BPB Reports

*Report*

# Effects of Flumazenil Disuse on the Incidence of Falls in Inpatients After Gastrointestinal Endoscopy Under Midazolam-Induced Sedation

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Received December 4, 2025; Accepted January 8, 2026

**Moderate midazolam sedation is often used in gastrointestinal endoscopy to induce stress-free conscious sedation. Conversely, flumazenil can reverse midazolam-induced sedation and cause temporary awakening and resedation. However, the effects of flumazenil disuse on the incidence of inpatient falls are unknown. In this study, we performed a retrospective cohort analysis of the incidence of falls in inpatients who underwent gastrointestinal endoscopy under midazolam-induced sedation with or without flumazenil. This study included 1,424 procedures, of which 559 involved flumazenil use. The frequency of inpatient falls did not significantly differ between the flumazenil and nonflumazenil use groups (2/559 episodes [0.36%] vs. 2/865 episodes [0.23%], P = 0.648). The inverse probability of treatment weighting analysis could not determine the association of flumazenil disuse with the incidence of inpatient falls (odds ratio, 0.57; 95% confidence interval, 0.08-4.14; *P* = 0.58). Our results indicate that the association between flumazenil disuse and the incidence of inpatient falls remain unclear.**

**Key words** inpatient falls, midazolam, flumazenil, gastrointestinal endoscopy, procedural sedation analgesia

## INTRODUCTION

Gastrointestinal (GI) endoscopy is widely performed for observation, polypectomy, endoscopic mucosal resection, endoscopic retrograde cholangiopancreatography, and endoscopic submucosal dissection.[1)] However, GI endoscopy induces discomfort, such as fear and anxiety, which could decrease patient willingness to undergo the procedure and affect the quality of the procedure.[1)] Therefore, moderate sedation by a short-acting sedative–hypnotic or dissociative drug is often applied. The benzodiazepine midazolam is often preferred.[2)]

Benzodiazepines are positive allosteric modulators of the gamma-aminobutyric acid type A receptor and produce sedative–hypnotic, anxiolytic, anticonvulsant, and muscle-relaxant effects. Therefore, benzodiazepines are used for multiple indications, including insomnia, anxiety, acute seizure, and procedural sedation. Benzodiazepines can cause adverse effects, such as sedation, dizziness, and impaired psychomotor function, which may increase the risk of falls, particularly among older adults.[3–6)] However, these studies focused on benzodiazepine hypnotics. Therefore, midazolam was not included in their analyses. Midazolam is predominantly used for single-dose or short-term procedural sedation. Consequently, the midazolam safety has been evaluated primarily with respect to immediate, procedure-related adverse events, while falls have received little attention.[7)] Because the median time to return to normal after midazolam sedation is 7.5 h,[7)] patients are likely to experience falls after sedation, and an increased risk of postoperative falls has indeed been reported.[8)] As falls require additional examination or treatment and increase the length and cost of hospital stay,[9)] the rate of inpatient falls in patients undergoing GI endoscopy under midazolam-induced sedation needs to be elucidated.

Flumazenil, a specific antagonist for benzodiazepines, can reverse midazolam-induced conscious sedation, specifically midazolam-induced oversedation, in clinical settings.[10)] Therefore, flumazenil can shorten the recovery time after midazolam sedation.[11)] However, since flumazenil is eliminated more quickly from the body than midazolam, and the duration of action is short at generally 30–60 min, resedation by re-emergence of midazolam often occurs and could increase the risk of respiratory depression.[12,13)] Furthermore, serious adverse events, such as seizures and cardiac arrhythmias, have been reported in patients treated with flumazenil.[14)] Therefore, the American Society of Anesthesiologists recommends against the routine reversal of sedative agents using flumazenil

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except in respiratory depression and to implement sufficient patient monitoring if flumazenil is administered.[15] In a similar response, a practical guide for safe sedation was created in Japan.[16] Thus, in our hospital, routine reversal of midazolam with flumazenil was stopped in August 2023.

However, the impact of flumazenil disuse on the incidence of inpatient falls was not considered in the American Society of Anesthesiologists recommendation. Because flumazenil causes temporary awakening and resedation, the impact of flumazenil disuse on inpatient falls has not been investigated. In this study, we retrospectively analyzed the incidence of inpatient falls in patients who underwent GI endoscopy under midazolam-induced sedation with or without flumazenil.

## MATERIALS AND METHODS

**Study Design and Participants** We performed a retrospective cohort analysis of inpatients aged ≥15 years who underwent GI endoscopy under midazolam-induced sedation at Osaka Metropolitan University Hospital between March 2023 and April 2024. The exclusion criteria included concomitant use of other sedative drugs for GI endoscopy, lack of essential information, and loss of follow-up for any reason, such as discharge from the hospital on the day of GI endoscopy. The study protocol was approved by the Human Subjects Review Committee of Osaka Metropolitan University (approval no. 2024-076). The requirement for informed consent was waived by the Human Subjects Review Committee of our hospital, and participants were free to opt out if they no longer wished to participate.

**Data Collection** We reviewed the patients' medical records and extracted the following data: age, sex, height, body weight within 30 days, type of GI endoscopy procedure, concomitant drugs, and laboratory results before GI endoscopy. Drugs known to be fall risks, including antihypertensives, diuretics, antidepressants, antipsychotics, benzodiazepines, and Z-drugs, were considered if used on the same day as GI endoscopy. The endpoint was the rate of inpatient falls, defined as in-hospital falls from the end of GI endoscopy to 9:00 a.m. the next day, before most patients were discharged. This observation period was considered sufficient given the half-lives of flumazenil and midazolam. Data on falls were collected from patients' medical records and incident reports.

**Statistical Analysis** The statistical analysis of categorical data was conducted using Fisher's exact test. The Mann–Whitney U test was used to compare continuous variables. To account for indication bias due to the lack of randomization, propensity score-adjusted analyses using the inverse probability of treatment weighting method were performed. The propensity score for flumazenil use was estimated for each case using a logistic regression model with the following factors as independent variables: age, sex, height, body weight, midazolam dose, strong opioid use, naloxone use, total bilirubin >upper limit of normal (ULN)×1.5, aspartate aminotransferase >ULN×3, alanine aminotransferase >ULN×3, serum creatinine >ULN×1.5, antihypertensive or diuretic use, antidepressants use, antipsychotic use, benzodiazepines and Z-drugs use. All statistical analyses were performed using EZR version 1.68 (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).[17]

## RESULTS

**Patient Characteristics** GI endoscopy under midazolam-induced sedation was performed 1,740 times between March 2023 and April 2024. After excluding 316 endoscopies (use of other sedative drugs [n = 137], lack of essential information [n = 133], and loss to follow-up [n = 46]), we analyzed 1,424 procedures. Of these, 559 involved flumazenil use. Table 1 shows the characteristics of the included patients. Compared with the nonflumazenil use group, the flumazenil use group was older and had a higher proportion of strong opioid use, naloxone use, antihypertensive or diuretic use, and alanine aminotransferase ≤ ULN×3.

**Inpatient Falls** Of the 1,424 procedures, 4 (0.28%) were associated with inpatient falls. The frequency of inpatient falls did not differ significantly between the flumazenil and nonflumazenil use groups (2/559 episodes [0.36%] vs. 2/865 episodes [0.23%], P = 0.648). The inverse probability of treatment weighting analysis also revealed that flumazenil disuse was not associated with inpatient falls (odds ratio, 0.57; 95% confidence interval, 0.08-4.14; $P = 0.58$). The characteristics of patients who experienced falls are shown in Table 2.

## DISCUSSION

This is the first retrospective study to evaluate the incidence of falls in patients who underwent GI endoscopy under midazolam-induced sedation with or without flumazenil. The rate of inpatient falls was 0.36% in patients who received flumazenil and 0.23% in patients who did not, with no significant difference. The inverse probability of treatment weighting analysis also revealed no significant difference.

In the flumazenil group, the use of strong opioids, naloxone, and antihypertensive or diuretic agents was significantly higher than that in the nonflumazenil group. In patients with concomitant opioid use, respiratory depression is likely to be more pronounced.[18] Accordingly, the proportion of patients requiring both flumazenil and naloxone may have been higher. Conversely, in patients without concomitant opioid use, naloxone and flumazenil may have been used less frequently. In addition, because some antihypertensives and diuretics are metabolized by cytochrome P450 3A4, the same enzyme that metabolizes midazolam, concomitant use may have resulted in metabolic competition.[19] Moreover, older patients may have delayed midazolam clearance, which could also result in prolonged sedation and a higher likelihood of flumazenil administration.[20] Because the observation time in this study was conducted from GI endoscopy until 9:00 a.m. the next day, the incidence of falls among hospitalized patients after GI endoscopy at our hospital was approximately 2.80 per 1,000 patient-days. Furthermore, because the incidence of inpatient falls in Japanese acute care hospitals is 1.42–3.8 per 1,000 patient-days,[9,21,22] the incidence of falls among hospitalized patients after GI endoscopy in Japan was unknown but considered within that given range. However, the odds ratio for inpatient falls associated with perioperative midazolam use was slightly increased (1.10 in total knee arthroplasty and 1.11 in total hip arthroplasty).[8] In contrast, midazolam sedation in GI endoscopy might not be associated with greatly increasing the incidence of falls in hospitalized patients.

Herein, the rate of falls among inpatients after GI endoscopy under midazolam-induced sedation was very little with or

**Table 1.** Comparison of Patient Characteristics and in Patients Falls between the Flumazenil and Nonflumazenil Groups

| Factor | Group | Flumazenil use (n=559) | Non-Flumazenil use (n=865) | p.value |
|---|---|---|---|---|
| Age (years) | Median [IQR] | 72.00 [59.00, 79.00] | 68.00 [55.00, 77.00] | 0.003 |
| Sex, n (%) | Male | 345 (61.7%) | 496 (57.3%) | 0.11[a)] |
| | Female | 214 (38.3%) | 369 (42.7%) | |
| Height (cm) | Median [IQR] | 161.20 [153.95, 168.00] | 162.00 [154.50, 168.20] | 0.319 |
| Body weight (kg) | Median [IQR] | 56.00 [47.30, 65.55] | 54.90 [48.00, 65.05] | 0.706 |
| BMI (kg/m$^2$) | Median [IQR] | 21.66 [19.45, 24.09] | 21.26 [19.12, 24.06] | 0.176 |
| Procedure, n (%) | ERCP | 59 (10.6%) | 101 (11.7%) | 0.747[a)] |
| | ERCP and Upper GI endoscopy | 0 (0.0%) | 1 (0.1%) | |
| | Upper GI endoscopy | 282 (50.4%) | 411 (47.5%) | |
| | Lower GI endoscopy | 184 (32.9%) | 307 (35.5%) | |
| | Upper and lower GI endoscopy | 2 (0.4%) | 2 (0.2%) | |
| | Double-balloon endoscopy | 32 (5.7%) | 43 (5.0%) | |
| Midazolam dose in endoscopy (mg) | Median [IQR] | 4.00 [3.00, 5.00] | 4.00 [3.00, 5.00] | 0.16 |
| Strong opioid use in endoscopy, n (%) | Yes | 168 (30.1%) | 190 (22.0%) | <0.001[a)] |
| | No | 391 (69.9%) | 675 (78.0%) | |
| Naloxone use in endoscopy, n (%) | Yes | 157 (28.1%) | 43 (5.0%) | <0.001[a)] |
| | No | 402 (71.9%) | 822 (95.0%) | |
| Total bilirubin, n (%) | >ULN×1.5 | 24 (4.3%) | 49 (5.7%) | 0.27[a)] |
| | ≤ULN×1.5 | 535 (95.7%) | 816 (94.3%) | |
| AST, n (%) | >ULN×3 | 15 (2.7%) | 37 (4.3%) | 0.147[a)] |
| | ≤ULN×3 | 544 (97.3%) | 828 (95.7%) | |
| ALT, n (%) | >ULN×3 | 12 (2.1%) | 38 (4.4%) | 0.027[a)] |
| | ≤ULN×3 | 547 (97.9%) | 827 (95.6%) | |
| Serum creatinine, n (%) | >ULN×1.5 | 50 (8.9%) | 73 (8.4%) | 0.772[a)] |
| | ≤ULN×1.5 | 509 (91.1%) | 792 (91.6%) | |
| Antihypertensive or diuretic use, n (%) | Yes | 283 (50.6%) | 382 (44.2%) | 0.019[a)] |
| | No | 276 (49.4%) | 483 (55.8%) | |
| Antidepressants use, n (%) | Yes | 15 (2.7%) | 35 (4.0%) | 0.187[a)] |
| | No | 544 (97.3%) | 830 (96.0%) | |
| Antipsychotic use, n (%) | Yes | 11 (2.0%) | 20 (2.3%) | 0.714[a)] |
| | No | 548 (98.0%) | 845 (97.7%) | |
| Benzodiazepines or Z-drugs use, n (%) | Yes | 77 (13.8%) | 131 (15.1%) | 0.49[a)] |
| | No | 482 (86.2%) | 734 (84.9%) | |
| In-patient fall, n (%) | Yes | 2 (0.36%) | 2 (0.23%) | 0.648[a)] |
| | No | 557 (99.6%) | 863 (99.8%) | |

a): Fisher's exact test other: Mann-Whitney U-test
IQR: interquartile range, BMI: Body Mass Index, ERCP: endoscopic retrograde cholangiopancreatography, GI: gastrointestinal, ULN: upper limits of normal, AST: aspartate transaminase, ALT: alanine transaminase, Z-drugs: zolpidem, zopiclone and eszopiclone

without flumazenil and has no significant differences, potentially because appropriate supervision—conducted since flumazenil use in our hospital—may minimize the occurrence of inpatient falls. Therefore, although flumazenil disuse could prolong nonwaking time, appropriate supervision conducted according to established guidelines[16] for patients under the influence of midazolam might prevent inpatient falls. In fact, as all four fall cases in the present study occurred >2 h after GI endoscopy and might not be subject to the influence of flumazenil, flumazenil use or disuse may have little impact on the incidence of falls. Therefore, these four patients may have common risk factors for inpatient falls associated with hypnotics, such as older age; in fact, all four were elderly.[23,24]

This study has several limitations. First, the data were obtained from a single institution, and the study was conducted retrospectively; thus, information bias could not be excluded and hospital-specific environmental conditions in this single-center setting may limit the generalizability of the findings. Second, falls were identified from medical records and incident reports; therefore, falls without injury may not have been reported by patients and could have been missed. Third, because the incidence of falls is extremely low, we could not perform multivariate analysis to adjust for confounding factors. In addition, the wide confidence interval suggests that the lack of statistical significance does not necessarily indicate the absence of a flumazenil effect. Therefore, further studies with larger sample sizes are warranted to draw definitive conclusions. Fourth, because midazolam was administered in this study as a short-term exposure for procedural sedation, prior evidence on fall incidence and risk assessment from chronic benzodiazepine use may not be directly applicable. Accordingly, further studies using assessment strategies optimized for short-term procedural sedation are needed. Finally, although inpatient falls are also associated with hospital-specific environmental and physical factors such as activities of daily living, these were not investigated in this study because of its retrospective design.

**Table 2.** Characteristics of Patients Who Experienced Falls Postendoscopy

| Patient No. | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Age (years) | 68 | 75 | 88 | 76 |
| Sex | Male | Female | Female | Female |
| Height (cm) | 168 | 140 | 148.6 | 153 |
| Body weight (kg) | 42.7 | 40 | 43 | 50 |
| BMI (kg/m$^2$) | 15.1 | 20.4 | 19.5 | 21.4 |
| Procedures | ERCP | Upper GI endoscopy | Upper GI endoscopy | Upper GI endoscopy |
| Midazolam dose in endoscopy (mg) | 5 | 4 | 2 | 3 |
| Flumazenil dose in endoscopy (mg) | 0.2 | 0.2 | No | No |
| Strong opioid use in endoscopy | No | No | No | No |
| Naloxone use in endoscopy | No | No | No | No |
| Total bilirubin (mg/dL) | 0.6 | 0.4 | 0.6 | 1.4 |
| AST (IU/L) | 78 | 22 | 25 | 44 |
| ALT (IU/L) | 60 | 15 | 13 | 19 |
| Serum creatinine (mg/dL) | 0.77 | 0.52 | 0.63 | 0.84 |
| Drugs except for GI endoscopy used within the 24 h before the fall | Lemborexant<br>Tofisopam<br>Risperidone<br>Potassium chloride<br>Alfacalcidol | Magnesium oxide<br>Celecoxib<br>Mirogabalin<br>Tramadol<br>Acetaminophen<br>Rebamipide | Sennoside<br>Aspirin<br>Escitalopram<br>Carvedilol<br>Eldecalcitol<br>Vonoprazan<br>Rosuvastatin<br>Calcium L-Aspartate | Etizolam<br>Furosemide<br>Spironolactone<br>Tolvaptan<br>Metformin<br>Levocarnitine<br>Teprenone<br>Vonoprazan<br>Thrombin<br>Cefmetazole |
| Hours after sedation | >12 | 4-6 | 10-12 | 2-4 |
| Place of fall | Around Bed | Around Bed | Corridor | Toilet |
| Injury | No damage | Bruises | Bruises | No damage |

BMI: Body Mass Index, ERCP: endoscopic retrograde cholangiopancreatography, GI: gastrointestinal, AST: aspartate transaminase; ALT: alanine transaminase

**Conclusion** The findings of our study indicate that, with regard to falls among gastrointestinal endoscopy patients administered midazolam, no clear difference was observed between the flumazenil-administered group and the non-administered group. Although further studies with larger sample sizes are warranted due to the small number of events, it remains unclear whether flumazenil use affects the incidence of inpatient falls.

**Acknowledgments** The authors would like to thank all the patients who participated in the study, their families, and the staff of the Osaka Metropolitan University Hospital.

**Funding** No funding was received for conducting this study.

**Conflict of interest** The authors declare no conflict of interest.

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