



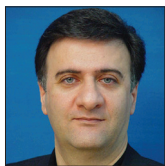
Original Article

# Effects of ketamine versus dexmedetomidine maintenance infusion in posterior spinal fusion surgery on acute postoperative pain

Nasim Nikoubakht, Mahzad Alimian, Seyed Hamid Reza Faiz, Pooya Derakhshan, Mohammad Saleh Sadri

Department of Anesthesiology, School of Medicine, Iran University of Medical Sciences, Tehran, Iran.

E-mail: Nasim Nikoubakht - nikoobakht.n@iums.ac.ir; \*Mahzad Alimian - alimian.m@iums.ac.ir; Seyed Hamid Reza Faiz - hrfaiz@hotmail.com; Pooya Derakhshan - pooyaderakh@yahoo.com; Mohammad Saleh Sadri - dr.mohamad.sadr@gmail.com



**\*Corresponding author:**

Mahzad Alimian,  
Pain Research Center,  
Anesthesiology Department,  
Iran University of Medical  
Sciences, Tehran, Iran

alimian.m@iums.ac.ir

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## ABSTRACT

**Background:** One of the most challenging issues after posterior spinal fusion (PSF) surgery is providing appropriate pain control measures to enhance recovery of the patients. We aimed to compare effects of ketamine versus dexmedetomidine infusion during maintenance of anesthesia on acute postoperative pain in PSF surgery.

**Methods:** In a double-blinded randomized clinical trial, 87 patients candidates for PSF surgery were randomly assigned into three groups. Anesthesia protocol for all groups was the same except: the first group received 0.2 mcg/kg/h dexmedetomidine infusion, the second received 0.1 mg/kg/h ketamine infusion, and control group received normal saline infusion as a placebo. Pain intensity by VAS scale and level of sedation by Ramsey scale were assessed, and amount of opioid prescribed after surgery was measured and compared for patients during the recovery and at 2, 4, 6, 12, and 24 h after surgery in three groups, and hypotension and bradycardia during operation were reported.

**Results:** There was a significant difference among the groups regarding pain intensity and amount of opioids during recovery and at 2, 4, 6, 12, and 24 h after surgery. Pain intensity and amount of opioids for ketamine and dexmedetomidine groups were significantly lower than those in the controls during recovery and at the hours after surgery. There was no significant difference regarding bradycardia and hypotension and level of sedation during recovery and at the hours after surgery.

**Conclusion:** Both ketamine and dexmedetomidine infusions during maintenance of anesthesia are effective in reducing acute postoperative pain effectively after PSF surgery.

**Keywords:** Acute postoperative pain, Dexmedetomidine hydrochloride, Ketamine hydrochloride, Posterior spinal fusion surgery

## INTRODUCTION

One of the most challenging issues after surgery is providing appropriate pain control measures to enhance recovery of the patients.

Patients' pain comes with unwanted side effects and complications. Meanwhile, the acute postoperative pain is considered as an annoying problem for patients after surgery and the severe pain can cause unfavorable hemodynamic and metabolic responses. About 21% of patients

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experience moderate-to-severe postoperative pain.<sup>[5,13]</sup> Inadequate postoperative pain management can result in such complications as long recovery and hospitalization, increased hospital costs, and decreased patient satisfaction.<sup>[12]</sup> The effective postoperative pain management is currently a part of the surgical process and not only reduces a patient's suffering but also decreases mortality, promotes rapid hospital discharge, improves a patient's quality of life, and reduces hospital costs. The effective postoperative pain management entails a multimodal approach involving several drugs with different mechanisms of action.<sup>[6]</sup> There are many different treatment options for reducing the postoperative pain, and each has its own benefits,<sup>[16]</sup> including the administration of opioids before or during surgery. Medications such as dexmedetomidine and ketamine can be used during surgery to relieve pain. Ketamine as a NMDA and HCN1 receptor blocker causes analgesic and hypnotic effects. The analgesic effects of the ketamine can be combined with the antinociceptive effects of the opioids. Dexmedetomidine can cause analgesic effects through effects on alpha 2 receptors in the central nervous system and inhibitory effects on the posterior spinal cord. The fusion technique is commonly used to prevent further degeneration of the lumbar spine and trauma to the cord and stabilization of spine and reducing pain. In this operation, a bone bridge is formed between the outer surfaces of lumbar spine in the painful area to relieve the pain by immobilizing the disc. There are several different techniques to perform this surgery and each has its own benefits and risks. Surgical techniques include an anterior/posterior fusion or both sides of the disc.<sup>[7,17]</sup> Given that, the posterior spinal fusion (PSF) is the most common type of fusion surgery, and therefore, postoperative pain management and the use of anesthetic techniques associated with better postoperative pain control are emphasized.

Accordingly, the aim of this study was to compare the effects of ketamine versus dexmedetomidine infusion during surgery on the acute postoperative pain in PSF surgery.

## MATERIALS AND METHODS

The study population consisted of patients candidate for PSF surgery who hospitalized in the hospital with which the authors are affiliated, in Tehran, Iran, during 2019–2020. A double-blinded randomized clinical trial was conducted on 87 patients undergoing PSF surgery. The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences (ethical code: IR.IUMS.FMD.REC.1397.213) and registered in Iranian Registry of Clinical Trials (IRCT) with ID: IRCT20180723040570N2. The sample size was estimated using the following formula. The sample size was 29 subjects per group. In the following relation, the values of Type I error ( $\alpha$ ) and Type II error ( $\beta$ ) are estimated 5% and 2%, respectively. Furthermore, the values of standard deviations (SD) S1 and S2 are equal to 27.8

and 22, respectively, and the effect size ( $d$ ) is 18.6 based on the values obtained for Fugl-Meyer Motor Scale in the study of Colette *et al.* (2011).<sup>[3]</sup>

$$n = \frac{(S_1^2 + S_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{(d)^2}$$

After acquisition of informed consent and eligibility of patients according to inclusion and exclusion criteria, they were included in the study. The exclusion criteria included: PSF surgery due to traumatic fracture; those with a history of chronic mental disorder on medication; a history of systemic diseases such as heart failure and liver, renal, lung, and infectious diseases; history of hypertension (blood pressure higher than 140/90 mm Hg); and a history of diabetes (a fasting blood sugar level higher than 120 mg/dL) and history of addiction. Furthermore, patients with a history of seizure disorders and increased intracranial pressure, as well as patients with arrhythmia or heart rhythm disorders or AV block were excluded from the study.

Patients aged 18–70 years who were candidates for nontraumatic elective PSF surgery with a minimum of 2 and a maximum of 5 level involved rated AS: ASA1 or ASA2 were included in the study. The patients were randomly divided into three groups by block randomization: ketamine group (ROTEX-Germany)  $n = 29$ , dexmedetomidine group (MEDONX-Canada)  $n = 29$ , and control group  $n = 29$ . The patients took no sedatives or narcotics the night before surgery. In the operating room, standard monitoring was implemented (SAADAT ALBORZ B5, Iran) including electrocardiography, pulse oximetry, BIS monitoring (VISTA – Netherland), and noninvasive blood pressure monitoring and arterial line to measure their systolic and diastolic and mean arterial blood pressure. After IV cannulation with an 18 gauges needle, 0.5 cc/kg of lactated ringer was infused. Anesthesia protocol in all three groups was identical, including 25  $\mu$ g/kg midazolam (EXIR, Iran), 3  $\mu$ g/kg fentanyl (Caspian, Iran), 2 mg/kg propofol (B.BRAUN – Germany), 0.5  $\mu$ g/kg atracurium (Aburailhan – Iran), and 1 mg/kg lidocaine (CASPIAN – Iran) for induction. All patients were given 0.1 mg/kg IV morphine (DAROUPAKSH – Iran) to reach the appropriate level of analgesia after changing their position and stabilizing of the vital signs. During the surgery, they received a standard dosage of fentanyl (1  $\mu$ g/kg/h) so as to maintain the appropriate analgesia. Anesthesia maintenance regimen included 50–150  $\mu$ g/kg propofol (B.BRAUN – Germany) with control of hemodynamic symptoms and the depth of anesthesia (by setting propofol dosage to maintain target BIS levels of 40–60) and 0.2 mg/kg atracurium/30 min (ABURAIHAN – Iran). During surgery, the first group received 0.2 mcg/kg/h dexmedetomidine infusion (MEDONEX – Canada) through infusion pump, the second group received 01 mg/kg/h ketamine infusion (ROTEX – Germany), and control group received the normal saline infusion used as a placebo. All patients had

an arterial line and their blood pressure and heart rate were measured before and during surgery. More than 30% decrease in heart rate (compared to baseline resting heart rate) or heart rate of fewer than 50 beats/min was considered as bradycardia and more than 30% reduction in arterial pressure (compared to baseline mean arterial pressure [MAP]) MAP < 60 mmHg was regarded as hypotension. The protocol for bradycardia treatment was IV atropine 0.01 mg/kg body weight (CASPIAN – Iran) and those with hypotension, intermittent intravenous dose of 40 mcg phenylephrine (BB PHARMA – Iran) until the MAP reached above 60 mmHg. More than 30% increase in heart rate compared to baseline before surgery (with a target BIS range of 40–60 and IV fluid therapy based on standard protocol of 4-2-1) was considered as tachycardia and more than 30% increase in mean arterial pressure compared to baseline before surgery (with a target BIS range of 40–60 and IV fluid therapy based on standard calculations) was regarded as hypertension. For hemodynamic control in these cases, labetalol 2 mg/min and TNG 5 µg/min as a baseline were infused and increased to target levels. The total dose of propofol infused (Caspian, Iran) and the time of surgery was recorded. At the end of surgery, for pain control, all patients had (Accufuser CTx, South Korea), an autofuser/containig2g Apotel (EXIR – Iran) and 500 µg fentanyl (Caspian, Iran). Filled with up to 100 cc volume with hypertonic saline, the pump was set at an infusion rate of 4 cc/h for all patients. If the value of a visual analog pain scale (VAS) was >3 while receiving infusion, 0.3 mg/kg pethidine (CASPIAN – Iran) was injected. The amount of the opioids and number of injection prescribed for the patients were recorded during the first 24 h after surgery. Furthermore, the level of sedation (assessed by Ramsey scale) and pain intensity (assessed by VAS scale) were measured for patients during the recovery and at 2, 4, 6, 12, and 24 h after surgery, and their bradycardia and hypotension rates from induction to extubation were recorded and compared during surgery. Surgical team was identical in groups. For statistical analysis of the data, quantitative variables are expressed as means ± SD and qualitative variables as percentages. If the data were normally distributed, analysis of variance, or ANOVA, was used to compare the quantitative variables and if data were not normally distributed, the Kruskal-Wallis test was employed. The Chi-square test or Fisher's exact test was used to compare the qualitative variables. Statistical analysis was performed using SPSS version 25.  $P < 0.05$  was regarded as statistically significant.

## RESULTS

A total of 87 patients undergoing PSF surgery who hospitalized in Rasoul Akram Hospital in Tehran, Iran, during 2019–2020, were included in the study.

As shown in [Table 1], there was no significant difference among the groups with respect to age and sex ( $P > 0.05$ ).

Based on the results of ANOVA and Kruskal-Wallis test,

**Table 1:** Comparison of the patient's characteristics by age and sex.

Variable	Ketamine group n (%)	Dexmedetomidine group n (%)	Control group n (%)	P value
Age				
40>	2 (6.9)	3 (10.3)	1 (3.4)	0.86
40–60	17 (58.6)	15 (51.7)	16 (55.2)	
>60	10 (34.5)	11 (37.9)	12 (41.4)	
Sex				
Male	18 (62.1)	20 (60.9)	17 (58.6)	0.707
Female	11 (37.9)	9 (31)	12 (41.4)	

there was no significant difference among the groups in terms of level of sedation during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P > 0.05$ ). The repeated measures ANOVA results showed that intragroup measurement of level of sedation was significantly decreased in the three groups during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ) [Table 2].

There was no significant difference among the groups in terms of level of sedation during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P > 0.05$ ).

The results of ANOVA and Kruskal-Wallis test showed that there was a significant difference among the groups with respect to the pain intensity during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ). Furthermore, a significant difference was observed between the ketamine and control groups with respect to the pain intensity during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ). Moreover, there was a significant difference between dexmedetomidine and control groups in terms of the pain intensity during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ). The repeated measures ANOVA results indicated that there was a significant difference among the intragroups with respect to the pain intensity during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ) [Table 3]. There was a significant difference among the groups with respect to the pain intensity during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ).

As shown in [Table 4], there was no significant difference among the groups with respect to hypotension and bradycardia during surgery ( $P > 0.05$ ). There was no significant difference among the groups ( $P > 0.05$ ).

As shown in [Table 5], there was a significant difference among the groups with respect to the amount of opioids prescribed during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ). Furthermore, there was no significant difference between the ketamine and dexmedetomidine groups in terms of the amount of opioids prescribed ( $P > 0.05$ ). Furthermore, a significant difference was found between ketamine and control groups with respect to the

**Table 2:** Comparison based on the level of sedation during the recovery and at 2, 4, 6, 12, and 24 h after surgery.

Measurement time	Ketamine group Mean±SD	Dexmedetomidine group Mean±SD	Control group Mean±SD	P value
During the recovery	2.72±0.79 <sup>b</sup>	2.48±0.63 <sup>c</sup>	2.45±0.63	0.781
2 h after surgery	2.28±0.99 <sup>b</sup>	1.93±0.75 <sup>c</sup>	1.83±0.65	0.145
4 h after surgery	1.93±0.79 <sup>b</sup>	1.66±0.67 <sup>c</sup>	1.59±0.5	0.862
6 h after surgery	1.66±0.67 <sup>b</sup>	1.45±0.57 <sup>c</sup>	1.45±0.5	0.912
12 h after surgery	1.41±0.56 <sup>b</sup>	1.31±0.54 <sup>c</sup>	1.31±0.47	0.851
24 h after surgery	1.21±0.41 <sup>b</sup>	1.17±0.38 <sup>c</sup>	1.14±0.35	0.459
P value	<0.001	<0.001	<0.001	

a: There is a significant difference between the two groups of ketamine and dexmedetomidine ( $P < 0.05$ ). b: There is a significant difference between ketamine and control groups ( $P < 0.05$ ). c: There is a significant difference between the two groups of dexmedetomidine and control ( $P < 0.05$ ).

**Table 3:** Comparison based on pain intensity during the recovery and at 2, 4, 6, 12, and 24 h after surgery.

Measurement time	Ketamine group Mean±SD	Dexmedetomidine group Mean±SD	Control group Mean±SD	P value
During the recovery	4.66±1.26 <sup>b</sup>	4.55±1.15 <sup>c</sup>	5.48±1.47	0.021
2 h after surgery	4.97±1.15 <sup>b</sup>	4.97±1.05 <sup>c</sup>	6.55±1.45	0.005
4 h after surgery	5.59±1.249 <sup>b</sup>	5.72±1.38 <sup>c</sup>	7.07±1.38	0.001
6 h after surgery	5.66±1.37 <sup>b</sup>	5.59±1.45 <sup>c</sup>	7.24±1.24	0.001
12 h after surgery	5.14±1.43 <sup>b</sup>	5.31±1.28 <sup>c</sup>	7.3±1.29	0.001
24 h after surgery	4.28±1.38 <sup>b</sup>	3.79±1.34 <sup>c</sup>	6.28±1.5	0.009
P value	<0.001	<0.001	<0.001	

a: There is a significant difference between the two groups of ketamine and dexmedetomidine ( $P < 0.05$ ). b: There is a significant difference between ketamine and control groups ( $P < 0.05$ ). c: There is a significant difference between the two groups of dexmedetomidine and control ( $P < 0.05$ ).

**Table 4:** Comparison based on hypotension and bradycardia during surgery.

Variable	Ketamine group, n (%)	Dexmedetomidine group, n (%)	Control group, n (%)	P value
Hypotension				
Yes	1 (3.4)	4 (13.8)	0 (0)	0.063
No	28 (96.6)	25 (86)	29 (100)	
Bradycardia				
Yes	2 (6.9)	3 (10.3)	0 (0)	0.226
No	27 (93.1)	26 (89.7)	29 (100)	

amount of opioids prescribed ( $P < 0.05$ ). In addition, there was a significant difference between dexmedetomidine and control groups with respect to the amount of opioids prescribed ( $P < 0.05$ ). There was a significant difference among the groups with respect to the amount of opioids prescribed during the recovery and at 2, 4, 6, 12, and 24 h after surgery ( $P < 0.05$ ).

## DISCUSSION

The results of the present study demonstrate that there was a significant difference among the groups with respect to the pain intensity during the recovery and at 2, 4, 6, 12, and 24 h

after surgery ( $P < 0.05$ ). However, there were no significant differences between ketamine and dexmedetomidine groups with respect to the pain intensity. Furthermore, there was a significant difference among the groups with respect to the amount and number of opioids prescribed during the recovery and at 2, 4, 6, 12, and 24 h after surgery. Moreover, there was no significant difference among the groups in terms of level of sedation during the recovery and at 2, 4, 6, 12, and 24 h after surgery.<sup>[6]</sup> There are many different treatment options for reducing the postoperative pain, and each has its own benefits,<sup>[16]</sup> including the administration of opioids before or during surgery. In one study, Suzuki *et al.* reported that dextromethorphan combined with ketamine can significantly reduce pain intensity and need for narcotic drugs in the postoperative phase,<sup>[14]</sup> which are consistent with our findings. However, in our study, combination therapy was not used in the groups. In the study of Aziz *et al.*, it has been showed that the dexmedetomidine group exhibited more benefits in sedation and pain levels, additional sedative/analgesic requirements, and extubation time. No significant differences were found between the two groups with respect to the outcome measures, except heart rate, which was significantly lower in the dexmedetomidine group.<sup>[1]</sup> Moreover, in the study of Reichert *et al.*, no statistically significant differences were found between the propofol and dexmedetomidine groups when assessing the outcomes of

**Table 5:** Comparison based on the frequency of opioids prescribed during the recovery and at 2, 4, 6, 12, and 24 h after surgery.

Variable	Ketamine group Mean±SD	Dexmedetomidine group Mean±SD	Control group Mean±SD	P value
The amount of opioids prescribed	1.48±0.63b	1.34±0.48c	2.1±0.72	0.001

opioid requirements and the time to extubation,<sup>[11]</sup> which are consistent with our results. Furthermore, the results of the study of Anger *et al.* demonstrated that dexmedetomidine therapy led to a higher incidence of hypotension and analgesic consumption compared to propofol-based sedation therapy,<sup>[2]</sup> which are not consistent with our results. This discrepancy may be due to differences in the drug compared with dexmedetomidine and the study populations. The results of the study of Gharaei *et al.* showed that preemptive low-dose ketamine as a bolus has opioid-sparing effects in opioid abusers undergoing moderate sedation,<sup>[4]</sup> which are not consistent with our results. This discrepancy may be due to differences in the study design and the study populations. In line with the results of the present study, Ranadhir *et al.* reported that in patients undergoing lumbar instrumentation surgery, opioid consumption, VAS scores, PCA pump demands, inhalational agent consumption, and hospital stay were comparable when either ketamine or dexmedetomidine was used as intraoperative anesthetic adjuvants.<sup>[8]</sup> In the study of Parikh *et al.*, it has been demonstrated that small dose of ketamine reduced postoperative pain, decreased morphine consumption, and delayed patients request for analgesia beyond the clinical duration of action of ketamine after open renal surgery<sup>[9]</sup> which are in line with our findings. The results of the study of Tufanogullari *et al.* showed that dexmedetomidine infusion perioperatively is safe and can minimize narcotic requirements and reduce duration of stay after laparoscopic bariatric procedures,<sup>[15]</sup> which are consistent with our results.

The result of the study of Rahimzadeh *et al.* showed that dexmedetomidine had a significant lowering impact on intraoperative blood pressure and heart rate compared to remifentanyl ( $P < 0.001$ ). The mean of postextubation and recovery pain score in patients taking remifentanyl was significantly higher than patients taking dexmedetomidine ( $P < 0.05$ ).<sup>[10]</sup>

## CONCLUSION

Both ketamine and dexmedetomidine are effective in reducing the acute pain after PSF surgery. The lack of significant difference between the ketamine and dexmedetomidine may be due to a low dose of the dexmedetomidine. Therefore, it is recommended to examine the different doses of dexmedetomidine or combination of ketamine and dexmedetomidine in the future studies.

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## Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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