois, United States of America), the statistical analysis was carried out through the utilization of histograms and the Shapiro-Wilks test, it was possible to ascertain whether or not the data distribution in question was normal. The mean and standard deviation (SD) of the quantitative parametric variables were calculated using an unpaired Student's t-test. A comparison was made between the two groups immediately. The study offered quantitative non-parametric data and employed the Mann Whitney test to analyze the data. The present analysis employed the median and the interquartile range (IQR). Depending on the specifics of the situation, either The Chi-square test or Fisher's exact test was employed to analyze qualitative characteristics. The values for the qualitative variables were given as the frequency as well as the percentage for each variable. It was necessary to have a two-tailed P value that was less than 0.05 in order for the conclusion to be judged statistically significant.

Results

A total of 100 patients were evaluated for their suitability in this study. Out of them, 8 patients were found ineligible due to specific reasons: 3 patients experienced chronic pain and 5 patients were already on opioid therapy. In addition, two patients decided not to participate in the study. Subsequently, the remaining 90 patients were randomly allocated into two equal groups, each consisting of 45 patients. Every assigned patient was monitored and assessed using statistical methods.

Table 1: Demographic data and duration of surgery of the studied groups

		KM group (n=45)	D group (n=45)	P*
Age (years)		40.58±9.64	40.49±9.32	0.965
Sex	Male	25 (55.6%)	26 (57.8%)	0.832
	Female	20 (44.4%)	19 (42.2%)	
Weight (Kg)		87.27±6.78	88.0±5.78	0.582
Duration of surgery(hrs)		2.82±1.01	2.82±0.99	0.964

Data are presented as mean ± SD or frequency (%). Group KM: Ketamine and magnesium, Group D: Dexmedetomidine.

Both groups did not differ significantly from one another in terms of demographic data or the surgery time. Table (1)

It was determined through the comparison of the NRS between the two groups that there was no statistically significant difference at any point in time 24 hours after the operation (p value greater than 0.05).

In group KM: There were statically significant increase in mean values of NRS in group KM at 2hrs, 12hrs, 18hrs, 24hrs compared to NRS at 30 min. postoperatively (P value<0.05)

But there was insignificant change in NRS at 6 hrs. Compared to that at 30 min postoperatively.

In group D: There were statically significant increase in mean values of NRS in group D at 2hrs, 12hrs, 18hrs, 24hrs compared to NRS 30 min. postoperatively (P value<0.05)

But there was insignificant change in NRS at 6 hrs. Compared to that at 30 min postoperatively.

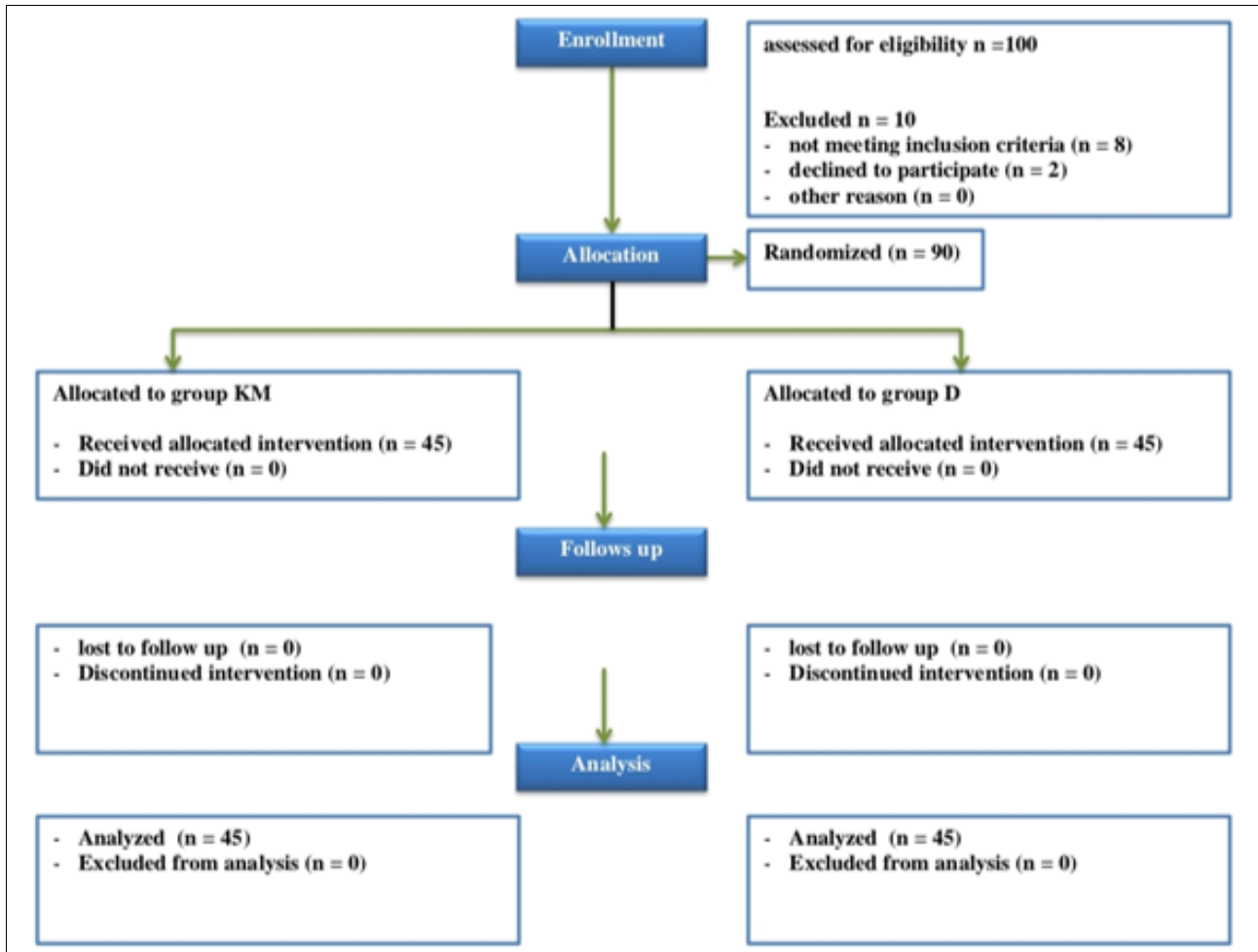


Fig 1: CONSORT Flowchart of the studied patients

Comparison between the two studied groups according to NRS

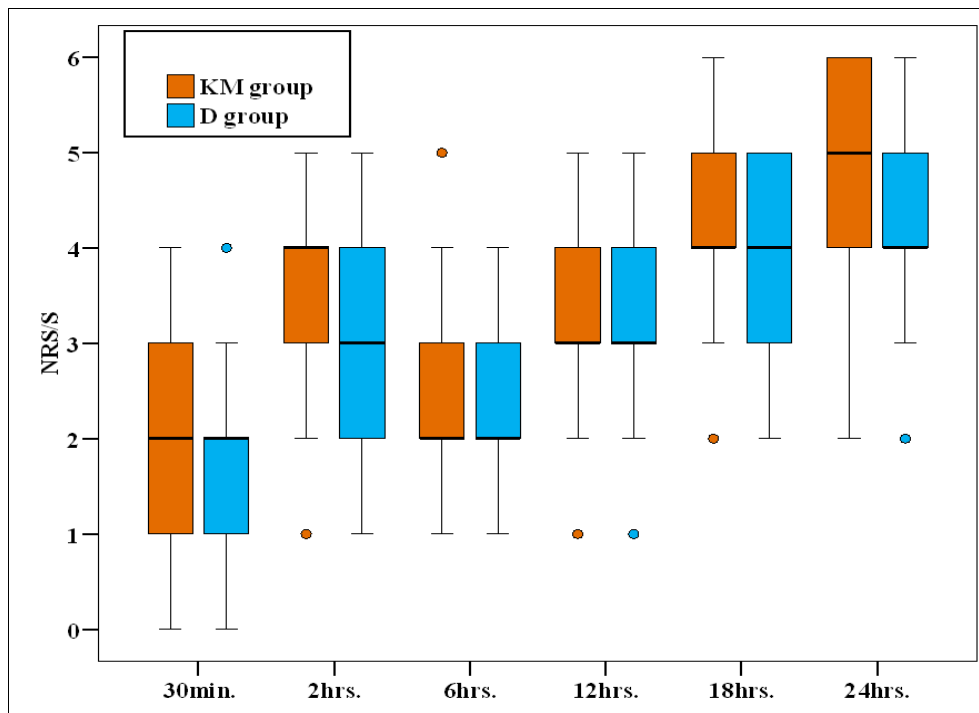


Fig 2: Comparison between the two studied groups according to NRS

Table 2: Comparison between the two studied groups according to RAMSY scale:

Ramsey scale	KM (n = 45)	Group D (n = 45)	U	P*
30min.				
Min. -Max.	1.0 – 4.0	1.0 – 5.0	452.500*	<0.001*
Mean ±SD.	2.09 ± 0.85	3.13 ± 0.97		
Median (IQR)	2.0 (1.0 – 3.0)	3.0 (3.0 – 4.0)		
2hrs.				
Min. -Max.	1.0 – 2.0	1.0 – 4.0	217.500*	<0.001*
Mean ±SD.	1.67 ± 0.48	2.84 ± 0.71		
Median (IQR)	2.0 (1.0 – 2.0)	3.0 (2.0–3.0)		
6hrs.				
Min. -Max.	1.0 – 3.0	1.0 – 3.0	813.0	0.083
Mean ±SD.	1.73 ± 0.91	1.93 ± 0.50		
Median (IQR)	1.0 (1.0 – 2.0)	2.0 (2.0–2.0)		
12hrs.				
Min. -Max.	1.0 – 3.0	1.0 – 2.0	950.500	0.564
Mean ±SD.	1.58 ± 0.58	1.62 ± 0.49		
Median (IQR)	2.0 (1.0 – 2.0)	2.0 (1.0 – 2.0)		
18hrs.				
Min. -Max.	1.0 – 2.0	1.0 – 2.0	945.0	0.441
Mean ±SD.	1.18 ± 0.39	1.24 ± 0.43		
Median (IQR)	1.0 (1.0 – 1.0)	1.0 (1.0 – 1.0)		
24hrs.				
Min. -Max.	1.0 – 2.0	1.0 – 2.0	967.500	0.537
Mean ±SD.	1.11 ± 0.32	1.16 ± 0.37		
Median (IQR)	1.0 (1.0 – 1.0)	1.0 (1.0 – 1.0)		

IQR: Inter quartile range SD: Standard deviation U: Mann Whitney test

p: p value for comparing between the two studied groups

*: Statistically significant at $p \leq 0.05$

Group KM: Ketamine and magnesium

Group D: Dexmedetomidine

The 1st 2 hrs showed there was statically significant difference between the 2 groups in the level of sedation assessed by Ramsey scale more for group D than group KM (p value <0.05 at 30 min and 2 hrs postoperatively).

At the 6th, 12th, 18th, 24th hrs there was no statically significant difference between the 2 groups as regard Ramsey sedation scale

Table 3: Comparison between the two studied groups according to 1st time rescue analgesia and total dose of morphine consumption postoperatively:

	KM (n = 45)	Group D (n = 45)	P*
First time rescue analgesia	6.18±6.20	8.87±7.23	0.068
Total dose of opioid	(8.13±2.76)	(7.33±2.76)	0.185

Data are presented as median (IQR). *Significant p value >0.05. Group KM: Ketamine and magnesium, Group D: Dexmedetomidine.

There was no significant difference between the two study groups according to 1st time rescue analgesia and total dose of morphine consumption postoperatively.

Table 4: Comparison between the two studied groups according to patients' satisfaction and complications

	KM (n = 45)	Group D (n = 45)	P*	
Patient satisfaction	(2.69±0.90)	(2.60±0.94)	0.626	
Complications	Bradycardia	0 (0.0%)	10 (22.2%)	<0.001
	Vomiting	0(0.0%)	9(20%)	<0.003
	Hypotension	0 (0.0%)	12 (26.7%)	<0.001
	Agitation	8(17.8%)	0(0.0%)	<0.006
	Delerium	8(17.8%)	0(0.0%)	<0.006

Data are presented as mean ± SD or frequency (%). *Significant p value >0.05. Group KM: Ketamine and magnesium, Group D: Dexmedetomidine

There was no significant difference in patient satisfaction between the two groups. there was significant increase in the rate of complications in group D than group KM

Discussion

Pain is a complex phenomenon that includes various dimensions and is unique to each individual patient. Pain experience variations are shaped by biological reaction, psychological state and features, and social setting [15].

The cause of acute postoperative pain is complex and includes multiple factors. Surgical operations result in tissue damage. Surgical injury evokes a multitude of responses in the pain matrix, ranging from heightened sensitivity in the peripheral and central pain pathways to emotions such as dread, worry, and frustration.

Regarding the analgesic impact, Throughout the first day after the surgery, there was no statistically significant difference in the NRS between the two groups. Ketamine functions as a non-competitive antagonist of NMDA receptors, inhibiting their activity in both the CNS and peripheral nervous systems. The use of subanaesthetic dosages of ketamine during surgical procedures has the potential to effectively reduce hyperalgesia as well as acute and chronic postoperative pain relief. The wind-up phenomena is prevented by blocking NMDA receptors, which allows for this to be accomplished [16]. Concurring with our study, Garg *et al.* [17] reported that When either ketamine or dexmedetomidine were used as additional anesthetics during lumbar instrumentation surgery, there were no significant differences in opioid usage, VAS scores, PCA pump requirements, inhalational agent usage, and length of hospital stay. There were three groups to which 66 patients allocated for spinal surgery were randomly assigned. Participants in Group K received a 0.25 mg/kg ketamine dosage initially, and then an hourly continuous infusion of 0.25 mg/kg ketamine thereafter. Furthermore,

midazolam was given in a single dosage at a rate of 10 micrograms per kg of body weight and as a continuous infusion at a rate of 10 mcg per kilogram of body weight per hour. All these medications were combined in the same infusion pump. Group D received an initial dosage of dexmedetomidine at a concentration of 0.5 µg/kg, followed by a continuous infusion at a rate of 0.3 µg/kg/h.

Group C received regular saline. Individuals who participated in the study began taking their study medications one hour after surgery and continued for another. The difference between our study and this one was that they used ketamine-midazolam combination instead of ketamine-mg in the postoperative period. In addition, our study got support by Hassan *et al.* [18] who showed that Reducing consumption of postoperative morphine and intraoperative fentanyl was observed when magnesium was added to ketamine infusion during breast cancer procedures. Our results are in line with those of other studies showing that a combination of ketamine and magnesium infusions provides comparable pain relief as a higher dose of ketamine administered alone.

As regards the 1st time to rescue analgesia, our study showed insignificant difference between the two groups. It ranged between 30 minutes to 6 hrs postoperatively. In line with our findings, Parikh *et al.* [19] who found that postoperative pain, delayed patients' requests for analgesia, and decreased morphine were all alleviated by a small dosage of ketamine. Also, Patel *et al.* [20] who recorded that the analgesic effectiveness of dexmedetomidine was relatively significant. In the postoperative period, it was discovered that receiving dexmedetomidine infusion lowers the amount of fentanyl that is consumed.

As regard to total dose of opioid needed postoperatively, our study found that when it came to the total amount of morphine that was consumed postoperatively, neither group was significantly different from the other. Agreeing with the current study, Abdelmageed *et al.* [21] who found that The intraoperative administration of dexmedetomidine resulted in a reduction in the postoperative overall intake of morphine within the first day. In their conclusion, the authors indicated that this result provides solid evidence for the existence of an opioid sparing action that was caused by dexmedetomidine. Against our study, Anger *et al.* [22] found that When compared to propofol-based sedation medication, dexmedetomidine therapy resulted in a larger intake of analgesics, which is not consistent with the findings that we obtained. In an academic medical center, the research was conducted in a cardiac surgery intensive care unit that included 20 beds. A sedative medication consisting of either dexmedetomidine or propofol was administered to adult patients who were undergoing mechanically ventilated postcardiac surgery upon admission to the intensive care unit. It is possible that this difference is the result of variances between the medication and dexmedetomidine, as well as variations between the investigation's populations. Confirming the findings of our study Aziz *et al.* [23] conducted a study on 28 patients who had undergone cardiac operations. The subjects were assigned at random to either receive morphine or dexmedetomidine. The average dose of morphine was 13.2 µg/kg/h, while the average dose of dexmedetomidine was 0.12 µg/kg/h. According to the findings, the dexmedetomidine group showed more benefits in terms of drowsiness and pain levels, as well as increased sedative and analgesic requirements and the amount of time

required for extubation. Regarding the effect on haemodynamics, namely heart rate and blood pressure, there was an obvious reduction in both blood pressure and heart rate in group D compared to group KM during the surgery. However, there was no noticeable distinction between the two groups following the procedure. In agreement with our study, Rahimzadeh *et al.* [24] demonstrated that Dexmedetomidine had a greater effect on reducing the patient's intraoperative blood pressure and heart rate in comparison with remifentanyl. Patients ranging in age from 15 to 65 years old were considered to be candidates for PSF surgery in a clinical trial that was conducted using a double-blind, randomized testing method. In study carried out by Rokhtabnak *et al.* [25] In the comparison between dexmedetomidine and magnesium sulfate (MgSO₄), it was seen that the dexmedetomidine group had a reduced number of patients who required the administration of nitroglycerine or analgesic rescue medication. This indicates that controlling blood pressure was simpler to achieve in the dexmedetomidine group. As regard to complications; hypotension, bradycardia and PONV were more detected in group D, while agitation and delirium were observed in group KM. But in comparison with opioids, intraoperative opioids have more incidence for nausea and vomiting. Ziemann-Gimmel *et al.* [26] mentioned that Opioid-free anesthesia is a method that has been shown to lessen the occurrence and severity of PONV following bariatric surgery. In the Classic group, which consisted of 59 patients, patients were given opioids and volatile anesthetics in order to undergo general anesthesia. Patients administered opioid-free TIVA with propofol, ketamine, and dexmedetomidine were included in the total IV. anaesthesia (TIVA) group, which consisted of 60 individuals. The results we obtained were in line with the conclusions of the study. An inherent limitation of this study is the small sample size. This investigation was conducted in a single location. The number of patients who were followed up on was restricted for a relatively brief period of time. It is necessary to conduct additional comparison studies with a bigger sample size and a longer follow-up period in order to validate our findings and determine the optimal dosage of the therapeutic agent. Also, we measured postoperative pain intensity in general not in relation to rest or movement.

Conclusions

The use of KM sulphate or Dexmedetomidine as intraoperative infusion in PSF surgeries is effective in controlling pain, delaying 1st time of rescue analgesia, decreasing opioid consumption without any significant difference between the two groups.

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Conflict of Interest: Nil

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