Short-term vital sign changes following sedative psychotropic initiation in hospitalized patients: A retrospective cohort study

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SUMMARY

Objective: Sedative psychotropic medications, such as olanzapine, quetiapine, mirtazapine, and trazodone, are commonly used in hospitalized patients to manage psychiatric symptoms, such as insomnia, restlessness, and agitation. Despite their widespread use, data on their short-term effects on vital signs in medically complex patients are limited. Understanding these effects is crucial for optimizing patient safety in acute care settings. This retrospective cohort study aimed to assess the effect of olanzapine, quetiapine, mirtazapine, and trazodone on vital signs (systolic and diastolic blood pressure, heart rate, oxygen saturation, and body temperature) in non-intensive care unit hospitalized patients.

Method: Among 871 screened consultation episodes, 184 patients met eligibility criteria and were included in the final analysis. Vital signs were collected at six standardized time points, 24 h before and after medication initiation. Linear mixed-effects models with subject-specific random intercepts were used to examine the treatment group, phase (pre–post), time of the day, and group-by-phase interactions. Multiple tests across the five primary phase effects were conducted using the Holm correction.

Results: Across all vital sign outcomes, fixed-effect estimates were small and indicated minimal physiological change. Heart rate showed a modest unadjusted decrease from pre- to post-exposure ($\beta = -1.72$ beats/min, 95% CI -3.11 to -0.33; $p = .017$); however, this association did not remain statistically significant after adjustment for multiple comparisons (Holm-adjusted $p = .083$). No statistically significant phase effects or group-by-phase interaction effects were observed for systolic blood pressure, diastolic blood pressure, or oxygen saturation.

Discussion: In this medically complex inpatient cohort, commonly used sedative psychotropic agents (olanzapine, quetiapine, mirtazapine, and trazodone) did not produce clinically meaningful short-term changes in the vital signs.These findings support the cautious but routine use of these agents in inpatients, with standard monitoring. Further prospective studies are recommended to explore the long-term outcomes and potential drug interactions.

Key Words: Hospitalized patients, non-benzodiazepine psychotropic sedatives, short-term effects, vital signs

INTRODUCTION

Psychiatric consultations are integral to the care of hospitalized patients in the medical and surgical wards. The demand for such consultations varies, with studies indicating that approximately one-third of hospitalized patients require psychiatric evaluation during their hospital stay (1,2). The primary reasons for psychiatric consultations in these settings include a spectrum of acute psychiatric disturbances including agitation, delirium, depression, anxiety, and substance withdrawal (3,4).

Addressing psychiatric symptoms in medically and surgically hospitalized patients is clinically important. Untreated psychiatric symptoms can complicate the management of primary medical and surgical conditions. For instance, severe anxiety, depression, or agitation may impede patient compliance with medical regimens and postoperative care instructions, thereby influencing recovery outcomes (5,6). Moreover, psychiatric conditions such as delirium are associated with increased morbidity and mortality rates, contributing to prolonged hospital stays, increased healthcare expenditures, and elevated risks of long-term cognitive impairment

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(1). Additionally, untreated psychiatric disorders may exacerbate physiological stress responses, adversely affecting cardiovascular and immune functions, which are critical for the recovery process in medically and surgically ill patients (7). Effective management of psychiatric symptoms enhances patient satisfaction and quality of life and optimizes clinical outcomes (8). Therefore, integrating psychiatric care into comprehensive patient management strategies is essential to improve health outcomes and optimize healthcare resource utilization.

In this context, commonly utilized psychiatric medications in medical and surgical wards include traditionally categorized antipsychotics, antidepressants, and sedative hypnotics. Medications such as olanzapine and quetiapine are favored for their sedative properties and efficacy in managing agitation and delirium, with a reduced risk of extrapyramidal side effects compared with older antipsychotics (9). Medications such as trazodone and mirtazapine, renowned for their sedative effects, are beneficial for treating insomnia and anxiety, particularly in older adults, owing to their favorable side effects (10).

Olanzapine and quetiapine exert their therapeutic effects through the complex interplay of receptor antagonism. For example, olanzapine antagonizes dopamine D2, serotonin 5-HT2A, histamine H1, and alpha-1 adrenergic receptors. These actions contribute to the sedative properties and potential for orthostatic hypotension due to vasodilation (11). Quetiapine similarly antagonizes serotonin 5-HT2A and alpha-1 adrenergic receptors, affecting the heart rate and blood pressure regulation (12). Trazodone antagonizes serotonin 5-HT_2A, histamine H_1, and α_1-adrenergic receptors, thereby contributing to its sedative and hypnotic properties. In hospitalized or older adults, while it is less likely to cause major direct respiratory suppression or marked thermoregulatory disruption, vigilance regarding oxygen saturation, body temperature changes, and orthostatic hypotension is still warranted, given the sedative and adrenergic blockade-related effects (13,14). Mirtazapine primarily antagonizes central presynaptic adrenergic autoreceptors/heteroreceptors and histamine H_1 receptors (and additionally 5-HT_2A/5-HT_2C/5-HT_3 receptors), leading to sedative and hypnotic effects. Its peripheral α_1-adrenergic antagonism and sedative burden contribute to the potential for orthostatic hypotension, especially in vulnerable hospitalized or geriatric patients (15). These receptor interactions, particularly adrenergic and histaminergic antagonism, underscore the potential for immediate physiological changes in vital signs, including blood pressure, heart rate, oxygen saturation, and body temperature, which are critical for monitoring complex patients. Although these drugs are effective in the management of psychiatric symptoms and are chosen because of their favorable side-effect profiles, case reports have shown that even at low single doses, they can cause life-threatening conditions such as hypotension, bradycardia, and hypothermia (16-21).

However, there is a scarcity of real time studies examining the effects of these selected agents on vital signs such as blood pressure, heart rate, body temperature, and oxygen saturation in medically complex patients, a population often excluded from clinical trials (22). Most studies have focused on long-term outcomes or specific adverse events rather than immediate physiological responses. Understanding acute physiological effects is critical because any significant changes in vital signs could indicate adverse reactions or interactions with other medications used to treat primary medical conditions. Given the current gap in the literature, this study aimed to retrospectively investigate the short-term effects of olanzapine, quetiapine, mirtazapine, and trazodone on the vital signs of hospitalized patients. This study aimed to enhance the safety and efficacy of psychiatric interventions in medically complex hospitalized patients by providing insights into the real-time effects of these psychotropic agents on vital signs.

METHODS

Participants

This study was approved by the Ethics Committee of Koc University (protocol number: 2025.204.IRB2.091). This retrospective study screened 871 consultation cases from Koc University Hospital, hospitalized over a 7-month period, and referred for psychiatric evaluation. The reasons for psychiatric consultation included sleep problems, anxiety, depression, delirium, and agitation.

Table 1. Reasons for ineligibility among screened consultation episodes (n=680)

Reason for ineligibility	n	% of ineligible (n=680)	% of screened (n=871)
ICU consultations	6	0.9	0.7
Discharge prescription only	74	10.9	8.5
Repeat consultation within 7 days	45	6.6	5.2
Already receiving a target study medication (not a new start)	94	13.8	10.8
Behavioral recommendations and/or melatonin only	75	11.0	8.6
Initiated non-sedating antidepressant (excluding trazodone/mirtazapine) or a mood stabilizer	248	36.5	28.5
Initiated benzodiazepine (non-target)	31	4.6	3.6
Initiated antipsychotic other than quetiapine/olanzapine	107	15.7	12.3

Note: Counts are mutually exclusive by construction (one primary ineligibility reason per screened episode).

The main selection criterion was the administration of olanzapine, quetiapine, trazodone, or mirtazapine after psychiatric consultation. Patients who were not advised to use one of these medications or who had already been using one of the selected drugs were excluded from the study. If the same patient consulted more than once in the same week, only the first consultation was considered. Consultations from the intensive care unit were also excluded because of possible instability in the vital signs.

Of the 871 screened consultation episodes, 680 were deemed ineligible after applying prespecified criteria, primarily because the consultation did not result in a new initiation of a target sedative psychotropic. The most common ineligibility reason was initiation of a non-target antidepressant or a mood stabilizer (n=248; 36.5% of ineligible), followed by initiation of a non-target antipsychotic (n=107; 15.7%), and cases in which the patient was already receiving a target study medication prior to consultation (n=94; 13.8%). Additional ineligible episodes included consultations resulting in behavioral recommendations and/or melatonin only (n=75; 11.0%), consultations for discharge prescription only (n=74; 10.9%), initiation of a benzodiazepine (n=31; 4.6%), repeat consultations within 7 days (n=45; 6.6%), and ICU consultations (n=6; 0.9%). A complete breakdown is provided in Table 1.

After screening, 191 cases were eligible; 7 eligible cases were excluded because the recommended target medication was not administered, yielding a final analytic sample of 184.

Extracted data and variables

Patient files were examined for recorded vital signs including diastolic blood pressure, systolic blood pressure, heart rate, body temperature, and oxygen saturation. Vital signs were collected during the 24 h immediately preceding the first dose of psychotropic medication and during the 24 h immediately following the first dose at corresponding standardized time points. Six standardized time points (1AM, 6AM, 10AM, 1PM, 6PM, and 10 PM) were selected to capture comprehensive diurnal variations in vital signs and align with standard hospital vital sign monitoring protocols, ensuring consistency in data collection both pre and post medication initiation (Figure 1).

In addition, age, biological sex, primary diagnoses, known chronic illnesses, daily drug regimens, consultation dates, and consultation notes were recorded for each participant. As the major diagnosis for hospitalization may affect the vital signs, the major comorbidities/diagnoses were divided into three categories: oncological diseases, infectious diseases, and other disorders (cardiovascular diseases, pulmonary diseases, endocrine and metabolic diseases, neurological diseases). Patients were administered one of four psychotropic medications (olanzapine, quetiapine, mirtazapine, or

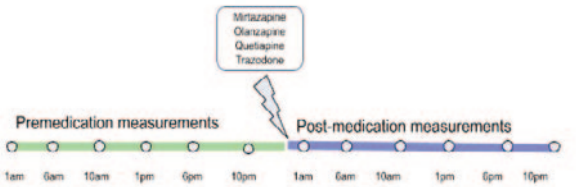


Figure 1. Time points when vital signs were recorded before and after medication initiation

trazodone), as prescribed by the psychiatric consultation service. The initial dose ranges used were mirtazapine, 15 mg, olanzapine 2.5–5 mg, quetiapine 12.5–25 mg, and trazodone, 25–50 mg. All medications were administered orally, typically once daily, for the first 24 hours of observation. In addition, the current usage of antihypertensive drugs (diuretics, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, and their combinations) was recorded, and 184 patients were divi-ded into two groups: those who used antihypertensive drugs (n=85) and those who did not (n=99).

Statistical Analysis

Descriptive statistics were computed for demographic and clinical variables, including means, medians, and standard deviations for continuous variables and frequencies and percentages for categorical variables. Baseline continuous variables were compared across treatment groups using one-way analysis of variance (ANOVA) or the Kruskal-Wallıs test, and categorical variables were compared using chi-square or Fisher's exact tests, as appropriate based on distributional assumptions. We performed repeated measurements of five physiological outcomes (systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation, and temperature) using linear mixed-effects models. For each outcome, the fixed effects structure included group, phase (post vs. pre), time (within-day order), and group x phase interaction. Subject-specific random intercepts accounted for heterogeneity between the subjects. Models were estimated with maximum likelihood for likelihood ratio testing, and standard errors were used to compute Wald's 95% confidence intervals for parameter estimates. For block-wise inference on fixed effects, we computed likelihood ratio tests by comparing the full models with reduced models that omitted the term of interest. Because we examined the phase effect across the five outcomes, we controlled for multiple comparisons using Holm's method (family wise error rate, =0.05).

Missing repeated-measures data were handled within a mixed-model framework that accommodated unbalanced longitudinal data without imputation. The post-medication 1:00 AM time point had a higher rate of missing observations (~50%), consistent with the overnight clinical workflow, where vital signs may not be recorded if patients are sleeping and clinically stable. As this represented the earliest physiological response window after medication administration, it was retained for the primary analysis. Missingness at all other time points ranged from 10 to 30%.

RESULTS

Sample Characteristics

Of the 871 consultation episodes screened, 680 were ineligible after applying prespecified criteria, leaving 191 eligible episodes. Seven eligible episodes were excluded because the recommended target medication was not administered, resulting in a final analytic cohort of 184 patients. The primary reasons for hospitalization in the study sample were oncological disorders (n=109), infectious diseases (n=31), neurological disorders (n=10), cardiovascular diseases (n=8), renal and hepatic insufficiency (n=10), pulmonary diseases (n=8), orthopedic surgery (n=4), and non-oncological abdominal surgery (n=4). The mean age was 68.2±14.4 (median =70, min=20, max=100), and 40.2% of the sample were females. Of the patients, 21.4% had a diagnosis of delirium, and 16.9% had an ongoing infection. Of the patients, 46.2% were taking antihypertensive medications. The most

	Total	Mirtazapine	Olanzapine	Quetiapine	Trazodone	p
Sample size N (%)	184 (100)	86 (46.8)	17 (9.2)	58 (31.5)	23 (12.5)	
Age (mean–SD)	68.24–14.37	65.9–14.83	66.1–12.87	73.3–12.65	65.7–15.31	0.025
Sex						
Male	110 (59.8%)	50(58.1%)	10(58.8%)	39 (67.2%)	11(47.8%)	0.46
Female	74 (40.2%)	36(41.9%)	7(41.2%)	19(32.8%)	12(52.2%)	
Accompanying Diagnosis						
Oncological Disease	109 (59.2%)	61(70.9%)	6(35.3%)	28(48.3%)	14(60.9%)	p<0.001
Infectious Disease	31(16.8%)	8(9.3%)	4(23.5%)	16(27.6%)	3(13%)	0.024
Delirium	40(21.7%)	5 (5.9%)	11(64.7%)	22(37.9%)	2(8.7%)	p<0.001
Other comorbidities	136 (73.9%)	59(68.6%)	13(76.5%)	46(79.3%)	18(78.3%)	0.32
Antihypertensive use						
No	99 (53.8%)	51 (59.3%)	11(64.8%)	26(44.8%)	11(47.9%)	
Yes	85 (46.2%)	35 (40.7%)	6 (35.2%)	32(55.2%)	12(52.1%)	0.25

Table 2. Sample characteristics of the total sample and study groups

commonly prescribed drugs were mirtazapine (46.8%), quetiapine (31.5%), trazodone (12.5%), and olanzapine (9.2%). The demographic and clinical variables of the total sample and the medication groups are shown in Table 2.

In the comparative analysis of mean age across drug groups, the quetiapine group exhibited a significantly higher mean age than the other groups, with no significant age differences observed among the remaining drug groups (Kruskal-Wallis variance analysis, p=0.025). The prevalence of oncological disorders was notably higher in the mirtazapine group (70.9%) and lower in the olanzapine group (35.3%) (p<0.001). The occurrence of delirium also differed significantly between the groups (p<0.001), with the olanzapine group demonstrating a markedly higher incidence (64.71%). Additionally, significant group differences were observed in the occurrence of infection (P =0.024), with the quetiapine group having the highest rate (28.07%) and the mirtazapine group having the lowest (9.3%). No significant differences were identified between the groups with respect to other comorbidities (p=0.32). Antihypertensive use did not differ significantly between groups (p=0.25).

Linear Mixed-Effects Models

For systolic and diastolic blood pressure, oxygen saturation, and temperature, neither the phase main effect nor the group x phase interaction indicated a systematic pre–post change; confidence intervals spanned the null, and omnibus model tests were non-significant. Random-intercept mixed-effects models demonstrated an adequate fit, suggesting that individual-level variability was appropriately modeled.

The 1.00 am post-dose timepoint had ~50% missing data (vs. 10–30% at other time points), reflecting overnight workflow patterns rather than a systematic loss. This time point was retained given its clinical relevance as the first post-dose observation and mixed-model tolerance for unbalanced data.

In summary, while heart rate exhibited a modest unadjusted decline from pre-to post-intervention, multiplicity-adjusted analyses did not provide definitive evidence of a consistent physiological change across outcomes. The full numeric results, including estimates, standard errors, CIs, omnibus tests, and fit indices, are available in the tables and figures.

DISCUSSION

The findings of this retrospective analysis provide valuable insights into the effects of commonly prescribed sedative psychotropic medications (olanzapine, quetiapine, mirtazapine, and trazodone) on the vital signs of a cohort of hospitalized patients. Given the increasing reliance on these medications to manage psychiatric symptoms in medically complex populations, understanding their physiological effects is crucial to ensure patient safety and optimize therapeutic outcomes.

The primary outcome of this study indicated that there were no significant changes in vital signs, including systolic and diastolic blood pressure, heart rate, oxygen saturation, and body temperature, within 24 h of the administration of the selected psychotropic medications. This is a noteworthy finding, especially considering the high prevalence of comorbidities within the study population, where nearly 60% of the patients had an oncological disease. While previous research has highlighted various adverse events associated with sedative hypnotics, such as drowsiness and dizziness, there

Table 3. Linear Mixed-Effects Model Estimates for Vital Sign Outcomes

Outcome	Effect	Estimate (Beta)	95% CI	Wald x†/F	p	Holm-adjusted p	Interpretation
Heart rate	Phase (Post vs Pre)	-1.72	-3.11 to -0.33	5.67	0.017	0.083	Trend; NS after correction
Systolic BP	Phase (Post vs Pre)	0.42	-1.50 to 2.35	0.21	0.65	0.65	No effect
Diastolic BP	Phase (Post vs Pre)	0.36	-1.10 to 1.82	0.16	0.7	0.7	No effect
Oxygen saturation	Phase (Post vs Pre)	0.01	-0.10 to 0.12	0.33	0.56	0.56	No effect
Temperature	Phase (Post vs Pre)	0.02	-0.03 to 0.06	1.02	0.31	0.31	No effect

Estimates represent fixed effects for the post-phase versus pre-phase change. Holm correction was applied across the five primary phase tests. NS = non-significant after correction.

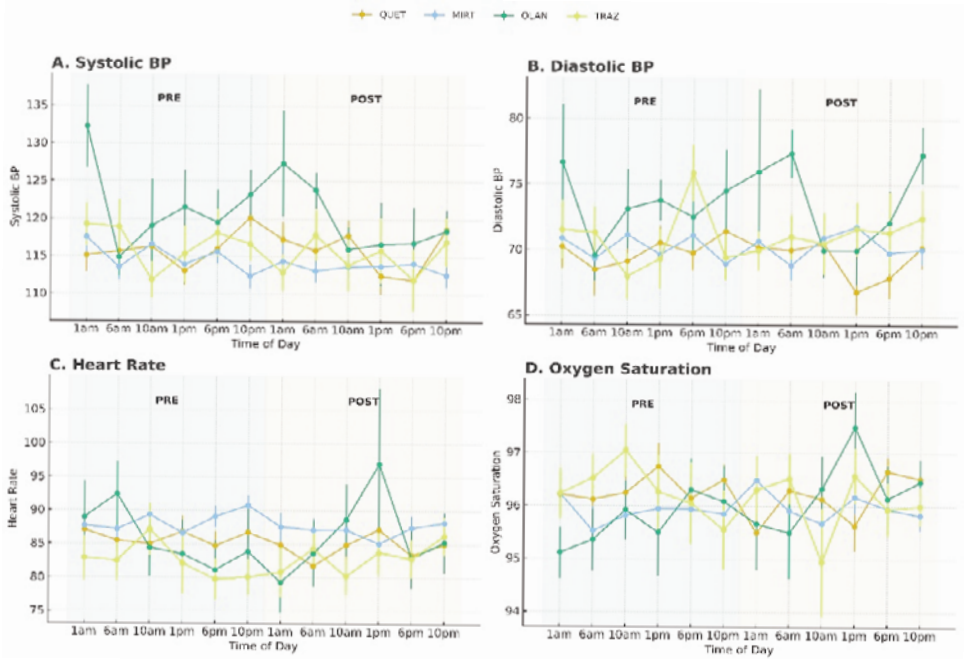


Figure 2. Vital sign trajectories before (PRE) and after (POST) psychotropic medication administration across four drug classes. The blue and orange shaded areas represent the PRE and POST post-medication periods, respectively. The lines show group means with standard errors. Groups: MIRT-mirtazapine; OLAN-olanzapine; QUET -quetiapine; TRAZ-trazodone.

has been limited empirical data specifically examining their impact on vital signs, such as blood pressure, heart rate, and oxygen saturation (23). Our study fills this gap by providing empirical data on the short-term hemodynamic and respiratory effects of these drugs in a clinical setting. For practitioners, these results suggest that routine vital sign monitoring, which is already the standard for hospitalized patients, is sufficient to detect rare adverse events.

The lack of significant differences in the vital signs between the medication groups in this study may be attributed to several factors. First, the patient population had a high prevalence of comorbid conditions, which could have influenced the stability of vital signs, despite the use of sedative hypnotics. Second, the dosages of the medications were tailored to minimize adverse effects, reflecting the clinical practice of cautious prescribing.

Published case reports have described serious cardiopulmonary and hemodynamic events following single-dose exposure to several of the study medications. Examples include bradycardia after a single 30 mg dose of mirtazapine (16), bradycardia and hypotension reported with olanzapine at doses of 2.5–10 mg even in otherwise healthy individuals (24-26), cardiopulmonary arrest after a single 25 mg dose of quetiapine and sustained hypotension after initiation at 50 mg (18,27), and bradycardia after a 50 mg dose of trazodone (21,28). Although these reports underscore potential idiosyncratic vulnerability and the importance of clinical monitoring, causal inference is limited by their design and the frequent presence of baseline medical risk factors and co-medications. In contrast, evidence from larger observational cohorts and synthesis studies has generally not corroborated a high incidence of severe acute physiological instability at therapeutic doses in monitored settings (29-31). The results of our study confirm previous studies suggesting that psychotropic drugs are frequently associated with adverse events in the elderly, severe hemodynamic instability is less common than feared when low doses are used (32,33). For instance, a meta-analysis by (9) regarding antipsychotics in delirium treatment highlighted that while sedation is a frequent side effect, severe cardiovascular events requiring discontinuation are relatively rare compared with placebo administration.

The patient population included in the study comprised elderly patients hospitalized for diseases, such as cancer, delirium, and serious infections. In general, this population requires sedative medications for insomnia, agitation, and anxiety. In this population, drug selection is challenging because of comorbid diseases, polypharmacy, and unstable

vital signs due to critical illness. Benzodiazepines are not a good choice in this group because of the risk of increasing confusion and depressing respiration. Instead, antidepressants and antipsychotics with sedative-hypnotic effects are preferred by many psychiatrists (34). In this study, mirtazapine was prescribed more frequently in the oncologic patient group, which is understandable considering the antiemetic and appetite-enhancing effects of mirtazapine, since these patients usually complain of nausea and lack of appetite, most of them being cachectic. In the delirium group, quetiapine was the preferred drug. Considering that these patients often have hyperactive delirium and symptoms, such as agitation, visual hallucinations, and delusions, it is rational to prefer an antipsychotic with a shorter half-life (35). Although trazodone is a reliable sedative antidepressant with a short half-life and anxiolytic properties, it is less preferred than mirtazapine for several reasons. First, mirtazapine has additional antiemetic properties, and its antihistaminic effects are more pronounced (36). Second, the sublingual form of mirtazapine is available as an advantage for patients with swallowing difficulties and nausea while taking the drug. The fact that olanzapine is less preferred than quetiapine, despite being a cardiac-safe and highly effective drug for acute agitation, may be due to the preference for drugs with shorter half-lives because of the risk of excessive sedation in this patient group.

Despite these promising findings, several limitations of this study remain to be acknowledged. The retrospective nature of the study inherently limits control over confounding variables and restricts the ability to draw definitive causal conclusions regarding the relationship between medication administration and vital sign changes. Because eligibility required a new initiation of a target sedative psychotropic and excluded ICU consultations, the analytic cohort represents a selected subset of consulted inpatients. Accordingly, these results should be interpreted within the context of a selected consultation-based cohort, and may not generalize to all medically complex inpatients. Second, the lack of a similar number of patients in the drug groups, and the small number of patients in the trazodone and olanzapine groups may have affected the results in terms of comparison. Additionally, the sample size, although adequate for preliminary analysis, may limit the generalizability of the findings. Future prospective studies or randomized controlled trials could help validate our findings and assess whether certain patient populations (e.g., those with cardiovascular diseases) are more vulnerable to adverse effects. Long-term outcomes were associated with psychotropic-induced vital sign changes, particularly in relation to mortality, length of hospital stay, and rehospitalization.

Another limitation is the lack of detailed information regarding the concurrent use of other medications, particularly those that could influence the cardiovascular parameters. The interactions between psychotropic medications and other pharmacological agents remain underexplored and understanding these interactions is essential for optimizing patient safety. Importantly, the first post-dose time point (1:00 AM) exhibited higher missingness (~50%), which is consistent with routine overnight nursing practices in medically stable patients. Because this represents the earliest physiological window following medication administration, exclusion removes clinically meaningful information. The retention of this time point and the use of mixed-effects modeling minimized bias and preserved interpretability. Sensitivity analyses excluding the 1:00 AM time point yielded similar findings, supporting the robustness of the results (available upon request).

In conclusion, this retrospective analysis contributes to the growing body of the literature on the use of psychotropic medications in hospitalized patients. These findings indicate that olanzapine, quetiapine, mirtazapine, and trazodone have a minimal impact on vital signs within the first 24 h of administration, suggesting that these medications can be safely utilized in acute care settings when used at conservative doses. However, vigilant monitoring of vital signs, particularly in patients with comorbidities, remains paramount. Our findings and current literature mainly highlight the impact of interindividual differences, emphasizing that factors such as comorbid cardiac conditions, age, concurrent medications, and variables influencing drug absorption play a crucial role. As psychiatric care becomes increasingly integrated into the management of hospitalized patients, further research

is essential to refine our understanding of the physiological implications of psychotropic medications, ultimately enhancing patient safety and therapeutic efficacy in acute care settings.

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All authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work in accordance with ICMJE authorship criteria.

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