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# The Effect of Intranasal Administration of Remifentanil at Different Doses on Electroconvulsive Therapy-Induced Hemodynamic Changes in Adults

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**Abstract**

**Background:** Remifentanil seems to play an important role in reducing heart rate (HR) and blood pressure during electroconvulsive therapy (ECT)-induced seizures. The majority of studies have focused on the role of the intravenous administration of this drug in combination with other anesthetics; however, the effect of intranasal administration of this drug has received less attention so far. We evaluated the effect of the intranasal administration of remifentanil at different doses on ECT-induced hemodynamic changes.

**Methods:** This double-masked clinical trial was conducted on 80 ECT candidates divided into four groups. Before starting the ECT, the four study groups, namely REM-25, REM-50, REM-75, and control, intranasally received remifentanil at 25, 50, and 75 µg and placebo, respectively. Anesthesia induction drugs were injected 1 minute after the intranasal administration of remifentanil or placebo. Patient's HR, diastolic blood pressure (DBP), mean arterial pressure (MAP), systolic blood pressure (SBP), and peripheral capillary oxygen saturation (SpO2) were evaluated and recorded before and 1, 5, 10, and 20 minutes after the end of convulsive movements.

**Results:** The patients' SBP and MAP with 137.30 ± 14.37 mm Hg and 100.50 ± 11.06 mm Hg, respectively, had the highest mean in the control group as compared to three remifentanil groups 5 minutes after ECT ($P$ value = 0.042). In addition, the increase in patients' HR in the REM-75 group, with an average of 7.70 ± 12.54 bpm, was significantly lower than that of the REM-25 and REM-50 groups, with means of 16.15 ± 13.80 bpm and 13.15 ± 8.03 bpm, respectively. Moreover, the controls, with an average of 23.00 ± 11.74 bpm, had the greatest increase in HR ($P$ value < 0.05).

**Conclusion:** The intranasal administration of remifentanil at different doses did not affect the length of ECT-induced seizures; however, its maximum dose (75 µg) showed the greatest decrease in patients' SBP, MAP, and HR five minutes after administration.

**Keywords:** Electroconvulsive therapy, Hemodynamic changes, Remifentanil, Intranasal

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## Introduction

Electroconvulsive therapy (ECT) is one of the most effective and increasingly used methods for treating psychiatric diseases, especially severe and refractory depression (1,2). Although performing ECT under general anesthesia is one of the safest treatment procedures, with a mortality rate less than 2 per one hundred thousand, the induction of seizures increases blood pressure (BP) and heart rate (HR) (1,3). These hemodynamic changes extend to the postictal phase and usually cease within 10 to 20 minutes of seizures (4); however, they can be associated with unwanted complications in individuals suffering from cardiovascular or respiratory problems. Consequently, several studies have been conducted to reduce or control hemodynamic changes following ECT by prescribing sedatives or narcotics.

Remifentanil is an ultra-short-acting opioid that is used in combination with other drugs, such as propofol, to maintain anesthesia with hemodynamic stability and rapid wake-up from anesthesia (5). Moreover, remifentanil is administered as continuous infusion in controlled hypotension (6). It seems that this drug can be used to reduce ECT-induced hemodynamic changes, considering its analgesic effects and its effect on reducing BP and HR. In this regard, some studies have considered the intravenous administration of remifentanil to be effective in reducing seizure-induced changes (7,8).

However, no study has yet addressed the impact of the intranasal administration of three different doses of this drug on patients.

Intravenous remifentanil is presently employed in surgical settings during general anesthesia. Rapid-onset

delivery methods for fentanyl, including nasal sprays, sublingual or buccal tablets, and lollipops, are mainly applied off-label in pediatric patients. Transdermal fentanyl matrix patches can be used in children over two years of age who are opioid-tolerant. While sufentanil is primarily utilized in general anesthesia, remifentanil and alfentanil are applicable for analgesic sedation. Remifentanil is especially suitable for short or outpatient surgeries. However, so far, no attempt has been made to administer medicine through the nose in ECT because the attempt to insert an intravenous line may be fruitless or children may not fully cooperate when they are admitted to the operating room.

This method of drug administration can be more efficient and easier, as the nasal cavity has a rich vascular network that allows for the direct absorption of medications through the mucous membrane into the bloodstream, bypassing issues related to gastrointestinal degradation and first-pass hepatic metabolism. Considering the close anatomical relationship between the human nose and brain, there is a rapid flow of blood and cerebrospinal fluid, causing rapid effects on the brain. As a result, the rate of uptake and the time to reach peak plasma concentrations are comparable to intravenous injections and are generally faster than subcutaneous and intramuscular drug administration routes (9).

Therefore, we evaluated the effect of different doses of intranasal administration of remifentanil on ECT-induced hemodynamic changes.

## Methods

### *Study population*

The study population of this double-masked, randomized controlled clinical trial was all adult ECT candidates who were referred to Isfahan Khorshid Hospital. From this population, the sample size of 80 patients (4 groups consisting of 20 patients each) was selected at an 80% test power, a 95% confidence level, and considering the mean HR criterion in previous studies (7), 57 ± 4 bpm and 61 ± 7 bpm in the control and remifentanil groups, respectively, and the margin of error of 5, resulting from the mean difference of this variable.

The study included patients who were ECT candidates for the first time, were aged 18 years and over, had the American Society of Anesthesiologists (ASA) physical status classification of II, had no fever, and were willing to cooperate. Moreover, those with an allergy to remifentanil or nasal diseases that would interfere with the intranasal administration of the drug were not included. The patients were excluded and replaced with another candidate in case of any changes in the anesthesia method (need for intubation) or conditions in which the patient required medication or the seizure duration was too short or too long (Figure 1).

### *Study protocol*

Written consent was obtained from eligible patients. A total of 80 patients were randomly selected through convenience sampling and subsequently assigned to four groups using random allocation software.

Then, patients' demographic and clinical information, including age, mean arterial pressure (MAP), sex, HR, systolic blood pressure (SBP), weight, diastolic blood pressure (DBP), and peripheral capillary oxygen saturation (SpO2) in the supine position were measured and recorded before the nurse of the electroshock unit performed any operations.

First, before starting the ECT, remifentanil at doses of 25, 50, and 75 μg was intranasally administered to the patient's nostrils in the first, second, and third groups, respectively. In the control group, patients intranasally received a placebo in both nostrils.

To observe the double-masked conditions, the nurse of the electroshock unit prepared doses of remifentanil and placebo every day in equal volumes, then placed them in bags, coded with the labels A (25 μg/kg), B (50 μg/kg), C (75 μg/kg), and D (1.5 cc NS), and provided to the anesthesiologist. To create the same volume, all doses of the first group (A) contained 0.5 cc of remifentanil + 1 cc of normal saline (NS), the second group (B), 1 cc of remifentanil + 0.5 cc of NS, the third group (C), 1.5 cc of remifentanil, and the fourth group (D) or the control group, 1.5 ml of NL.

Then, one minute after the intranasal administration of remifentanil or placebo, anesthetic drugs, including midazolam, sodium thiopental, and suxamethonium choline, were injected based on patients' weights. Patients underwent ECT 30 to 45 seconds after receiving suxamethonium choline. During ECT, a mask was fitted over the mouth and nose of the patient, and the flowmeter was set to deliver $O_2$ at 8 L/min.

### *Primary outcomes*

At the end of convulsive movements, patients' DBP, SBP, MAP, HR, and SpO2 were measured and recorded once more by an anesthesiologist at 1, 5, 10, and 20 minutes. The seizure and recovery time (the time it took from the end of the seizure to the patient's response to verbal commands) were also recorded.

### *Statistical analysis*

Finally, the gathered data were entered into SPSS 25. Data were expressed as frequency (percentage) or mean ± standard deviation (SD). For inferential statistics, the chi-square test, one-way analysis of variance (ANOVA), and repeated measures ANOVA were employed as the results of the Kolmogorov-Smirnov test indicated that the data followed a normal distribution. A significance level of less than 0.05 was applied in all analyses.

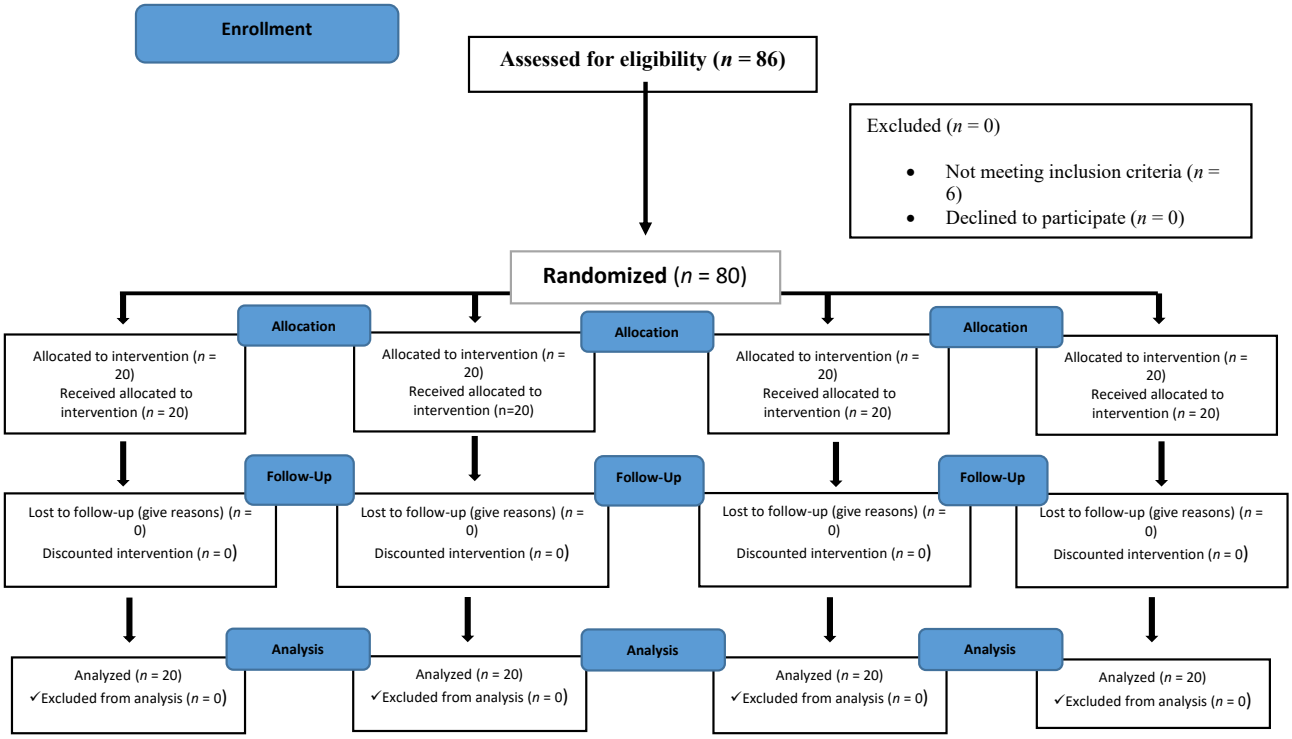


**Figure 1.** Study flow diagram

## Results

The control group consisted of 11 (55%) females and 9 (45%) males with a mean age of 32.67 ± 8.75 years. The REM-25 group included 15 (75%) females and 5 (25%) males with an average age of 37.70 ± 7.91 years. The REM-50 group comprised 11 (55%) females and 9 (45%) males with an average age of 38.40 ± 12.53 years. The REM-75 group included 5 (25%) males and 15 (75%) females with a mean age of 35.55 ± 4.67 years. Statistically, the four groups showed no significant difference in age, height, sex, weight, BMI, seizure time, and recovery time (*P* value > 0.05) (Table 1).

Evaluating patients' BP in the four groups revealed that SBP, DBP, and MAP showed no significant difference between the four groups at baseline and 1 minute after ECT (*P* value > 0.05); however, SBP and MAP with the means of 137.30 ± 14.37 mm Hg and 100.50 ± 11.06 mm Hg, respectively, had the highest mean in the control group compared to the other three intervention groups 5 minutes after ECT (*P* value = 0.042). In other words, the increase in SBP and MAP in the intervention groups was less than in the controls 5 minutes after ECT. However, the three groups showed no significant difference at other evaluated times up to 20 minutes after ECT (*P* value > 0.05). Also, changes (increase) in SBP and MAP had the highest mean in the control group with 1.50 ± 7.97 mm Hg and 3.75 ± 5.40 mm Hg, respectively, 20 minutes after ECT. Moreover, changes (increase) in SBP and MAP had the lowest increase in the REM-75 group with the mean of 0.20 ± 7.37 mm Hg and 1.45 ± 4.53 mm Hg, respectively, 20 minutes after ECT. However, this difference was not significant (*P* value < 0.05) (Table 2).

Patients' HR significantly increased in all four groups over 20 minutes of ECT (*P* value < 0.001). However, this increase in the REM-75 group, with a mean of 7.70 ± 12.54 bpm, was significantly less than the increase in the REM-25 and REM-50 groups, with a mean of 16.15 ± 13.80 bpm and 13.15 ± 8.03 bpm, respectively. Moreover, the controls with an average of 23.00 ± 11.74 bpm had the highest increase in HR (*P* value < 0.05). In contrast, the four groups showed no significant difference in SpO2 levels in each of the studied times (*P* value > 0.05) (Table 3).

Finally, among the reported complications, only tachycardia showed a significant difference between the four groups, with tachycardia in the control and REM-25 groups reported as 35% and 10%, respectively. No cases of tachycardia were observed in the other groups (*P* value = 0.046). Other complications such as HTN, hypotension, bradycardia, hypoxia, headache, nausea and vomiting, and myalgia were infrequent, and no significant difference was detected between the four groups in this regard (*P* value > 0.05) (Table 4).

## Discussion

The intranasal administration of remifentanil at different doses and the administration of drugs, including midazolam, sodium thiopental, and succinylcholine for induction of anesthesia, did not affect the duration of seizures. In contrast to our findings, the increased duration of seizures associated with adding remifentanil to intravenous anesthetics and a reduction in the dose of intravenous anesthetics have been reported in previous

**Table 1.** Basic and clinical characteristics of patients in the four study groups

| Variables | Control group | REM-25 group | REM-50 group | REM-75 group | *P* value |
|---|---|---|---|---|---|
| Sex | | | | | |
| Male | 9 (45.0%) | 5 (25.0%) | 9 (45.0%) | 5 (25.0%) | 0.319 |
| Female | 11 (55.0%) | 15 (75.0%) | 11 (55.0%) | 15 (75.0%) | |
| Age (y) | 32.67±8.75 | 37.70±7.91 | 38.40±12.53 | 35.55±4.67 | 0.204 |
| Weight (kg) | 76.94±16.30 | 75.15±6.39 | 75.10±10.48 | 76.30±16.69 | 0.965 |
| Height (cm) | 171.67±10.05 | 168.45±8.09 | 171.65±8.43 | 170.00±4.96 | 0.544 |
| BMI (kg/m$^{2)}$ | 26.11±5.57 | 26.60±2.99 | 25.38±1.92 | 26.26±4.64 | 0.800 |
| Seizure time (s) | 25.60±3.35 | 26.30±2.34 | 27.10±2.83 | 26.55±2.54 | 0.400 |
| Recovery time (min) | 30.00±3.24 | 30.00±3.97 | 29.75±2.55 | 29.50±1.54 | 0.400 |

**Table 2.** Determination and comparison of patients' SBP, DBP, and MAP in the four study groups

| Variables | Control group | REM-25 group | REM-50 group | REM-75 group | *P* value |
|---|---|---|---|---|---|
| SBP (mm Hg) | | | | | |
| Baseline | 130.15±11.25 | 129.10±13.29 | 130.50±15.00 | 129.90±14.97 | 0.072 |
| $T_1$ | 130.20±14.28 | 132.45±17.64 | 135.90±14.91 | 135.00±21.74 | 0.647 |
| $T_5$ | 137.30±14.37 | 133.15±17.70 | 132.20±8.56 | 131.60±18.36 | 0.041 |
| $T_{10}$ | 133.95±11.55 | 131.20±15.23 | 132.50±9.97 | 132.60±12.68 | 0.123 |
| $T_{20}$ | 131.65±10.39 | 130.50±17.79 | 131.10±9.58 | 130.10±12.05 | 0.509 |
| Change | 1.50±7.97 | 1.40±13.79 | 0.60±19.06 | 0.20±7.37 | 0.801 |
| DBP (mm Hg) | | | | | |
| Baseline | 82.95±8.85 | 83.95±11.74 | 85.25±7.96 | 87.20±10.95 | 0.570 |
| $T_1$ | 87.00±10.69 | 85.80±11.61 | 88.35±12.82 | 91.40±11.66 | 0.473 |
| $T_5$ | 83.95±11.18 | 82.10±12.40 | 87.15±15.81 | 85.10±8.66 | 0.622 |
| $T_{10}$ | 81.70±9.75 | 82.55±15.89 | 85.15±10.14 | 84.40±9.87 | 0.613 |
| $T_{20}$ | 80.30±7.14 | 82.90±12.86 | 83.85±10.29 | 85.23±19.26 | 0.620 |
| Change | -2.64±8.70 | -1.05±10.67 | -1.40±6.55 | -1.97±14.95 | 0.127 |
| MAP (mm Hg) | | | | | |
| Baseline | 96.70±9.78 | 98.20±13.73 | 97.85±12.16 | 98.45±8.13 | 0.137 |
| $T_1$ | 100.45±12.81 | 99.10±14.27 | 99.65±13.69 | 99.20±16.87 | 0.558 |
| $T_5$ | 100.50±11.06 | 98.75±11.67 | 98.75±7.58 | 98.50±14.89 | 0.012 |
| $T_{10}$ | 94.50±9.80 | 98.90±9.87 | 102.35±17.57 | 98.65±8.54 | 0.239 |
| $T_{20}$ | 92.95±11.87 | 101.35±17.66 | 100.85±16.62 | 99.90±9.79 | 0.111 |
| Change | 3.75±5.40 | 3.15±26.36 | 3.00±13.33 | 1.45±4.53 | 0.694 |

Baseline: before intervention, T1: 1 minute after ECT, T5: 5 minutes after ECT, T10: 10 minutes after ECT, T20: 20 minutes after ECT.
REM: remifentanil, SBP: systolic blood pressure, DBP: diastolic blood pressure, MAP: mean arterial pressure.

studies (10,11). Many intravenous anesthetics have anticonvulsant effects. Since remifentanil does not have anticonvulsant effects, reducing the dose of intravenous anesthetics may directly affect the seizure duration (12,13).

It is important to note that remifentanil was administered intranasally in the present study. Although the mentioned administration method differs from the intravenous administration in previous studies, it can be stated that due to the anatomical relationship between the nose and the brain, it affects the brain more quickly and can be considered comparable to intravenous injection.

Consistent with the present study, the findings of the research conducted by Nasseri et al and Andersen et al intravenously administered a combination of anesthetics such as thiopental 1 mg/kg with remifentanil 1 μg/kg and methohexital 0.5 mg/kg with remifentanil 1 μg/kg and found no impact on the duration of ECT-related seizures (8,14). Therefore, the effect of different anesthetics and different concentrations of remifentanil (in addition to intravenous/intranasal administration) can be considered to affect remifentanil's impact on the duration of ECT-related seizures. However, both studies have reported better stability in patients' cardiovascular parameters in spite of no changes in the duration of seizures.

In this respect, the findings of our study evaluating

**Table 3.** Measurement and comparison of patients' HR and SpO2 in the four study groups

| Variables | Control group | REM-25 group | REM-50 group | REM-75 group | *P* value |
|---|---|---|---|---|---|
| HR (bpm) | | | | | |
| Baseline | 84.10±14.49 | 84.70±18.62 | 88.40±18.37 | 87.10±17.99 | 0.848 |
| $T_1$ | 98.30±13.67 | 99.75±14.64 | 97.30±14.09 | 101.15±17.05 | 0.858 |
| $T_5$ | 102.80±16.71 | 102.70±16.11 | 100.60±14.29 | 102.15±24.18 | 0.975 |
| $T_{10}$ | 103.30±16.64 | 103.55±18.00 | 103.15±19.54 | 100.75±17.99 | 0.970 |
| $T_{20}$ | 107.10±19.42 | 100.85±16.66 | 101.55±21.25 | 94.80±18.28 | 0.238 |
| Change | 23.00±11.74 | 16.15±13.80 | 13.15±8.03 | 7.70±12.54 | 0.040 |
| SpO2 (%) | | | | | |
| Baseline | 96.70±1.63 | 96.05±1.23 | 96.30±1.56 | 95.90±1.39 | 0.409 |
| $T_1$ | 96.90±1.97 | 96.20±4.11 | 95.70±5.10 | 96.45±1.43 | 0.680 |
| $T_5$ | 96.00±5.87 | 97.85±3.41 | 97.50±2.58 | 97.05±2.33 | 0.194 |
| $T_{10}$ | 97.40±3.02 | 96.35±2.08 | 96.65±2.11 | 97.45±1.99 | 0.230 |
| $T_{20}$ | 96.90±3.31 | 96.40±1.69 | 96.40±1.89 | 96.65±1.39 | 0.468 |
| Change | 0.20±2.93 | 0.35±3.09 | 0.10±2.20 | 0.75±1.93 | 0.824 |

Baseline: before intervention, T1: 1 minute after ECT, T5: 5 minutes after ECT, T10: 10 minutes after ECT, T20: 20 minutes after ECT
HR: heart rate, SpO2: peripheral capillary oxygen saturation.

**Table 4.** Comparison of the frequency distribution of complications in the four study groups

| Complication | Control group | REM-25 group | REM-50 group | REM-75 group | *P* value |
|---|---|---|---|---|---|
| HTN | 6 (30.0%) | 4 (20.0%) | 3 (15.0%) | 2 (10.0%) | 0.397 |
| Hypotension | 0 (0%) | 0 (0%) | 0 (0%) | 2 (10%) | 0.104 |
| Tachycardia | 7 (35.0%) | 2 (10.0%) | 0 (0%) | 0 (0%) | 0.046 |
| Bradycardia | 1 (5%) | 0 (0%) | 0 (0%) | 0 (0%) | 0.386 |
| Hypoxia | 2 (10%) | 0 (0%) | 0 (0%) | 0 (0%) | 0.104 |
| Headache | 1 (5%) | 0 (0%) | 0 (0%) | 0 (0%) | 0.386 |
| Nausea and vomiting | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5%) | 0.386 |
| Laryngospasm | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | - |
| Myalgia | 3 (15%) | 2 (10%) | 1 (5%) | 0 (0%) | 0.308 |

hemodynamic parameters, such as SBP, DBP, MAP, HR, and SpO2, showed that the mean SBP and MAP in the fifth minute after ECT was significantly higher in the controls compared to the subjects receiving the three doses of remifentanil (25, 50, 75 μg) intranasally. During this time, the increase in SBP and MAP in remifentanil groups was smaller than in the control group. In other words, BP at higher doses of remifentanil (75 μg) was associated with a smaller increase, although this difference was not significant over longer periods. Intranasal administration of remifentanil can show its effectiveness more evidently in the first minutes of administration. Moreover, the increase in patients' HR was lower in the remifentanil groups compared to the control group, i.e., with an increase in the remifentanil dose, the control of the patient's cardiovascular responses and stability was better.

Remifentanil has an acute attenuating effect on cardiovascular responses that can cause a decrease in MAP and HR during general anesthesia (15). Tajabadi et al also concluded that the intravenous administration of remifentanil at 100 μg could reduce changes in hemodynamic parameters without affecting the seizure or recovery time (7). Nasseri et al reported that the administration of remifentanil at the dose of 1 μg/kg could reduce the increase in MAP and HR following ECT without changing the seizure time (8). However, regarding the intranasal administration of remifentanil, Yao et al evaluated the effect of the intranasal administration of remifentanil at different doses on the quality of LMA implantation in children. They showed that the effective dose for successful LMA implantation is 1 μg/kg in combination with the inhaled *gas* of inspired *sevoflurane* (16).

In ECT, the sympathetic neuronal response that follows the brief parasympathetic nerve response has the most significant impact on changes in circulatory dynamics, with SBP being regarded as the key parameter of these dynamics (13,17,18). A rapid rise in SBP increases the risk of aneurysm rupture and is also linked to a higher likelihood of hemorrhagic stroke (19-21). However, comprehensive screening for aneurysms and vascular

malformations in patients is challenging, leaving the potential risk of asymptomatic aneurysms and cerebral venous artery abnormalities a significant concern in ECT. Consequently, the intranasal administration of remifentanil may be viewed as a safe option in this study, as it can help stabilize hemodynamic parameters while minimizing the associated complications of the drug.

Tachycardia was observed in both the REM-25 and control groups. However, no case of tachycardia was found at higher doses of remifentanil. Other complications, like HTN, bradycardia, hypotension, hypoxia, headache, vomiting and nausea, and myalgia, were infrequent and non-significant.

In line with the present study's findings, another study has addressed the role of intravenous remifentanil (1 µg/kg) in reducing transient tachycardia, commonly seen after ECT (8). Additionally, previous studies have shown that the peak increase in MAP following electrical stimulation was significantly lower in the high-dose remifentanil group. Thus, administering higher doses of intravenous remifentanil (>100 µg) may help mitigate the transient tachycardia after ECT stimulation. However, doses of remifentanil between 150 and 200 µg have been linked to significant hypotension just before ECT and longer recovery times (7,18). It can be concluded that remifentanil, as a potent opioid analgesic, may effectively manage the acute hyperdynamic response to the ECT stimulus (7).

## Conclusion

The intranasal administration of remifentanil along with anesthetic drugs did not affect the duration of ECT-related seizures; however, it was able to minimize the increase in hemodynamic responses, including SBP, MAP, and HR, with better effect at higher doses of remifentanil (75 µg). Tachycardia was higher in the control and low-dose remifentanil (25 µg) groups as compared with the other groups. Therefore, further evidence on the effectiveness and safety of remifentanil at different doses and various administration routes (intravenous and intranasal) is required to achieve reliable results.

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**Writing-review & editing:** Behzad Nazemroaya.

**Competing Interests**

The authors declare that they do not have any conflict of interest.

**Ethical Approval**

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1399.251) and was also registered with the Iranian Registry of Clinical Trials (identifier: IRCT20200825048515N20).

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