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# Effect of intramuscular midazolam premedication on patient satisfaction in women undergoing general anaesthesia: a randomised control trial

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## ABSTRACT

**Objective** To determine the effect of premedication with intramuscular midazolam on patient satisfaction in women undergoing general anaesthesia.

**Trial design, setting and participants** Double-blind, parallel randomised control trial at a tertiary care medical centre in South Korea. Initially, 140 women aged 20–65 years who underwent general anaesthesia and had an American Society of Anesthesiology physical status classification of I or II were randomly assigned to the intervention group or the control group, and 134 patients (intervention n=65; control n=69) completed the study.

**Intervention** Intramuscular administration of midazolam (0.05 mg/kg) or placebo (normal saline 0.01 mL/kg) on arrival at the preoperative holding area.

**Main outcomes** The primary outcome was the patient's overall satisfaction with the anaesthesia experience as determined by questionnaire responses on the day after surgery. Satisfaction was defined as a response of 3 or 4 on a five-point scale (0–4). The secondary outcomes included blood pressure, heart rate, oxygen desaturation, recovery duration and postoperative pain.

**Results** Patients who received midazolam were more satisfied than those who received placebo (percentage difference: 21.0%, OR 3.56, 95% CI 1.46 to 8.70). A subgroup analysis revealed that this difference was greater in patients with anxiety, defined as those whose Amsterdam Preoperative Anxiety and Information Scale anxiety score was ≥11, than that for the whole sample population (percentage difference: 24.0%, OR 4.33, 95% CI 1.25 to 14.96). Both groups had similar heart rates, blood pressure and oxygen desaturation.

**Conclusion** Intramuscular administration of midazolam in women before general anaesthesia in the preoperative holding area improved self-reported satisfaction with the anaesthesia experience, with an acceptable safety profile.

**Trial registration number** KCT0006002.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study prospectively investigated the role of midazolam premedication in women undergoing general anaesthesia to improve patient satisfaction.
⇒ The intervention in this study was the administration of intramuscular midazolam, the most widely used benzodiazepine, or placebo.
⇒ Limitations are the fact that the sample was drawn from a single ethnic group and that the study was not powered for subgroup analysis.

## INTRODUCTION

Preoperative anxiety is a common problem in patients undergoing surgery. Surgical patients are prone to anxiety due to fear of intraoperative awareness, postoperative pain, complications and mortality.[1 2] The incidence of preoperative anxiety varies depending on the assessment tool used and target population. One study using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) reported that 44% of patients were worried about anaesthesia.[1] Apart from an unpleasant emotional problem, anxiety positively correlated with postoperative pain, nausea, vomiting and adverse outcomes, such as infection and mortality,[2 3] and negatively correlated with patient satisfaction.[4 5]

Pharmacological intervention is an option for attenuating preoperative anxiety. Benzodiazepines are one of the main drug classes used for premedication prior to surgery, alongside beta-adrenoreceptor blockers and opioids.[6] Midazolam is a widely used benzodiazepine that produce anxiolytic and considerable anterograde amnesic effects. It has numerous advantages including a short half-life, minimal haemodynamic turbulence, and only mild respiratory depression.[7] In addition, midazolam can be easily administered via oral, rectal, intramuscular, intravenous and intranasal routes. Preoperative midazolam is often administered intramuscularly, with various studies having examined this route of administration.[8–11]

Some studies have reported the effect of premedication with benzodiazepines on patient satisfaction.[5 12–14] However,

Table 1 Baseline characteristics

| | Midazolam (n=65) | Placebo (n=69) |
|---|---|---|
| Age, mean (SD), years | 46.1 (11.1) | 47.3 (11.3) |
| Age group, n (%) | | |
| 20–35 | 10 (15.4) | 13 (18.8) |
| 36–50 | 29 (44.6) | 26 (37.7) |
| 51–65 | 26 (40.0) | 30 (43.5) |
| Body mass index, kg/m$^2$, mean (SD) | 23.8 (3.2) | 24.2 (2.9) |
| ASA physical status classification, n (%) | | |
| I | 27 (41.5) | 26 (37.7) |
| II | 38 (58.5) | 43 (62.3) |
| APAIS, mean (SD) | 17.5 (6.1) | 17.4 (6.3) |
| APAIS-A, mean (SD) | 11.1 (4.4) | 11.4 (4.5) |
| APAIS-I, mean (SD) | 6.4 (2.1) | 6.0 (2.4) |
| APAIS-A ≥11, n (%) | 36 (55.3) | 37 (53.6) |
| Length of surgery, mean (SD), minute | 89.9 (54.4) | 86.1 (50.8) |
| Type of surgery, n (%) | | |
| Gynecologic | 38 (58.5) | 30 (43.5) |
| Digestive | 16 (24.6) | 21 (30.4) |
| Orthopaedic | 7 (10.8) | 3 (4.3) |
| Ear, nose, and throat | 1 (1.5) | 7 (10.1) |
| Others | 3 (4.6) | 4 (5.8) |
| No of times underwent anaesthesia, n (%)* | | |
| 0 | 30 | 34 |
| 1 | 20 | 15 |
| 2 | 8 | 17 |
| ≥3 | 7 | 3 |
| Patient-controlled analgesia used, n (%) | 36 (55.4) | 30 (43.5) |

*Includes experiences of both general and regional anaesthesia.
APAIS, Amsterdam Preoperative Anxiety and Information Scale; APAIS-A, APAIS for Anxiety; APAIS-I, APAIS for Information desire; ASA, American Association of Anesthesiologists.

the beneficial role of benzodiazepines as premedication remains controversial. While the PremedX study reported no benefits of administering oral lorazepam as a premedication on patient satisfaction,[5] other studies have reported that premedication with midazolam before surgery and endoscopic procedures improves patient satisfaction.[7 12 15]

Certain clinical interventions are beneficial for high-risk populations but not for the general population.[16] Anxiety tends to be more common among women.[17–19] Therefore, we conducted a randomised controlled trial to assess the effect of premedication with midazolam on patient satisfaction in women.

## METHODS

### Study setting

The study was performed at a tertiary care university hospital in Wonju, South Korea. This study is reported in compliance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

### Participants

All consecutive female patients aged 20–65 years who underwent elective surgery under general anaesthesia between 17 March and 18 August 2021 were considered for enrolment in this study. Exclusion criteria included having an American Society of Anesthesiologists (ASA) physical status classification of III or higher, body mass index (BMI) 30 or higher, diagnosed with an airway obstruction, contraindication to benzodiazepines, currently being medicated with either benzodiazepines or opioids, being pregnant, breast feeding, having Child-Turcotte-Pugh class C hepatic dysfunction, acute narrow-angle glaucoma, inability to communicate, cognitive disorder and inability to understand the written information about the trial or the informed consent form.

### Study protocol

All participants received written information about the study on the day before surgery. Sufficient time was allowed for patients to learn about and understand the study before signing the informed consent form. Screening and enrolment were mainly conducted by one of the authors (YJ) under the supervision of the corresponding author. The day before surgery, an assessment of preoperative anxiety was conducted using the Korean version of the APAIS, which was previously reported by Kim *et al*.[20]

Patients were randomly assigned (1:1) to either the intervention or control group using a sealed envelope system. A random allocation sequence was created by one of the authors (SWS) using R statistical software V.4.0.4 (R Core Team, Vienna, Austria).[21] The corresponding author maintained the opaque envelopes containing the group allocation until they were opened by one of the authors (YJ) on the day of surgery.

A dedicated nurse was informed about which group each patient was allocated to and prepared the trial drug (midazolam 0.05 mg/kg) or placebo (normal saline 0.01 mg/kg) in a standard 1 mL syringe, according to group allocation. The volume of placebo was equivalent to the volume of premedication because the concentration of midazolam was 5 mg/mL. The draw-up needle was replaced with a 1.5-inch long 25-gauge needle.

Following arrival at the preoperative holding area and standard patient identification procedures, premedication or placebo was administered via intramuscular injection into the deltoid muscle on the non-dominant side by a second nurse who was blinded to group allocation. The surgical team and the attending anaesthesiologists were also blinded to group allocation but were able to access

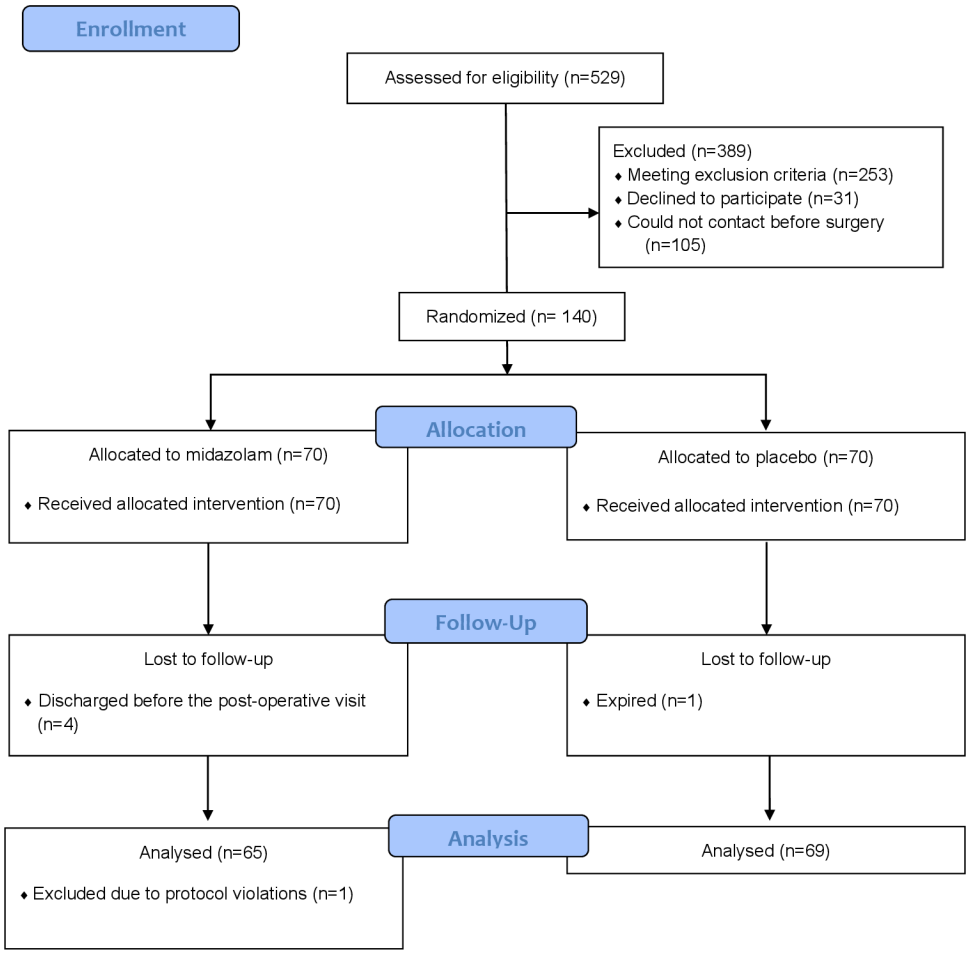


**Figure 1** Study flow diagram.

relevant information via an electronic order communication system if necessary for patient care.

Following the standard anaesthesia monitoring procedure, oxygen was administered via a facial mask at a rate of 10 L/min for 3 min. Remifentanil infusion was commenced and maintained at a rate of 0.1–0.2 µg/kg×min. Propofol was injected 1.5 mg/kg based on ideal body weight for induction of anaesthesia. After loss of

**Table 2** Safety profile by group

| | Arrival at the preoperative holding area | | Arrival at the operating room | | After 20 min in PACU | | |
|---|---|---|---|---|---|---|---|
| | Midazolam | Placebo | Midazolam | Placebo | Midazolam | Placebo | P value* |
| Heart rate, beats per minute | 66.6 (8.3) | 67.5 (10.3) | 72.6 (10.9) | 77.0 (14.0) | 70.9 (13.6) | 71.9 (14.2) | 0.22 |
| Systolic blood pressure, mm Hg | 119.2 (12.8) | 119.9 (15.4) | 131.4 (20.9) | 139.1 (21.4) | 134.5 (18.8) | 138.1 (19.4) | 0.11 |
| Diastolic blood pressure, mm Hg | 76.0 (9.3) | 78.0 (10.5) | 75.2 (11.8) | 79.0 (13.0) | 80.2 (10.5) | 82.3 (13.0) | 0.66 |
| Mean blood pressure, mm Hg | 90.0 (9.8) | 91.7 (11.4) | 93.6 (13.3) | 98.4 (14.0) | 98.0 (12.3) | 100.9 (14.3) | 0.39 |
| Incidence of oxygen desaturation†, n | 0 | 0 | 1 | 0 | 0 | 0 | |

Data for continuous variables are presented as mean (SD).
*Statistical significance of two-way repeated-measures ANOVA.
†Peripheral oxygen saturation <95%.
ANOVA, analysis of variance; PACU, postoperative care unit.

consciousness, desflurane was administered at 0.7–0.9 minimum alveolar concentration to constitute balanced anaesthesia. Rocuronium was administered as a neuromuscular blocker and endotracheal intubation was performed using a video laryngoscope from the initial attempt.

Following surgery, the patient was transferred to the post-anaesthesia care unit (PACU) and after 20 min of recovery, pain was evaluated using an 11-point Numeric Rating Scale (NRS) with a score of 0–10. In accordance with the medical centre's recovery protocol, the minimum recovery period following general anaesthesia was 30 min. Participants responded to this study's questionnaire after 20 min of recovery and on postoperative day (POD) 1 (online supplemental file 1 and online supplemental file 2).

### Variables and assessments

The primary outcome was overall satisfaction with the anaesthesia experience, which is either included as an item of various anaesthesia satisfaction questionnaires or used to validate them.[22 23] The questionnaire also measured satisfaction with premedication, intraoperative anaesthetic service, postoperative pain, and willingness to receive the same anaesthesia service if needed. Patients were asked to respond according to a five-point Likert scale ranging from 0 to 4, which has been used in several studies to measure patient satisfaction.[24–27] A response of 3 or 4 was defined as a positive response. The satisfaction levels of the intervention and control groups were then compared. A subgroup analysis of anxious patients, defined as those who had an APAIS score for anxiety (APAIS-A) of 11 or higher, was conducted.[5 20]

The secondary outcomes were safety profile, duration of recovery, postoperative pain and administration of rescue antiemetics in the PACU. The safety profile was measured in terms of heart rate, blood pressure and oxygen desaturation on arrival at the preoperative holding area, on arrival at the operating room, and after 20 min the PACU. Perioperative adverse events such as reintubation or mortality during hospitalisation were recorded. Perioperative peripheral oxygen saturation <95% was defined as oxygen desaturation. Intraoperative hypotension was defined as a mean blood pressure of <60 mm Hg.

### Statistical analysis

The original analysis was planned and performed assuming the primary outcome, Likert-scale responses, as a continuous variable. However, given that a Likert scale of 0–4 is discontinuous, more appropriate analytical methods were applied. Responses in the Likert scale format were converted to binary as described in 'Variables and assessments', and binary logistic regression analysis was considered an alternative analytic method. A power analysis was conducted, and the statistical power of the logistic regression analysis was 0.800. Accordingly, binary logistic analysis was adopted as the analytic method.

R statistical software (V.4.1.2) was used for statistical analysis and visualisation.[21] Binary logistic regression analysis was performed to analyse patient satisfaction. Two-way repeated-measures analysis of variance was used to identify statistically significant differences in blood pressure and heart rate between the groups.

Pain scores and other continuous variables were compared using a t-test. Categorical variables were analysed using $\chi^2$ tests, unless otherwise stated. Statistical significance was set at $p<0.05$.

### Sample size

We assumed that the variability of the primary outcome would be similar to that found in a prior study that used the same five-point Likert scale to determine patient satisfaction.[25] Comparison of means was assumed at the time the study was planned, and at a least 10% difference was considered to be clinically significant. The alpha value was set to 0.05 and the beta value was set to 0.2, which meant that having at least 63 patients per group would be sufficient to represent the population and identify differences between the groups. The projected drop-out rate was assumed to be 10%. Therefore, 70 patients were enrolled in each group.

### Patient and public involvement

Neither the patients nor members of the public were involved in the design and recruitment of the study. Trial results will be disseminated via peer-reviewed scientific journals or conference presentations and patients will not be notified individually.

## RESULTS

The CONSORT flow diagram of this study is shown in figure 1. One patient in the control group died of pulmonary thromboembolism on POD 1. One patient in the intervention group was later excluded during the data validation process because of a BMI>30. Baseline patient demographics and the types of procedures performed are presented in .table 1.

The mean and SD of APAIS-A and APAIS score for information desire (APAIS-I) of the whole patient sample were 11.3±4.5 and 6.2±2.3, respectively. There was no statistical difference in the vital signs on arrival at the preoperative holding area between the intervention and placebo groups (table 2). The mean time interval between arrival at the preoperative holding area and arrival at the operating room was 15.3±7.5 min.

For the primary outcome, patients who received midazolam tended to be more satisfied than those who received placebo (percentage difference: 21.0%; table 3 and figure 2). Patients who received midazolam were more satisfied with premedication and pain control than those who received placebo; however, this difference was not statistically significant. Patients who received midazolam were more willing to receive the same anaesthesia service

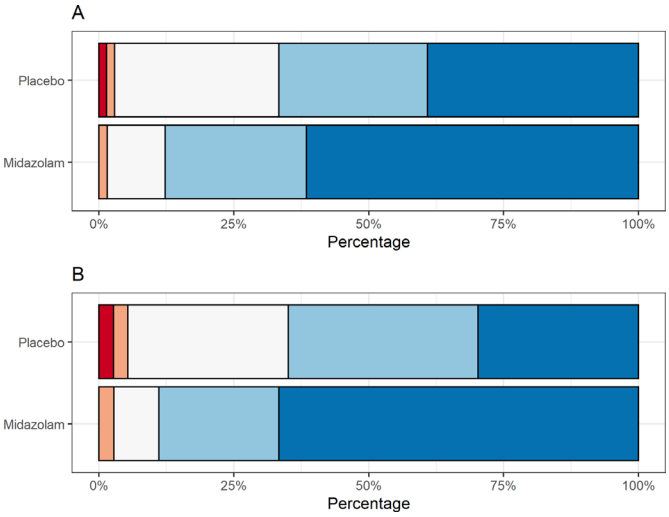


**Figure 2** Overall satisfaction with the anaesthesia experience for (A) all patients and (B) anxious patients with APAIS score for anxiety ≥11. APAIS, Amsterdam Preoperative Anxiety and Information Scale.

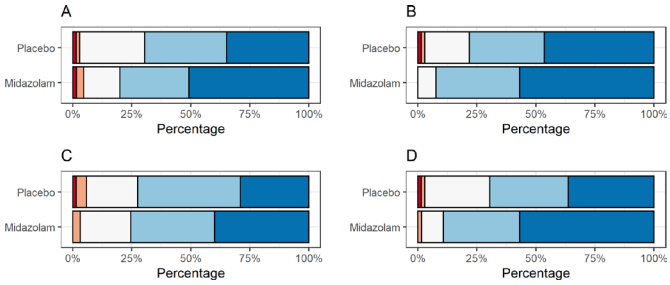


**Figure 3** Patient responses regarding (A) satisfaction with premedication, (B) satisfaction with anaesthesia in the operating room, (C) satisfaction with postoperative pain control and (D) willingness to receive the same anaesthesia if needed.

later, if needed, than patients who received the placebo, and this difference was statistically significant (figure 3).

In the subgroup analysis of patients with anxiety, there was no statistically significant difference between the groups in terms of their age, BMI, ASA physical status classification, APAIS score and type of surgical intervention received (table 4). Compared with the general sample, in this subgroup, the intervention group was more satisfied overall than the placebo group (percentage difference: 24.0%; figure 2 and table 4).

With regard to secondary outcomes, the assessment of time-treatment interactions showed no statistically significant differences in the heart rates and systolic, diastolic and mean blood pressures between the groups. The incidence of intraoperative hypotension was also similar between groups (table 5). One patient in the intervention group experienced oxygen desaturation ($SpO_2$ 94%) on arrival in the operating room. The intervention group had a slightly longer mean recovery duration; however, this difference was not statistically significant. The intervention group had significantly higher postoperative pain scores after 20 min of recovery. Postoperative pain scores on POD 1 and administration of rescue analgesic use in the 24 hours after surgery were similar in both groups. The number of patients rescue antiemetics was more than twice the number of patients in the placebo group.

## DISCUSSION

Patient satisfaction is gaining recognition as an important healthcare outcome that represents the quality of healthcare from a patient perspective.[28] The preoperative management of surgical patients should be conducted in consideration of patient satisfaction.[29] Patient satisfaction with anaesthesia is determined by various factors, such as patient demographics, intraoperative awareness and quality of recovery.[30]

In this study, among women undergoing general anaesthesia, patients who received premedication with intramuscular midazolam were more satisfied with the anaesthesia experience than those who received premedication with placebo. This difference was even more pronounced in the patients with anxiety. Comparison of anxious patients with the rest of the intervention and control groups showed that premedication with midazolam had a protective effect against dissatisfaction with the anaesthesia experience caused by preoperative anxiety.

Midazolam is the most frequently used benzodiazepine for premedication.[31] Despite patients' frequent concern about intraoperative awareness,[1 32] the amnestic effect of midazolam is not associated with depth of sedation.[33 34]

**Table 3** Patient satisfaction by group

| | Midazolam (n=65) | Placebo (n=69) | OR (95% CI) |
|---|---|---|---|
| Satisfied overall, n (%)* | 57 (87.7) | 46 (66.7) | 3.56 (1.46 to 8.70) |
| Satisfied with premedication, n (%) | 52 (80.0) | 48 (69.6) | 1.75 (0.79 to 3.88) |
| Satisfied with anaesthesia in the OR, n (%)† | 60 (92.3) | 54 (78.3) | 3.33 (1.14 to 9.78) |
| Satisfied with postoperative pain control, n (%) | 49 (75.4) | 50 (72.5) | 1.16 (0.53 to 2.52) |
| Will receive the same anaesthesia if needed, n (%)* | 58 (89.2) | 48 (69.6) | 3.62 (1.42 to 9.25) |

*P<0.05
†P < 0.01
OR, operating room.

Table 4 Characteristics and outcomes of the anxiety subgroup

| | Midazolam (n=36) | Placebo (n=37) | OR (95% CI) |
|---|---|---|---|
| Age, mean (SD), years | 47.6 (11.5) | 47.9 (11.2) | |
| Body mass index, kg/m$^2$, mean (SD) | 24.3 (3.1) | 24.6 (3.2) | |
| ASA physical status classification, n | | | |
| I | 15 | 12 | |
| II | 21 | 25 | |
| APAIS-A, mean (SD) | 14.2 (3.1) | 14.8 (3.2) | |
| Type of surgery, n | | | |
| Gynecologic | 22 | 15 | |
| Digestive | 9 | 11 | |
| Others | 5 | 10 | |
| Satisfied overall, n, %* | 32 (88.9) | 24 (64.9) | 4.33 (1.25 to 14.96) |
| Satisfied with premedication, n, % | 30 (83.3) | 25 (67.6) | 2.40 (0.79 to 7.31) |
| Satisfied with anaesthesia in the OR, n, %* | 35 (97.2) | 27 (73.0) | 12.96 (1.56 to 107.57) |
| Satisfied with postoperative pain control, n, % | 28 (77.8) | 26 (70.3) | 1.48 (0.52 to 4.26) |
| Will receive the same anaesthesia if needed, n, %† | 34 (94.4) | 25 (67.6) | 8.16 (1.67 to 39.8) |

*P<0.05
†P < 0.01
APAIS-A, Amsterdam Preoperative Anxiety and Information Scale score for Anxiety; ASA, American Association of Anesthesiologists.

The pharmacological properties of midazolam, including its anxiolytic and amnestic effects, make it suitable as a premedication for general anaesthesia to enhance the anaesthetic experience while minimising the risks of cardiopulmonary complications.

No emergency airway intervention was required after the administration of midazolam. One patient in the intervention group experienced oxygen desaturation, however, the oxygenation levels normalised following the encouragement of deep breathing of ambient air. Heart rate, systolic blood pressure and mean blood pressure were lower in the intervention group than in the control group on arrival at the operating room. However, these differences were less than 10%. These differences were also observed in the PACU, but were not statistically significant.

Midazolam is manufactured in aqueous form and can be uniformly absorbed when administered via intramuscular injection. This route has some benefits over oral and intravascular administration.[35] Intramuscular administration offers a more rapid onset of anxiolysis than gastrointestinal administration, bypassing gastric factors and the substantial first-pass metabolism of the drug. Intramuscular injection can achieve effective anxiolysis comparable to that achieved through intravenous injection when vascular access is unavailable.

Premedication practices can vary considerably depending on the protocol of the anaesthesiology

Table 5 Secondary outcomes by group

| | Midazolam (n=65) | Placebo (n=69) | Mean differences between group (95% CI) | Relative risk (95% CI) |
|---|---|---|---|---|
| Recovery duration, min. | 36.3 (16.6) | 33.3 (6.0) | 2.97 (-1.25 to 7.20) | |
| Pain NRS-11 after 20 min of recovery† | 6.1 (2.3) | 5.0 (2.1) | 1.06 (0.32 to 1.81) | |
| Pain NRS-11 on POD 1 | 3.8 (2.1) | 3.1 (2.0) | 0.70 (0.00 to 1.40) | |
| The no of time rescue analgesics were used 24 hours after surgery, median (IQR) | 1 (1, 2) | 1 (0, 1) | 0.44 (-0.02 to 0.89) | |
| Intraoperative hypotension, n (%) | 21 (32.3) | 21 (30.4) | | 1.06 (0.64 to 1.75) |
| Administration of rescue anti-emetics, n (%) | 5 (7.7) | 10 (14.5) | | 0.53 (0.19 to 1.46) |

Data for continuous variables are presented as mean (SD).
*P<0.05.
†P<0.01
NRS, Numeric Rating Scale; POD, postoperative day.

department and the preferences of the anaesthesiologist.[9] To minimise the risk of adverse events such as respiratory depression, some anaesthesiologists prefer not to administer premedication before transferring the patient to the operating room. However, premedication for highly anxious patients in the preoperative holding area with a rapid-onset agent can help reduce dissatisfaction with the anaesthesia experience. This intervention is found to be especially effective in patients who are expected to stay in the preoperative holding area for more than 15 min.[8]

The intervention group had higher NRS-11 pain scores in the PACU than the placebo group. Frölich *et al* reported that the administration of midazolam increases short, intermittent, and sustained pain perception.[36] In our study, higher pain scores were not always negatively correlated with patient satisfaction. These findings are supported by Pozdnyakova *et al*, who also reported that higher pain scores did not correlate with worse patient satisfaction.[37] Patient satisfaction can be reduced when their expectations are not met. Therefore, providing appropriate and timely analgesia can minimise the reduction in patient satisfaction when the difference in pain scores is not substantial. The minimum difference required in the NRS-11 scores for determining a clinically significant difference in pain was reported to be 1.23,[38] suggesting that the difference in the groups' pain in this study was not clinically substantial.

This study has some limitations. The target population was relatively small. We enrolled relatively healthy young adults and excluded obese patients and those with a medical history of airway obstruction. Furthermore, all patients were ethnically Korean; therefore, the generalisability of this study's results is limited. However, it is worth noting that similar findings were reported in the ConCIOUS cohort.[38]

Only patients undergoing general anaesthesia with a restricted range of drugs were enrolled in this study. Patient satisfaction with the anaesthesia experience can vary according to the anaesthetic method and drug regimen. Finally, the power of the subgroup analysis was insufficient. Thus, additional research is needed to confirm benefits of preoperative midazolam administration in subgroups of different surgeries.

## CONCLUSION

Premedication with intramuscular midazolam before general anaesthesia on the day of surgery improved the satisfaction of women, with minimal risk of associated complications.

**Contributors** SWS: conceptualisation, methodology, validation, formal analysis, investigation, visualisation, writing-original draft, review and editing; YJ: methodology, data curation, investigation, project administration; HL: data curation, review and editing; JL: data curation, review and editing; KHL: conceptualisation, supervision, project administration, review and editing. KHL is responsible for overall content as the guarantor.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study was approved approved by by the Institutional Review Board of Wonju Severance Christian Hospital (approval number: CR320166). Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available on reasonable request.



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