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Original Article

Vancomycin Dose Prescribing Practices, Therapeutic Drug Monitoring, and Infusion-Related Histaminergic Reactions among Pediatric Patients

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ABSTRACT

To review vancomycin use, therapeutic drug Monitoring (TDM) use, and to assess the incidence of "infusion-related" histaminergic reactions for children receiving vancomycin. This prospective observational study was conducted in the pediatric wards and the intensive care unit of a tertiary care hospital in Pakistan over a 12-month period from January to December 2024. Patients were included if they were pediatric (aged 1 month to 14 years) and received vancomycin intravenously for more than 48 hours. A structured form was used to collect data on dosing, trough level, time of sample collection, infusion rate, and adverse reactions. Chi-square test, "Fisher's exact test, and Mann-Whitney U test" were used; p-values less than 0.05 were considered statistically significant. A total of 137 pediatric patients were recruited. Subtherapeutic vancomycin levels were seen in all age groups. Infants had a significantly higher frequency of supratherapeutic levels ($p = 0.006$). The serum creatinine level was significantly associated with elevated trough level ($p = 0.035$). Histaminergic reactions, mostly those that are infusion-related, were seen in 20 patients (14.6%) and were associated with infusion procedures, not with IgE-mediated mechanisms. There is considerable variability in prescribing and poor compliance with the therapeutic drug Monitoring (TDM) guidelines. Better monitoring, appropriate timing of drug level testing, and dose tailoring are crucial to improve vancomycin therapy in children.

Keywords: Vancomycin, Pediatric Patients, Therapeutic Drug Monitoring, Red Man Syndrome, Histaminergic Reactions, Drug Safety.

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INTRODUCTION

The drug vancomycin was first used in the late 1950s to treat life-threatening infections caused by Gram-positive bacteria, especially by penicillin-resistant bacteria, like Staphylococcus aureus (Cheng *et al*., 2022). Vancomycin is a critical glycopeptide antibiotic commonly used in pediatric patients to treat severe Gram-positive infections, particularly those caused by methicillin-resistant Staphylococcus aureus (MRSA). MRSA has become more widespread globally in recent decades, especially among hospitalized pediatric patients, leading to hospital stays for a long period, increased healthcare costs, and a greater burden of antimicrobial resistance (Tang *et al*., 2023).

Optimizing therapeutic exposure to vancomycin and minimizing the risk of toxicity requires individualized dosing due to the complexity of drug absorption, distribution, metabolism, and excretion in the growing child population, as well as vancomycin's narrow therapeutic window. This is usually done by therapeutic drug monitoring (TDM), in which blood levels of the drug are checked, and the dosage is adjusted (Abdul–Aziz *et al*., 2022). Especially during treatment durations more than 48 hours, evidence from various clinical settings suggests that vancomycin prescribing practices and (TDM) implementation remain suboptimal (Cafaro *et al*., 2024). Consequently, many patients do not reach their therapeutic goal, and there is a wide variability of clinical practice.

Vancomycin treatment also has side effects such as infusion-related histaminergic reactions (RMS), which are most commonly experienced (Alonso-Moreno *et al*., 2021; Upendrababu, 2018). In pediatric patients, a significant rate of RMS has been reported, and the following risk factors have been identified: high vancomycin doses, elevated serum vancomycin levels, and rapid infusion rates. In clinical practice, it is crucial to distinguish these histaminergic reactions from actual IgE-mediated allergic reactions, as this prevents unnecessary interruption of effective treatment and inappropriate switching to other antibiotics (Upendrababu, 2018). Assessing these parameters in the pediatric context in Pakistan is very critical to optimizing antimicrobial usage, patient safety, and therapeutic outcomes.

Hence, the objectives of this study were to determine the therapeutic drug monitoring protocol, assess vancomycin prescribing practices, and evaluate histaminergic reactions following vancomycin infusion in pediatric patients in Pakistan (Alvarez-Arango *et al*., 2021; Burns & Empey, 2021; Moussa *et al*., 2021).

METHODS AND MATERIALS

Study Design and Setting

This prospective observational study was conducted in the pediatric wards and the intensive care unit of a tertiary care hospital in Pakistan over a 12-month period from January to December 2024. Patients were included if they were pediatric (aged 1 month to 14 years) and received vancomycin intravenously for more than 48 hours. A structured form was used to collect data on dosing, trough level, time of sample collection, infusion rate, and adverse reactions. Chi-square test, “Fisher's exact test, and Mann-Whitney U test” were used; p-values less than 0.05 were considered statistically significant.

RESULTS AND FINDINGS

In all, 137 patients were analyzed. The baseline characteristics revealed that most of the patients were young (52.6%) and (56.2%) were males. The majority of patients were inpatients (72.3%), and fever (66.4%) was present. Comorbidities were seen in 65.7% of the patients, and concomitant nephrotoxic medications were used in 55.5%. The most common indications for vancomycin were pneumonia (35.8%) and meningitis (26.3%), with most patients being administered every 8 hours (73%). There was no significant abnormality in the initial values.

Table 1
Baseline Data (n=137)

Variable		n (%)/ Mean±SD/ Median (IQR)
Demographics		
Age (years)	Infant	38(27.7)
	Young Child (1 to 6 y)	72(52.6)
	Old Child (7 to 14 y)	27(19.7)
Gender	Male	77(56.2)
	Female	60(43.8)
Weight (kg)	Healthy	95(69.3)
Weight Category	Underweight	30(21.9
	Overweight	12(8.8)
Baseline Clinical Data		
Type of Admission	Emergency	38(27.7)
	In Patient	99(72.3)
Presence Of Fever	Positive	91(66.4)
	Negative	46(33.6)
Comorbidities	Present	90(65.7)
	Not Present	47(34.3)
Concomitant	Prescribed	76(55.5)
Nephrotoxic Medication	Not Prescribed	
		61(44.5)
Baseline lab		
WBC ×109/L	Normal	110(80.3)
	High	12(8.8)
	low	15(10.9)
Platelet ×109/L		265.14 ± 96.7
SCr (mg/dL)	Normal	120(87.8)
	High	8(5.8)
	Low	9(6.6)
Concomitant	piperacillin/tazobactam	48(35)
Nephrotoxic medications	meropenem	15(10.9)
	Aminoglycosides	49(35.8)
	Furosemide	7(5.1)

	others	
		18(13.1)
Vancomycin Therapy		
Indication for use	Meningitis	49(35.8)
	Pneumonia	36(26.3)
	Wound Infection	8(5.8)
	Other	
		44(32.1)
Dose Frequency	Every 6h	17(12.4)
	Every 8h	100(73)
	Every 12 h	20(14.6)
Initial Trough Levels		11.3 ± 1.89

However, therapeutic drug monitoring showed variations in the levels of vancomycin among patients. The subtherapeutic levels were seen in all age groups but were not statistically significant. Supratherapeutic levels, however, were more common in infants (13.2%), and this difference was statistically significant (p = 0.006). Subtherapeutic levels were significantly more common in patients in the ICU 28.0% compared to non-ICU patients 4.5%, p = 0.001.

Table 2

Characteristics of Patients Experiencing a Supratherapeutic or Subtherapeutic Initial Level

Variable		Subtherapeutic		Supratherapeutic	
		Frequency	P value	Frequency	P value
Age Group					
	Infant (n=38)	2(5.3)	0.510	5(13.2)	0.006
	Young Child (n=72)	6(8.3)	1.000	1(1.4)	0.082
	Old Child (n=27)	4(14.8)	0.252	0(0)	0.261
Weight Category	Normal (n=94)	6(6.4)	0.193	1(1.1)	0.012
	Over (n=30)	3(10.0)	0.725	4(13.3)	0.021
	Under (n=13)	3(23.1)	0.089	1(7.7)	0.457
Care Settings					
	ICU (n=25)	7(28.0)	0.001	3(12.0)	0.074
	NONICU (n=112)	5(4.5)	0.001	3(2.7)	0.074
Admission Type	Emergency(n=99)	1(2.6)	0.179	2(5.3)	0.669
	Indoor(n=38)	11(11.1)	0.179	4(4.0)	0.669

A clinical evaluation of the variables weight category and type of admission revealed no significant differences between subtherapeutic and supratherapeutic levels. No significant relationship was observed between vancomycin dose and development of acute kidney injury (AKI) or rising serum creatinine levels in terms of renal safety outcomes.

Table 3
Risk Factors Are Associated with AKI and SCr Elevation

Variables		AKI(n=13)		Elevated SCr(n=7)	
		n(%)/Mean ±SD	P value	n(%)/Mean ±SD	P value
Vancomycin dose (mg/kg/day)		16.89	0.609	16.89	0.227
Trough Levels (mg/L)		11.30 ± 1.79	0.083	11.31±1.80	0.035
Frequency of the Therapy	Every6h(n=17)	1(5.9)	1.000	0	0.596
	Every8h(n=100)	12(12.0)	0.185	7(7.0)	0.189
	Every12h(n=200)	0	0.216	0	0.593
Concomitant Nephrotoxic Medications	Piperacillin/Tazobactam(n=48)	3(6.3)	0.542	1(2.1)	0.421
	Aminoglycosides(n=49)	4(8.2)	0.771	1(2.0)	0.421
	Meropenem(n=15)	2(13.3)	0.636	2(13.3)	0.170
	Furosemide(n=7)	1(14.3)	0.511	1(14.3)	0.313
	Others(n=18)	3(16.7)	0.379	2(11.1)	0.230
Age Group	Infant(n=38)	5(13.2)	0.349	2(5.3)	1.000
	Young Child(n=72)	6(8.3)	0.672	4(5.6)	1.000
	Old Child(n=27)	2(7.4)	1.000	1(3.7)	1.000
Weight Category	Normal weight(n=95)	8(8.5)	0.546	4(4.3)	0.678
	Underweight(n=30)	4(13.3)	0.481	2(6.7)	0.647
	Overweight(n=12)	1(7.7)	1.000	1(7.7)	0.511
Care Settings	ICU(n=25)	3(12.0)	0.705	0	0.349
	NON-ICU(n=112)	10(8.9)	0.705	7(6.3)	0.349

However, serum creatinine was significantly related to trough levels (p = 0.035), suggesting that renal impairment might be related to increased drug exposure. Concomitant nephrotoxic drugs (aminoglycosides and piperacillin/tazobactam) were not associated with AKI or high serum creatinine levels in a statistically significant manner. Appropriate timing of drug level sampling seemed to be a contributing factor to inappropriate therapeutic levels, so that appropriate monitoring of the levels is important. In 20 patients (14.6%), infusion-related histaminergic reactions were observed. The reactions were not correlated with IgE-mediated reactions. When assessing the safety of dosing according to the serum creatinine, 59.2% of the patients had normal SCr at baseline. On day 3, normal levels were observed at 36.2%, and a minority had raised levels or suffered from AKI. The relative incidence of AKI (increase in SCr ≥ 50%) was mild (33.3% on day 3 and 66.7% on day 6) and no AKI was seen after the treatment was completed.

Table 4

Safety of the Recommended Dosing in the Medication Administration Guide (MAG) n (%)

	Baseline	Day 3	Day 6	Post Treatment
Normal SCr	Reference	77(59.2)	47(36.2)	6(4.6)
> 25 to 50% increase in SCr (elevated SCr)	Reference	2(50.0)	2(50.0)	0
≥ 50% increase in SCr (AKI)	Reference	1(33.3)	2(66.7)	0

DISCUSSION

The study evaluated vancomycin prescribing practices, therapeutic drug monitoring(TDM), and infusion-related histaminergic reactions in pediatric patients in Pakistan (Elbarbry, 2018). The findings highlight important gaps in dosing optimization, monitoring practices, and safety outcomes. A demographic trend was observed, with most patients being young children and a slight predominance of males (Nham *et al*., 2022). This observation aligns with previous pediatric data indicating that infectious diseases requiring vancomycin are more commonly reported in early childhood. Additionally, a high proportion of patients presented with fever and comorbidities, reflecting the clinical complexity of cases requiring vancomycin therapy. One of the key findings of the study was the variability in the trough levels. (Tsutsuura *et al*., 2021). Most patients exhibit subtherapeutic concentrations across all age groups. This suggests that standard dosing regimens may not be adequate in pediatric populations, likely due to significant pharmacokinetic variability. Notably, supratherapeutic levels were more frequently observed in infants, indicating a higher susceptibility to drug accumulation and potential toxicity. This may be explained by immature renal function and reduced drug clearance in this age group (Drennan *et al*., 2019; Tsutsuura *et al*., 2021). The study did not find a significant association between patient-specific factors such as age, weight, care setting, or admission type and therapeutic drug levels (Zamoner *et al*., 2019). This suggests the variability in drug exposure may be more strongly influenced by inconsistencies in monitoring practices rather than individual patient characteristics. In particular, improper timing of trough level sampling was identified as a contributing factor to inaccurate assessment of drug concentrations, emphasizing the importance of adherence to standard TDM protocols (Al-Sulaiti *et al*., 2020). Renal safety analysis showed no significant association between vancomycin dosing and the development of acute kidney injury (AKI) or elevated serum levels (Aljefri *et al*., 2019; Kan *et al*., 2022). However, a significant correlation between higher trough levels and increased serum creatinine (Aljefri *et al*., 2019; Wiles *et al*., 2019). These findings suggest that excessive drug exposure may contribute to the nephrotoxicity, reinforcing the importance of maintaining drug concentrations within the recommended therapeutic range (Dicu-Andreescu *et al*., 2022; Morales-Alvarez, 2020; Petejova *et al*., 2020). No significant relationship was observed between renal outcomes and concomitant use of nephrotoxic medications. (Mohamed *et al*., 2022). This may be due to a limited sample size or controlled clinical conditions. Furthermore, demographic factors such as age and body weight were not significantly associated with AKI, indicating that the drug exposure levels may be a more critical determinant of renal risk (Zasowski *et al*., 2018).

During treatment, some patients developed elevated serum creatinine levels or AKI; however, no long-term renal impairment was observed following therapy (Bellos *et al*., 2020). This suggests that early detection and appropriate management can reduce the risk of persistent nephrotoxicity (Uster & Wicha, 2022). A subset of patients experienced infusion-related histaminergic reactions. These findings highlight the importance of controlling infusion rates and differentiating such reactions from true allergic responses to avoid unnecessary discontinuation of the therapy (De Luca *et al*., 2020). Overall, the study reveals suboptimal compliance with TDM guidelines, variability in drug exposure, and inconsistencies in dosing practices. These findings support the need for standardized monitoring protocols, appropriate timing of drug level measurements, and individualized dosing strategies. The involvement of clinical pharmacists and multidisciplinary teams may further improve

treatment outcomes. Future research should focus on larger patients and incorporate advanced pharmacokinetic modeling to optimize vancomycin dosing in pediatric patients (Xie *et al*., 2021).

CONCLUSION

The study provides data on the wide heterogeneity in the use of vancomycin in children, and the high incidence of subtherapeutic levels, as well as the greater risk of supratherapeutic levels, especially in infants. Results suggest inadequate practice of therapeutic drug monitoring (TDM) with inappropriate timing of trough level sampling, which could be a cause of inconsistent exposure. While there was no direct association between the dose of vancomycin and renal toxicity, high trough levels were significantly associated with high serum creatinine, suggesting the need to keep therapeutic levels. The findings highlight the importance of standardized protocols for TDM, precise timing of drug level measurements and personalized dosing approaches. Pharmacist-led interventions and collaborative strategies enhance vancomycin therapy's safety and efficacy in children. Larger and more complex pharmacokinetic modeling is recommended for future studies for further optimization of OD dosing and subsequent clinical outcomes.

DECLARATION

Ethical Consideration: This study strictly adhered to the Declaration of Helsinki and relevant national and institutional ethical guidelines. All procedures performed in this study were consistent with the ethical standards of the Declaration of Helsinki. The study was conducted according to ethical standards for research involving human participants. Confidentiality as well as the privacy of participants' data were ensured. Since we collected data from a private clinic with no review board, we got ethical approval from our university review board, named ORIC (Office of Research, Innovation, and Commercialization), and got it signed by the head of the clinic.

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