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ARETROSPECTIVE OBSERVATIONAL STUDY: EVALUATING THE APPROPRIATENESS OF ANTIBIOTIC DOSING IN CHRONIC KIDNEY DISEASE PATIENTS AT A TERTIARY CARE HOSPITAL

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ABSTRACT: The renal system helps in the urinary excretion of drugs in unchanged form or metabolites. Since a majority of the drugs are eliminated by the kidneys, impairment in renal function can lead to drug accumulation, toxicity, and therapeutic failure. As a result, patients with impaired renal function require careful dose modifications. The purpose of this study was to determine the most frequently prescribed dose-unadjusted antibiotic and to assess the appropriateness and rationality of antibiotic dose adjustments in patients with Chronic Kidney Disease (CKD). Additionally, the study aimed to pinpoint the factors contributing to incorrect dosing adjustments. A retrospective observational study was conducted from December 2022 to November 2023 and medical records of the study subjects admitted to the nephrology department of Mallige Medical Centre, Bengaluru, were reviewed for antibiotic prescriptions. This study included 651 participants in total, with a $p < 0.05$ level for statistical significance. The findings showed that 35 different antibiotics were prescribed to patients with CKD, with 71.42% (25/35) requiring renal dose adjustments. Notably, 51% (332/651) of the reviewed prescriptions had unadjusted antibiotic doses, while the remaining prescriptions had proper adjustments. Statistical analysis using the Chi-Square test revealed significant correlations between improper antibiotic dose adjustments and the following factors: multiple antibiotic prescriptions per patient (p-0.000609), comorbidities (p-0.000942), length of hospitalization (p-0.023155) and CKD stage (p-0.032541). The study revealed that a substantial proportion of patients with renal impairment received unadjusted antibiotic dosing, thereby increasing their vulnerability to adverse drug reactions, therapeutic failure, and elevated risks of morbidity and mortality.

INTRODUCTION: Chronic Kidney Disease (CKD) poses a substantial global health burden, affecting an estimated 10 to 15% of adults globally. When combined with severe infections, CKD can increase the fatality rates among critically sick patients.

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Optimizing antibiotic therapy in these dynamic patients can be particularly problematic due to unanticipated physiological changes that affect the immune system and modify the pharmacokinetics as well as pharmacodynamics of antibiotics.

The complexity of care is further compounded by the need for renal replacement therapy, requiring careful consideration of dosing regimens to ensure optimal patient outcomes [1]. Chronic kidney disease is defined as kidney damage or decreased kidney function, that lasts longer than3 months resulting in one or more of the following: (1) GFR less than 60 mL/min/1.73 m^2; (2) albuminuria (defined as urine

albumin ≥30 mg/24 hours or urine albumin-to-creatinine ratio [ACR] ≥30 mg/g); (3) imaging or histology indicating kidney damage; (4) renal tubular diseases; or (5) kidney transplantation history [2, 3]. Based on the cause, GFR, and albuminuria, CKD is classified into different stages: Stage1 with normal/high GFR (GFR ≥90 mL/min/1.73 m^2), Stage 2 with mild GFR reduction(GFR:60–89 mL/min/1.73m^2), Stage 3a with mild to moderate reduction (GFR:45–59 mL/min/ 1.73m^2), Stage 3b with moderate to severe reduction (GFR:30–44 mL/min/1.73m^2), Stage 4 with severe reduction (GFR:15–29 mL/ min/1.73m^2), and Stage 5 with Kidney failure(GFR:<15 ml/min/1.73m^2) [2, 3, 4, 5].

The clinical manifestations of CKD include gross hematuria, nocturia, or oliguria and if CKD is advanced, patients may show pallor, myoclonic jerks, muscle atrophy, and mental disorientation. The National Kidney Foundation suggests a kidney profile test for CKD diagnosis, which includes determining the urine albumin-to-creatinine ratio and testing blood creatinine to determine GFR. Treatment strategies for CKD focus on reducing cardiovascular risk, slowing disease progression, managing complications, and addressing underlying causes, and therapeutic approaches may include: ACE inhibitors or ARBs for blood pressure control, statins and anti-platelet drugs for cardiovascular risk reduction, oral hypoglycemic agents for diabetes management, erythropoietin-stimulating agents for anemia, phosphate lowering medications and vitamin D for bone disorders, dialysis, and kidney transplantation [2, 3, 6].

A framework for diagnosing, categorizing, and treating acute kidney injury (AKI) and chronic kidney disease (CKD) is provided by the Kidney Disease Improving Global Outcomes (KDIGO) recommendations. However, the emergence of multidrug-resistant organisms (MDROs) has made CKD patients highly vulnerable to infections, which are the main cause of death in end-stage renal disease (ESRD) patients [7, 8, 9]. In elderly patients with CKD, achieving an optimal balance between pharmacodynamic efficacy and safety is a significant challenge for healthcare professionals. Accurate dose adjustment of antibiotics is crucial in this population, as 20% of elderly patients have advanced CKD. Accurate estimation of renal function is vital in elderly patients, but even with dosage adjustments based on renal function, there's still a risk of underexposure or overexposure to antibiotics. Therefore, a therapeutic drug monitoring (TDM)-guided approach to adjusting antibiotic dosages is essential to prevent drug-related toxicity in this vulnerable population [10].

The kidney's high concentration of drugs and metabolites makes nephrotoxicity and drug interactions common, particularly since many antibiotics are excreted through the urine. When GFR decreases, drugs or their metabolites accumulate, leading to prolonged action, altered distribution, and reduced renal drug metabolism [11]. As kidney function deteriorates, complications like anemia, hyperlipidemia, cardiovascular disease, and metabolic bone disorders can arise [12]. Antibiotic-induced nephrotoxicity is a primary cause of acute kidney injury (AKI) in hospitalized patients. This can result in structural and functional renal impairment. Antibiotic-induced acute kidney injury is a prevalent concern and therefore clinicians should identify its risk factors and select antibiotics with a lower risk of inducing AKI to protect vulnerable patients [13, 1].

A meticulous evaluation of antibiotic dosing recommendations is crucial, in considering the precision of renal function evaluations, the comparability of renal support therapy features, and the alignment of dosing strategies with the antibiotic's pharmacodynamic profile [15]. To ensure efficacy and prevent resistance, appropriate antibiotic use is vital, and dosages must be tailored to individual renal function to avoid adverse effects [16, 17]. This study aims to identify the most commonly prescribed unadjusted antibiotic and assess the appropriateness of antibiotic dose adjustments in CKD patients by comparing them to standard dosing guidelines. Additionally, it seeks to determine the factors contributing to incorrect renal dose adjustments.

MATERIALS AND METHODS:

Study Setting and Study Design: A retrospective analysis comprising 651 patients hospitalized in the nephrology department between December 2022 and November 2023 was carried out at Mallige Medical Centre in Bengaluru. The research review board of Mallige College of Pharmacy approved

the study (approval number MCP/RRB/012/22-23). Patients with CKD were chosen based on estimated Glomerular Filtration Rate (eGFR) values from hospital laboratory reports, and medical records were carefully examined for antibiotic prescriptions. The study comprised patients in CKD stages 3a (eGFR: 45-59), 3b (eGFR: 30-44), 4 (eGFR: 15-29), and 5 (eGFR: <15), eGFR values are reported in ml/min/1.73m2. A data collection form was created to capture patient demographics, comorbidities, CKD stage, serum creatinine, hospital stay duration, and antibiotic prescription details. Confidentiality of the collected data was maintained throughout the study. The appropriateness and rationality of prescribed antibiotics were assessed using the following references: "Adult Drug Information Handbook, 30th edition" published by Lexicomp®, Stanford HealthCare Antimicrobial Dosing Reference Guide 2022, and the National Formulary of India 2021.

Inclusion and Exclusion Criteria: Adult participants (aged 18 and older) of both sexes who had been diagnosed with stages 3a, 3b, 4, and 5 of Chronic Kidney Disease (CKD) and whose estimated Glomerular Filtration Rate (eGFR) was less than 60 ml/min/1.73 m^2 were included in the study. Additionally, at least one antibiotic that required a renal dosage adjustment had to be mandatorily prescribed to the participants. Pregnant patients and those with eGFR values less than 60 ml/min/1.73 m^2 who had not taken antibiotics with a renal dosage modification were excluded **Fig. 1.**

Data Analysis: The statistical analysis was carried out with IBM SPSS 2.0. An overview of demographic traits, CKD stage, number of antibiotic prescriptions, length of hospital stay, and compliance with antibiotic dosage changes advised by guidelines was given by descriptive statistics. The association between antibiotic dosage modification and renal function was investigated using a chi-square test. The threshold for statistical significance was $p < 0.05$.

RESULTS: The study reviewed medical records of 651 participants of which 61% were male and 39% were female. The age distribution showed that 40.55% of the subjects were above 61 years, followed by 38.09% in the 41-60 age category. Among the subjects with CKD, 83.10% had stage 5 disease, followed by 9.98% with stage 4, 3.84% with stage 3b, and 3.07% with stage 3a. Hypertension (83.87%) and type 2 Diabetes (68.20%) were the most common comorbidities **Fig. 2.** The length of hospitalization was ≤7 days for 34.56% of the subjects and >7 days for 65.43% **Table 1.** Out of 651 prescriptions reviewed, 51.15% (N=332) had unadjusted antibiotic doses **Table 2**. Additionally, 75.11% of the subjects were prescribed more than one antibiotic for their current illness.

The study found that 35 different antibiotics were prescribed to CKD patients in our hospital. Notably, 71.42% (25/35) of these antibiotics required dosage adjustment in renal patients. **Table 3** provides a comprehensive list of prescribed antibiotics, their frequencies, and adjustment status. Descriptive statistical analysis revealed that Meropenem was the most commonly unadjusted antibiotic, followed by Piperacillin/tazobactam, Vancomycin, Ciprofloxacin, and Colistin. To investigate the reasons behind renal dose unadjustments, a Chi-square analysis was performed between suspected factors and the number of unadjusted drug cases. Six variables were considered, and the test revealed that four variables were statistically significant (p-value <0.05): multiple antibiotic prescriptions per patient (p-0.000609), comorbidities (p-0.000942), length of hospitalization (p-0.023155) and CKD stage (p-0.032541) were associated with inappropriate drug dose adjustments **Table 4.**

TABLE 1: STUDYPOPULATION; DEMOGRAPHICANDCLINICAL FEATURES (N=651)

Variables		Frequency	Percentage
Age	<20	40	6.14 %
	21-40	99	15.20 %
	41-60	248	38.09 %
	>61	264	40.55 %
Gender	Male	396	60.82%
	Female	255	39.17%
CKD Stage	Stage 3a	20	3.07 %
	Stage 3b	25	3.84%

	Stage 4	65	9.98%
	Stage 5	541	83.10%
Comorbidity present	Yes	590	90.62%
	No	61	9.37%
Length of hospitalization (in days)	≤7	225	34.56%
	>7	426	65.43%
Antibiotics	Only 1 antibiotic prescribed	162	24.88%
	>1 antibiotic prescribed	489	75.11%

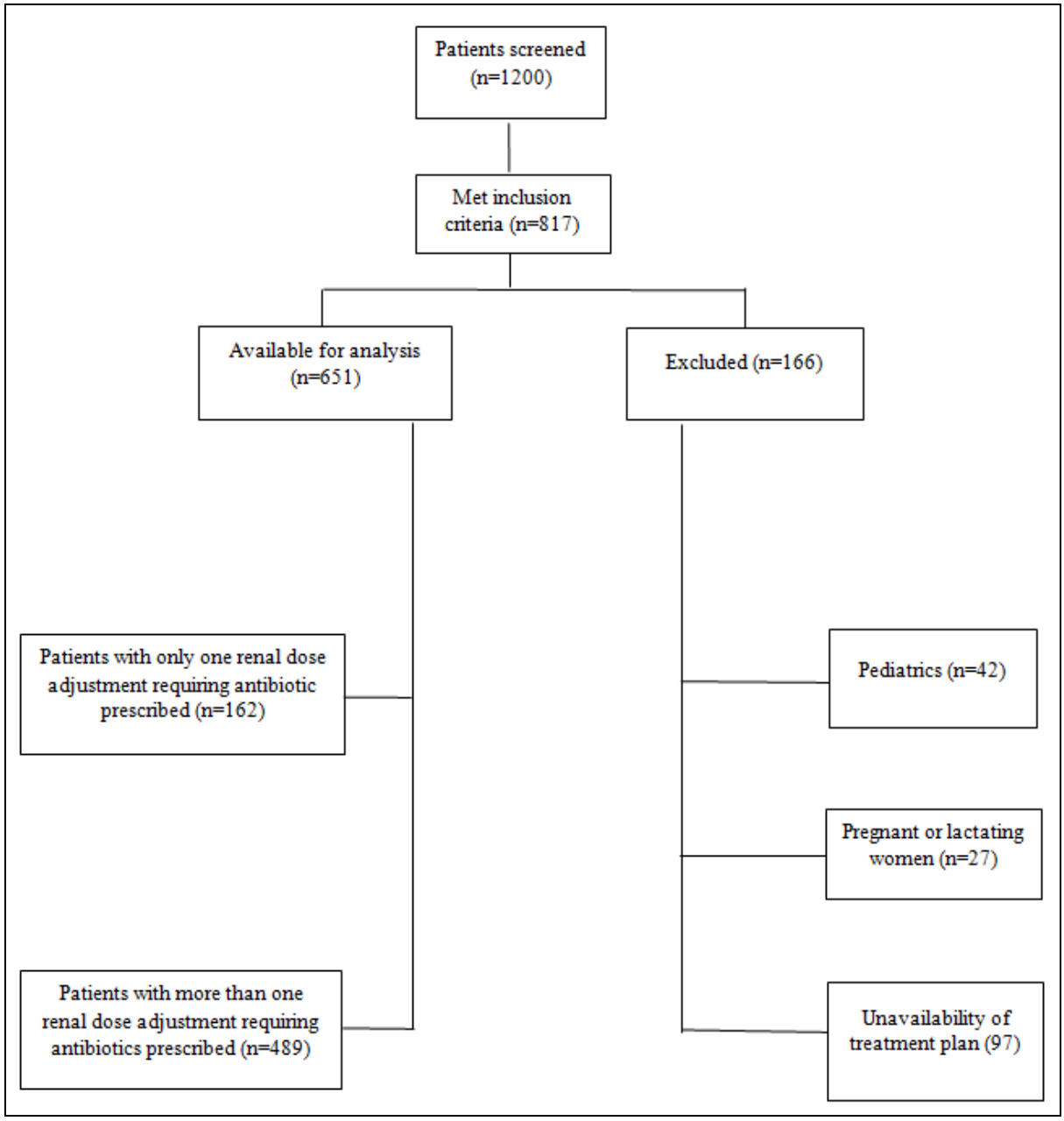

FIG. 1: FLOW CHART ILLUSTRATING THE SELECTION PROCESS OF SUBJECTS BASED ON THE INCLUSION AND EXCLUSION CRITERIA

TABLE 2: FREQUENCY OF PRESCRIPTIONS WITH AND WITHOUT THE NECESSARY ADJUSTMENTS

Variable	Frequency	Percentage
Total number of prescriptions reviewed	651/651	100 %
Total number of prescriptions found with unadjusted dose of antibiotics	332/651	51 %
Total number of antibiotics prescribed	35	100 %
Number of antibiotics requiring renal dose adjustment	25/35	71.42 %
Number of antibiotics not requiring renal dose adjustment	10/35	28.57%

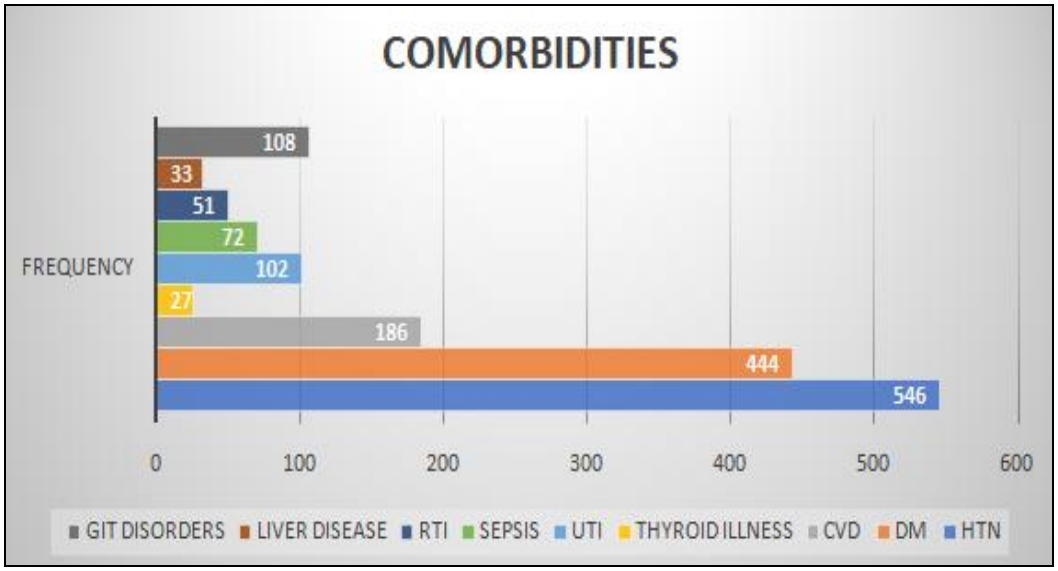

FIG. 2: GRAPH SHOWING THE NUMBER OF PATIENTS WITH COMORBIDITIES

TABLE 3: LIST OF ANTIBIOTICS REQUIRING RENAL ADJUSTMENT, APPROPRIATELY ADJUSTED, ORUN ADJUSTED

Antibiotics	Frequency	Percentage	Adjustment required	Adjusted, n (%)	Unadjusted, n (%)
Meropenem	623	95.69 %	Yes	322(51.68 %)	301 (48.31 %)
Colistin	467	71.73 %	Yes	289(61.88%)	178 (38.11 %)
Piperacillin/Tazobactam	637	97.84 %	Yes	348(54.63 %)	289 (45.36 %)
Amikacin	481	73.88 %	Yes	389(80.87 %)	92 (19.12 %)
Ciprofloxacin	644	98.92 %	Yes	378 (58.69%)	266 (41.30 %)
Ceftazidime	387	59.44 %	Yes	259 (66.92 %)	128 (33.07 %)
Vancomycin	590	90.62 %	Yes	332 (56.27%)	258 (43.72 %)
Cotrimoxazole	532	81.72 %	Yes	401 (75.37 %)	131 (24.62 %)
Linezolid	511	78.49 %	No		
Cefoperazone/Sulbactam	548	84.17%	Yes	347 (63.32 %)	201 (36.67 %)
Clarithromycin	601	92.31 %	Yes	426 (70.88 %)	175 (29.11 %)
Teicoplanin	513	78.80 %	Yes	376 (73.29 %)	137 (26.70 %)
Imipenem/Cilastin	481	73.88 %	Yes	447 (92.93 %)	34 (7.06 %)
Ceftriaxone/Sulbactam	634	97.38 %	No		
Doxycycline	629	96.62 %	No		
Nitrofurantoin	387	59.44 %	Yes	269 (69.50 %)	118 (30.49 %)
Cefixime/Clavulanic acid	592	90.93 %	No		
Tigecycline	517	79.41 %	No		
Amoxicillin/Clavulanic acid	584	89.70 %	Yes	411(70.37 %)	173 (29.62 %)
Polymixin-B	401	61.59 %	Yes	289(72.06 %)	112 (27.93 %)
Clindamycin	610	93.70 %	No		
Cefuroxime	458	70.35 %	Yes	291 (63.53%)	167 (36.46%)
Moxifloxacin	371	56.98 %	No		
Aztreonam	356	54.68 %	Yes	285 (80.05%)	71 (19.94%)
Cefditoren	413	63.44 %	Yes	386 (93.46%)	27 (6.53%)
Levofloxacin	467	71.73 %	Yes	308 (65.95 %)	159 (34.04 %)
Cefpodoxime	425	65.28 %	Yes	281 (66.11%)	144 (33.88%)
Norfloxacin	337	51.76 %	Yes	251 (74.48 %)	86 (25.51 %)
Azithromycin	591	90.78 %	No		
Biapenem	258	39.63 %	Yes	216 (83.72%)	42 (16.27%)
Fosfomycin	271	41.62 %	No		
Faropenem	503	77.26 %	Yes	482 (95.82%)	21 (4.17%)
Ertapenem	449	68.97 %	Yes	288 (64.14%)	161 (35.85%)
Ampicillin/sulbactam	363	55.76 %	Yes	245(67.49%)	118(32.50%)
Rifaximin	290	44.54 %	No		

TABLE 4: MEDICATION DOSING ERROR PREDICTORS IN CKD PATIENTS

Variables		Frequency	Patients with unadjusted antibiotics	p-value
Age	<20	40	18	
	21-40	99	43	0.073313
	41-60	248	113	
	>61	264	158	
Gender	Male	396	197	0.651082
	Female	255	135	
CKD stage	Stage 3a	20	13	0.032541
	Stage 3b	25	14	
	Stage 4	65	53	
	Stage 5	541	252	
Comorbidity present	Yes	590	277	0.000942
	No	61	55	
Length of hospitalization (in days)	≤7	225	91	0.023155
	>7	426	241	
Antibiotics	Only 1 antibiotic prescribed	162	51	0.000609
	>1 antibiotics prescribed	489	281	

DISCUSSION: Renal impairment is a condition when one or both kidneys cannot function properly on their own. It can sometimes be temporary and occur suddenly, referred to as acute kidney injury or it can be a chronic condition that gets worse over a time period, referred to as chronic kidney disease. Very often, renally compromised patients are treated with antibiotics for various comorbidities. Renal impairment can alter the pharmacokinetic parameters of most of the drugs. Inappropriate dosing and prescription of antibiotics in patients with kidney dysfunction can lead to increased risks of therapeutic failure, mortality rates, toxicity, and emergence of resistance. From the current research and the existing literature, we found that medication dosing errors due to renal dose un adjustments are more prevalent in CKD patients. This study sought to assess compliance with the approved dosing guidelines of antibiotics in CKD patients by comparing the antibiotic dosage adjustments and also by identifying the factors associated with incorrect renal dose adjustments.

The current study's findings showed that over half of the CKD patients received antibiotics without proper renal dose adjustments. Patients with comorbid illnesses such as sepsis, urinary tract infections, catheter-related bloodstream infections and respiratory tract infections were prescribed multiple antibiotics, resulting in prolonged hospital stays, increased risk of dosing errors, and antibiotic resistance. As statistically proven from the study, the main predictors for this dosing error were more than one antibiotic prescribed for a patient (p-0.000609), comorbidities (p-0.000942), length of hospitalization (p-0.023155) and CKD stage (p-0.032541). Thus, strict adherence to the standard dosing guidelines is of paramount importance to avoid any unexpected adverse drug effects and further complications.

Individualization of antibiotic doses based on patient eGFR values or creatinine clearance is necessary for renally compromised patients. Improper dose adjustments lead to prolonged hospital stays, adding an economic burden to the patient. Thus clinicians whenever dose adjustments requiring antibiotics are needed for the patient, should be carefully prescribed according to the updated standard dosing guidelines matching the altered elimination rates of the patients. This not only improves patient outcomes but also supports the patient pharmacoeconomically.

The unadjusted doses may lead to several adverse drug effects such as carbapenem-induced neurotoxicity, mainly seizure, increased risk of nephrotoxicity and exacerbation of the renal insufficiency with piperacillin/tazobactam and vancomycin, neurological and psychiatric disorders or collagen associated events and hypoglycemia can be seen with patients treated with unadjusted doses of fluoroquinolones [18, 19, 20, 21]. Several comparative studies involving combination antibiotic therapies have shown that vancomycin with piperacillin/tazobactam is associated with a higher risk of acute kidney injury than both vancomycin with cefepime and vancomycin with meropenem, and thus to lower the risk of drug induced acute kidney injury, teicoplanin with

piperacillin-tazobactam is a better alternative to vancomycin with piperacillin/tazobactam in ICU patients [22, 23, 24]. Drugs such as colistin, polymyxin B and amikacin are also known to cause acute kidney injury and therefore continuous monitoring is required during the administration of these drugs [25, 26, 27].

Although our study highlighted the significance of dose adjustments of antibiotics in CKD patients and also identified the factors contributing to the dosing errors, it had a key limitation. As a retrospective study we couldn't directly observe the patients for any potential adverse drug effects and to suggest any interventions. Our findings thus emphasize the increased concern for careful dose adjustments in CKD patients. Therefore we strongly recommend implementing of antimicrobial stewardship program and providing ongoing education to healthcare professionals including doctors, clinical pharmacists, and nurses, on updated antibiotic prescribing recommendations and guidelines in hospitals.

CONCLUSION: The present study revealed that a substantial proportion of CKD patients received unadjusted doses of antibiotics. More than one antibiotic prescribed for the same patient, comorbidities, the length of hospital stay, and CKD stage were found to be statistically associated with inappropriate dose adjustment of antibiotics. Therefore, physicians must take necessary precautions in rationalizing the doses of renally excreting or highly restricted antibiotics to minimize drug toxicity, therapeutic failure, and antibiotic resistance.

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CONFLICT OF INTEREST: Regarding this work, the authors disclose no conflicts of interest.

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