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Impact of propofol infusion-based sedation on anesthesia-related adverse events in endoscopic ultrasonography: A prospective observational study

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Abstract

Procedural sedation is recommended for endoscopic ultrasonography (EUS) to enhance patient comfort and optimize procedural conditions. This study aimed to evaluate the impact of continuous propofol infusion as the main component of the sedation protocol on anesthesia-related adverse events during EUS. This single-center observational prospective cohort study was conducted in the endoscopy unit of a territorial hospital. Seventy-five patients were enrolled from April 24 to June 24, 2024. The sedation protocol included intravenous administration of midazolam (0.02 mg/kg), propofol (0.5 mg/kg), and ketamine (0.25 mg/kg), followed by continuous propofol infusion for anesthesia maintenance. Standard monitoring, the Bispectral Index (BIS), and non-invasive end-tidal CO2 monitoring were applied. Adverse events were defined as arrhythmias, bradycardia (HR <60 bpm), hypotension (SAP <90 mmHg or MAP <60 mmHg), desaturation (SpO2 ≤90%), need for mask ventilation, bleeding, vomiting, unintended movements, coughing during probe insertion, and hiccups. Severe outcomes included death, unplanned endotracheal intubation, or transfer to the intensive care unit (ICU). 87 patients were screened, and 12 were excluded, resulting in a final cohort of 75 patients. The most common indication for EUS was cholecystitis with gallstones. During induction, midazolam (median [IQR]: 2 [1] mg), propofol (80 [53] mg), and ketamine (27.5 [10] mg) were administered. Continuous propofol infusion was administered at a median rate of 6 [1] mg/kg/h. Adverse events included patient movements (34.7%), cough and hiccups (25.3%), hypotension (6.7%), desaturation (14.7%), arrhythmia (10.7%), excessive secretions (13.3%), vomiting (1.3%), and bronchospasm (4%). Body mass index and propofol bolus during induction were identified as independent risk factors for adverse events, with a cutoff propofol dose of 1.15 mg/kg. No severe complications or unplanned ICU transfers occurred. This study reveals the safety of propofol infusion-based sedation during EUS, associated with a low incidence of anesthesia-related adverse events, with no significant cardiopulmonary complications observed.

Keywords: Non-operating room anesthesia, endoscopic ultrasonography, procedural sedation, propofol infusion, patient safety, adverse events

Introduction

Endoscopic ultrasonography (EUS) combines imaging and ultrasound capabilities to assess digestive tract disorders, offering high-resolution imaging of the pancreas and surrounding structures from the stomach or duodenum [1-5]. Thus, it plays a crucial role in diagnosing and treating pancreaticobiliary system disorders [6-8]. Despite its diagnostic benefits, EUS itself poses risks such as bleeding, infection, and damage to teeth, as well as anesthesia-related complications such as aspiration, cardiovascular events, and respiratory depression [9,10]. Therefore, optimal anesthesia management and comprehensive monitoring are critical for effective periprocedural patient care.

EUS utilizes larger echoendoscopes, with diameters ranging from 12 to 20 mm, compared to the standard 9 to 11 mm endoscopes. The increased size of the echoendoscope probe and the expanding therapeutic applications of EUS contribute to these procedures' complexity and extended duration. To enhance patient comfort during the procedure and to allow the performer to operate under optimal conditions, minimal to moderate sedation is recommended for diagnostic EUS, while deep sedation or general anesthesia is recommended for therapeutic EUS procedures [11]. The adequacy of mild or moderate sedation is influenced by various factors, including the patient's anxiety level, body mass index (BMI), American Society of Anesthesiologists (ASA) classification,

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cardiopulmonary comorbidities, medication history, and previous tolerance of sedation. Benzodiazepines (e.g., midazolam) and opioids (e.g., fentanyl, meperidine) are commonly administered for moderate sedation, while propofol-based sedation is increasingly favored for its rapid onset and shorter recovery time. Additionally, balanced propofol sedation (BPS), which combines propofol with an opioid and benzodiazepine, allows for better sedation control while minimizing respiratory depression. Sedation protocols in non-operating room anesthesia (NORA) have increasingly become procedure- and patient-specific [12]. In this context, our study is significant in establishing a sedation model specifically tailored for the EUS procedure. Nevertheless, standard conditions for NORA must be met at the facility where the procedure is to be performed [13].

In this study, we administered continuous propofol infusion as the main component of procedural sedation for patients undergoing therapeutic EUS in the endoscopy unit of a tertiary care hospital. We aimed to evaluate the impact of this sedation method on anesthesia-related adverse events and to contribute to the safe and effective expansion of procedural sedation tailored specifically to the EUS procedure.

Material and Methods

Study design and population

This is a single-center observational cohort study conducted in the endoscopy unit of Samsun Training and Research Hospital, a territorial hospital in Samsun, Türkiye. The study received ethical approval from the Clinical Research Ethics Committee of Samsun University Faculty of Medicine on March 13, 2024, under the reference number GOKAEK 2024/6/11. After registration at clinicaltrials.gov (NCT06389045), the study was conducted from April 24 to June 24, 2024, in accordance with the principles of the Declaration of Helsinki (2013). All patients involved in the study provided written informed consent.

The inclusion criteria were:

- Scheduled EUS procedures,
- Outpatient/ambulatory/inpatient status,
- Patients who are conscious and cooperative prior to the procedure,
- Patients capable of providing informed consent,
- Patients who do not meet any exclusion criteria.

The exclusion criteria were:

- Patients with an ASA score ≥4,
- Individuals under 18 years of age,
- Pregnancy or lactation,
- Patients with a predicted difficult airway,
- Patients who do not provide informed consent.

Preoperative period

Patients scheduled for EUS were evaluated by an anesthesiologist, who provided information on their medications and preoperative fasting requirements and prepared them for the procedure. Patients were admitted to the preoperative preparation room, where standard ASA monitoring was applied. Since the procedures were planned to be performed in the left lateral position, peripheral venous cannulation was established via the dorsum of the right hand in all patients. In accordance with the perioperative fluid management guidelines from the enhanced recovery after surgery (ERAS) protocol [14], patients fasted from clear liquids for at least two hours before anesthesia induction, and ringer's lactate was administered to maintain euvolemia. Preoperative hemodynamic parameters, including heart rate (HR) (bpm), oxygen saturation percentage (SpO2%), the fraction of inspired oxygen (FiO2), non-invasive blood preassure (NIBP) (mmhg) [systolic arterial pressure (SAP), diastolic arterial pressure (DAP), and mean arterial pressure (MAP)] were recorded. Subsequently, hemodynamically stable patients were transferred to the procedure room.

EUS Procedure and Sedation Protocol

All EUS procedures were performed in the endoscopy unit using the Fujifilm Endoscopic Ultrasonography System (Model: FS-L2702D, Fujifilm, Japan) by the same gastroenterologists (K.D. and U.E.A.) employing a linear/radial echoendoscope. Patients were positioned in the left lateral position, and bite blocks were placed in the patients' mouths to protect the EUS probe and ensure procedural comfort before administering anesthesia.

All patients in the procedure room underwent standard ASA monitoring, complemented by Bispectral Index (BIS) [15] (Covidien, Minneapolis, MN, USA) and non-invasive end-tidal carbon dioxide (EtCO2) monitoring [16] (Capnostream 35, Minneapolis, MN, USA). Supplemental oxygen was administered at 6 l/min, continuous pulse oximetry was recorded throughout the procedure, and automated NIBP measurements were taken every 5 minutes.

Anesthetic drug administration was initiated with a single intravenous dose of 0.02 mg/kg midazolam, 0.5 mg/kg propofol, and 0.25 mg/kg ketamine. Continuous propofol infusion was initiated at a dose of 6 mg/kg/h using the Mindray BeneFusion eVP device (Mindray, Shenzhen, China) for anesthesia maintenance. The infusion rate was subsequently adjusted—either increased or decreased—based on intraprocedural hemodynamic stability, the occurrence of adverse effects such as hypotension or respiratory depression, and patient tolerance to ensure optimal sedation depth and procedural safety [17]. The device was calibrated with each patient's weight, and the infusion was recorded using the dosage mode (mg/kg/hour). Baseline and intraoperative values for HR, SpO2%, SpO2/FiO2 ratio, SAP (mmHg), DAP (mmHg), MAP (mmHg), BIS, and EtCO2 were recorded. The indications for the procedure (e.g., gastric submucosal lesion, gallstone, pancreatic cyst, pancreatic tumor), procedure duration, anesthetic drug dosages used during induction (mg) and maintenance (mg/kg/h), and the duration of monitoring in the post-anesthesia care unit (PACU) were also documented.

Upon completion of the procedure, patients were transferred to the PACU, where standard ASA monitoring was applied. Each patient was assessed using the post-anesthetic discharge score (PADS) [18,19]. Discharge criteria included achieving a post-procedure score of 9 or higher and the presence of a competent adult to accompany the patient.

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Data Collection

Patient data were recorded using specially designed tracking forms created for this study and subsequently transferred into a Microsoft Excel database. The tracking forms captured demographic characteristics, comorbidities, medical treatments, airway assessments, preoperative blood results, any anesthesia-related adverse events or allergic reactions, as well as hemodynamic parameters during and after the procedure, the dosage and method of drug administration (bolus in mg or infusion in mg/kg/h), and discharge time.

Outcomes

The primary outcome was to evaluate the effect of propofol infusion on anesthesia-related adverse events in patients undergoing EUS in endoscopy unit. The adverse events were defined as arrhythmias (new onset rhythm disturbances during the procedure), bradycardia (HR<60 beats per minute), hypotension (SAP<90 mmHg or MAP<60 mmHg), desaturation (SPO2%≤90), need for mask ventilation, bleeding, vomiting, unintended patient movements, coughing during EUS echoendoscope probe insertion, and hiccups. More severe outcomes included death, unplanned endotracheal intubation, or the need for transfer to the intensive care unit (ICU). The secondary outcome was the duration of recovery from anesthesia. Data on bolus and infusion drug dosages used for induction and maintenance and patient demographics, EUS indications, and comorbidities were also recorded.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) program (IBM Corp., Armonk, NY, USA). Sample size calculations, based a on similar study [20] and conducted using G*Power software, indicated that a minimum of 67 cases was required to achieve 95% confidence (1-α), 95% test power (1-β), and an effect size of d=0.44. The study was completed with 75 patients, considering potential data loss. Normality tests were conducted using the Kolmogorov-Smirnov test for overall data and the Shapiro-Wilk test for subgroup analyses with sample sizes of 30 or fewer. Data were presented according to normality test results: quantitative data as mean (± standard deviation) or median (interquartile range), and categorical data as frequency (and percentage). Comparisons between quantitative variables were made using the Mann-Whitney U test, while chi-square (χ^2) or Fisher's exact test was used for categorical data comparisons. Variables affecting adverse events were assessed using binary logistic regression analysis, with a p-value of <0.05 considered statistically significant for all tests. The relationship between propofol bolus dose and adverse event prediction was evaluated using receiver operating characteristic (ROC) analysis, and the area under the receiver operating characteristic curve (AUC) was determined.

Results

A total of 87 patients were screened, with 12 exclusions, resulting in a final cohort of 75 patients (36 females, 39 males) with a mean age of 65 years (Figure 1). The majority were classified as ASA II or III, and the mean BMI was 27.9 kg/m². Common comorbidities included hypertension (46.7%), diabetes mellitus (32%), and coronary artery disease (12%), while 24% were smokers. The primary indication for EUS was cholecystitis with gallstones (58.7%), followed by biliary tract masses (38.7%). Further demographic and clinical details are provided in Table 1.

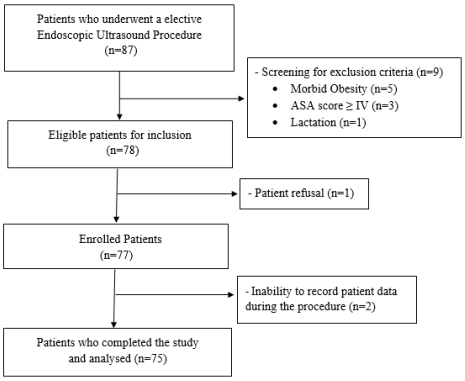

Figure 1. The flowchart of the study

Table 1. Patient demographic and clinical characteristics

Parameters	Value
Age (years) median (IQR)	65 (18)
Gender n (%)	
Male	39 (52)
Famale	36 (48)
ASA n (%)	
ASA I	4 (5.3)
ASA II	39 (52)
ASA III	32 (42.6)
BMI (kg/m²) n (%) mean±SD	27.9±5
Normal	25 (33.3)
Overweight	26 (34.7)
Obesity I	17 (22.7)
Obesity II	5 (6.7)
Obesity III	2 (2.7)
Smoke n (%)	18 (24)
Alcohole n (%)	2 (2.7)
Comorbıdıtıes n (%)	
Hypertension	35 (46.7)
Diabetes	24 (32)
Coroner artery disease	9 (12)
Chronic renal failure	1 (1.3)
Cerebrovascular disease	2 (2.7)
Liver failure	7 (9.3)
COPD	3 (4)
Asthma	9 (12)
OSA	1 (1.3)
Indication of EUS n (%)	
Calculous cholecystitis	44 (58.7)
Mass in the bile ducts	29 (38.7)
Idiopathic liver failure	2 (2.7)

ASA: American Society of Anesthesiologists, BMI: body mass index, COPD: chronic obstructive pulmonary disease, EUS: endoscopic ultrasound, OSA: obstructive sleep apnea

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EUS procedures lasted 20 (15) [median (IQR)] minutes. The anesthesia recovery time was 5 (7) [median (IQR)] minutes. Patients were followed in PACU for 20 (10) [median (IQR)] minutes. In terms of intraoperative anesthetic drug consumption, midazolam: 2 (1) mg [median (IQR)], propofol: 80 (53) mg [median (IQR)], and ketamine: 27.5 (10) mg [median (IQR)] were administered during induction while continuous propofol infusion at a rate of: 6 (1) mg/kg/h [median (IQR)] for anesthesia maintenance. The preoperative, intraoperative, and postoperative respiratory and hemodynamic parameters are presented in Table 2.

Table 2. Hemodynamic and respiratory variables

Parameters	Preoperative median (IQR)	Intraoperative median (IQR)	Postoperative median (IQR)	P
Heart Rate (bpm)	81 (15)	80 (19)	78 (16)	0.026
SpO2 (%)	97 (3)	98 (2)	98 (4)	0.036
SpO2/FiO2	461.9 (14)	196 (4)	280 (11.4)	0.000
EtCO2	-	29.5 (11)	-	NA
PAS (mmHg)	139 (40)	127.5 (44)	125 (24)	0.000
PAD (mmHg)	80 (18)	70.5 (29)	76 (18)	0.000
PAM (mmHg)	102.5 (26)	89.5 (33)	92 (25)	0.003
BIS	-	71 (15)	-	NA

SpO2: peripheral oxygen saturation, FiO2: fraction of inspired oxygen, EtCO2: partially exhaustive CO2 end pressure, PAS: systolic arterial blood pressure, PAD: diastolic arterial blood pressure, PAM: mean arterial blood pressure, BIS: bispectral index, bpm: beats per minute, mmHg: millimiters of mercury, IQR: interquartile range

The most common adverse events were patient movements (34.7%), cough/hiccups (25.3%), and desaturation (14.7%), while hypotension (6.7%), arrhythmia (10.7%), excessive secretions (13.3%), vomiting (1.3%), and bronchospasm (4%) occurred less frequently. No severe cardiac or respiratory complications or ICU transfers were recorded. Further details are provided in Table 3.

Table 3. Adverse events

Adverse event	n (%)
Movements	26 (34.7)
Cough and hiccups	19 (25.3)
Hypotension	5 (6.7)
Desaturation	11 (14.7)
Arrhythmia	8 (10.7)
Secretions	10 (13.3)
Vomiting	1 (1.3)
Bronchospasm	3 (4)

Table 4 presents the binary logistic regression analysis results conducted to identify independent risk factors for adverse events. The analysis revealed that BMI (odds ratio [OR], 1.425; 95% confidence interval [CI], 1.052-1.930; P=0.022) and the propofol bolus administered during anesthesia induction (mg/kg) (OR, 23.470; 95% CI, 1.831-300.813; P=0.015) were identified as independent risk factors for adverse events. Conversely, the midazolam (mg/kg) (OR, 49.000; 95% CI, 0-1.6E+46; P=0.695) and ketamine (mg/kg) (OR, 0.033; 95% CI, 0.000-5.759; P=0.195) used during anesthesia induction, as well as the dose of propofol infusion (mg/kg/h) (OR, 1.317; 95% CI, 0.441-3.935; P=0.622) used for anesthesia maintenance, were not significantly associated with adverse events. The receiver operating characteristic (ROC) curve analysis for the propofol dose administered during induction provided an estimated cutoff value of 1.15 mg/kg for predicting adverse events [AUC, 0.716; 95% CI, 0.600-0.832; P=0.002 (Figure 2)]. The sensitivity and specificity at this cutoff value were 63% and 62%, respectively. Due to the relatively low sensitivity and specificity, additional testing of the cutoff value's predictive performance was conducted. The positive predictive value was 64.1%, and the negative predictive value was 64.9%.

Table 4. Bivariate logistic regression model: association between variables and adverse events

	Beta	SE	OR (95% CI)	p
Age	-0.011	0.038	0.989 (0.918-1.066)	0.779
BMI	0.354	0.155	1.425 (1.052-1.930)	**0.022**
ASA Score	1.206	1.296	3.339 (0.263-42.362)	0.352
Coroner artery disease	-1.504	1.458	0.222 (0.013-3.872)	0.302
COPD	16.929	40.961	22.674 (0.000 -)	1.000
Asthma	-0.317	1.510	0.729 (0.038-14.057)	0.834
Smoke	-0.292	0.986	0.747 (0.108-5.156)	0.767
Midazolam	17.715	45.246	49.000 (0-1.6E+46)	0.695
Propofol	3.156	1.301	23.470 (1.831-300.813)	**0.015**
Ketamine	-3.406	2.631	0.033 (0.000-5.759)	0.195
Propofol infusion	0.275	0.558	1.317 (0.441-3.935)	0.622

ASA: American Society of Anesthesiologists, BMI: body mass index, COPD: chronic obstructive pulmonary disease

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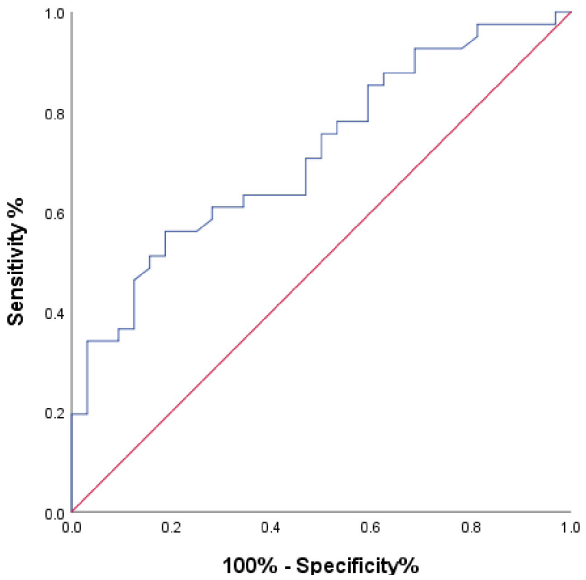

Figure 2. ROC analysis

Discussion

This study assessed the anesthetic management and safety of propofol infusion-based sedation in EUS, focusing on its impact on perioperative outcomes and adverse events. The findings indicate the procedure was well-tolerated, with no severe cardiopulmonary complications or ICU transfers observed. Notably, BMI and the propofol bolus dose administered during induction emerged as independent risk factors for adverse events. In contrast, the continuous propofol infusion used for anesthesia maintenance was not significantly associated with adverse outcomes or prolonged recovery time. Furthermore, ROC analysis identified a propofol induction dose cutoff of 1.15 mg/kg for predicting adverse events; however, its sensitivity and specificity were suboptimal, limiting its clinical utility. These results underscore the importance of individualized sedation strategies and careful titration of propofol infusion to enhance safety and optimize patient outcomes in EUS.

The popularity of NORA in recent years is also reflected in procedures such as Endoscopic Ultrasound (EUS). The large size of the EUS echoendoscope distinguishes it from other endoscopic procedures. Complications, including hypoxia, hypercarbia, hypotension, and arrhythmias, may arise from sedation-induced sympathetic inhibition or vasovagal episodes during esophageal intubation [12,21-23]. According to the British Society of Gastroenterology guidelines on sedation in gastrointestinal endoscopy [11], moderate or deep sedation is recommended for EUS, depending on whether it is diagnostic or therapeutic. Although a consensus on a specific procedural sedation protocol for EUS has not yet been established in the literature, in this study, we proposed propofol infusion as a main component of a sedation strategy aimed at minimizing anesthesia-related adverse effects while ensuring patient safety.

De Vico et al. (2023) demonstrated that sedation with propofol and remifentanil in patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) is both feasible and safe, reporting adverse events at rates similar to our study, including accidental movements (25%), cough and hiccups (20%), hypotension (3%), and desaturation (2%), without any major cardiac or respiratory complications. Similarly, Grendelmeier et al. [24] supported the use of propofol as a safe sedative agent during flexible bronchoscopy, further validating its applicability across various endoscopic procedures. Besides demonstrating the safety of propofol infusion for EUS, our study revealed a statistically significant effect of propofol bolus administration during induction and BMI on adverse events. Although the clinical significance of this statistical finding is debatable, it can be concluded that these factors should be carefully considered during sedation planning.

Adjusting the propofol dose based on ideal body weight, titrating the drug slowly, and potentially using it in combination with other sedative agents may reduce the risk of adverse events. An appropriate sedation protocol should aim to prevent unintentional patient movements and minimize anesthesia-related adverse events. However, propofol's rapid onset and short half-life can lead to fluctuations in plasma concentration when administered as intermittent bolus injections [25]. While plasma peak levels can lead to sedation-related adverse events such as hypoxemia and hypotension, lower levels may result in a rapid decrease in sedative effect, leading to unintended patient movements [26]. From this perspective, opting for continuous propofol infusion rather than intermittent bolus administration may help achieve a more stable, effective plasma concentration and prevent fluctuations in plasma propofol level that could cause adverse events. Lee et al. [27] compared continuous infusion with intermittent bolus administration of propofol in patients undergoing ERCP, reporting that continuous infusion was superior in maintaining a constant level of sedation without increasing adverse events.

The implementation of comprehensive, advanced monitoring techniques, including Bispectral Index (BIS) and end-tidal CO2 (EtCO2), alongside standard ASA monitoring, represents a significant strength of our study. This rigorous monitoring approach allowed for a thorough evaluation and documentation of adverse events, as well as enabling timely and appropriate intervention. However, our study has some limitations. The single-center nature of our study limits the generalizability of our findings. Studies with larger sample sizes could enable the detection of rarer adverse events. Additionally, while the observational design may introduce bias and prevent drawing definitive conclusions about the causality between propofol infusion and adverse events, the consistency in procedures and sedation protocols was maintained through the involvement of the same gastroenterologists and anesthesiologists. Comparative studies using different sedative agents and administration techniques could provide further data to optimize sedation strategies specific to EUS. Besides, there is a need for further randomized controlled trials to investigate the long-term impact of adverse events during EUS on patient outcomes.

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Conclusion

This study demonstrates that propofol infusion-based sedation during EUS is associated with a low incidence of anesthesia-related adverse events, with no significant cardiopulmonary complications observed. These findings strongly affirm the efficacy and safety of propofol infusion as a preferred sedation strategy in EUS procedures, emphasizing its critical role in enhancing patient safety and procedural success in clinical practice.

Conflict of Interests
The authors declare that there is no conflict of interest in the study.

Financial Disclosure
The authors declare that they have received no financial support for the study.

Ethical Approval
The study received ethical approval from the Clinical Research Ethics Committee of Samsun University Faculty of Medicine on March 13, 2024, under the reference number GOKAEK 2024/6/11. Informed consent was obtained from all subjects and/or their legal guardian(s). The Declaration of Helsinki was adhered to in this study. All methods were performed in accordance with the relevant guidelines and regulations.

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