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Original Article

A Prospective Study on the Utilization Pattern of Antibiotics and Assessing its Dosage Appropriateness in Patients Undergoing Haemodialysis

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ABSTRACT

Background: Antibiotic use is common in haemodialysis patients, increasing the risk of multidrug resistance and toxicity. Monitoring renal function and ensuring prescribing practices are essential to prevent adverse outcomes in renally ill patients. **Materials and Methods:** This prospective observational study was conducted by comparing patient antibiotic regimens to globally accepted guidelines, the primary outcome was to assess their dose appropriateness by collecting patients Serum creatinine levels to evaluate renal function by using Cockcroft-Gault formula, MDRD equation, and CKD-EPI equation. These three recognised strategies were used for determining the dosage appropriateness for antibiotics based on each patient's creatinine clearance. **Results:** The study population was predominantly male (64.5%), with a mean age of 46.6 years in adults and 71.1 years in the elderly. Hypertension, diabetes, CKD, and other renal diseases were common, with sepsis and metabolic acidosis as key factors for initiating dialysis. A total of 126 antibiotics, mainly Meropenem and Piperacillin-tazobactam, were prescribed; 15 were inappropriately dosed, and only 8 antibiotics were prescribed which doesn't require dose adjustments. The study showed improvement in post-HD serum creatinine compared to pre-HD serum creatinine (95% CI, 6.02±2.48 vs 5.01±1.94, p=0.0049). While 70.8% received appropriately dosed antimicrobials, 18.9% had inappropriate doses, emphasizing the need for improved dose optimization based on creatinine clearance. **Conclusion:** This study highlights the significant antibiotic exposure in haemodialysis patients, emphasizing the need for targeted interventions and antimicrobial stewardship to improve prescribing practices and patient safety.

Keywords: Antibiotics, Chronic kidney disease, Haemodialysis, Creatinine clearance, Renal dose adjustments.

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INTRODUCTION

End-Stage Renal Disease (ESRD), the second leading cause of mortality, has infections as a significant consequence. Research on infectious diseases has focused on the possible misuse of broad-spectrum antibiotics in the inpatient setting and the subsequent growth of bacterial resistance in both general and ESRD populations.[1] The risk of bacteraemia in haemodialysis patients are 26 times higher than in the general population, and 1/2 to 3/4 of the causal organisms of bacteraemia in HD patients are gram-positive bacteria. Less than one-fourth of the causative species of bacteraemia in HD patients are Gram-negative bacteria, while half to three-quarters is Gram-positive.[2] Polypharmacy, comorbidities, and variations in drug clearance make prescribing for Haemodialysis (HD) patients difficult and complex. Typically, a complicated regimen is needed, along with ongoing therapeutic monitoring and modification by either increasing the time between doses, decreasing the dosage, or doing both.[3]

The growth and spread of Multidrug-Resistant Organisms (MDROs), Clostridium difficile infections, medication-drug interactions, and adverse drug events are only a few of the harmful downstream effects that can happen even when antimicrobials significantly reduce patient morbidity and death rates.[4] Patients using haemodialysis exhibit clinical characteristics such as frequent bacterial infections and high hospitalization rates that encourage extensive antibiotic use.[5] Because haemodialysis patients are more susceptible to infections and sepsis, antibiotics must be used in the outpatient haemodialysis environment. On the other hand, improper administration of antibiotics can result in adverse medication events, such as drug responses and infections with bacteria resistant to antibiotics and Clostridium difficile. Optimizing the usage of antibiotics can enhance patient outcomes, infection cure rates, and adverse event rates.[6] More Severe renal insufficiency results in increased anion gap acidosis

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and insufficient excretion of organic and other conjugate anions of acids (non-volatile acids). Uremic acidosis is often moderate, but as it persists, this kind of metabolic acidosis is linked to several negative consequences, even if the severity of the condition can vary greatly among uremic patients.[7]

Worldwide, infection is a major cause of hospitalization and death among haemodialysis patients. There have been significant attempts made globally to optimize the use of antibiotics because improper use is a major factor in the acceleration of antimicrobial resistance.[8]

In HD patients, catheter-related infections, such as Exit-Site Infections (ESIs) and Catheter-Related Bloodstream Infections (CRBSIs), increase morbidity and ultimately death.[9] Individuals with Chronic Kidney Disease (CKD) are significantly more likely to get antibiotic dosages that are not appropriate for their kidney function. Numerous studies have demonstrated the high rate of noncompliance with renal dosage recommendations. Antibiotics were the most frequently unadjusted medicines, with 58.2% of those that needed renal adjustment having incorrect dosages.[10] So, Haemodialysis (HD) is a treatment that circulates a patient's blood through an artificial kidney to remove waste and excess fluid, aiming to manage uraemia in advanced renal failure. When conservative treatments no longer control the effects of renal failure, HD is needed. Renal function is commonly evaluated using equations for Creatinine Clearance (CrCl) or Glomerular Filtration Rate (GFR), but these are not interchangeable. The Cockcroft-Gault (CG) formula is traditionally used to estimate CrCl for dosing in Chronic Kidney Disease (CKD), but for patients with severe kidney impairment, the CKD-EPI and MDRD equations provide more accurate GFR estimates.[11]

The main goal of this study is to assess how well antibiotics work for people receiving haemodialysis. Identifying common infections and pathogens, classifying patients according to underlying diseases and comorbidities, comparing current antibiotic therapy with standard guidelines, optimising dosage regimens based on creatinine clearance, and calculating mortality rates in this patient population are examples of secondary objectives.

MATERIALS AND METHODS

The study was conducted over 6 months; prospective observational research was carried out at the dialysis unit of the Department of Nephrology at a Tertiary care hospital to evaluate the antibiotic prescribing trend among haemodialysis patients. The study comprised the patients who fulfilled the inclusion requirements. Patient information was obtained from the medication charts, and the relevant laboratory values were meticulously reviewed and recorded. This research will evaluate antibiotics prescribed by healthcare providers, comparing current usage to standard guidelines (Sanford Guide to Antimicrobial Therapy) and monitoring necessary dosage adjustments before and after dialysis sessions.

Inclusion and exclusion criteria

Patients over the age of 18 who have acute kidney injury, Chronic Kidney Disease (CKD) that is progressing to End-Stage Renal Disease (ESRD), are receiving haemodialysis while taking antibiotics, or have elevated blood urea nitrogen, creatinine, hyperkalaemia, severe metabolic acidosis, or renal dysfunction are included in the study. Patients who have undergone renal or liver transplants and require emergency dialysis are also included. Patients who have ingested poisons or toxins necessitating dialysis are excluded, while paediatrics and pregnant women are also excluded.

Study Instrument

To ensure a thorough assessment of antimicrobial consumption trends in haemodialysis patients, this study used a structured data extraction tool to methodically gather antibiotic prescriptions, renal function measures, and patient information. A comprehensive evaluation of prescription patterns and medication modifications was made possible by the data gathered from various sources, including patient drug treatment charts, medical records, the hospital's computerized database, and registrations for haemodialysis units. Serum creatinine levels and microbiological laboratory data, such as culture sensitivity reports and Minimum Inhibitory Concentration (MIC) values, were taken from the laboratory master file in order to assess the effect of antibiotic medication on renal function. Understanding renal clearance variances and adjusting antibiotic dosage correspondingly required the use of these data points. To reduce toxicity and maximize therapeutic effectiveness, the Sanford Antimicrobial Guidelines were used to determine if the recommended antibiotics were dosed adequately, particularly in patients with compromised renal function. Additionally, by closely examining test results to reduce the emergence of multidrug-resistant organisms and guarantee that prescribed medicines matched sensitivity trends, antimicrobial stewardship measures were strengthened. This study sought to improve antimicrobial decision-making and protect renal function in haemodialysis patients by combining several data sources with rigorous evaluation processes, as shown in Figure 1.

Statistical Analysis

Microsoft Excel was used to enter the data, while JASP 0.16.4 was used for statistical analysis. The results are shown as percentages, numbers, or Mean±SD. The Shapiro-Wilk test was used to determine normality. Paired *t*-tests were employed for data that was regularly distributed, while the Wilcoxon signed-rank test was utilised for data that was inconsistent. The Chi-square test was used to evaluate the associations between qualitative variables. A p-value of < 0.05 with a 95% confidence interval was considered statistically significant.

RESULTS

The study included 79 patients, of whom 64% were male and 36% were female, indicating that the study was primarily conducted on adults, with 53% of the patients between the ages of 18 and 59. Among patients on haemodialysis who received antibiotics, common comorbidities included hypertension (79%), diabetes mellitus (73%), chronic kidney disease on maintenance dialysis (63%), acute kidney injury and other renal conditions (51%), and anaemia (19%). Additional conditions reported were coronary artery disease, thyroid disorders, and Type 1/2 respiratory diseases (Table 1).

The study population's infections were evaluated; sepsis accounted for 43% of cases, metabolic acidosis for 38%, and lower respiratory tract infections for 36%. Other conditions, such as urosepsis and pyelonephritis, were also observed in the study population (Table 1).

The patients' microorganisms' pattern was also evaluated, and the results showed that gram-positive bacteria predominated over gram-negative bacteria. Of the study population, 63 microorganisms were found, with 58 patients having a single microorganism and 5 patients having two. Additionally, 16 patients did not have positive bacterial culture reports. Acinetobacter was found in 23% of patients, whereas Klebsiella pneumonia was found in 26% of patients, and a total of 10 microorganisms were assessed (Table 2).

During the research, 79 patients were prescribed a total of 125 antibiotic treatments. The most frequently prescribed antibiotic was Meropenem, which was given to 26.2% of the patients, followed closely by piperacillin-tazobactum prescribed to 25.3%. This pattern indicates a preference for broad-spectrum antibiotics, particularly Meropenem and piperacillin-tazobactam, due to their effectiveness in treating a variety of bacterial infections. Cefoperazone combined with sulbactam was prescribed less frequently, representing 3.17% of the treatments, followed by tigecycline at 3.96% and cotrimoxazole at only 0.79% (Table 3).

The study also focused on evaluating the appropriateness and prescribing patterns of ten antibiotics in patients undergoing haemodialysis. Current prescriptions were compared against globally recognized standard guidelines, and the antibiotics were classified into three categories: appropriate, inappropriate, and optimal. An optimal antibiotic dose refers to drugs that require no renal dose adjustments, such as ceftriaxone, ensuring consistent efficacy regardless of kidney function. Out of the 79 individuals assessed, 56 received appropriate antibiotics, 15 received an

Table 1: Baseline characteristics of the study population with comorbidities.

Demographics	Number of Patients Undergone Dialysis (*n*=79)	
Gender	N (%)	
Males	51(64.5)	
Females	28(35.4)	
Age (Years	N (%)	Mean±SD
Adults (18-59)	42(53.1)	46.6±9.92
Elderly (>60)	37(46.8)	71.1±7.08
Comorbidities	N (%)	
Hypertension	63(79)	
Diabetes Milletus	58(73)	
CKD & CKD On Mhd	50(63.2)	
AKI &Acute on CKD	41(51.8)	
Anaemia of Chronic Disease	15(18.9)	
Infections and contributing factors for initiating haemodialysis		
Sepsis	34(43.3)	
Metabolic acidosis	30(38)	
LRTI	29(36.7)	
UTI	13(16.4)	
BSI	12(15.1)	
Laboratory Parameters	Mean±SD	*p* value
Pre HD serum creatinine (mg/dL)	6.02±2.48	*p*=0.0049
Post HD serum creatinine(mg/dL)	5.01±1.94	

Table 2: **The pattern of pathogen isolates in the study population.**

Parameter	N	Name of the microorganism	N (%)
Total number of patients without microbiological isolates.	16	*Klebsiella pneumonia*	17(26)
Total number of microbiological isolates.	63	*Acinetobacter Baumannii*	15(23)
Total number of patients with a single isolate.	58	MSSA	03(4.6)
Total number of patients with two isolates.	05	MRSA	04(6.2)
		VRE	03(4.6)
		CONS	07(10.9)
		Burkholderia Cepacia	03(4.6)
		Pseudomonas Aeruginosa	02(3.125)
		Enterobacter	04(6.2)
		E Coli	5(7.8)
		Enterococcus	1(1.5)

Table 3: **The 10 most commonly prescribed antibiotic regimens.**

Antibiotics	Indications	Total (125) N(N%)	No of inappropriate N(N%)	Reasons for inappropriate prescribing
Piperacillin + Tazobactum	Sepsis, SSTI	32(25.6)	06(18)	Incorrect dose, frequency
Meropenem	RTI, BSI, NF	33(26.4)	08(24)	Incorrect dose, frequency
Ceftriaxone	LRTI, RTI, Meningitis	09(7.2)	00	-
Vancomycin	MRSA, BSI	07(5.6)	00	-
Linezolid	MSSA, septic shock	03(2.4)	00	-
Imipenem+Cilastin	Worsening sepsis	07(5.6)	01(14.2)	Incorrect frequency, microbiology
Cefperazone+Sulbactam	Polynephritis	04(3.2)	01(14.2)	Incorrect dose, frequency, spectrum too broad
Colistin	Severe Sepsis	20(16)	06(30)	
Tigecycline	CAP	05(4.0)	00	-
Cotrimoxazole	Urosepsis, UTI	01(0.8)	00	-
Others	BSI, CRBSI, Sepsis	04(3.2)	00	-

inappropriate dose of antibiotics, and 8 received antibiotics that were optimally prescribed, tailoring doses to each individual's creatinine clearance levels to ensure efficacy and minimize risks (Table 4).

In 4.76% of cases, colistin was not given per the customized creatinine clearance guidelines. The next medication used was piperacillin combined with tazobactam (2.25 g). Vancomycin was correctly administered to lower the risk of MRSA infections. Furthermore, ceftriaxone and tigecycline did not need any changes to their renal dosage. However, 5.5% of patients were prescribed meropenem incorrectly (Table 4).

Serum creatinine levels before and after haemodialysis were subjected to the Shapiro-Wilk test of normalcy. The results revealed a considerable departure from normalcy, suggesting that the data is not normally distributed. Haemodialysis significantly affected the study population's serum creatinine levels, according to the findings of the Shapiro-Wilk test, a statistical test used to assess whether a dataset is normally distributed.

A paired sample *t*-test was used to compare pre- and post-haemodialysis serum creatinine levels; the results showed a *p*-value of less than 0.01, indicating a statistically significant difference between the two measurements.

DISCUSSION

Healthcare professionals should carefully evaluate antibiotic prescribing patterns based on patient and disease characteristics, creatinine levels, and susceptible microbial patterns. Antibiotics are mostly prescribed to patients in various departments of ICU, urology and nephrology. Since the patient's renal function has been compromised, antibiotics should be tailored or adjusted based on their creatinine clearance to prevent toxicity and nephrotoxicity.

The dose and dosing interval chosen for the regimen were frequently linked to classifying an antibiotic as inappropriate. As a result, greater or more frequent dosage may result in side effects, toxicity, an extended hospital stays for the patient, higher expenses, treatment failure, and a higher chance of antibiotic-resistant bacteria with substandard dosage. Additionally, 15 medications were deemed inappropriate in this study because of their adverse

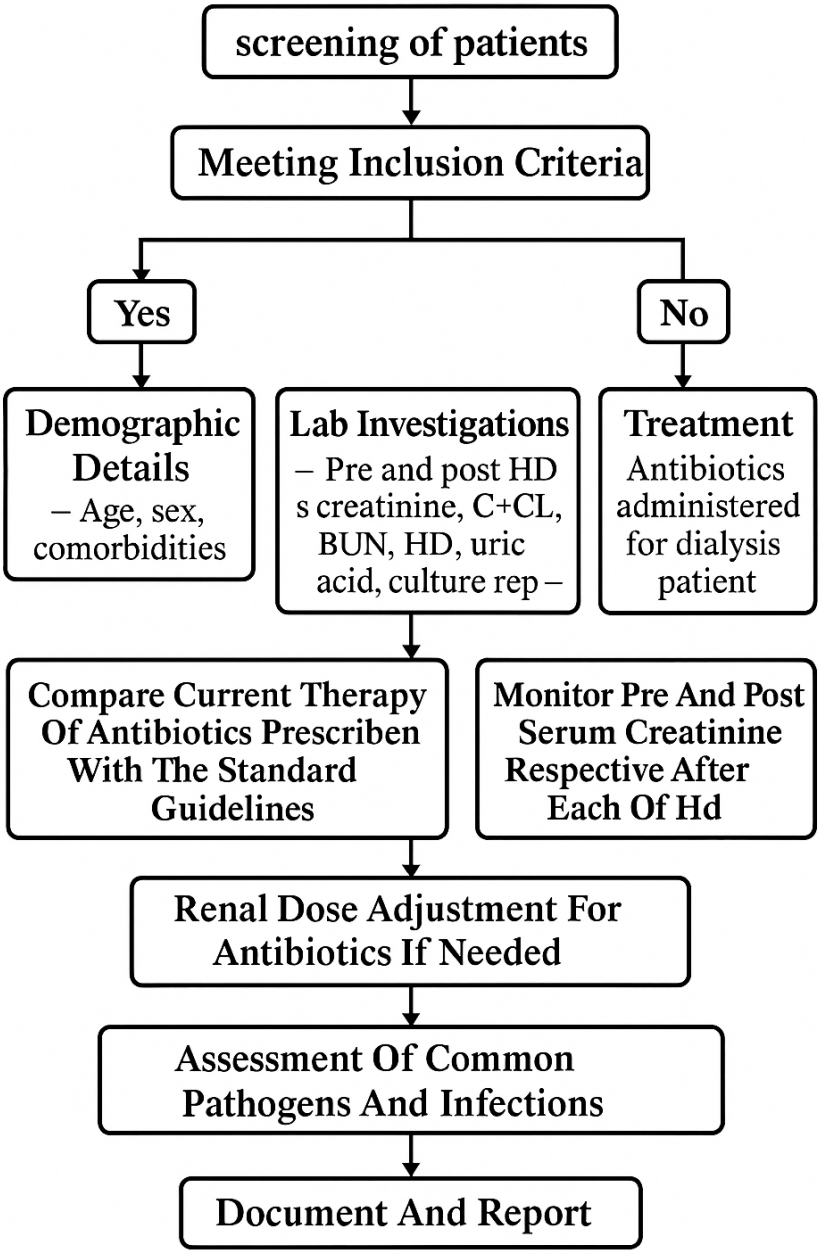

Figure 1: Flow chart of the study.

Table 4: Comparison of antibiotic prescriptions in haemodialysis patients: Guideline adherence and Renal function appropriateness.

1. Compliance with standard guidelines				
Antibiotics	**Yes**		**No**	
	N	%	N	%
PIPTAZ 2.25 Gm Q6H	03	2.38	02	1.58
PIPTAZ 2.25 Gm Q8H	23	18.25	04	3.17
Meropenem 500 mg	23	17.46	07	5.55
Meropenem 1 gm	02	1.58	01	0.79
Colistin	14	11.11	06	4.76
Imipenem + Cilastin	06	4.76	01	0.79
Cefoperazone/Salbactum	04	3.17	01	0.79
Vancomycin	07	5.55	00	00
Cotrimoxazole	01	0.79	00	00
Linezolid	03	2.38	00	00
2. Classification of Antimicrobials based on Patient-Tailored Creatinine Clearance.			**Patients N(N%)**	**Antimicrobials N(N%)**
Optimal dose			08(10.1)	18
Inappropriate dose			15(18.9)	22
Appropriate dose			56(70.8)	86

effects on patient outcomes, inappropriate antibiotic resistance, and a too limited or wide spectrum.

Vancomycin and piperacillin-tazobactam were found to be the most often used parenteral antibiotics in the Himali *et al.*, investigation. In contrast, the results of our study show that the most common selection in clinical practice was meropenem, which was followed by piperacillin-tazobactam. This discrepancy highlights possible differences in prescribing practices, which might be impacted by regional microbiological profiles, institutional policies, or increases in antibiotic resistance.[3]

In contrast to the study conducted by Hui K *et al.*, which identified vancomycin, piperacillin-tazobactam, cephazolin, and ceftriaxone as the most commonly prescribed antibiotics, the present study found that meropenem is the most frequently prescribed IV antibiotic, followed by piperacillin-tazobactam, highlighting a discrepancy between the two studies.[8] The present study indicated that vancomycin was prescribed appropriately in 7 out of 126 antibiotic prescriptions, aligning with the findings of Hui K *et al.*, who also noted that vancomycin was mostly prescribed appropriately, particularly as an empirical treatment due to the risk of MRSA infections; thus, both studies demonstrate consistency in their assessment of appropriate vancomycin use.[8]

The present study found that the most inappropriately prescribed antibiotic was meropenem, followed by piperacillin-tazobactam, in terms of dosage regimen and frequency. Similarly, the study by Hui K *et al.*, identified cephazolin and meropenem as the most inappropriately prescribed antibiotics. Both studies highlight the inappropriate prescribing of meropenem, indicating a consistent trend between the two.[8]

CONCLUSION

This study provides significant insights into the high levels of antibiotic exposure among patients receiving haemodialysis, despite its limited sample size. The improper dosage and frequency of antibiotic therapy have been highlighted as a significant problem. This highlights how urgently focused interventions are needed to boost antimicrobial stewardship and enhance drug usage in this group. Resolving these issues can improve therapy results and patient safety. Data shows that individuals receiving haemodialysis have a high burden of antibiotic exposure and noteworthy cases of improper antibiotic administration. In order to maximise antibiotic usage in this group, this study emphasises the need for antimicrobial stewardship and continuous education programs. These initiatives are necessary to reduce the spread of resistant organisms and, more significantly, to improve patient outcomes and safety.

LIMITATIONS

The accuracy and generalisability of the results may be impacted by a number of significant limitations in the current investigation. First off, the research only lasted six months, which is a rather short time frame that could not have been enough to record long-term patterns or results. Furthermore, there were

not many participants included, which would have affected the results' representativeness and statistical power. The lack of culture reports describing the resistance patterns of the majority of microbiological isolates, which are crucial for directing the proper antibiotic therapy, is a major drawback. Additionally, important metrics such antibiotics' Therapeutic Drug Monitoring (TDM), Defined Daily Dose (DDD), and Minimum Inhibitory Concentration (MIC) were not evaluated. Another difficulty is the growing number of organisms resistant to antibiotics, which can distort outcomes and restrict the use of conventional treatment methods. The interpretation of therapeutic results in this group is further complicated by the fact that haemodialysis patients may have changed pharmacokinetics, which can affect both the toxicity and efficacy of medications due to reduced renal function and the effects of dialysis.

CONFLICT OF INTEREST

The authors declare that they have no conflicting interests".

ABBREVIATIONS

ESRD: End-stage renal disease; **CKD:** Chronic kidney disease; **HD:** Haemodialysis; **AKI:** Acute kidney injury; **MRSA:** Methicillin-resistant Staphylococcus aureus; **SSTI:** Skin and soft tissue infection; **NF:** Necrotizing fasciitis; **CKD ON MHD:** Chronic kidney disease on maintenance haemodialysis; **VRE:** Vancomycin-resistant enterococcus; **MSSA:** Methicillin-susceptible Staphylococcus aureus; **UTIs:** Urinary tract infections; **LRTI:** Lower Respiratory tract infection.

ETHICAL CONFIRMATION

This study did not require ethical approval because it was an observational study that did not involve any intervention, treatment, or administration of medication. The research was conducted by observing and analysing existing data, without modifying any treatment plans or affecting the participants' care in any way.

SUMMARY

This study evaluated the use of antibiotics in haemodialysis patients and found significant cases of improper dosage in addition to a high exposure rate. The study population included mean ages of 46.6 years for adults and 71.1 years for elderly patients, with a preponderance of males (64.5%). Common comorbidities were diabetes, hypertension, and chronic renal disease. Only eight of the 126 antibiotics that were administered-mostly Meropenem and Piperacillin-tazobactam-were prescribed correctly, and fifteen of them were dosed incorrectly. Serum creatinine levels were regularly checked after dialysis and ranged from 4.5 to 6.5 mg/dL. A 20% death rate was mostly caused by metabolic acidosis and sepsis. The most often isolated pathogens were gram-negative organisms, including Klebsiella pneumoniae and Acinetobacter species. These findings highlight the importance of strong antimicrobial stewardship, and focused educational programs must be implemented to guarantee appropriate antibiotic use, prevent resistance, and improve clinical outcomes in this vulnerable group.

AUTHOR'S CONTRIBUTION

- Dr. Sachin A H-corresponding author, E-mail: sachinah1806@gmail.com, responsible for conducting literature review and supervising the overall study including data collection, manuscript formatting, submissions and handling the revisions.
- Dr. Merit Koju-conducted the literature review and initial drafting of the manuscript and maintained the collected data for analysis.
- Dr. Banjara Raju Prabhudev-served as a co-guide, Assistant professor, Department of Pharmacy Practice, contributed during several preliminary versions of the study text and helped in making critical suggestions and posing challenging questions.
- Dr. Balakeshwa Ramaiah-served as a guide and HOD of Pharmacy Practice and contributed with expertise in methodology and editing the final manuscript.
- All the authors equally contributed to the reviewing and approval of the final manuscript.

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