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Low Dose Midazolam versus Propofol for Conscious Sedation During Diagnostic Endoscopy for Day Case Surgery: A randomized clinical trial

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ABSTRACT

Background: As endoscopy is an invasive and painful procedure, it is necessary to use a suitable sedative in terms of anesthetic efficacy. There is a lack of evidence comparing the use of propofol versus midazolam for sedation in endoscopy in developing countries.
Objective: To compare low-dose midazolam versus propofol in terms of time required for achieving conscious sedation and time to recovery in patients undergoing diagnostic endoscopy for day-case surgery.
Method: The study was a randomized controlled trial. One hundred patients who met the inclusion criteria were enrolled and split into two groups of fifty each at random by computer-generated allocation sequence after providing written informed permission. Propofol was given to patients in group B, while midazolam was given to patients in group A. Endoscopy was performed after the time to conscious sedation was recorded. Following that, recovery time was noted, and as the data was non-normal in distribution, outcome measures between both groups were compared using the Mann-Whitney U test.
Results: The median age of patients in the midazolam group was 42.5 (IQR: 18) years and in the propofol group was 39 (IQR: 16.25) years. The median time to conscious sedation in the midazolam group was 2.5 (IQR: 1) minutes, and in the propofol group, it was 2 (IQR: 1) minutes. (p=0.04). The propofol group's median recovery time was 16 (IQR: 3) minutes, while the midazolam group's was 18 (IQR: 3) minutes ($p < 0.001$).
Conclusion: In patients who underwent diagnostic endoscopy, propofol was significantly associated with shorter time to achieve conscious sedation and recovery compared to midazolam.
Keywords: Endoscopy, Conscious Sedation, Midazolam, Propofol

INTRODUCTION: Endoscopy is an essential procedure used for diagnosing various disorders related to the gastrointestinal tract and is routinely required for screening cancers [1]. However, it has been found to be linked with pain and an unpleasant memory, and thus patients often have anxiety regarding this procedure [2]. For ensuring compliance and giving appropriate treatment, this problem related to endoscopy needs to be addressed [3]. Keeping this in view, various countries have adapted the routine use of conscious sedation while performing endoscopy in patients [4].

Conscious sedation involves a treatment protocol in which sedatives are administered in order to overcome the unpleasant feeling associated with various procedures [5]. According to the American Society of Anesthesiology (ASA), sedation is categorized into four levels, i.e., minimal, moderate, deep sedation and general anesthesia [6]. For endoscopy, the sedation level that is required is conscious sedation or moderate sedation. During this conscious sedation, there is voluntary stabilization of respiratory as well as cardiovascular functions that is associated with a clear response to stimulation in terms of hearing and touch [7].

During endoscopy, the drugs that are used regularly for sedation are benzodiazepines and opioids. Midazolam, a benzodiazepine, has strong effects in terms of ataraxia, amnesia, and sedation [8]. Additionally, if opioids are given along with midazolam, then the sedation effects are improved, thus resulting in high satisfaction of patients. However, midazolam has certain disadvantages. Firstly, it leads to respiratory depression, and secondly, the onset of action is of long duration, and recovery occurs slowly [9]. Because of these drawbacks, propofol use is being increased steadily, as it has fast sedation induction, quick recovery, and is associated with less incidence of respiratory depression. However, propofol itself is associated with side effects such as hypotension and apnea [10].

Numerous international studies have been conducted that have compared midazolam with propofol for conscious sedation in patients undergoing endoscopy. However, the local data in Pakistan is scarce. Therefore, the current study aimed to compare low-dose midazolam (0.025 mg/kg) versus propofol in terms of time required for achieving conscious sedation and time to recovery in patients undergoing diagnostic endoscopy. The study would help in providing guidance to the anesthesiologists about a better drug with an early onset of action and quick recovery, which can lead to better satisfaction of the patient, thus ensuring compliance with diagnostic protocols. In this study, gastrointestinal endoscopic procedures were referred to collectively as "Endoscopy." Analyses were performed using aggregated endoscopic data because the available information did not differentiate between upper and lower gastrointestinal endoscopy.

METHOD: This was a parallel-group, randomized, superiority trial with a 1:1 allocation ratio. The study was carried out for six months, from October 2025 to March 2026, at the Department of Anesthesia and ICU, Sheikh Zayed Hospital, Lahore, following approval from the Ethical Review Committee (CPSP/REU/ANS-2019-072-2247 dated 07-05-24). A total of 100 patients who were referred for diagnostic endoscopy for day-case surgery were enrolled. With a 95% confidence interval and 80% test power, a sample of 100 patients (50 in each group) was computed, by keeping the predicted mean induction time (time to reach conscious sedation) for patients receiving propofol was 3.6±2.46 [2], while for those getting midazolam it was 1.87±0.73 [1]. A non-probability consecutive sampling technique was used.

Inclusion criteria: Patients between the ages of 18 and 60, of both genders, who were referred for diagnostic endoscopy for day-case surgery were included.

Exclusion criteria: Patients with ASA status III or IV, who were chronic alcoholics or those who had been using sedatives or drugs like benzodiazepine for a long period, and patients with known allergies or previous adverse reactions to midazolam and/or propofol were excluded.

The study included 100 patients who met the inclusion criteria. Every patient provided written informed consent. Every participant had their clinical history, physical examination, and demographic information recorded in a pre-made proforma. Every patient's baseline vital signs were noted. Every patient had an IV line secured. Eligible participants were randomly allocated in a 1:1 ratio using a computer-generated randomization sequence. An impartial investigator made sure the allocation was concealed. Until data processing was finished, participants and study staff—including outcome assessors—were blinded to treatment allocation.

Drugs were administered to both groups by an independent anesthesiologist, who was not part of the study. Those in group B (n=50) got a bolus injection of 0.5 mg/kg of propofol, while those in group A (n=50) received an intravenous dosage of 0.025 mg/kg of midazolam. Level of sedation was assessed clinically till conscious sedation [described as a drug-induced, minimally depressed state of consciousness that, when evaluated clinically using the ASA sedation classification, preserved the patient's capacity to maintain an airway on their own and responded adequately to verbal and physical stimuli] was reached, and the time to achieve conscious sedation [defined as time (in minutes) from first injection to onset of conscious sedation] was noted down on the proforma. A further injection of 10 mg of propofol was administered if the target level was not met or if the patients were not sufficiently sedated. The trial was triple-blind. The research drugs were produced in accordance with the randomization sequence by an independent anesthesiologist who was not engaged in patient enrollment, drug administration, intraoperative treatment, or outcome assessment. Only the participant identifying number was written on the identical opaque syringes that held the trial medications. As a result, throughout the study, the participants, the anesthesiologist giving the drug, and the researchers in charge of evaluating the results were all kept in the dark about the treatment allocation. After the data collecting and statistical analysis were finished, the allocation code was revealed. Prior to the surgery, baseline vital signs

were taken. All patients underwent intravenous cannulation prior to sedation. Until they had recovered, all patients were constantly monitored for heart rate (using a three-lead ECG), blood pressure (using an automated blood pressure cuff and serial readings every five minutes), and oxygen saturation (using pulse oximetry). Visual inspection and palpation were used to track respiratory effort, respiratory rate, and chest wall excursion. Every five minutes, skilled nurses documented all monitoring information. Additional oxygen was administered when oxygen desaturation (peripheral oxygen saturation < 90%) persisted for more than 20 seconds. All patients then underwent diagnostic endoscopy. During endoscopy, continuous vital monitoring was done. The endoscopy and recovery unit was always equipped with resuscitation tools. In order to get a moderate level of sedation based on ASA criteria, the level of sedation was evaluated every three to five minutes during the procedure or if patients experienced pain. Patients were moved to the recovery unit for ongoing hemodynamic monitoring following the endoscopic operation. The modified Aldrete score was used to evaluate the patients' state of recovery. A modified Aldrete score of 10 was required to be released from the recovery unit and sent home. Once endoscopy was done, the patients were evaluated for time to recovery [defined as time (in minutes) from completion of endoscopy to reaching an Aldrete score of 10 that indicated full recovery]. Any side effects reported by the patients during or after the procedure were recorded. Conscious sedation was only used in the presence of a guardian or a family member for safety reasons. Additionally, patients were instructed not to drive within six hours of the assessment. All findings were noted down and were subjected to statistical analysis.
SPSS version 25.0 was used to analyze the data. The Shapiro-Wilk test was used for normality assessment, and it was found that the data was non-normal in distribution, so median and interquartile range were used to display quantitative variables, including age, time to conscious sedation, and time to recovery. Frequency and percentages were used to display qualitative factors, including gender, side symptoms (bradycardia and hypoxemia), and endoscopic diagnostics. Age and gender stratification was applied to the data. A p-value of ≤0.05 was deemed significant when using a post-stratification Mann-Whitney U test. A Mann-Whitney U test (as non-normal data) was used to compare the two groups' recovery and conscious sedation times; a p-value of ≤0.05 was deemed significant.

RESULTS: The participants' flow in the study is shown in the Consort flow chart (Figure 1)

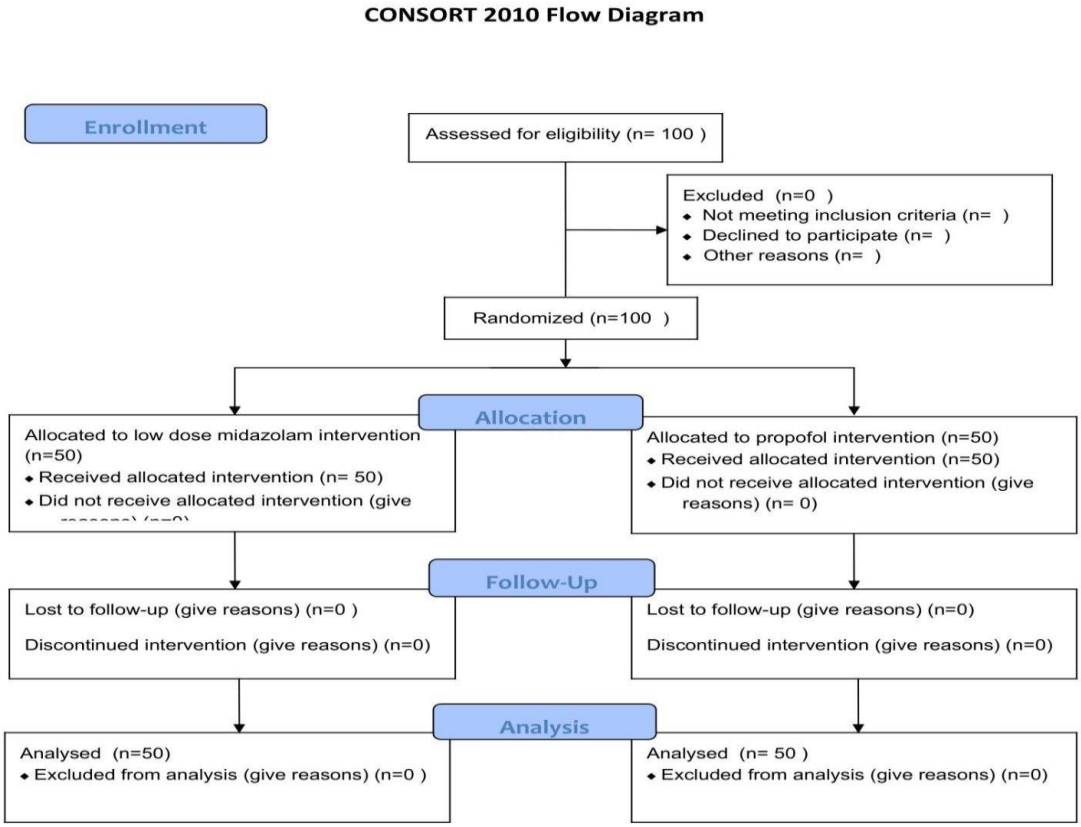

Figure 1: Consort participants flow diagram

The median age of patients in the midazolam group was 42.5 (IQR: 18) years and in the propofol group was 39 (IQR: 16.25) years. In the midazolam group, there were 26 (26%) males and 24 (24%) females; in the propofol group, there were 27 (27%) males and 23 (23%) females. Regarding side effects, 45 (45%) patients in the midazolam group experienced no side effects, 3 (3%) experienced bradycardia, and 2 (2%) experienced hypoxemia. In contrast, 47 (47%) patients in the propofol group experienced no side effects, 1 (1%) experienced bradycardia, and 2 (2%) experienced hypoxemia. The investigation lacked the specific power to identify variations in adverse occurrences. Safety results should be viewed cautiously since the trial may not have had enough power to detect differences in adverse events across groups because the sample size was determined based on the primary outcome, i.e., time to conscious sedation. With respect to diagnosis on endoscopy, in the midazolam group, no findings were labeled in 32 (32%) patients, ulceration was seen in 13 (13%) patients, and a mass was present in 5 (5%) patients, and in the propofol group, no findings were labeled in 30 (30%) patients, ulceration was seen in 14 (14%) patients, and a mass was seen in 6 (6%) patients (Table I).

Table 1: Frequency of baseline demographic and clinical characteristics of the patients in both groups (n=100)

Variable	Group A (Midazolam) (n = 50)	Group B (Propofol) (n = 50)	p-value
Age (years), Median (IQR)	42.5 (18)	39.0 (16.25)	0.229
Age group, n (%)			0.518
18–30 years	8 (16.0)	11 (22.0)	
31–45 years	23 (46.0)	25 (50.0)	
46–60 years	19 (38.0)	14 (28.0)	
Gender, n (%)			0.841
Male	26 (52.0)	27 (54.0)	
Female	24 (48.0)	23 (46.0)	
Side effects, n (%)			0.593
None	45 (90.0)	47 (94.0)	
Hypoxemia	3 (6.0)	1 (2.0)	
Bradycardia	2 (4.0)	2 (4.0)	
Diagnosis on endoscopy, n (%)			0.908
No findings	32 (64.0)	30 (60.0)	
Ulceration	13 (26.0)	14 (28.0)	
Mass	5 (10.0)	6 (12.0)	

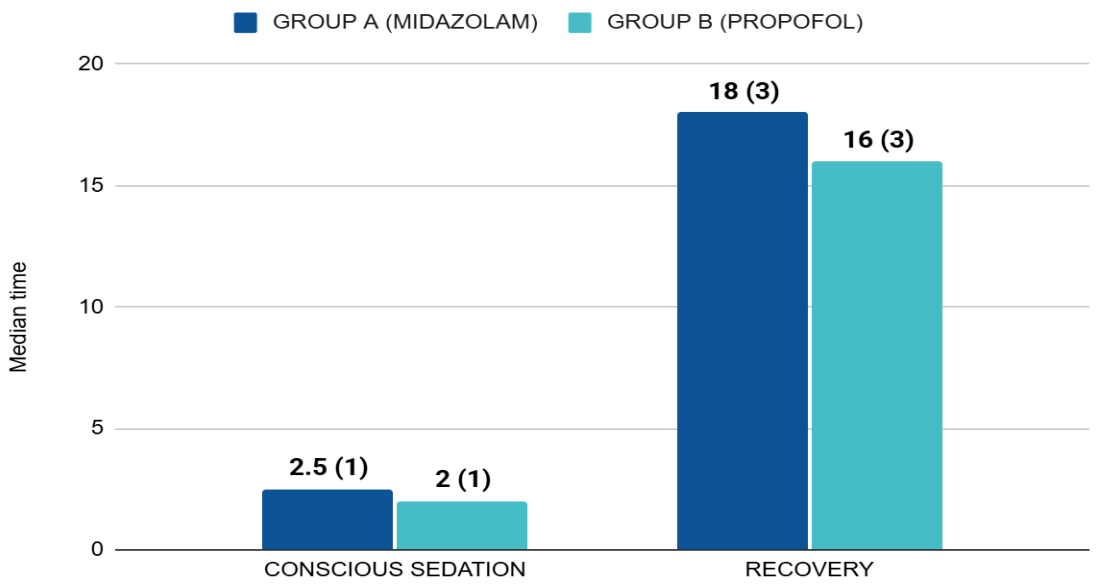

Figure 2: Bar chart showing the median time to achieve conscious sedation in each treatment group. Data are presented as median values with interquartile ranges (IQRs) represented by error bars (n=100)
The median time to conscious sedation was 2.5 minutes (IQR: 1 minute; confidence interval 95%: 1.668-2.204)) in the midazolam group and 2.0 minutes (IQR: 1 minute; confidence interval 95%:1-1.2) in the propofol group. Between-group comparison was performed using the Mann–Whitney U test (Z=-2.054, *p* = 0.04). Patients receiving propofol achieved faster recovery than those receiving midazolam, with a median recovery time of 16 (IQR: 3; confidence interval 95%: 12.5-15.4) minutes compared with 18 (IQR: 3; confidence interval 95%:7.8-8.3) minutes in the midazolam group (Z=-5.092, *p* < 0.001) (Table II).

Table 2: Comparison of clinical outcomes in both groups (n=100)

Variable	Group A (Midazolam) (n = 50)	Group B (Propofol) (n = 50)	p-value
Time to conscious sedation, Median (IQR), minutes	2.5 (1)	2.0 (1)	**0.040**
Time to recovery, Median (IQR), minutes	18 (3)	16 (3)	**<0.001**

Data was stratified for time to conscious sedation and time to recovery with respect to age and gender (Table III & IV), and it was found that median time to conscious sedation had a significant association with male gender, and median time to recovery had a statistically significant association with all age groups and gender, as was indicated by a p-value of < 0.05.

Table 3: Stratification of median time to conscious sedation (in minutes) with respect to age and gender (n=100)

Age Group	Group A (Midazolam)	Group B (Propofol)	p-value
18–30 years	2.5 (1.75)	2 (1)	0.238
31–45 years	2 (1)	2 (1)	0.286
46–60 years	2 (1)	2 (1)	0.439
Gender	**Group A (Midazolam)**	**Group B (Propofol)**	**p-value**
Male	2.5 (1)	2 (0)	0.036

Age Group	Group A (Midazolam)	Group B (Propofol)	p-value
Female	2 (1)	2 (1)	0.515

Table 4: Stratification of median time to recovery with respect to age and gender (n=100)

Age Group	Group A (Midazolam)	Group B (Propofol)	p-value
18–30 years	17.5 (1.75)	17 (2)	0.050
31–45 years	18 (3)	16 (3)	**0.001**
46–60 years	18 (3)	15.5 (4)	**0.001**
Gender	Group A (Midazolam)	Group B (Propofol)	**p-value**
Male	18 (2.25)	16 (3)	**0.001**
Female	18.5 (3)	16 (4)	**<0.001**

DISCUSSION: According to the current study's findings, patients who had endoscopies had far shorter median times to conscious sedation and recovery in the propofol group than in the midazolam group. The study's median overall age of 41 years suggested that most of the patients were middle-aged men. Regarding side effects, there was no discernible difference between the two groups.

Because endoscopic treatments often result in pain and/or discomfort, pre-endoscopy sedation is recommended to lower anxiety and create the conditions required to perform the examination safely [11, 12]. It also increases the likelihood that the procedure will be repeated [13]. Sedation encompasses a range of sedative states, such as mild sedation (anxiolysis), moderate sedation (awareness), severe sedation, and general anesthesia [14]. Both moderate and deep sedation can be used for routine upper gastrointestinal endoscopy; however, moderate sedation, sometimes known as "conscious sedation," is typically safer than deep sedation and offers most patients enough anxiolysis, pain relief, and amnesia [15]. The use of conscious sedation during routine endoscopic operations varies greatly by area [16]. Although endoscopy is often performed without sedation in many European countries, over 98% of upper gastrointestinal endoscopies and colonoscopies are performed under sedation [17]. Several drugs are available to achieve moderate sedation during upper gastrointestinal endoscopies [18, 19]. Propofol is given alone in around 25% of instances, whereas a short-acting benzodiazepine (midazolam) and a narcotic (pethidine) are combined in nearly three-fourths of cases [20]. In terms of attaining early sedation and recovery, it is unclear which of these medications is superior. Therefore, the current study compared the effect of midazolam and propofol in terms of median time to conscious sedation and median recovery time.

The median time to conscious sedation in our study was 2.5 (1) minutes for the midazolam group and 2 (1) minutes for the propofol group. The difference between the two groups was statistically significant, meaning that propofol was linked to a significantly shorter time to achieve conscious sedation (p=0.04). In a meta-analysis, Tsai et al. found that the mean weighted difference between propofol and midazolam in terms of conscious sedation time was -2.76 minutes. This difference was statistically significant and suggested that propofol was linked to a shorter time to achieve sedation [18] . According to Tabiri et al., the propofol group's mean time to sedation was considerably shorter than the midazolam group's (4.6 minutes versus 8.9 minutes; p<0.001) [20]. These results corroborate the findings of our investigation, which showed that in patients undergoing endoscopy, propofol was substantially related to a shorter time to attain conscious sedation when compared to midazolam. The absolute reduction was only 0.5 minutes, or roughly 30 seconds, even though this difference attained statistical significance. Such a minor variation is unlikely to provide a significant clinical benefit given the brief duration of endoscopic operations and the regular workflow in endoscopy units. Therefore, the practical importance of this finding should be interpreted cautiously, even though propofol may

enable a little faster onset of drowsiness. Future research should concentrate on outcomes including procedure success, recovery time, patient satisfaction, and safety profiles that have more therapeutic significance. On the other hand, Kim et al. found that the mean conscious sedation induction time for patients having endoscopy was 1.80±0.73 for those getting propofol and 1.87±0.731 for those receiving midazolam [11]. These findings are not in line with our study findings, and the difference might be attributed to the dosage as well as the speed with which the anesthetic was given, the age of the patient, cardiac condition, and the use of adjuvant medications.

The median time to recovery in our study was 18 (3) minutes for the midazolam group and 16 (3) minutes for the propofol group. The difference between the two groups was statistically significant, meaning that propofol was linked to a significantly shorter time to recovery (p=0.000). According to a study by Wahab et al., the mean recovery time after endoscopy was 31.06±6.25 minutes for the midazolam group and 6.06±2.13 minutes for the propofol group (p<0.001) [19]. In a meta-analysis, Tsai et al. found that the mean weighted difference in recovery time between propofol and midazolam was -2.76 minutes. This difference was statistically significant and suggested that propofol was linked to a shorter recovery time [18]. According to a study by Tabiri et al., the propofol group's mean recovery time from sedation was considerably shorter than the midazolam group's (12.6 minutes versus 33.7 minutes; p < 0.001) [20]. These results corroborate the findings of our study, which showed that in patients who had endoscopies, propofol was significantly linked to a shorter recovery period than midazolam. The 2.3-minute decrease in recovery time is probably clinically significant, in contrast to the slight variation in the amount of time needed to attain conscious sedation. In high-volume endoscopic facilities, quicker recovery may enable earlier patient discharge, enhance workflow effectiveness, and boost patient throughput. As a result, propofol's quicker recovery time is a real clinical benefit that should be taken into account when choosing a sedation plan for endoscopic procedures. Conversely, Kim et al. discovered that the propofol group's mean recovery time was 21.31±3.41, whereas the midazolam group's was 21.83±4.09. This difference was not statistically significant (p=0.171) [1]. The length of the surgery, adjuvant medications used, and drug quantities employed may all have an impact on the results, which could explain the discrepancy between our study's findings and those of Kim et al.

This study has various strengths. First, by using a consistent randomization procedure, selection bias was reduced and participants were distributed equally among research groups. Second, by lowering the possibility of performance and assessment bias, blinding participants, researchers, and/or outcome assessors improved the findings' internal validity. Additionally, the results' repeatability and dependability were enhanced by the use of standardized outcome measures and predetermined study protocols.

When used as a single medication for short-term sedation during diagnostic endoscopic operations, propofol produces its hypnotic effect quickly, has little effect on essential processes, awakens quickly, and is obviously inexpensive.

To better understand potential differences in indications, results, and therapeutic impact, future research should distinguish between upper and lower gastrointestinal endoscopic operations. Additionally, prospective studies with more precise procedural classification could help explain if observed trends differ between these subtypes of endoscopy and increase the precision of epidemiological analysis.

There were some limitations to the current investigation. First, there is a problem with the data' generalizability because the study was conducted in a single center and the sample size was limited. Second, there was no evaluation of how satisfied people were with propofol and midazolam. Additionally, the medications' analgesic effectiveness was not evaluated. Lastly, our study did not assess the outcomes in terms of upper and lower GI endoscopy, which could have affected the results.

CONCLUSION: The current study concluded that in patients who underwent diagnostic endoscopy as day-case surgery, propofol was significantly associated with shorter time to recovery compared to midazolam. Additionally, although propofol was associated with a shorter time to conscious sedation, i.e., 0.5 minutes (30 seconds) quicker than midazolam, such a minor variation is unlikely to provide a significant clinical benefit given the brief duration of endoscopic operations and the regular workflow in endoscopy units. The current study findings propose that propofol has superior anesthetic properties compared to midazolam and can be used in patients who have to undergo endoscopy in order to reduce anxiety and improve patients' satisfaction with the

procedure. Further studies must be conducted on a larger sample size for validating the findings of the current study.

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