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AN OBSERVATIONAL STUDY ON DRUG–DRUG INTERACTIONS IN THE CRITICAL CARE UNIT OF A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Polypharmacy among critically ill patients significantly elevates the risk of drug-drug interactions (DDIs), which can compromise patient safety and clinical outcomes. Understanding the prevalence and impact of these interactions is crucial for enhancing patient safety, optimizing therapeutic efficacy, and minimizing adverse events. Effective DDI management necessitates diligent monitoring, medication reconciliation, and informed clinical decision-making.

Method: This study aimed to identify and classify major drug interactions in ICU patients into pharmacodynamic and pharmacokinetic categories, using Lexicomp software for risk assessment. The number of prescribed medications was recorded, and therapeutic outcomes, observed effects, and severity of interactions were analysed to determine the potential for clinically significant DDIs.

Results: The study included 93 ICU patients who were prescribed various medications, among which 123 drug interactions were identified. Of these interactions, 15% were classified as major, 69% as moderate, 10% as minor, and 6% as contraindicated. Clopidogrel and heparin were commonly involved as object drugs, while azithromycin and bisoprolol frequently acted as precipitant drugs. Notably, azithromycin and heparin were associated with major interactions. Approximately 28% of interactions had clinically observable effects, with pharmacodynamic interactions being slightly more prevalent. The identified DDIs commonly resulted in adverse outcomes such as toxicity, bleeding, and hypotension. A higher incidence of DDIs was noted in patients over 60 years of age and among female patients.

Conclusion: Drug-drug interactions are prevalent in critically ill patients, particularly among those who are older and experiencing polypharmacy. Regular medication review and vigilant monitoring are imperative to mitigate risks and improve patient outcomes.

INTRODUCTION

Drug-drug interaction refers to a pharmacological or clinical response to the co-administration of two or more drugs that differs from the effects observed when each drug is administered individually. DDIs are distinct from the side effects of individual drugs and can significantly alter therapeutic outcomes depending on various factors, including the number of drugs taken, duration of therapy, patient age, and disease severity.

Patients with chronic illnesses or those undergoing long-term treatments are particularly vulnerable to DDIs due to the frequent need for multiple concurrent medications. [1]

Critically ill patients are especially at risk, as they often receive polypharmacy—the simultaneous use of multiple medications—to manage complex and rapidly changing clinical conditions.

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Studies estimate that 58–67% of DDIs occur during ICU admissions, largely attributed to the high incidence of infections and the broad spectrum of medications used to manage them (2).Understanding the nature and impact of common DDIs is crucial to prevent adverse outcomes in these high-risk populations.

DDIs are generally categorised into two types:

- Pharmacokinetic interactions, which affect drug absorption, distribution, metabolism, or excretion.
- Pharmacodynamic interactions, which occur at the receptor or physiological system level, leading to additive, synergistic, or antagonistic effects.

The cytochrome P450 (CYP) enzyme system is particularly important in pharmacokinetic interactions. Enzyme induction increases the metabolism of drugs, potentially reducing their efficacy, whereas enzyme inhibition slows drug metabolism, increasing plasma concentrations and the risk of toxicity. [3]

In these interactions, precipitant drugs alter the pharmacokinetics or pharmacodynamics of object drugs, often leading to clinically significant consequences. Polypharmacy is a major risk factor for DDIs: the probability of an interaction increases from 6% with two drugs to 50% with five drugs and nearly 100% with ten drugs. [1]

The presence of multiple medications and comorbid conditions in critically ill patients necessitates routine screening for potential DDIs. Such interactions can lead to adverse drug reactions, medication errors, reduced treatment adherence, prolonged length of hospital stays, and increased healthcare costs. They can also result in antagonistic or synergistic effects, which may either compromise therapeutic efficacy or intensify toxicity, especially with drugs that have a narrow therapeutic index (e.g., digoxin, warfarin, phenytoin). [4]

Despite the risks, co-administration of certain drugs is sometimes essential to achieve desired synergistic therapeutic effects. In clinical practice, DDIs are classified by severity into four categories:

- Contraindicated: The combination should be avoided due to potentially fatal or serious outcomes.
- Major: May cause serious adverse events, hospitalization, or therapeutic failure.
- Moderate: Requires medical management but is not immediately life-threatening.
- Minor: Usually tolerable and does not require clinical intervention.

Additionally, interaction risk ratings (A, B, C, D, X) help prioritise clinical action:

- A: No known interaction
- B: No action needed
- C: Monitor therapy
- D: Consider therapy modification
- X: Avoid combination due to high risk[5]

To detect and evaluate DDIs, healthcare providers increasingly rely on digital tools and databases, including Lexicomp, Micromedex, Epocrates, and Medscape. However, discrepancies in classification and severity across platforms necessitate cross-referencing multiple sources for accurate assessment. [12]

Hence this study aims to evaluate drug-drug interactions among patients admitted to the critical care unit of a tertiary care hospital. Secondary objectives include determining the prevalence of major DDIs, classifying them by severity, analyzing risk ratings using Lexicomp, identifying pharmacokinetic and pharmacodynamic interactions, and characterizing the object and interacting drugs, along with the observed and theoretical effects.

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METHODS

This prospective observational study was conducted in the Critical Care Unit of a tertiary care unit in Bangalore from March 2024 to September 2024. The objective was to assess the prevalence and nature of DDIs among patients admitted to the unit who met the study's inclusion criteria.

Medication charts of the enrolled patients were thoroughly reviewed, and all prescribed medications were evaluated for potential interactions using data collection forms. Drug interactions were identified using Lexicomp drug interaction data base through manual entry and cross verified through Medscape drug interaction application .Interactions were distinguished as Observed and theoretical interactions on the basis of documented clinical effects and toxicity reported along with clinical evidences. Clinically observed drug drug interactions were identified through correlation of observed adverse effects like unexpected bleeding, hypotension, renal impairment with co-administered drug pairs. Some interactions were also assessed through abnormal lab parameters like increase INR, creatinine, electrolyte imbalance also by verification from the databases references from Lexicomp also cross verified with Medscape drug interaction.

The causal link was between the drug pair and observed drug outcomes were established based on temporal association and exclusion of alternative etiologies such as underlying disease. Each suspected interaction was scored independently and the causality categorized as definite, probable, possible or doubtful. In addition to medication chart analysis, an extensive medical history was obtained from either the patient or their caregiver. This included information on current and past medical conditions, ongoing treatments, and any known history of adverse drug reactions. Data supporting potential or observed DDIs were collected and recorded for further analysis.

INCLUSION AND EXCLUSION CRITERIA

All patients admitted to the Critical Care Unit of the hospital during the study period were considered eligible for inclusion, regardless of gender or underlying disease conditions.

The exclusion criteria were as follows:

- Patients admitted to general wards or other non-critical care units
- Children under the age of 14 years
- Patients admitted to the Neonatal Intensive Care Unit (NICU)
- Pregnant women
- Immuno-compromised patients
- Patients under OTC medications and herbal supplements

These criteria were strictly adhered to ensure that the sample population accurately reflected the objectives of the study, focusing specifically on drug-drug interactions within the critical care setting.

RESULTS

A total of 93 patients were included in the study to evaluate DDIs based on variables such as age, gender, polypharmacy, and other contributing factors. Of these, 55.79% were under the age of 65, while 43.95% were aged 65 years and older. The gender distribution showed a slight female predominance, with 48 males (51.62%) and 45 females (48.38%).

A total of 1,612 medications were prescribed across all patients, with an average of 17.3 drugs per patient. The majority of patients (63.3%) were prescribed between 14 and 21 medications, while 19.36% received 7–13 drugs, and 18.27% were prescribed more than 22 medications. Higher rates of DDIs were observed among older patients (age >60 years), females, those with longer hospital stays (>5 days), and patients on more than 10 medications. (Table 1)

A total of 123 drug interactions were identified of which 85(69.1%) were moderate,18(14.64%) were major, 13(10.57%) were minor and 7(5.69%) were contraindicated. In terms of

interaction mechanism, 80(65.04%) were

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Table 1. Clinical manifestations and frequencies in patients

Characteristics	Characteristics	N (%)
Age	20-83	56.5 (17%)
Gender	Male	52 (61%)
	Female	33 (39%)
Reason for admission	Sepsis	31 (20.26%)
	Septic shock	16 (34%)
	UTI	29 (18.95%)
	LRTI	24 (15.69%)
	Infected wound	14 (9.15%)
	urosepsis	9 (5.8%)
	*Others	22 (14%)
Length of stay (days) b	4-57	15 (10%)

IQR: interquartile range
a mean (SD) instead of n.
b. Median (IQR) instead of n.
*Others: RTA 7 (4.5%), pyelonephritis 4 (2.6%), endocarditis 2 (1.31%), poisoning 2 (1.31%), cardiogenic shock 2 (1.31%), encephalopathy 4 (2.6%), cellulitis 1 (0.65%).

However, according to the WHO AWaRe classification, meropenem, ertapenem, vancomycin, and teicoplanin fall under the Watch category. These agents were therefore included in the study as part of the hospital's reserve antibiotic list defined by institutional protocol.

Upon analyzing the 85 subjects' medication details collected from the HICU unit, the most frequently used antibiotics were meropenem (28%), colistin (17%), and linezolid (14%). (Figure 2) A few reserve antibiotics were used empirically as well. They were meropenem 28.6%, colistin 17.3%, linezolid 14.5%, and tigecycline 9.8%.

Table 2 represents the ATC-DDD classification, utilization pattern, ATC codes, frequency, and the calculated DDD/100 bed days. The occupancy index was 0.44 during the study period, with 22 as the total inpatient bed count in the HICU.

Table 2: Reserve group antibiotics consumption based on DDD/100bed days

SI NO	DRUG	ATC CODE	ROUTE	DDD (WHO)	DDD	DDD/100 BED DAYS
1	TIGECYCLINE	J01AA12	P	0.1	226.5	13
2	LINEZOLID	J01XX08	P	1.2	224.5	7.9
3	MEROPENEM	J01DH02	P	3	458.1	7.34
4	CEFTAZIDIME+AVIBACTAM	J01DD02	0	4	121.1	6.9
5	AZTREONAM	J01DF01	P	4	108.5	6.2
6	TEICOPLANIN	J01XA02	P	0.4	89	5.11
7	VANCOMYCIN	J01XA01	0	2	59.5	3.4
8	IMEPENAM	J01DH51	P	2	58	3.3
9	POLYMIXIN B	J01XB02	P	0.15	27	1.5
10	ERTAPENAM	J01DH03	P	1	21.5	1.2
11	COLISTIN	J01XB01	0	9	13.8	0.79

P- Parenteral route 0-oral route

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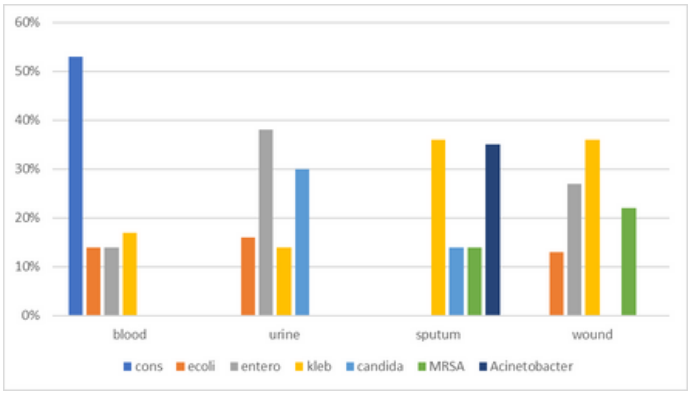
Distributions of organisms and frequency of resistance

A total of 137 isolates were collected from the 85 patients. The distribution of pathogens in the entire cohort was as follows: 23% Enterobacter spp., 18.9% Klebsiella spp., 13% CONS, 12.4% Acinetobacter spp., and 13% E. coli. Figure 1 represents the isolated pathogens. CONS was isolated mainly from the blood culture; enterococcus was predominant in urine samples, and klebsiella in sputum secretion and wound sites. We noticed a high percentage of Acinetobacter baumannii in sputum alongside Klebsiella (as shown in Fig. 1).

Fig 1: Distribution of the main infection site



Hospital-acquired infections, mainly CLABSI and SSI, were studied during the period, which together accounted for slightly more than one-fourth of the total samples. Among the multidrug-resistant isolates, MDR Klebsiella spp. was found to be the highest microorganism. The detailed data of MDR isolates is shown in Table 3. In the study, the average number of microorganisms per patient was 2.4, and the average number of microorganisms acquired was 1.87(1-2). Superinfection is a new isolate pathogen (or pathogens) (other than the initial pathogen) after 48 h of antibiotic treatment or within one week of treatment discontinuation. Table 3 shows microorganism isolates causative for superinfection in the study population

Table 3: Descriptive analysis of infectious micro-organisms and HAI.

M.O	Total	%
ACINETOBACTER SP	17	12.41%
CONS	19	13.87%
ECOLI	13	9.49%
ENTEROCOCCUS SP	32	23.36%
KLEBSELLA SP	26	18.98%
MRSA	10	7.30%
PSEUDOMONAS AUROGINOSA	5	3.65%
HOSPITAL ACQUIRED		
CLASBI [n (%)]	11	44%
SSI [n (%)]	14	56%
SUPERINFECTION [n (%)]	24	
RESISTANCE PHENOTYPE		
MDR Acinetobacter spp	10	17%
MDR Acinetobacter	7	12%
VRE	5	8.70%
MDR Pseudomonas	3	5.20%
MDR Klebsiella spp	13	22%
MDR klebsiella pneumoniae	3	5.20%
MRSA	10	17%
MDR E. coli	4	7%
MDR Proteus mirabilis	1	1.70%
MDR Providencia rettgeri	1	1.70%

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Superinfections occurred in 24 out of 85 cases. Microorganism isolates from superinfections revealed Candida and Enterococcus in 21%; Acinetobacter and Klebsiella in 12%; E. coli in 3%; VRE and Burkholderia cepacia in 6% of cases; and E. coli, CONS, VGS, MRSA, and Providencia rettegiri in 3%. Major sites of superinfection were in urine.

A chi-square test was performed to evaluate the association between the length of stay (LOS) and the acquisition of microorganisms (M.O.) during hospitalization. A higher proportion of infections were acquired after more than two weeks of hospitalization (n = 76) compared to those acquired within the first two weeks (n = 19). The chi-square test demonstrated a statistically significant association between the duration of hospital stay and microorganism acquired. ($\chi^2 = 14.87$, df = 3, $p < 0.05$). Where χ^2 = Chi-square, n = no. of microorganisms, and df = degrees of freedom.

DISCUSSION

The data of 85 patients admitted to the hospital and diagnosed with infection during the period of January 2024 to June 2024 were analyzed. The demographic result of the study revealed male preponderance. The mean age of patients enrolled in the study was 56.5 years. A wide spectrum of clinical diagnoses for which restricted antibiotics were indicated Included various infections like sepsis, septic shock, UTI, LRTI, infected wound, pyelonephritis, and endocarditis. Other conditions included poisoning, RTA, and AFI. Sepsis accounted for 31 cases (20.26%), while septic shock was observed in 25 cases (16.34%). Urinary tract infections (UTIs) were noted in 29 cases (18.95%), and lower respiratory tract infections (LRTIs) in 24 cases (15.69%). Infected wounds were present in 14 cases (9.15%), and urosepsis in 9 cases (5.88%). Road traffic accidents (RTAs) were the cause for 7 cases (4.58%), while pyelonephritis appeared in 4 cases (2.61%). Endocarditis, poisoning, and cardiogenic shock each accounted for 2 cases (1.31%), while encephalopathy was noted in 4 cases (2.61%). Other conditions contributed to 1 case (0.65%). These conditions required restricted antibiotics due to the development of infection during the course of hospitalization.

The most common comorbidities observed were diabetes mellitus (DM) in 38 cases (24.20%) and hypertension (HTN) in 37 cases (23.57%). Chronic kidney disease (CKD) and acute kidney injury (AKI) were each noted in 10 cases (6.37%). Heart disease was present in 19 cases (12.10%), while respiratory disease accounted for 11 cases (7.01%). Hypothyroidism and neurological conditions (neuro) were both observed in 6 cases (3.82%), and liver disease was seen in 3 cases (1.91%). Gastrointestinal (gastro) disorders were present in 7 cases (4.46%), and blood diseases were noted in 10 cases.

Drug Utilization

Drug utilization DDD/100 bed days was applied in the analysis of in-hospital drug use. The ATC/DD system is a tool for presenting drug utilization statistics. DDD of tigecycline was found to be 13, linezolid 7.9, meropenem 7.34, ceftazidime 6.9, aztreonam 6.2, teicoplanin 5.11, vancomycin 3.4, imipenem 3.3, polymyxin B 1.5, ertapenem 1.2, and colistin 0.79. In the study on antimicrobial usage and cost conducted by Fatma Bozkurt in a teaching hospital, the Defined Daily Dose (DDD) was reported to be 2.9 for linezolid and 9.2 for carbapenems. (10) Meropenem was given in 47 cases out of 88, making it the most frequently used reserve antibiotic. It was followed by colistin (n=37) and linezolid (n=31). (10)

Meropenem was used most commonly for empiric treatment prior to the culture sensitivity test, also mostly when patients' clinical condition worsened.

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According to a review by Miriam Hurst, meropenem has proven to be effective in treating severe infections, especially those acquired in hospital settings or intensive care units. The most frequently diagnosed conditions in the reviewed studies included pneumonia and other lower respiratory tract infections, along with a significant number of intra-abdominal infections (11).

In the study the use of reserve antibiotics was based on the culture sensitivity. These antibiotics were indicated for resistant strains like MRSA, VRE, and multi-drug-resistant organisms. In a similar study conducted by Emmerson, the major infecting organisms were aerobic Gram-negative bacilli (AGNB), e.g., Pseudomonas aeruginosa, Acinetobacter baumannii, Klebsiella aerogenes, and Enterobacter spp., and the Gram-positive cocci, such as methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus faecium (VRE), and coagulase-negative Staphylococcus epidermidis (CONS) (12)

In our study, Klebsiella pneumoniae was predominantly isolated from sputum and wound sites, with fewer cases found in blood and urine samples. Methicillin-resistant Staphylococcus aureus (MRSA) was primarily detected in wound sites, highlighting the need for improved postoperative care. Similarly, a parallel study by Carmen et al. reported that Staphylococcus aureus was most commonly found in wound secretions, blood, and bronchial aspirates.

The second most frequently isolated organism was K. pneumoniae, mainly from bronchial aspirates, urine, and wound sites. Notably, their study also identified a significant proportion of Candida albicans in blood cultures. Whereas a higher incidence of Candida species was observed in urine samples, followed by sputum in our study (13).

Hospital acquired infection: CLABSI and SSI

Coagulase-negative staphylococci (CONS), Acinetobacter, Burkholderia, Klebsiella, viridans group streptococci (VGS), and Enterococcus are the primary organisms responsible for central line-associated bloodstream infections (CLABSI). CONS is the most frequent cause, accounting for 61.54% of cases, while the other microorganisms each contribute 7.69% of infections. In the study population, Enterococcus was the leading cause of surgical site infections (SSI), representing 24% of cases. E. coli and MRSA were each responsible for 14%. CONS and Acinetobacter contributed to 9% of SSIs, while VRE, Citrobacter, Pseudomonas species, and Stenotrophomonas maltophilia each accounted for 5% of infections.

The study found an average of 2.4 microorganisms per patient, with an average of 1.87 microorganisms acquired. Data on healthcare-associated infections (HAI), particularly CLABSI and SSI, revealed a total of 25 HAIs. Superinfections were identified in 24 out of 85 cases, with the majority occurring in the urinary tract. Several multidrug-resistant organisms (MDROs) were detected, including MDR Acinetobacter spp., Acinetobacter baumannii, and MDR

Pseudomonas aeruginosa, MDR Klebsiella spp., MDR Klebsiella pneumoniae, MDR E. coli, MDR Proteus mirabilis, MDR Providencia rettgeri, VRE, and MRSA.

Superinfection

The study uncovered that the majority of superinfection was due to fungal infection, mainly Candida and Enterococcus species (21.88%). Acinetobacter and Klebsiella were 12%, VRE and Burkholderia cepacia were 6% of cases, and E. coli, CONS, VGS, MRSA, and Providencia rettegiri were 3%.

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In a similar study conducted by Hessa Al Muqati, the main isolated microorganisms after 48 h were Candida spp., about 43.79% of all superinfections (n = 67), followed by Enterobacteriaceae spp. 17% (n = 26), Staphylococcus spp. 11.11% (n = 17), Pseudomonas spp. 9.80% (n = 15), and Clostridioides difficile 5.88% (n = 9) (14).

CONCLUSION

The analysis of antimicrobial use and microbial isolates in the High-Intensity Care Unit (HICU) revealed high reliance on reserve antibiotics, with meropenem (28%), colistin (17%), and linezolid (14%) being the most prescribed. In terms of utilization as per DDD/100 bed days, the most highly utilized drug was tigecycline, followed by linezolid and meropenem, with a DDD of 226.5 (13 DDD/100 bed days), 224.5 (7.9 DDD/100 bed days), and 458.1 (7.3 DDD/100 bed days), respectively. The least consumed drug was colistin, with a DDD of 13.8 (0.79 DDD/100 bed days). Reserve antibiotics were required for the management of infections caused by Enterobacter spp., Klebsiella spp., coagulase-negative staphylococci (CONS), Acinetobacter spp., Escherichia coli, methicillin-resistant Staphylococcus aureus (MRSA), and Pseudomonas aeruginosa. Out of the 137 isolates identified, 57 were multidrug-resistant (MDR) microorganisms, highlighting a critical concern regarding the rise of antimicrobial resistance (AMR). Extended hospital stays resulted in the acquisition of hospital-acquired infections, which also required reserve antibiotics for management. Our study highlights the considerable reliance on reserve antibiotics, primarily driven by the rise in antimicrobial resistance (AMR). Severe infections and prolonged hospital stays were identified as major factors necessitating their use.

The ATC/DDD system proved to be an effective tool for drug utilization comparison, and the DDD values calculated in this study provide valuable baseline data. This baseline can serve for future comparisons, enabling trend analysis within the same hospital over time or benchmarking against other institutions, and would help in supporting antimicrobial stewardship initiatives.

LIMITATIONS

This study has certain limitations that need to be acknowledged. First, the relatively small sample size restricts the generalizability of the findings. Second, while the Defined Daily Dose (DDD) analysis provides a valuable baseline for measuring the use of reserve antibiotics, it serves primarily as an initial reference point. Further research involving a larger dataset and extended timeframes will be required to validate these findings and enable meaningful comparisons of reserve antibiotic utilisation across different settings. Third, the study primarily focused on a limited number of hospital-acquired infections. As a result, the spectrum of infections captured may not fully reflect the wide range of clinical scenarios in which reserve antibiotics are prescribed. This narrowed scope may have led to underrepresentation of certain pathogens and antibiotic use patterns, highlighting the need for future studies.

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Not applicable

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Conflicts of Interest

The authors declare that there are no conflicts of interest related to this study. The research was conducted independently, and the findings represent the unbiased results and interpretations of the authors.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request. The data will be made available to qualified researchers for non-commercial purposes only, subject to ethical and privacy considerations. Due to privacy restrictions, participant data cannot be publicly shared, but can be accessed by contacting the corresponding author.

Protection of humans and animals.

The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval

The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics Committee. The SAGER guidelines were followed according to the nature of the study.

Declaration on the use of artificial intelligence.

The authors declare that no generative artificial intelligence was used in the writing of this manuscript