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Evaluation of immunochromatography-based urine drug screening and blood drug concentrations in suspected acute poisoning: insights into negative urine drug screening results

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Abstract

Background Immunochromatography-based urine drug screening (UDS) can have false-positive or false-negative results; thus, interpretation of results requires careful evaluation. A UDS-negative result simply indicates that target drugs were not detected in urine and does not rule out acute poisoning. This study aimed to determine the presence of drugs in the blood and blood drug concentrations in suspected cases of acute poisoning with UDS-negative results.

Methods In this single-center, retrospective, observational study, we included 501 patients who attended Tokai University Hospital Advanced Emergency Medical Center, Japan, between January 1, 2014 and December 31, 2023 and were diagnosed with acute poisoning with negative UDS results. The primary outcome included the detection rate of UDS items and non-UDS items in blood samples. The secondary outcome included the classification of blood drug concentrations (below therapeutic range, within therapeutic range, above therapeutic range). Blood drug concentrations were measured using a gas chromatography–mass spectrometer and liquid chromatography–tandem mass spectrometer.

Results Blood drug concentrations were detected in 498 (99.4%) of the 501 participants. Despite negative UDS results in urine, UDS items were detected in blood samples of 239 patients (58.8%). Non-UDS items were detected in 430 participants (86.3%). Benzodiazepines were the most commonly detected UDS items, with many cases exhibiting blood drug concentrations above the therapeutic range. In non-UDS items, non-benzodiazepine hypnotics, antipsychotics, and over-the-counter (OTC) medications were often detected.

Conclusion This study demonstrates that negative UDS results do not rule out the presence of drugs in acute poisoning cases. Moreover, a comprehensive evaluation, including physical and laboratory findings, is essential for accurate diagnosis and treatment.

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Introduction

Immunochromatography-based urine drug screening (UDS) kits are widely used in medical practice, law enforcement settings, workplace testing, and drug laboratories [1, 2]. In emergency medical practice in Japan, UDS kits are used when acute poisoning is suspected. UDS is a qualitative test that helps determine the presence of drugs [3]. In Japan, most drug intoxication cases involve intentional overdoses of prescription psychotropic medications, whereas illicit drug use is relatively uncommon. Therefore, UDS is mainly used as an initial screening tool for suspected overdose of commonly available medications rather than for detecting illicit drugs. It is economical, easier to perform, and provides results more rapidly than quantitative analyzers [4, 5].

False positives and false negatives are common in UDS results. Regarding the items that can be detected by UDS, some reports indicate that certain drugs are more likely to provide false-positive or false-negative results [3, 4]. In particular, UDS is known to produce false-negative and false-positive results, particularly for tricyclic antidepressants (TCA), due to cross-reactivity in immunoassays. Negative results also include drug doses that are below the detectable limit; thus, it is not possible to make a definitive diagnosis based on such a result [4–6]. New drugs not included in UDS are also undetectable [7]. Thus, quantitative analysis of blood samples using analytical equipment is preferable for the definitive diagnosis of acute poisoning, and UDS results need to be carefully evaluated [7, 8].

It is well-known in the areas of emergency medicine and addiction/substance abuse that UDS results are difficult to evaluate. A UDS-negative result simply indicates that target drugs were not detected in urine; it may reflect concentrations below the detection threshold or substances not included in the test panel, and therefore does not rule out acute poisoning.

Although it has been stated that a "UDS-negative result does not mean that the drug is absent," few studies have directly compared UDS-negative results with quantitative blood drug concentrations in real-world clinical settings. Understanding these discrepancies between UDS results and actual drug exposure is crucial for accurate interpretation. In Japan, where intentional overdoses of prescription and over-the-counter (OTC) medications are commonly encountered in emergency departments and many of these substances are not included in UDS panels, UDS-negative results are more likely to be overinterpreted as ruling out acute poisoning. Therefore, the present study focused particularly on patients with UDS-negative urine results by investigating drugs detected in the blood and their concentrations, in order to clarify the clinical meaning and limitations of UDS negativity.

Methods

Study design

This study is a single-center, retrospective, observational study.

Setting

We surveyed individuals diagnosed with acute poisoning at the Tokai University Hospital Advanced Emergency Medical Center ("our center" hereafter) between January 1, 2014, and December 31, 2023. Our center is a medical institution located in the western region of the Kanagawa Prefecture (approximately 50 km from Tokyo). Our center has a toxicology laboratory that performs quantitative analysis of blood samples of numerous medicinal toxicants.

Patients

Patient data were extracted from the database maintained at our center. Overall, 2,659 patients with a diagnosis of acute poisoning were enrolled in the study. Of these, 501 patients with a negative UDS result were included in this study after undergoing UDS and measurement of blood drug concentrations for suspected acute poisoning caused by prescription drugs, OTC drugs, or illegal drugs (Fig. 1). One patient who had been examined approximately 200 times during the study period for acute poisoning by the same drug was excluded due to the inaccuracy in qualitative and quantitative tests owing to short intervals between visits. Furthermore, alcohol intoxication was excluded at the time of data extraction as it is registered differently from acute intoxication.

Variables

Study variables included age, gender, history of psychiatric consultations, exposure mode (e.g., self-harm, suicide, accident, insomnia, and unknown), emergency department outcome (hospitalization, return home), length of stay, UDS items, and blood drug concentrations.

UDS kits used at our center include TriageDOA® and Status DS10, which use patient urine collected at the emergency department. These rapid multi-panel tests detect drugs in urine within approximately 5–10 min. The items common to both the kits are phencyclidine (PCP), benzodiazepines (BZO), barbiturates (BAR), TCA, opioids (OPI), cocaine (COC), amphetamines (AMP), and cannabis (THC). Moreover, the StatusDS10 includes methadone (MTD) and methamphetamine (MET).

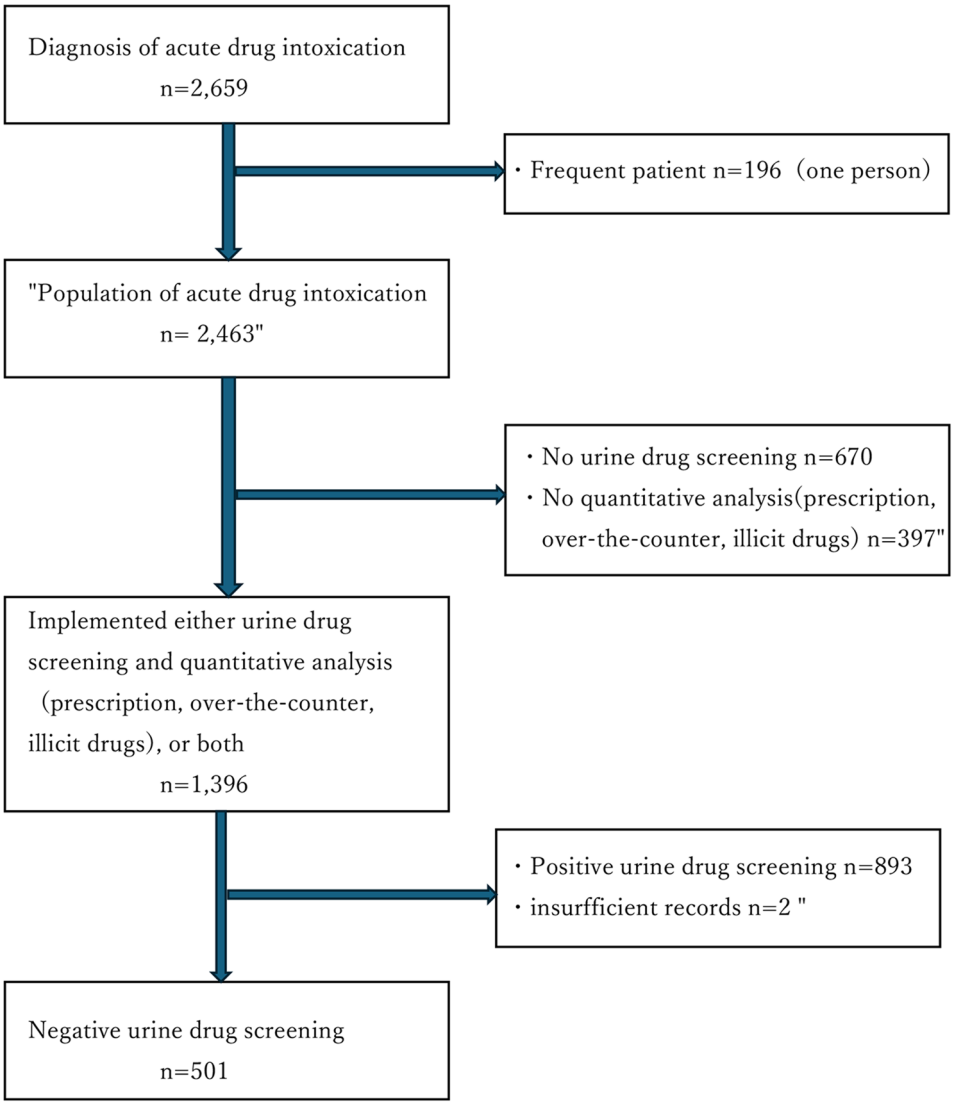

Fig. 1 Inclusion criteria
In total, 501 patients with suspected acute poisoning who visited the emergency department were analyzed using UDS and quantitative analysis of blood samples

Drugs not included in the test panels of the UDS kits were defined as non-UDS items and were evaluated using quantitative blood analysis. Among non-UDS items, non-benzodiazepine hypnotics (non-BZO) were defined as sedative–hypnotic agents that do not belong to the benzodiazepine class, such as zolpidem and zopiclone. Other sleeping drugs included agents with distinct pharmacological mechanisms, such as ramelteon, suvorexant, and lemborexant.

Blood drug concentrations were measured using gas chromatography–mass spectrometry and liquid chromatography–tandem mass spectrometry using blood samples collected at the emergency department. Blood samples were collected upon arrival, and urine samples were collected within the subsequent 1 h, resulting in some variability in the timing between blood and urine sampling. In this study, blood drug concentrations were used as the gold standard to determine if a negative UDS result is a true negative or not. Furthermore, blood drug concentrations were classified as follows: "below the therapeutic range," "within the therapeutic range," or "above the therapeutic range." This classification was based on "Drug and chemical blood-level data 2001" [9] and "Revisited: Therapeutic and toxic blood concentrations of > 1,100 drugs and other xenobiotics" [10]. Blood drug concentrations of general prescription and OTC loxoprofen and bromovalerylurea were based on the literature [11, 12]. Notably, blood drug concentrations of other sleeping drugs and OPI are not measured.

Table 1 Characteristics of patients

Variable categories		Number of cases (*n*)	Percentage (%)
total		501	100
gender			
	female	368	73.2
age			
	median interquartile range	35 (24–50)	
psychiatric past history		357	71.0
cause			
	self-harm	328	65.2
	suicide	73	14.5
	insomnia	20	4.0
	accident	17	3.4
	unknown	21	4.2
	other	42	8.3
ER outcome			
	admission	435	86.5

Table 2 Detection rate of UDS items in samples positive for blood drugs

Detection drugs	*n* = 293	
	Number of case (*n*)	Percentage (%)
PCP	0	0
BZO	288	98.3
COC	0	0
AMP	0	0
THC	1	0.3
OPI	0	0
BAR	1	0.3
TCA	12	4.1
MED	0	0
MET	0	0

Outcomes

Primary outcomes included the detection rate of blood drug concentrations for the following: (i) UDS items, (ii) non-UDS items, and (iii) UDS-negative cases with no detectable blood drug concentrations on quantitative analysis. Furthermore, UDS and non-UDS items partially overlapped, as some participants used both.

Secondary outcomes included drug items detection rate for the following: (i) UDS item-specific detection rate in the group with UDS items detected, (ii) non-UDS item-specific detection rate in the group with non-UDS items detected, and classification according to blood drug level for each drug detected.

Statistics

Continuous variables are presented as medians, quartile deviations, and percentages (%), whereas categorical variables are presented as percentages.

Ethical considerations

The study was approved by the Research Ethics Committee of Tokai University School of Medicine, and patient consent was waived as the data were anonymized.

Patient and public involvement

Patients and the public were not involved in the development, design, and analysis of this study.

Results

Subject attributes

Table 1 summarizes the characteristics of the 501 participants, including gender, age, history of psychiatric consultation, exposure triggers, and emergency department outcomes. Most patients were women and had a history of psychiatric consultation. Many patients presented to the emergency department due to self-harm.

Detection rate of blood drug concentrations

Blood drug concentrations were detected in 498 (99.4%) of the 501 participants, including UDS items in 293 (58.8%) and non-UDS items in 430 (86.3%), whereas no drugs were detected in 3 participants (0.6%).

Drug items detection rates

{i). Table 2 presents the UDS item-specific detection rate in the study group along with the UDS items detected. BZO were detected in the majority of the 293 participants that were detected to have UDS items. Additionally, TCA, BAR, and THC were detected less frequently. OPI were not measured in this study; therefore, no results for OPI are presented in Table 2.

(ii). Table 3 presents the non-UDS item-specific detection rate in the group with non-UDS items detected. Of the 430 participants with non-UDS items detected, OTC drugs were identified in > 30%, while non-BZO and atypical antipsychotics were detected in approximately 25%. In contrast, illicit drugs not included in the UDS items were not detected.

Classification according to blood drug concentrations

Tables 4 and 5 depict the classification of each drug included in the UDS and non-UDS items by blood drug concentrations.

BZO: Fifteen BZO agents were detected in 386 cases. Blood drug concentrations were most frequently detected in the therapeutic range, and etizolam, nitrazepam, and

Table 3 Detection rate of non-UDS items in samples positive for blood drugs

Detection drugs	*n* = 430	
	Number of cases (*n*)	Percentage (%)
Non-benzodiazepine	104	24.2
Other sleeping drugs	20	4.7
Cyclic antidepressants	23	5.3
SSRI/SNRI/SARI	74	17.2
Typical antipsychotics	78	18.1
Atypical antipsychotics	114	26.5
Other anticonvulsants	49	11.4
Other psychotics	20	4.7
Other illicit drugs	0	0
General prescription	63	14.7
Over-the-counter	147	34.2

Non-benzodiazepine hypnotic: sedative–hypnotic agents that do not belong to the benzodiazepine class (e.g., zolpidem and zopiclone)

Other sleeping drugs: hypnotic agents with pharmacological mechanisms distinct from benzodiazepines and non-benzodiazepine hypnotics (e.g., ramelteon, suvorexant, and lemborexant)

SSRI: selective serotonin reuptake inhibitor (e.g., sertraline and escitalopram)

SNRI: serotonin-norepinephrine reuptake inhibitor (e.g., venlafaxine and duloxetine)

SARI: serotonin antagonist and reuptake inhibitor (e.g., trazodone)

brotizolam were more frequently detected above the therapeutic range than in the therapeutic range.

TCA: Four TCA agents were detected in 12 cases. Most of the TCA in the 12 cases were below the therapeutic range, with desipramine being the only one in the therapeutic range. Moreover, no blood drug concentrations above the therapeutic range were detected.

BAR and THC: Only one case of each agent was detected, and none were detected to be above the therapeutic range.

Non-UDS items: Among non-UDS items, sleep-related drugs (non-BZO and other sleeping drugs), general prescription drugs, and OTC drugs were more frequently detected at concentrations above the therapeutic range. Other sleeping drugs included agents with distinct pharmacological mechanisms, such as ramelteon, suvorexant, and lemborexant. For drugs that overlap between general prescription drugs and OTC drugs, such as acetaminophen, loxoprofen, and diphenhydramine, results were shown separately for clarity. Prescription and OTC acetaminophen were detected at concentrations in all three categories, with most cases exceeding the therapeutic range. Prescription and OTC loxoprofen were detected at concentrations within and above the therapeutic range. Prescription diphenhydramine was detected in only a few cases, and all concentrations were detected in the below therapeutic range. In contrast, OTC diphenhydramine was detected across all concentration ranges, with most cases exceeding the therapeutic range. Furthermore, antidepressants, antipsychotics, anticonvulsants, and other psychotropic drugs did not differ in the number of detections below the therapeutic range, in the therapeutic range, or above the therapeutic range.

Table 4 Classification by blood drug concentrations (UDS items)

Drugs by item		Blood drug concentration categories *n* = 293		
		Below therapeutic range	Therapeutic range	Above therapeutic range
BZO				
	alprazolam	1	14	5
	estazolam		4	4
	etizolam	6	18	44
	quazepam	1	2	1
	clotiazepam	11	7	1
	clonazepam	10	5	2
	diazepam	9	4	
	triazolam		4	1
	nitrazepam	4	21	33
	flunitrazepam	5	63	20
	flurazepam	1		
	brotizolam	1	18	22
	bromazepam	11	10	3
	loraxzepam	5	14	
	lormetazepam			1
TCA				
	amoxapine	5		
	amitriptyline	1		
	clomipramine	2		
	desipramine		4	
BAR				
	barbital	1		
THC				
	tetrahydrocannabinol		1	

Discussion

In this study, we investigated drugs and blood drug concentrations detected in UDS-negative blood samples among cases of suspected acute intoxication. Blood drug concentrations were detected for UDS as well as many other items in most participants.

UDS items

Reported causes of false-negative UDS results include urinary drug and metabolite levels below cutoff values, different chemical structural formulas within the same class, and low sensitivity for UDS [3, 4, 7, 13]. The low detection rates observed for most drug categories in Table 2 reflect the study design, as only patients with negative urine drug screening results were included. Benzodiazepines were detected more frequently than other drug classes; however, iatrogenic administration during emergency treatment cannot be excluded in some

Table 5 Classification by blood drug concentrations (non-UDS items)

Drugs by item	Blood drug concentration categories *n* = 430		
	Below therapeutic range	Therapeutic range	Above therapeutic range
non-BZO			
zolpidem	8	9	44
zopiclone	11	7	26
antidepressant			
mianserin		2	2
maprotiline	2		
mirtazapine	5	3	11
trazodone hydrochloride	13	2	4
sertraline		10	2
paroxetine		15	7
fluvoxamine	7	4	1
milnacipran	5		
duloxetine	1	0	1
antipsychotics			
chlorpromazine	8	9	4
levomepromazine	17	15	4
sulpiride	15	7	2
perphenazine			1
fluphenazine			2
aripiprazole	9	11	6
olanzapine	1	4	7
quetiapine	10	12	26
zotepine		3	
perospirone			3
risperidone	16	12	15
anticonvulsant			
carbamazepine	1	1	4
sodium valproate	12	13	12
lamotrigine		2	1
levetiracetam			1
other psychiatrics			
lithium	3	7	6
methylphenidate		2	
general prescription			
theophylline		1	3
amlodipine		1	1
nifedipine		1	1
biperiden			12
promethazine		2	12
insulin		1	2
eperisone			1
tizanidine		1	
acetaminophen	4	1	8
loxoprofen		6	1
diphenhydramine	3		
OTC (main ingredients)			
acetaminophen	8	2	11
ibuprofen	16	5	16
salicylic acid	2	4	15
loxoprofen		6	1
caffeine	7	6	44
diphenhydramine	13	5	23
bromvalerylurea			2

cases and should be considered when interpreting these findings.

BZO

Triazolam, flunitrazepam, alprazolam, lorazepam, etizolam, brotizolam, and clothiazepam are likely to give false-negative results. In this study, BZO was detected, and the blood drug concentrations were not only in the therapeutic range but also above the therapeutic range in many cases. BZO has a sedative and respiratory depressant effect and can cause severe illness. Therefore, even if the UDS results were negative, it was considered necessary to suspect the patient of BZO consumption. Furthermore, in the present study, nitrazepam was detected in several participants. Previous reports have rarely described nitrazepam as a BZO that can cause false-negative results. It has been reported that drug dosage, pharmacokinetic elimination patterns, and exposure time affect UDS results [4]. Nitrazepam is mainly metabolized in the liver and excreted in the urine as the metabolites 7-acetamide and 7-amino. The excretion rate is 13%–20% 24 h after ingestion, with a urinary cutoff of 100,000 ng/mL (Status DS10) [14]. False-negative results for nitrazepam in this study could be attributed to the fact that the UDS was performed within a short time after the dose, the excretion rate was low and the urinary drug concentration was below the cutoff value, and the drug concentration was below the cutoff value even when combined with other BZOs (BZO: 300 ng/ml [TriageDOA®, Status DS10]). Thus, it must be reacknowledged that "BZO is prone to false negatives."

TCA

Amoxapine has been known to provide false negatives [3, 4, 7, 13]. In the present study, TCA were rarely detected, and blood drug concentrations were mostly below the therapeutic range.

BAR and THC

BAR is believed to have high sensitivity and specificity in UDS, and THC is known to be detectable for a long period of time after ingestion due to its slow urinary

excretion [4, 7, 15]. In the present study, BAR and THC were detected in low numbers, and blood drug concentrations were not above the therapeutic range.

The possibility that the patient could have taken BZO could not be ruled out in this study, even if the results were negative. However, it was believed that TCA, BAR, and THC would allow for evaluation to some degree.

Non-UDS items

It is well-known that certain drugs that are undetectable by UDS are often responsible for overdoses. A wide variety of drugs were detected in the present study. In the classification of their blood drug concentrations, the detected levels were relatively evenly distributed. However, blood drug concentrations above the therapeutic range were detected not only in non-BZO and antipsychotics (especially atypical antipsychotics) but also in many general prescription drugs and OTC drugs. These drugs act on various bodily systems, such as the circulatory, respiratory, and endocrine systems, and sustain the risk of causing serious conditions such as circulatory and respiratory failure. Therefore, even if the UDS results are negative, appropriate systemic management should be performed.

Thus, even with negative UDS results, it cannot be concluded that "acute poisoning can be ruled out." As UDS is not specific to acute poisoning but is used in a variety of settings for early detection of drug abuse, dependence, and drug offenses, it should be used as a supportive test in the evaluation of acute poisoning. Moreover, rather than evaluating based on UDS results alone, it was considered important to make a comprehensive evaluation and judgment, including physical and laboratory findings based on the toxidrome and patient information, such as the medication history of the patient.

Limitations

The limitations of this study include the lack of measurement of urinary drug concentrations (cutoff value), which prevents proper evaluation of negative UDS results, as UDS items have a minimum detectable concentration. Furthermore, it is not possible to compare drug concentrations in urine and blood. Moreover, OPI were not measured because these substances are strictly regulated under Japanese law and OPI misuse is extremely uncommon. As a result, quantitative OPI testing is not routinely available in our clinical setting. The UDS kits used in this study are those used at our center. However, there are various types of UDS kits. Therefore, a bias due to differences in UDS results caused by product characteristics cannot be ruled out. Moreover, the time of taking the drug or liver and kidney function are not reflected, and the possibility that factors related to metabolism and excretion may have influenced the results cannot be ruled out. Although false-positive results were not included in the present study, this study was intentionally designed to focus exclusively on UDS-negative cases, in which negative results are often overinterpreted as ruling out acute poisoning in emergency settings. Therefore, false-positive UDS results, including those related to TCA due to immunoassay cross-reactivity, could not be evaluated and should be addressed in future studies. As this is a single-center study, it is possible that there is a bias in the drugs that cause acute poisoning depending on the region, and that the drugs detected at other emergency centers might differ from those detected at our center.

Conclusions

To acknowledge the concept of negative UDS results in UDS for acute poisoning, we surveyed the detection rate of drugs and blood drug concentrations detected in UDS-negative cases. It is advisable to recognize that UDS is a supportive test, as it is highly likely that the patient is consuming a wide variety of medications, even when UDS results are negative.

Abbreviations

UDS	Urinary drug screening items
PCP	Phencyclidine
BZO	Benzodiazepines anxiolytics and sleeping pills
BAR	Barbiturates
TCA	Tricyclic antidepressants
OPI	Opioids
COC	Cocaine
AMP	Amphetamines
THC	Cannabis
MTD	Methadone
MET	Methamphetamine
Non-UDS items	Drugs not included in the UDS items

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Author contributions

Rie Yamamoto: Writing–Original Draft, Writing–Review & Editing, Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Visualization, Supervision, Project administration, Funding acquisition. Yukari Maki: Writing–Review & Editing, Conceptualization, Methodology, Resources. Yuri Iketani: Writing–Review & Editing, Conceptualization, Methodology, Resources. Tomoatsu Tsuji: Writing–Review & Editing, Conceptualization, Methodology, Resources. Takeshi Saito: Writing–Review & Editing, Investigation, Resources. Seiji Morita: Writing–Review & Editing, Supervision, Project administration.

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Data availability

The dataset from this study is securely held at Tokai University Hospital. As the dataset contains personally identifiable patient information, it cannot be made publicly available.

Declarations

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee of Tokai University School of Medicine (23R228). Patient consent was waived because the data

were anonymized. As this study involves a retrospective review of medical records, obtaining individual informed consent was deemed impracticable. Therefore, in accordance with ethical guidelines, we adopted an opt-out procedure by making information about the study publicly available and allowing individuals to refuse participation.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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