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Original Article

Comparison of Sedation Efficacy Between Remifentanil and Dexmedetomidine in Arteriovenous Fistula Placement Surgery

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ABSTRACT

Background: Arteriovenous fistula (AVF) placement is a surgical procedure performed under local anesthesia and often without the need for muscle relaxants in patients with end-stage renal disease. The results of studies comparing remifentanil (REM) and dexmedetomidine (DEX) in patients undergoing AVF placement are controversial. The present study compared sedation efficacy between REM and DEX in patients undergoing AVF placement.

Methods: The present double-blind randomized clinical trial enrolled 40 patients in the operating room of Shahid Hashemi-Nejad Hospital in 2 groups and compared sedation between REM and DEX at different times during and after the surgery using a visual analog scale and the Ramsay score. The data were recorded and analyzed using SPSS, version 22.

Results: The average pain score 120 minutes after the surgery was 4.9±0.72 and 4.3±0.80 in the DEX and REM groups, respectively (P=0.017). No significant difference was observed in the level of sedation between the 2 groups (P=0.113). The prevalence of tachycardia and bradycardia in the 2 groups was 10% (P=1.00) and 15% (P=1.00), respectively, and no significant difference was observed.

Conclusions: We found no significant differences between DEX and REM concerning sedation efficacy. Further studies with larger sample sizes in each group of patients and different procedural scenarios are recommended. ***(Iranian Heart Journal 2023; 24(2): 84-93)***

KEYWORDS: MPI, Gated SPECT, Phase analysis, Image reconstruction, Filtration

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Given the aging process and an increase in the prevalence of chronic diseases, such as diabetes mellitus, hypertension, and chronic kidney disease (CKD), careful assessment and management of patients can play a significant role in improving their quality of life and increasing their satisfaction. Both the mortality and morbidity of patients with CKD are significant and have become top priorities for healthcare providers globally. [1, 2]

The best treatment for patients with end-stage renal disease is kidney transplantation; nonetheless, due to the increasing number of these patients and the lack of available kidneys for transplantation, these patients may have to continue dialysis for a long time. [3,4] A safe and suitable intravenous (IV) access should be available for continuing dialysis several times a week over a long period. [1] The best way to ensure this access is the placement of an arteriovenous fistula (AVF). The side effects of AVF placement are low, and it delivers a favorable patency over time. [5, 6] The site of AVF placement is often located on the arm or the forearm, [1] and the surgical procedure is performed with the help of local anesthesia at the site of the incision and with continuous monitored anesthesia care throughout. [7] AVF placement is a surgical operation with local anesthesia and often without the need for muscle relaxants; therefore, pain caused by the procedure may not be controlled optimally during the operation. [8]

Remifentanil (REM) is a sedative agent with an ultra-short activity. It is an agonist of the μ-opioid receptor and is useful for relieving pain by decreasing the tone of the sympathetic nervous system. This agent is also used for general anesthesia in the induction and maintenance phases. The half-life of REM is 90 minutes, and its elimination is through renal excretion. [1]

Dexmedetomidine (DEX) is a sedative agent with different usages, including analgesia, anxiety amelioration, and sedation of intubated patients. It is a selective agonist of α-2 adrenoceptors and suppresses pain signals by inhibiting the secretion of norepinephrine. DEX reduces sympathetic activity and can decrease the heart rate (HR) and blood pressure (BP). [2] It is not easy to declare which agent is superior. Still, different aspects of the use of these drugs should be considered to attain optimal results. Many studies have compared these 2 agents and reported contradictory results.

The prevalence of hypotension is higher with the use of REM, [7] whereas DEX is associated with severe bradycardia and hypoxia. [8, 9] Although cardiorespiratory compromise is not a usual side effect of DEX, [10] hemodynamic changes, including bradycardia, hypotension, and hypertension, must be considered. [11, 12] A prior study revealed a significant elevation in blood glucose levels after DEX use. [13] Nevertheless, other studies have reported increased catecholamine levels and decreased blood glucose levels. [14-16]

Only a few investigations have compared the use of REM and DEX in patients undergoing AVF placement. Be that as it may, studies that have evaluated either of these 2 agents separately for AVF placement in patients with CKD have reported successful results. [17, 18]

The present study compared sedation efficacy between REM and DEX in patients undergoing AVF placement. Furthermore, in this research, other aspects were evaluated and compared between REM and DEX groups of patients, including the severity of pain after the surgical incision and during surgery with the aid of a visual analog scale pain score 0.5, 1, 1.5, and 2 hours after the commencement of the surgery and in recovery, the need for additional analgesic agents, the prevalence of vomiting, BP and

HR variabilities, and the level of sedation at the end of the surgery.

METHODS

The current double-blind randomized clinical trial was performed in the operating room of Shahid Hashemi-Nejad Hospital. The study population consisted of patients undergoing AVF placement with a sedative agent under monitoring. The inclusion criteria were comprised of age between 19 and 80 years and hemodynamic stability. The exclusion criteria were the presence of any history of cardiovascular diseases, chronic liver diseases, allergies to opioid agents, pregnancy, breastfeeding, recent respiratory infections, and severe bronchopulmonary diseases.

This study was approved by the Ethics Committee of Iran University of Medical Sciences (code: IR.IUMS.FMD.REC.1399.115) and was recorded in the Iranian clinical trials (code: IRCT20200502047269N1). The aim and the method of the study were clarified to the participants, and written informed consent was obtained from all the recruited patients. The patients' data remained confidential, and no additional charges were imposed on the patients. In the event of complications, all related costs were to be covered by the trial organizers.

First, demographic parameters were recorded. They included age, gender, height, weight, past medical history, and personal and social history. Before the procedure, the patients underwent routine monitoring, including noninvasive blood pressure monitoring, electrocardiography, peripheral oxygen saturation, and pulse rate. Additionally, IV access was fixed. Then, the patients were classified into 2 groups. DEX was administered to the first group and REM to the second one. The bolus and the maintenance doses of DEX were 1 µg/kg IV in 10 minutes, subsequently maintained with 0.5 µg/kg IV per hour. In addition, the bolus and the maintenance doses for REM were 1 µg/kg IV in 10 minutes and 0.2 µg/kg IV per minute, respectively. As for local anesthesia, an injection of 100 mg of lidocaine was administered to all the patients prior to the initial incision. The initial surgical incision was made when the maintenance dose was started. The severity of the pain was evaluated using a visual analog scale (VAS) score. The VAS score was reevaluated 10 minutes and then 0.5, 1, 1.5, and 2 hours after the end of the surgery in the recovery phase. The need for additional local analgesia and side effects, including nausea, vomiting, hypotension, hypertension, bradycardia, and tachycardia during and after the procedure, were compared between the 2 groups. At the end of the procedure, the Ramsay scores were determined and compared.

The data were recorded and analyzed using SPSS, version 22. In addition, the independent *t* test, the 2-way repeated measures (ANOVA), the Cochran Q test, the χ^2 test, and the Fisher exact test were used.

RESULTS

Demographic data

Forty patients were enrolled according to the inclusion and exclusion criteria and the following formula:

$$n_1 = n_2 = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \times (\sigma_1^2 + \frac{\sigma_2^2}{k})}{|\mu_1 - \mu_2|^2}$$

The study population was divided into 2 groups as mentioned in the Methods. DEX was administered to the first group and REM to the second one. Concerning the basic data, consisting of the mean age, the mean body mass index, gender, history of hypertension, diabetes mellitus, and addiction, no significant differences were found between the 2 groups.

Evaluation of the pain score in the 2 groups

The mean pain score at the commencement of the surgery just after the initial surgical incision in the DEX and REM groups was 5.9±1.17 and 5.4±1.27, respectively (*P*=0.203). The mean pain score 10 minutes after the commencement of the surgery in the DEX and REM groups was 4.4±1.39 and 4.8±1.01, respectively (*P*=0.385). The mean pain score was evaluated 30, 90, and 120 minutes after the end of the surgery in the recovery phase. After 30 minutes, the score was 4.5±0.89 and 4.55±0.83 in the DEX and REM groups, respectively (*P*=0.855). After 60 minutes, the score was 5.00±0.65 and 4.6±0.94 in the DEX and REM groups, respectively (*P*=0.126). After 90 minutes, the pain score was 4.65±0.59 in the DEX group and 4.5±0.76 in the REM group (*P*=0.577). Moreover, 120 minutes after the end of the surgery, the pain score was evaluated for the last time. It was 4.9±0.72 and 4.3±0.80 in the DEX and REM groups, respectively (*P*=0.017). According to the mentioned *P* values, the only significant difference in the pain scores between the 2 groups was 120 minutes after the end of the surgery, and it was significantly lower in the REM group (Table 1 and Fig. 1).

Table 1: Comparison of the pain score between the 2 groups

Indicator	DEX Group	REM Group	*P* value
At the beginning of surgery (after the surgical incision)	5.9 ± 1.17	5.40 ± 1.27	0.203
During the surgery (10 minutes after the commencement of the surgery)	4.40 ± 1.39	4.80 ± 1.01	0.385
30 minutes after the end of the surgery (recovery)	4.50 ± 0.89	4.55 ± 0.83	0.855
60 minutes after the end of the surgery (recovery)	5.00 ± 0.65	4.60 ± 0.94	0.126
90 minutes after the end of the surgery (recovery)	4.65 ± 0.59	4.50 ± 0.76	0.577
120 minutes after the end of the surgery (recovery)	4.90 ± 0.72	4.30 ± 0.80	0.017

DEX, Dexmedetomidine; REM, Remifentanil; BMI, Body mass index

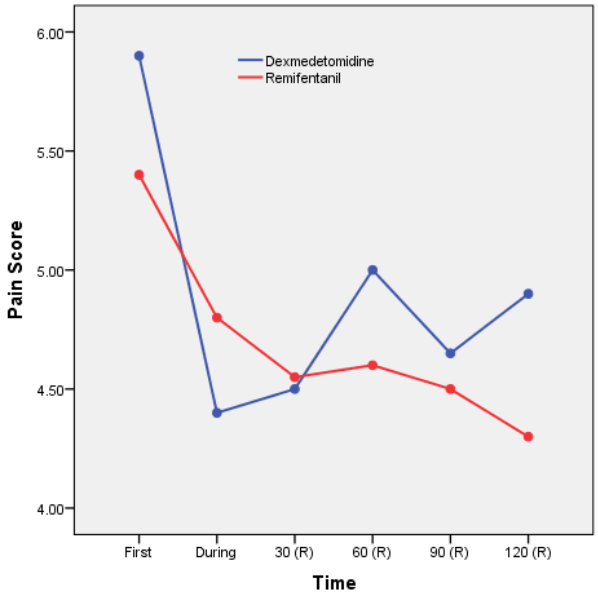

Figure 1: The image presents a comparison of the pain score at the beginning of the surgery, during surgery, and after the procedure at defined time points between the 2 study groups.

Comparison of sedation efficacy between the 2 groups

With regard to the level of sedation, the frequency of Score II (awake and calm with a clear response to vocal orders) in the DEX and REM groups was 20% and 0%, respectively. Score III (drowsy and having a clear response to vocal orders) in the DEX and REM groups was 65% and 75%, respectively. Score IV (drowsy and having a clear response to vocal orders while needing a louder voice) in the DEX and REM groups was 15% and 25%, respectively. There was no significant difference in the sedation level between the 2 groups (*P*=0.113).

The patients were also assessed according to their need for additional analgesia during the operation. It was observed that 10% of the DEX group and 15% of the REM group required additional analgesics, and the difference between the groups was not significant (*P*=1.00) (Table 2).

Side effects of the sedative agent

The side effects of DEX and REM were evaluated in the patients. The prevalence of nausea and vomiting in the DEX and the REM groups was 25% and 20%, respectively (*P*=1.00). BP changes were compared between the 2 groups. The prevalence of hypotension in the DEX and the REM groups was 15% and 25%, respectively (*P*=0.695). The prevalence of hypertension was 10% in the DEX group and 20% in the REM group (*P*=0.661). In addition, HR was evaluated and compared between the patient groups. The prevalence rates of tachycardia and bradycardia in the 2 groups were 10% (*P*=1.00) and 15% (*P*=1.00), respectively, and no statistically significant differences were found.

The 2-way repeated measure ANOVA analysis revealed that based on the use of different agents (DEX and REM), the mean pain score was not significantly different between the 2 groups (F=0.873, df=1, and *P*=0.356). However, the effect of the time of assessment on the mean score of pain was significant (F=14.057, df=5, and *P*<0.001). The analysis showed that the interaction of the group and time was significant (F=2.707, df=5, and *P*=0.038), and the slope changes of the pain score were different between the 2 groups of patients.

The results of the post hoc analysis of a 2-by-2 comparison of the mean pain score at the beginning of the surgery with all the recorded times during surgery and 30, 60, 90, and 120 minutes after the surgery revealed statistically significant differences between the 2 groups (*P*<0.001).

The assessment of the level of sedation using the Ramsay score revealed that 15% of the DEX group and 25% of the REM group had Score IV. Further, the frequency of Score III in the DEX and the REM groups was 65% and 75%, respectively, but the difference was not significant (*P*=0.113) (Table 2 and Fig. 2).

In patients requiring additional analgesics, lidocaine was injected locally. In the DEX group, it was injected for 2 patients with doses of 80 mg in one of them and 100 mg in the other. In the REM group, it was injected in 3 patients, with a dose of 100 mg in all of them.

The incidence of nausea and vomiting was reported in 5 patients in the DEX group and 4 patients in the REM group. Hypotension occurred in 5 patients in the REM group and 3 patients in the DEX group. Hypertension was a side effect in 2 patients in the DEX group and 4 patients in the REM group. In the DEX group, headaches were reported in 2 patients (10%) and apnea in 3 patients (15%). During surgery, 6 patients (30%) in the DEX group and 6 patients (30%) in the REM group were complicated by tachycardia. Thirty minutes after the surgery, bradycardia was detected in 1 patient (5%) in the DEX group and 2 patients (10%) in the REM group. Sixty minutes after the surgery,

bradycardia occurred in 1 patient (5%) in each group. Ninety minutes after the surgery, tachycardia was recorded in 2 patients (10%) in the DEX group and 1 patient (5%) in the REM group. Finally, 120 minutes after the surgery, 1 patient (5%) in the DEX group and 1 patient (5%) in the REM group were complicated by tachycardia. Given the low incidence of HR changes in the 2 groups of patients, the statistical comparison of the patients at consecutive times was not possible. In addition, requiring additional analgesic injections was not significantly different between the 2 groups of patients (Fig. 3).

Table 2: Comparison of the sedation level and the side effects of the analgesic agents during surgery between the 2 groups

Indicator		DEX Group	REM Group	*P* value
Level of sedation based on the Ramsay score	Score 2	20%	0%	0.113
	Score 3	65%	75%	
	Score 4	15%	25%	
Need for the injection of analgesics		10%	15%	1.00
Prevalence of nausea and vomiting		25%	20%	1.00
Prevalence of hypotension		15%	25%	0.695
Prevalence of hypertension		10%	20%	0.661
Prevalence of tachycardia		10%	10%	1.00
Prevalence of bradycardia		15%	15%	1.00

DEX, Dexmedetomidine; REM, Remifentanil

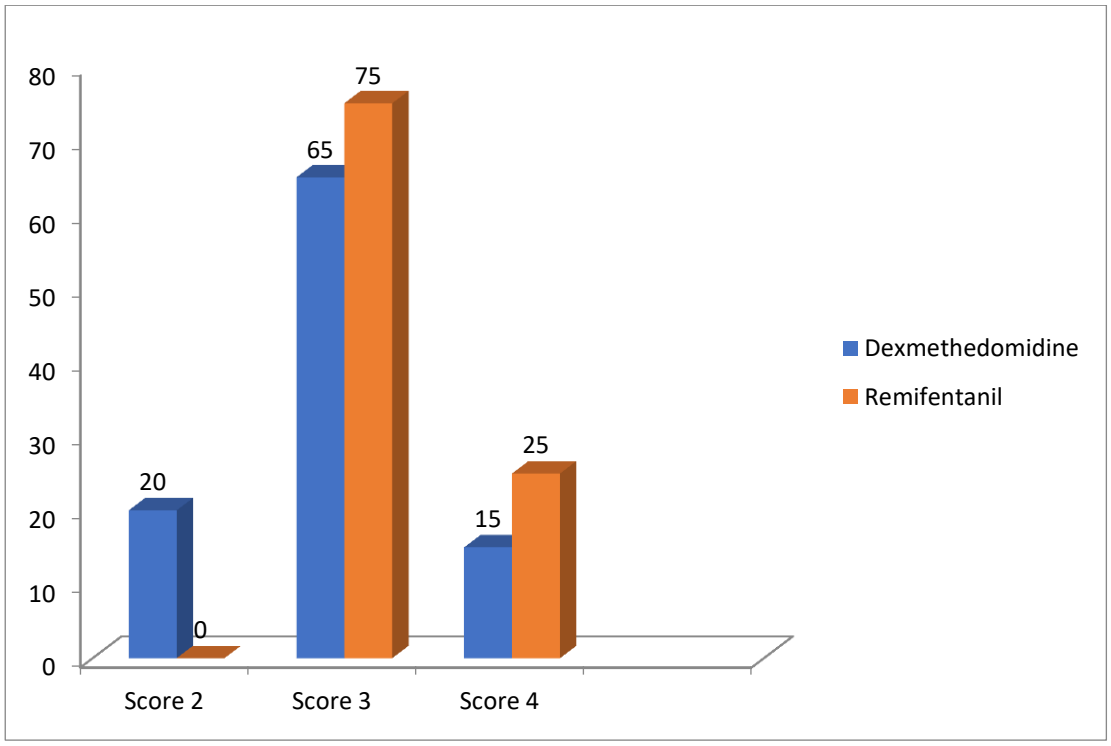

Figure 2: The image illustrates an evaluation of the sedation level at the last minutes of the surgery between the 2 study groups.

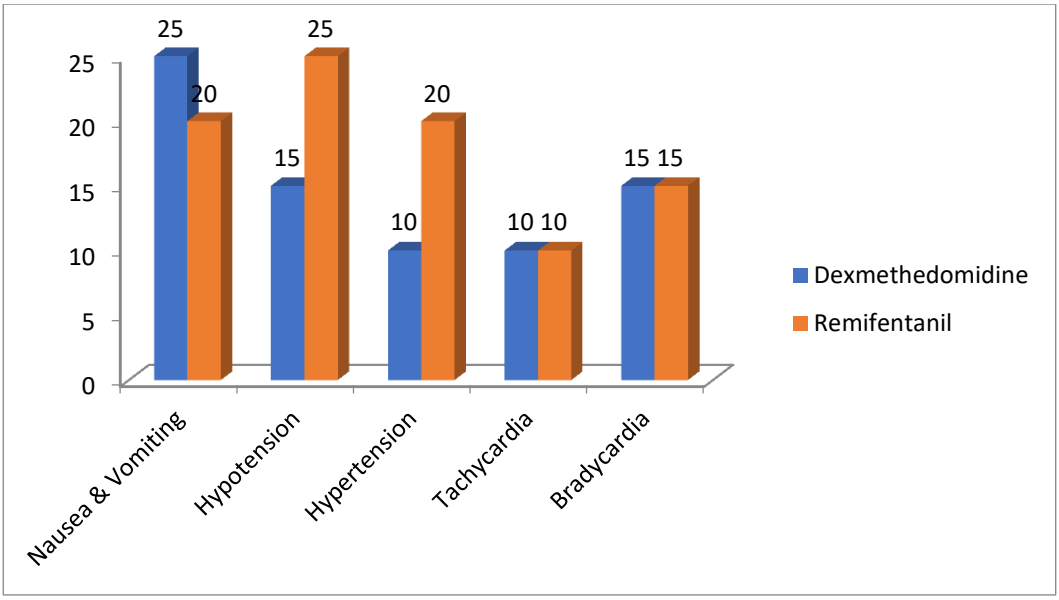

Figure 3: The image presents a comparison of the side effects of anesthetic agents during surgery between the 2 study groups.

DISCUSSION

Hemodialysis is associated with possible complications and can reduce the quality of life in patients with CKD. In addition to this physical and psychological burden, requiring an AVF placement may intensify physical and emotional problems with regard to pain and affect the hemodynamic status of patients. Therefore, using a sedative agent is of utmost importance in increasing patient satisfaction while reducing the overwhelming mental and physical burden. Different methods have been devised for patients undergoing AVF placement. Recently, however, using sedative agents with higher efficiency and lower side effects has been considered. In this regard, opioid agents and adrenergic agonists have been studied in clinical trials. In this research, the sedative effects of 2 agents, namely REM and DEX, were studied in patients with end-stage renal disease undergoing AVF placement.

We found that the sedative effect of DEX and REM did not differ significantly in most parts of the surgical procedure except for 120 minutes after the end of the surgery, when REM was more effective than DEX. In the comparison of the level of sedation based on the Ramsay score and the side effects of these 2 agents, consisting of nausea, vomiting, BP, and HR changes, we detected no significant differences between the 2 groups.

Only a few studies have compared REM and DEX in patients undergoing AVF placement. Nonetheless, investigations that have evaluated either of these 2 agents separately for AVF placement in patients with CKD have reported successful results. [17, 18]

Previous studies have compared DEX and REM from several aspects. In a systematic review and meta-analysis conducted by Grape et al [19] (2019), the pain score was lower in patients using DEX. Additionally, the prevalence of hypotension, shivering, nausea, and vomiting after the surgery in the REM group was doubled compared with the DEX group. In their study, the type of the surgery, the form of the use of the agents, and the time of the evaluation of patients were different from those in our study. In a study performed by Gazi et al [13] (2018), the severity of pain in the DEX group was lower

than that in the REM group. The mean arterial pressure during surgery was lower in the REM group; nevertheless, 30 minutes after the surgery, it was higher than in the DEX group. In their research, the patients underwent general anesthesia. In addition, the procedure was hysteroscopy, and the doses of the agents were different from those in our study.

The results of an investigation carried out by St-Pierre et al [20] (2019) are similar to our study. They concluded that there were no significant differences between the 2 groups in the severity of pain, needing extra lidocaine, nausea and vomiting episodes, and patient satisfaction. In our study, the sedation level based on the Ramsay score was not significantly different between the 2 groups.

A study by Menshawi and Fahim [21] (2021) revealed that adding DEX to bupivacaine conferred favorable anesthesia and reduced the need to inject postoperative analgesic agents. Notably, the type of anesthesia, the type of surgery, and the doses of the drugs used were different from those in our study. Their study was performed on patients undergoing video-assisted thoracoscopic surgeries (VATS) with general anesthesia.

In a study by Choi et al [22] (2016), the pain score was lower in the DEX group than in the fentanyl and REM groups. Additionally, HR and BP in the DEX group were lower than in the 2 other groups. Their study was different from our study in terms of the type of the surgery (laparoscopic hysterectomy), the doses of the agents, and the administration of 3 mg of ketorolac at the end of the surgery to patients. In a study by Kim et al [23] (2016), BP and HR on admission to the post-anesthesia care unit and 10 minutes afterward were higher in the REM group than in the DEX group. In addition, the respiratory rate after extubation in the REM group was lower than that in the DEX group. In their study, the type of anesthesia, the type of surgery, the use of propofol during surgery, and the doses of the agents were different from those in our study. Moreover, their patients underwent general anesthesia for a craniotomy.

Our literature review indicates that the reasons for the discrepancies between the results of studies are the variety in the type of anesthesia used for each operation, the use of various hypnotic and sedative groups, different doses of agents, and the duration of administration.

CONCLUSIONS

The results of the present study revealed that in patients undergoing AVF placement with sedative agents under monitored anesthesia care, there was no significant difference in the use of DEX and REM concerning their efficacy. The difference between these 2 agents was not significant in requiring additional analgesia, side effects, and the level of sedation. Given the aging of the population in the coming decades, invasive and noninvasive outpatient medical procedures will be inevitably increased. As a result, the treatment methods for these populations should be tailored in order that they can be efficient and low-risk while maintaining patient satisfaction. More studies with larger sample sizes to compare sedation efficacy between DEX and MED in common procedures, such as endoscopy, are recommended.

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