The Effect of Midazolam on Remifentanil-Induced Difficulty in Mask Ventilation: A Randomised Study

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ABSTRACT

Objective: To explore the impact of midazolam premedication on the difficulty of mask ventilation induced by remifentanil during general anaesthesia induction.

Study Design: A prospective, randomised, double-blind study.

Place and Duration of the Study: This study was conducted at Karaman Training and Research Hospital, Karaman, Turkiye, from May 2022 to January 2024.

Methodology: This study included 120 patients aged 18-60 years with ASA score I-II scheduled to undergo general anaesthesia for elective surgery. The patients were randomly divided into two groups: Group M and Group C. Patients in Group M received midazolam premedication before induction, while patients in Group C received saline. After the general anaesthesia induction, the level of mask ventilation difficulty for the patients was evaluated using the Warters scale as a primary outcome of the study, in which an independent Sample t-test was used for comparison.

Results: The groups showed a significant difference in Warters scale results distribution ($p < 0.001$). The mean Warters scores were 1.58 (2.03) in Group M and 3.40 (2.26) in Group C.

Conclusion: The study concluded that using midazolam premedication can help prevent difficulties with mask ventilation that may arise with the use of remifentanil during anaesthesia induction. The results also showed that midazolam premedication can facilitate mask ventilation for patients with risk factors for difficult mask ventilation.

Key Words: *Anaesthesia, General, Airway management, Midazolam, Opioids, Premedication, Remifentanil*.

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INTRODUCTION

Mask ventilation is an indispensable part of general anaesthesia induction as it is the only means of providing oxygenation for patients who are unconscious or who do not have spontaneous breathing.[1] Mask ventilation provides ventilation until the anaesthetist places a subglottic or supraglottic airway device in the airway of patients.

Despite many advantages of opioid-free anaesthesia methods, opioids are still usually used in anaesthesia practice. Remifentanil is an opioid derivative used during anaesthesia induction, which has a short-acting effect and the property of suppressing the stress response to intubation.[2,3] Remifentanil infusions used in balanced anaesthesia allow inhalational anaesthetics to be used at lower doses.

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However, despite these beneficial properties, the side effect profile of remifentanil is similar to that of other opioids in the group, with characteristics that can create muscle rigidity and respiratory depression. The occurrence of opioid-induced muscle rigidity can be seen when opioids are administered rapidly intravenously at high doses.[4] Rigidity of the chest and abdominal muscles makes ventilation of the lungs more difficult because of the challenges in mask ventilation during anaesthesia induction. The development of rigidity in the laryngeal muscles can cause impossible ventilation and life-threatening hypoxia.[5] Remifentanil used at routine doses in anaesthesia induction and maintenance can lead to muscular rigidity and cause difficulty in mask ventilation. Therefore, various studies have been conducted about neuromuscular blockers and hypnotic agents to prevent this significant side effect of remifentanil.[6,7] Previous studies have shown that midazolam premedication facilitates mask ventilation.[8] Based on this finding, the current study was planned considering that it could reduce the difficulty of mask ventilation due to remifentanil.

This prospective, randomised, double-blind study aimed to assess the impact of premedication with midazolam on the difficulty of mask ventilation induced by remifentanil during the induction of general anaesthesia in adults.

METHODOLOGY

The study was conducted at Karaman Training and Research Hospital, Turkiye, after obtaining approval from the Ethics Committee of the University Medical Faculty (Decision No: 08-2021/14). All procedures complied with the Helsinki Declaration. The study protocol was registered on clinicaltrials.gov with the number; NCT05369819. All patients provided written informed consent to participate in the study.

The study included 122 patients, aged 18-60 years, of American Society of Anesthesiologists (ASA) grade I-II, who were scheduled to undergo general anaesthesia for elective surgery.

The study exclusion criteria included body mass index (BMI) ≥35 kg/m^2, pregnancy, the presence of sleep apnoea (Sleep apnoea syndrome is having five or more episodes of apnoea or hypopnoea per hour of sleep, along with related symptoms), allergic reaction to midazolam, muscular disease, craniofacial disorder, dyspnoea, cervical spine disorder or a history of cervical spinal surgery, a history of chronic respiratory system disease, treatment with a chronic opioid, benzodiazepine, anticonvulsants or antipsychotic agents, or the need for any emergency surgery.

After being enlisted, the participants were allocated randomly to either the intervention (Group M) or the control group (Group C). Computer-generated random numbers were used to ensure concealment, and participants were assigned using a closed envelope method by a blinded anaesthetist. Participants, anaesthesia providers, and outcome assessors were blinded to group assignments. Finally, the blinded nurse administered medications to the patients in the preoperative room (PR) as outlined in the protocol detailed below.

In the PR, an anaesthetist blinded to the patient groups made a record for each patient of age, gender, height, weight, Mallampati score, inter-incisor gap, thyromental distance, sternomental distance, neck circumference, the presence of a beard, any missing teeth, and known snoring. The risk factors for difficult mask ventilation were recorded, including age over 55 years, male gender, BMI over 26 kg/m^2, Mallampati grade III or IV, snoring, a beard, and missing teeth.

Three minutes before admission to the operating room (OR), intravenous midazolam premedication (0.035 mg/kg midazolam and saline mixed to a volume of 3cc, with the maximum midazolam dose being 3 mg) was administered to the patients in Group M while still in the PR. For the patients in Group C, 3cc normal saline was administered intravenously. The patients' sedation and anxiety levels were assessed using the modified observer's assessment of alertness/sedation scale (MOAA/S, with points ranging from 0 to 5, where 5 = awake or minimally sedated and 0 = general anaesthesia) and the Numerical Rating Scale (NRS, range, 0–10; 0 = very calm, 10 = very anxious) before premedication. Three minutes after the premedication, the patients were admitted to the OR, and electrocardiogram (ECG), blood pressure, and pulse oximetry monitoring were performed. The sedation and anxiety levels were re-evaluated before induction.

A 7 cm high surgical pillow was used for the patient's head position. In the general anaesthesia induction of the patients after three minutes of pre-oxygenation, an intravenous remifentanil infusion (at a dose of 0.30 mcg/kg/min for three minutes) was administered, and then 1.5mg/kg propofol. Additional doses of 10 mg propofol were given if necessary until the patient lost consciousness, and the additional doses were recorded. Following the loss of consciousness, the patients were ventilated using a mask by an anaesthetist unaware of the groups. Face-mask ventilation was performed using a generic single-handed technique with face masks of a size appropriate to the face of the patient.

Difficulties in mask ventilation of the patients were evaluated over 30 seconds using the Warters grading scale by another anaesthetist who was blinded to the study protocol and the patient groups.[9] The Warters scale is based on the scoring of the increasing intervention levels required to ventilate the lungs, such as using an oropharyngeal airway, increasing inspiratory pressure, and the need for two-handed ventilation.[9] Higher points obtained on the scale indicate more difficult mask ventilation. The tidal volume provided during mask ventilation is monitored on the ventilator screen of the anaesthesia machine (Drager Primus, Lubeck, Germany). Based on the Warters ventilation score values, the aim was to create a volume at 5 ml/kg. In patients whose targeted volume could not be reached, an oropharyngeal airway was used until the target volume was achieved, positive inspiratory pressure above 20 cmH_2O was applied, and two-person mask ventilation was performed. Patients who applied these procedures were scored according to the Warters grading scale. Mask ventilation and subsequent continuous capnography monitoring were performed. After the evaluation, the patients were administered neuromuscular blocker medicines at routine doses and intubated, and then the procedure was completed. Heart rate, blood pressure, and pulse oximetry values were recorded. All anaesthetists involved in the research had at least four years of experience as consultants. The study excluded patients who could not be ventilated with a mask and whose oxygen saturation fell below 90%; a rescue plan was implemented appropriate to the ASA difficult airway management algorithm.

The effect of midazolam premedication on mask ventilation difficulty caused by the remifentanil infusion used in induction was evaluated with the Warters grading scale.

The effect of midazolam premedication on preoperative anxiety was assessed using an NRS scale and its impact on sedation with the MOAA/S scale. Changes in the heart rate, blood pressure, and pulse oximetry measurements were examined between the time points before and after induction and before neuromuscular blocker administration.

The study's data were statistically analysed using IBM Statistical Package for Social Sciences 22.0 (SPSS). Descriptive statistics were stated as mean ± standard deviation values for continuous variables and frequency and percentage (%) for categorical variables. The Kolmogorov-Smirnov test was employed to

assess the normality of the distribution in the statistical evaluation of quantitative data. Independent Samples t-test or the Mann-Whitney U test was used to compare numerical variables according to data distribution. Also, the paired or the Wilcoxon signed-rank test was used to analyse the anxiety and sedation levels between the reception area and the OR, respectively. The Chi-square and Fisher's Exact tests were used to analyse categorical variables. For a Warters score ≥2, risk ratios and 95% confidence intervals (CI) were given. The differences between scores and the 95% CI were calculated. Similarly, a subgroup analysis was performed to compare the Warters score values of patients with risk factors for difficult mask ventilation in both groups. A value of $p < 0.05$ was accepted as statistically significant.

To determine the required number of subjects, a pilot study involved 20 patients (10 pairs: 10 in the midazolam group and 10 in the control group) who underwent general anaesthesia. Using the Warters scale, the mean and standard deviation values for mask ventilation without midazolam premedication were calculated as 1.4 ± 0.699. When midazolam premedication was used for mask ventilation, the mean and standard deviation values for the Warters scale were 1.0 and 0.667, respectively. It was calculated that the study should include 55 patients per group to reveal a significant difference between the two ratios of 1.0 and 1.4 with 85% power and 5% error. Assuming that some patients might drop out of the study, a 10% patient increase in each group was implemented.

RESULTS

From the 122 patients initially enrolled in the study, the procedure could not be completed in two patients (one patient developed hypotension, and in one patient, oxygen saturation dropped below 90%), so the study was completed with the analyses of the data of 120 patients (Group M: n = 60, Group C: n = 60, Figure 1). The statistical findings obtained in the comparisons of the clinical characteristics of the patients in the groups are presented in Table I. There was no difference between the two groups regarding these characteristics (Table I).

The distribution of the Warters scale results demonstrated a statistically significant difference between the groups ($p < 0.001$). Also, subgroup analyses were performed for patients with more than two risk factors for difficult mask ventilation. These subgroup analyses showed a statistically significant difference (Table II).

In a comparison of anxiety (NRS) and sedation (MOAA/S) scores between groups, the midazolam group exhibited lower anxiety scores and higher sedation levels ($p < 0.001$, $p < 0.001$). The NRS values of patients in the control and midazolam groups in the preoperative waiting and operating rooms were 5.95 (0.89) - 6.16 (0.94) *vs.* 6.33 (1.05) - 4.03 (0.93), respectively. When these values were analysed, the decrease in anxiety scores in the midazolam group was statistically significant ($p < 0.001$), while the changes in the control group were insignificant ($p = 0.012$).

When the changes in heart rate and blood pressure were examined, there were decreases after induction as compared to that of before in both groups. During the group comparisons, the midazolam group had lower blood pressure values than the control group before induction and before neuromuscular blocker administration ($p = 0.047$).

Table I: Characteristics of patients of intervention and control groups.

Parameters	Midazolam (n = 60)	Control (n = 60)	p-value
Age (years)	40.35 ± 10.76	42.78 ± 13.71	0.282[b]
Gender (male/female)	37/23	29/31	0.142[a]
Weight (kg)	78.56 ± 14.77	77.01 ± 13.46	0.549[b]
BMI (kg/m^2)	26.62 ± 4.17	27.57 ± 3.91	0.345[b]
Mallampati class (I/II/III/IV)	10/38/12/0	13/41/5/1	0.223[a]
Snoring (yes/no)	33/27	28/32	0.361[a]
Beard (yes/no)	8/52	7/53	0.783[a]
Lack of teeth (yes/no)	4/56	6/54	0.509[a]
Interincisor gap (cm)	4.45 ± 0.57	4.28 ± 0.55	0.104[b]
Thyromental distance (cm)	7.97 ± 1.11	7.63 ± 1.26	0.120[b]
Sternomental distance (cm)	16.13 ± 1.42	15.46 ± 2.22	0.052[b]
Neck circumference (cm)	36.41 ± 3.54	35.53 ± 3.77	0.118[b]
Cormack-lehane grade (I/II/III/IV)	22/30/6/2	32/22/5/1	0.320[a]

Continuous values are shown as mean (standard deviation); Categorical variables are expressed as frequencies; [a] Chi-square test and [b] t-test. BMI, Body mass index.

Table II: Warters ventilation score during anaesthetic induction.

	Midazolam		Control		p-value (a)	Estimated Differences (95% CI)	Risk Ratio (95% CI) b	p-value (b)
	n	Score	n	Score				
Total	60	1.58 ± 2.03	60	3.40 ± 2.26	<0.001	-1.82 (-2.59 to -1.04)	0.112 (0.048 to 0.262)	<0.001
≥2 risk factors	40	2.02 ± 2.14	39	3.69 ± 2.42	0.002	-1.66 (-2.69 to 0.64)	0.502 (0.342 to 0.738)	<0.001

Values are indicated as mean (standard deviation). CI, Confidence interval.
(a) Comparisons of the difficulty of mask ventilation between the groups using t-test in total patients and subgroup patients (those with more than 2 risk factors), (b) Risk ratios, and comparisons of the incidence of difficulty needing more than an airway device during mask ventilation (≥2 Warters score) between groups using Fisher's exact test.

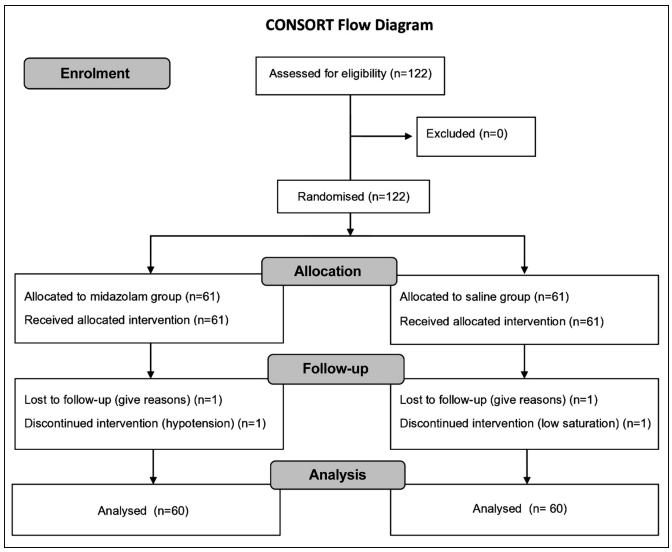

Figure 1: Consolidated standards of reporting trials (CONSORT) diagram for the trial.

DISCUSSION

In this study, the Warters grading scale was used to examine the effect of midazolam premedication on mask ventilation difficulty due to the use of remifentanil. The data obtained showed that using midazolam premedication could reduce the need for multiple attempts to provide adequate mask ventilation. According to the study results, midazolam premedication facilitated mask ventilation in all patients and those with risk factors for difficult mask ventilation. Although previous studies have reported that midazolam facilitates mask ventilation during general anaesthesia induction and reduces opioid-induced muscle rigidity, the current study is the first to have shown the positive impact of midazolam premedication on difficulties with mask ventilation caused by remifentanil.[8,10]

Midazolam is a benzodiazepine derivative that is widely used in premedication because of its anxiolytic effect. Midazolam creates an inhibitor effect by binding to gamma-aminobutyric acid A receptors (GABAA).[11,12] Previous studies have suggested that midazolam affecting alpha-2 GABAA receptor subunits leads to muscle relaxation in the upper respiratory pathways.[8] There are also studies reporting that the use of hypnotic medicines, including benzodiazepines, in premedication can alleviate the severity of opioid-related chest wall rigidity by increasing gabaergic activation.[7,10] When all these mechanisms are considered together, the effect of midazolam facilitating mask ventilation found in this study was not surprising but was an expected effect.

Remifentanil, commonly used in anaesthesia induction, has side effects similar to other opioids but tends to cause more hypotension, muscle rigidity, and nausea compared to alfentanil or fentanyl.[3] This underscores the importance of the current study on midazolam premedication, which can help prevent mask ventilation difficulties associated with remifentanil. Remifentanil can cause muscle rigidity, especially at high doses, but similar rates of rigidity have been observed even with lower doses.[6,7] This situation highlights the importance of midazolam premedication in improving mask ventilation.

A study investigated the effects of various medications on rigidity induced by alfentanil, finding that midazolam reduced muscle rigidity, though the participant count was very low.[10] In that study, neuromuscular blockers were ineffective at reducing rigidity. However, another study showed that priming with rocuronium and vecuronium decreased remifentanil-related mask ventilation difficulty.[6] When neuromuscular blockers are used for this purpose, regardless of the range and doses of neuromuscular blockers, there is a possibility of the emergence of side effects such as low saturation, regurgitation, and aspiration. Moreover, when priming is applied, patients may feel anxiety due to dyspnoea and injection pain. Therefore, there could be a series of additional problems in the administration of neuromuscular blockers to prevent ventilation difficulty due to rigidity.

The midazolam premedication used in the current study caused no discomfort in any patient and decreased preoperative anxiety, thereby increasing patient comfort. Midazolam showed an anxiolytic effect in the current study data obtained from the comparisons of anxiety levels between the groups using the NRS. Dexmedetomidine, as one of the alpha-adrenergic agonists, has been used to prevent opioid-induced muscle rigidity. It has been reported in a study that mask ventilation difficulty formed by bolus remifentanil administration was prevented by dexmedetomidine. However, the reliability of the results of that study is overshadowed by the fact that all the patients in the study received midazolam premedication, and evaluation of mask ventilation difficulty was made according to a subjective scale.[13]

Identifying patients with risk factors for difficult mask ventilation before anaesthesia induction may reduce potential adverse outcomes. Many studies have investigated the relationship between difficult mask ventilation and factors such as age, gender, BMI, and obstructive sleep apnoea (OSA).[14,15] The known risk factors for difficult mask ventilation have been stated in literature as age >55 years, BMI >26 kg/m^2, missing teeth, a beard, and a history of snoring.[16-18] The subgroup analysis conducted in this study showed that midazolam premedication improved mask ventilation in patients with risk factors for difficulty in mask ventilation.

There were some limitations to this study. There is no definitive information about the dosage of remifentanil used in anaesthesia induction, so it is used in a very wide dose range.[19] The dose selected in the current study is only one of the doses used. Therefore, the positive effect determined in this study should be examined in similar studies where different remifentanil doses have been used. A second limitation was that although mask ventilation difficulty was evaluated based on the Warters scale, determination with controlled airway pressure of tidal volumes could provide

more objective results. Also, this study did not utilise a scale that assesses the adequacy of mask ventilation based on capnography measurements.[20] Another situation is that an experienced anaesthetist applying mask ventilation can recognise a sedated patient. To prevent this form of bias in the current study, according to the Warters scale, the scoring was done by a different anaesthetist than the one who performed the mask ventilation. Finally, the preventative effect of midazolam was evaluated only on mask ventilation difficulty caused by remifentanil. Future studies could use EMG measurements to assess the preventive effect of midazolam on chest wall rigidity.

CONCLUSION

This study demonstrated that midazolam premedication can be used to prevent mask ventilation difficulty, which can be associated with using remifentanil during anaesthesia induction. The results obtained in this study also showed that midazolam premedication had a facilitating effect in patients with risk factors for difficult mask ventilation.

ETHICAL APPROVAL:
This study was conducted after obtaining the approval of the Ethics Committee of Karamanoglu Mehmetbey University Faculty of Medicine (08-2021/14). It was registered in clinicaltrials.gov with the number NCT05369819. The study was conducted in line with the Declaration of Helsinki.

PATIENTS' CONSENT:
All patients provided written informed consent to participate in the study.

COMPETING INTEREST:
The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:
RY: Conception or design of the work, acquisition, analysis, interpretation, and drafting of the work and revision of the manuscript.
BB: Analysis, interpretation, drafting of the work, and revision of the manuscript.
Both authors approved the final version of the manuscript to be published.

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