NIVELES DE ANTIBIÓTICOS CUANDO Y COMO

ALVARO CORRAL ALAEJOS

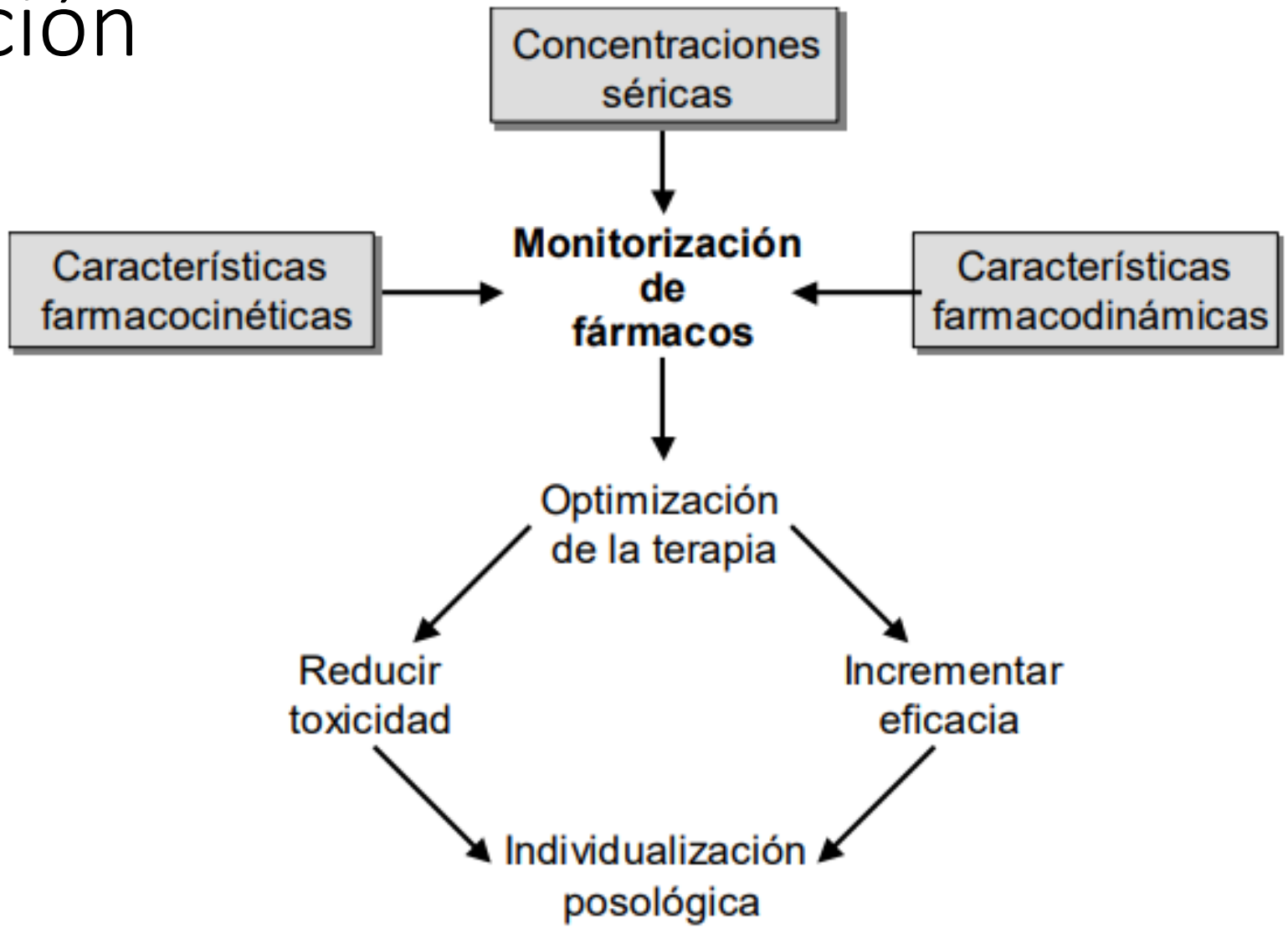
L.E. FARMACIA HOSPITALARIA

14 - Noviembre - 2022

Complejo Asistencial de Zamora

INDICE

1. Definición



2. Justificación

Monitorización farmacocinética

Estrecho margen terapéutico

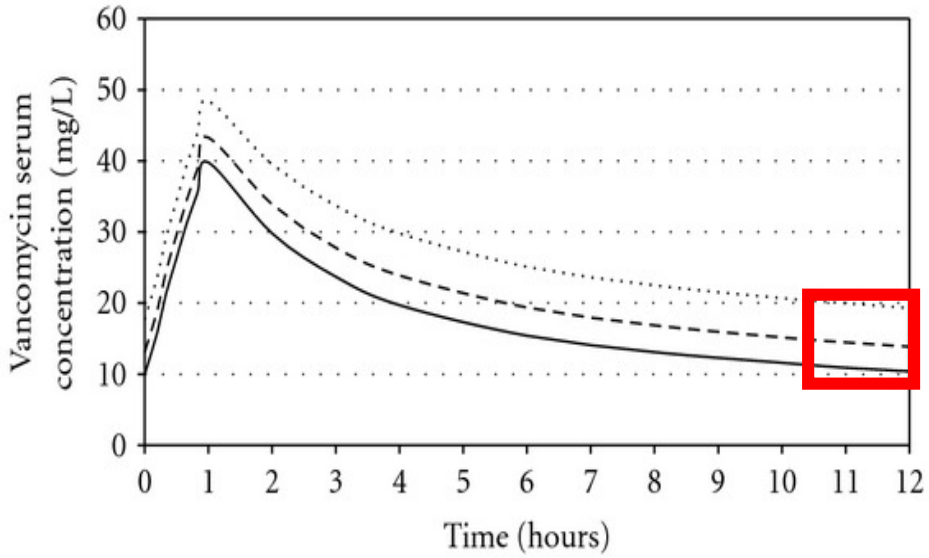
Relación concentración – Respuesta

No medida de eficacia con otros parámetros

Elevada variabilidad farmacocinética

Individualización posológica

VANCOMICINA



Pharmaceutics. 2022 Mar; 14(3): 489.
Published online 2022 Feb 23. doi: 10.3390/pharmaceutics14030489
PMCID: PMC8955715
PMID: 35335866

Pharmaceutics

Clinical Practice Guidelines for Therapeutic Drug Monitoring of Vancomycin in the Framework of Model-Informed Precision Dosing: A Consensus Review by the Japanese Society of Chemotherapy and the Japanese Society of Therapeutic Drug Monitoring

Kazuaki Matsumoto,[1] Kazutaka Oda,[2] Kensuke Shoji,[3] Yuki Hanai,[4] Yoshiko Takahashi,[5] Satoshi Fujii,[6] Yukihiro Hamada,[7] Toshimi Kimura,[7] Toshihiko Mayumi,[8] Takashi Ueda,[9] Kazuhiko Nakajima,[9] and Yoshio Takesue[9,10,*]

Andrzej Czyrski, Academic Editor, Joanna Sobiak, Academic Editor, and Matylda Resztak, Academic Editor

Paciente crítico

Pacientes jóvenes con buena función renal

Paciente con cualquier técnica de sustitución renal

Paciente 55a. Cirugía Colon

- ✓ Fiebre, aumento RFA:
- ✓ FR: Cr: 0,62 mg/dL

Líquido peritoneal

Cultivo aerobio

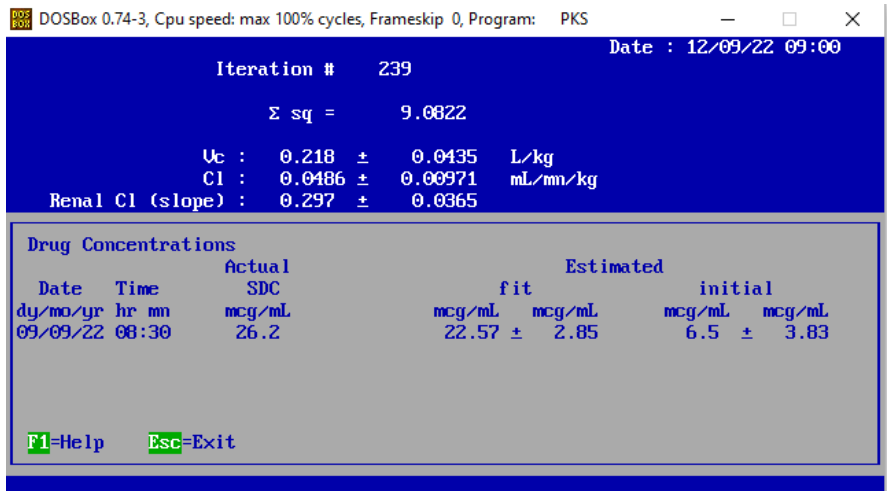
Líquido peritoneal - Cultivo aerobio

Enterococcus faecalis
Se aísla Enterococcus faecalis

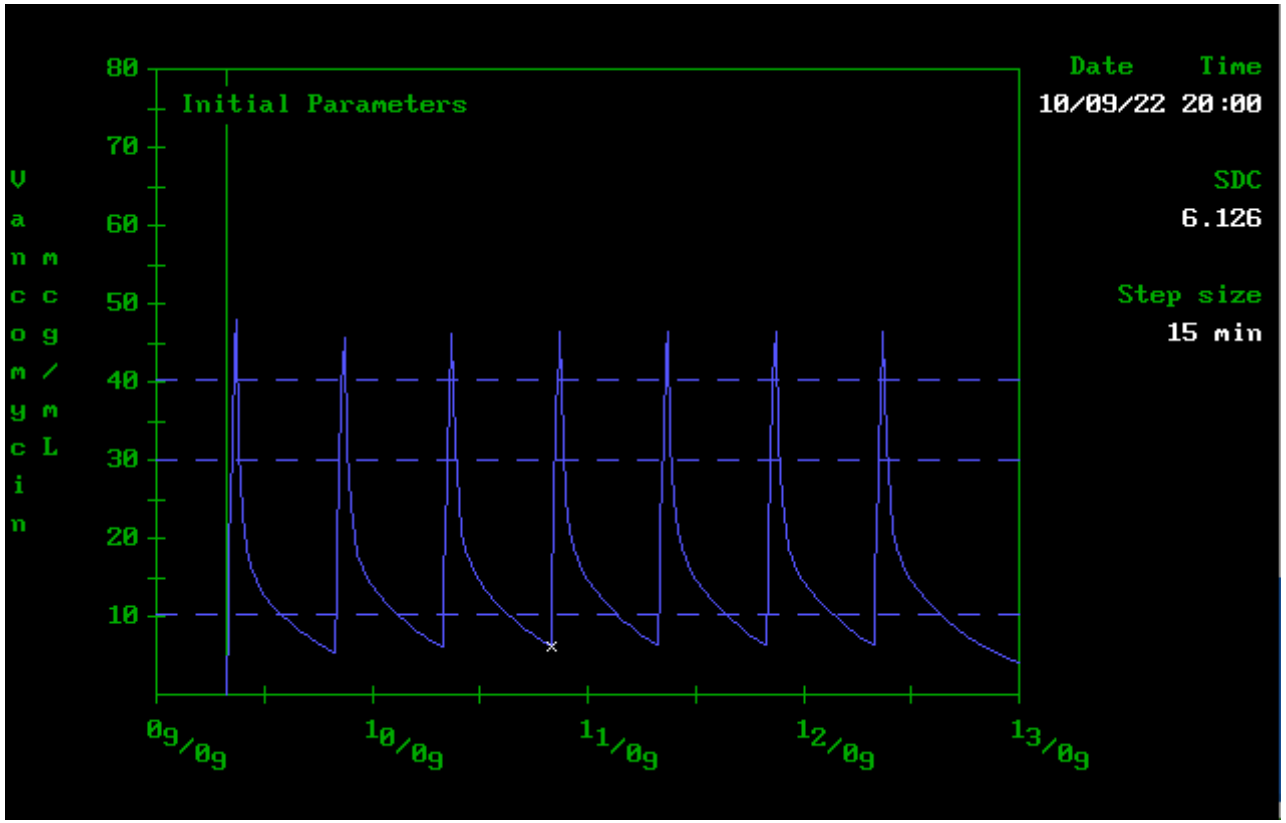
Enterococcus faecium
Se aísla Enterococcus faecium

Amoxicilina	S	-
Ampicilina	S (<= 2.0)	R (>= 32.0)
Piperacilina/Tazo	-	-
Cefuroxima - Axetil	-	-
Ceftazidima	-	-
Ceftriaxona	-	-
Cefepima	-	-
Meropenem	-	-
Gentamicina	-	-
Tobramicina	-	-
Ciprofloxacino	-	-
Trimethoprim/Sulfa	-	-
Linezolid	S (2.0)	S (2.0)
Teicoplanina	S (<= 0.5)	S (<= 0.5)
Vancomicina	S (1.0)	S (<= 0.5)

Inicio vancomicina 1g/12h



Extracción errónea



Paciente 55a. Cirugía Colon

- ✓ Fiebre, aumento RFA:
- ✓ FR: Cr: 0,62 mg/dL

Líquido peritoneal

Cultivo aerobio

Líquido peritoneal - Cultivo aerobio	Enterococcus faecalis Se aísla Enterococcus faecalis	Enterococcus faecium Se aísla Enterococcus faecium
Amoxicilina	S	-
Ampicilina	S (<= 2.0)	R (>= 32.0)
Piperacilina/Tazo	-	-
Cefuroxima - Axetil	-	-
Ceftazidima	-	-
Ceftriaxona	-	-
Cefepima	-	-
Meropenem	-	-
Gentamicina	-	-
Tobramicina	-	-
Ciprofloxacino	-	-
Trimethoprim/Sulfa	-	-
Linezolid	S (2.0)	S (2.0)
Teicoplanina	S (<= 0.5)	S (<= 0.5)
Vancomicina	S (1.0)	S (<= 0.5)

Inicio vancomicina 1g/12h

DOSBox 0.74-3, Cpu speed: max 100% cycles, Frameskip 0, Program: PKS

Date : 12/09/22 09:00

Iteration # 239

Σ sq = 9.0822

Vc : 0.218 ± 0.0435 L/kg
Cl : 0.0486 ± 0.00971 mL/mn/kg
Renal Cl (slope) : 0.297 ± 0.0365

Drug Concentrations

		Actual	Estimated			
			fit		initial	
Date	Time	SDC				
dy/mo/yr	hr mn	mcg/mL	mcg/mL	mcg/mL	mcg/mL	mcg/mL
09/09/22	08:30	26.2	22.57 ±	2.85	6.5 ±	3.83

F1=Help Esc=Exit

Extracción errónea

Poblacionalmente cambio a 1000mg c/8h

DOSBox 0.74-3, Cpu speed: max 100% cycles, Frameskip 0, Program: PKS

Date : 12/09/22 09:00

Iteration # 221

Σ sq = 0.0310

Vc : 0.211 ± 0.0415 L/kg
Cl : 0.0499 ± 0.00998 mL/mn/kg
Renal Cl (slope) : 0.711 ± 0.0921

Drug Concentrations

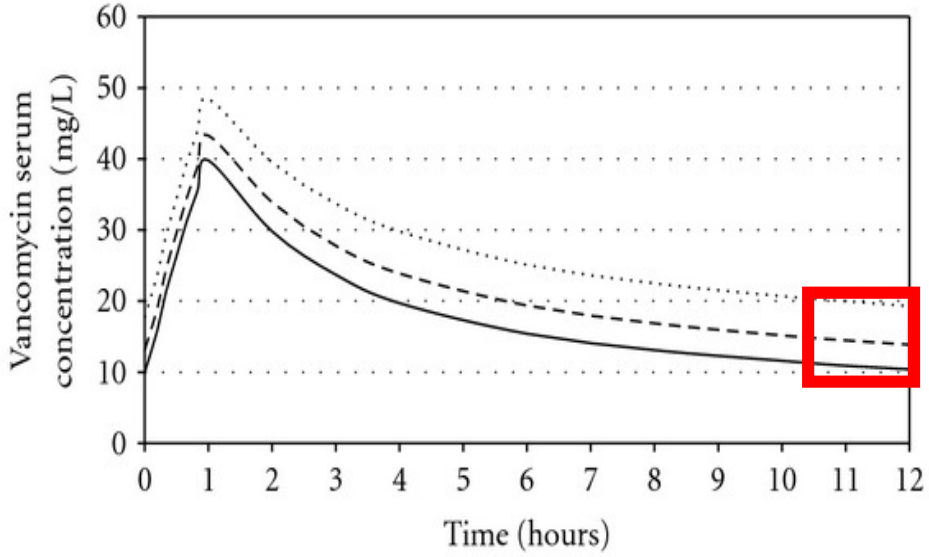
		Actual	Estimated			
			fit		initial	
Date	Time	SDC				
dy/mo/yr	hr mn	mcg/mL	mcg/mL	mcg/mL	mcg/mL	mcg/mL
12/09/22	07:30	13.8	13.7 ±	3.11	12.6 ±	6.32

F1=Help Esc=Exit

Horas de administración y extracción

AUC/CMI: 548. Mantener misma dosis

VANCOMICINA



Pharmaceutics. 2022 Mar; 14(3): 489.
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Pharmaceutics

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Andrzej Czyrski, Academic Editor, Joanna Sobiak, Academic Editor, and Matylda Resztak, Academic Editor

Paciente crítico

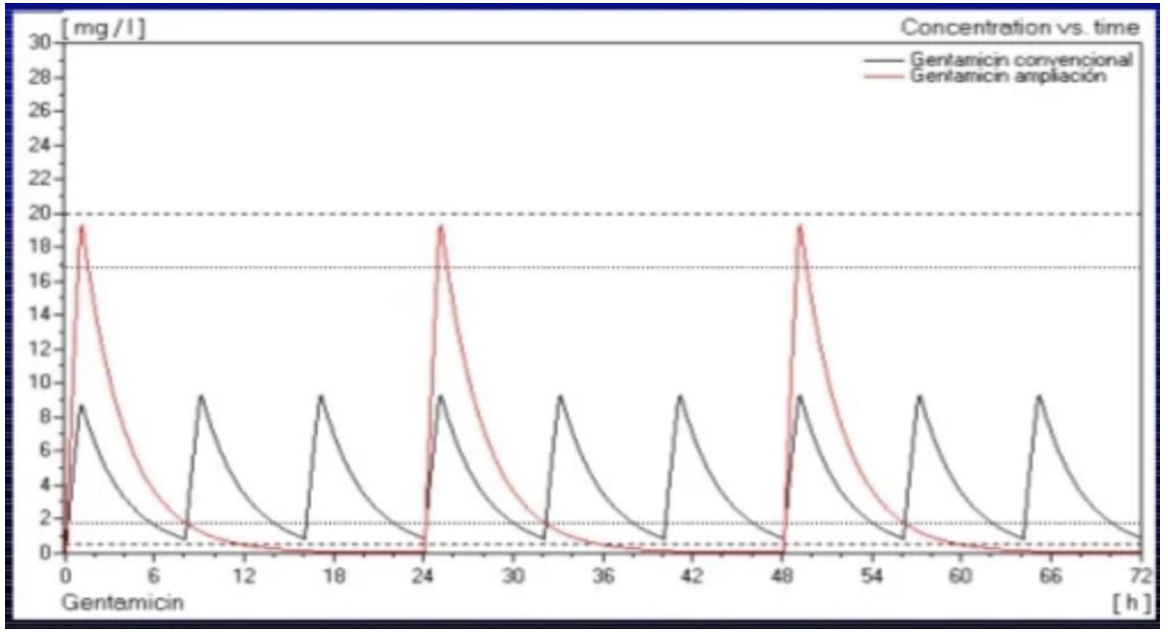
Pacientes jóvenes con buena función renal

Paciente con cualquier técnica de sustitución renal

Recordar: Nunca 1500mg c/12h.

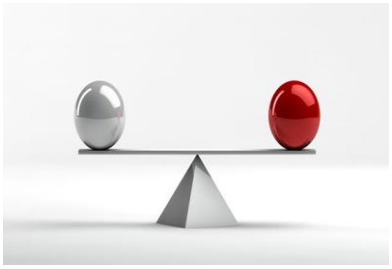
AMINOGLUCÓSIDOS

- Actividad conc-dependiente
- Cmax – Eficacia
- Cmin toxicidad
- Determinación Cmax y Cmin; 1-2º día



Régimen convencional

- Cmax inferiores
- ¿Acumulación?
- No efecto post-antibiótico



Ampliación de intervalo

- Cmax superiores
- Contraindicado en IR
- Efecto post-antibiótico

Relación Cmax/CMI: 8-12

Drug-Induced Diseases

Aminoglycoside-I
A Focus on Monit
of Literature

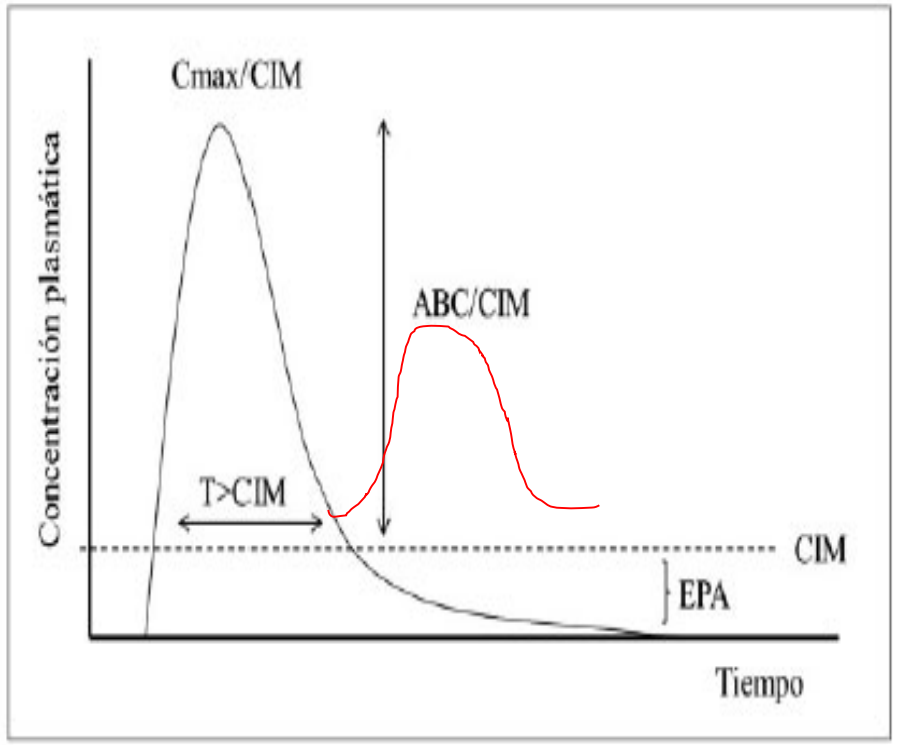
Christopher J. Destache, P

obacteriaceae, *Pseudomonas,* and *Acinetobacter*. Once-daily dosing of AGs not only has pharmacodynamic advantages but also has been shown to reduce the nephrotoxicity potential of these drugs. Additionally, there are cost-saving advantages using this dosing. Identifying patients with multiple risk factors for the potential of nephrotoxicity and determining the length of therapy will assist with appropriate use of these potent antimicrobials.

Clinical pharmacists are able to monitor AG therapy and provide dosing recommendations for busy clinicians. The use of once-daily dosing reduces the intensity of the pharmacokinetic monitoring, is efficacious with reduced toxicity, and is cost effective. Identifying microorganism susceptibilities are important for choosing the appropriate therapy. Identifying risk factors for the development of AG-induced nephrotoxicity is important for determining the length of AG therapy. If a patient has many risk factors for the development of nephrotoxicity, then choosing another antimicrobial regimen may be appropriate. In some cases, due to resistance, AG therapy is one of the last therapeutic resorts. In these cases, appropriate close monitoring is important for both once-daily and conventional regimens. Conventional AG dosing still requires appropriate peak and trough serum concentrations depending on site of infection. Once-daily dosing of AG therapy reduces the number of serum concentrations but still requires clinical monitoring. Monitoring of the therapy is important from both an efficacy and a toxicity standpoint. Most physicians appreciate this role of the clinical pharmacist in monitoring therapy and providing recommendations.

Journal of Pharmacy Practice
2014, Vol. 27(6) 562-566

DOI: 10.1177/0897190014546102
jpp.sagepub.com
SAGE



Tiempos de muestreo:

AI: 1h y 8h post-dosis

RC: previo y 1h post-dosis

Ampliación de intervalo

Régimen conencional

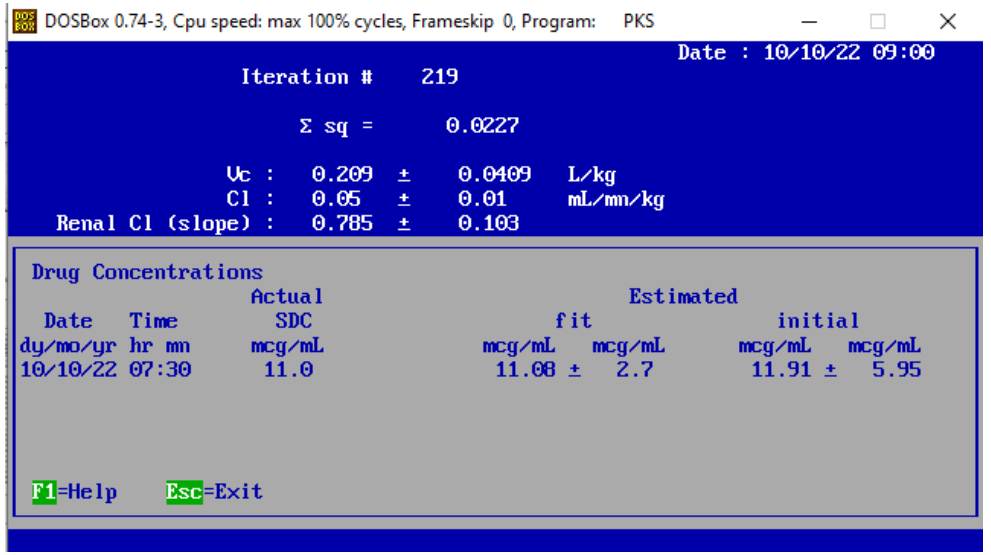
	AMICACINA	GENTA/TOBRAMICINA
Cmax (mcg/mL)	>50	>20-25
Cmin	Efecto post-antibiótico (40% intervalo)	
Cmax (mcg/mL)	25-30	6-8
Cmin (mcg/mL)	1-4	0,5-1,5

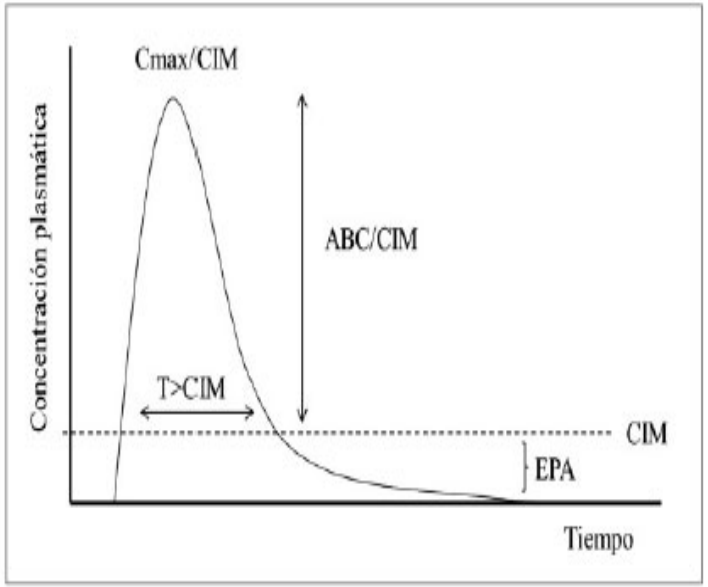
Paciente 54a. Sospecha endocarditis

- ✓ FR: 117 mL/min. P 73kg
- ✓ Inicio AB empírica: Vancomicina + Gentamicina

Estimación poblacional dosis vancomicina: 750mg c/8h
Inicio dosis de gentamicina 240mg c/24h.

Solicitados niveles vancomicina pre-dosis →
y gentamicina pre-dosis y una hora tras la administración.





FARMACOLOGÍA

VANCOMICINA SUERO	11.0	µg/mL
GENTAMICINA SUERO	<0.3	µg/mL

DOSBox 0.74-3, Cpu speed: max 100% cycles, Frameskip 0, Program: PKS

Date : 10/10/22 09:30

Iteration # 106

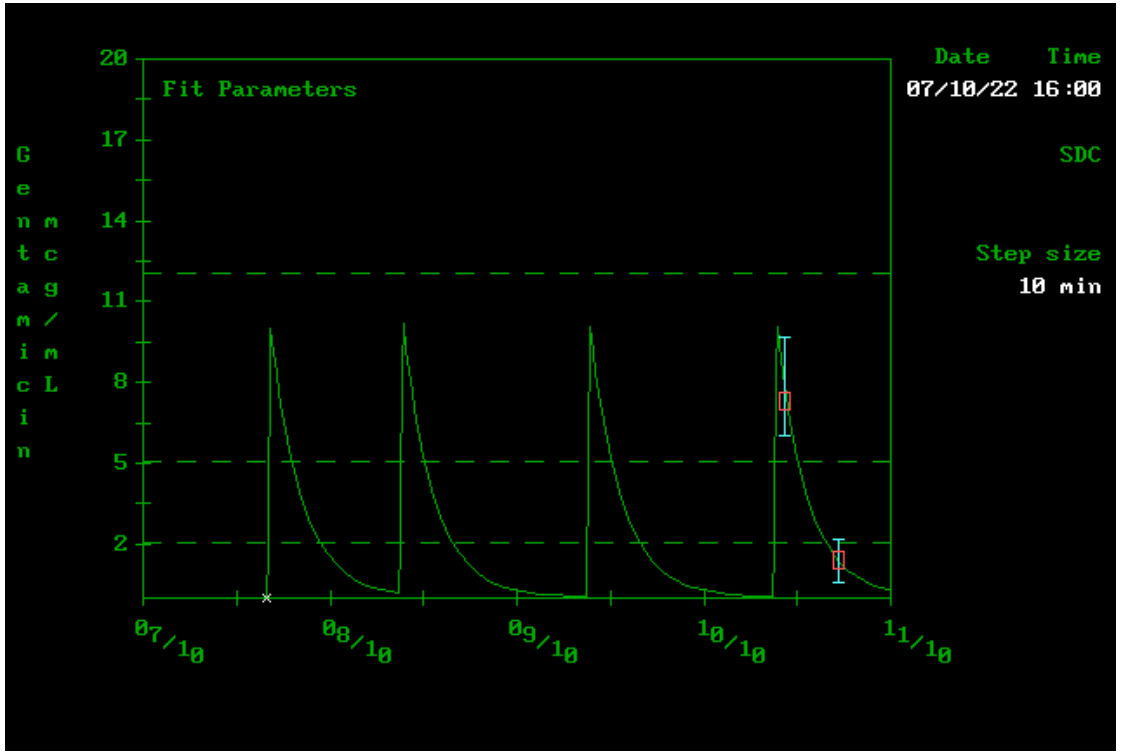
Σ sq = 1.0106

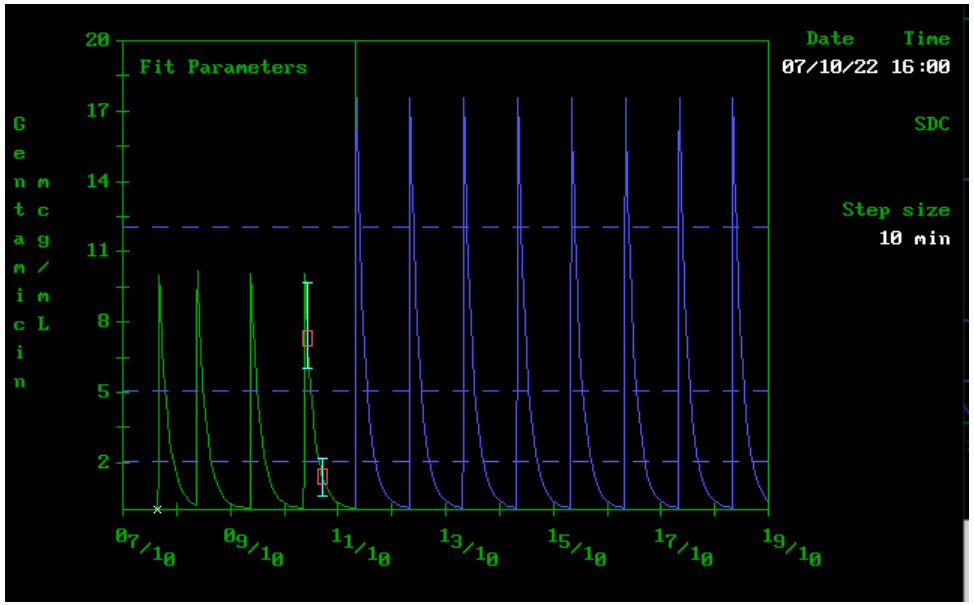
Vd :	0.319	±	0.0521	L/kg
Cl :	0.0415	±	0.0104	mL/mn/kg
Renal Cl (slope) :	0.702	±	0.0883	

Drug Concentrations

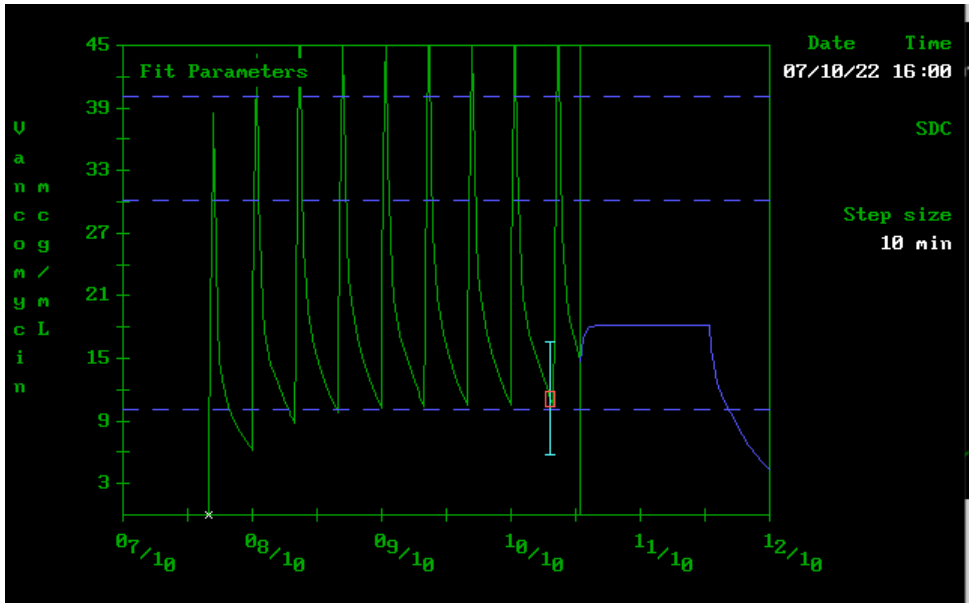
		Actual	Estimated			
			fit		initial	
Date	Time	SDC				
dy/mo/yr	hr mn	mcg/mL	mcg/mL		mcg/mL	
10/10/22	10:30	7.3	7.79	± 0.91	8.54	± 2.06
10/10/22	17:30	1.4	1.33	± 0.42	0.63	± 0.85

F1=Help Esc=Exit





Gentamicina 360mg c/24h



Vancomicina 2800mg c/24h PC

Linezolid

- Cmin [2 – 7] mcg/mL. → AUC/CMI: 100 – 120
- S CMI ≤ 2; R ≥4. CMI 2-4 Menor susceptibilidad a linezolid
- Toxicidad concentración dependiente

Clinical Pharmacokinetics (2022) 61:789–817
https://doi.org/10.1007/s40262-022-01125-2

REVIEW ARTICLE

A Review of Population Pharmacokinetic Analyses of Linezolid

Enrique Bandín-Vilar[1,2,3] · Laura García-Quintanilla[1,2,3] · Ana Castro-Balado[1,2,3] · Irene Zarra-Ferro[1,2] · Miguel González-Barcia[1,2] · Manuel Campos-Toimil[4] · Víctor Mangas-Sanjuan[5,6] · Cristina Mondelo-García[1,2] · Anxo Fernández-Ferreiro[1,2]

Accepted: 25 March 2022 / Published online: 14 June 2022

Abstract
In recent years, many studies on population pharmacokinetics of linezolid have been conducted. This comprehensive review aimed to summarize population pharmacokinetic models of linezolid, by focusing on dosage optimization to maximize the probability of attaining a certain pharmacokinetic-pharmacodynamic parameter in special populations. We searched the PubMed and EMBASE databases for population pharmacokinetic analyses of linezolid using a parametric non-linear mixed-effect approach, including both observational and prospective trials. Of the 32 studies, 26 were performed in adults, four in children, and one in both adults and children. High between-subject variability was determined in the majority of the models, which was in line with the variability of linezolid concentrations previously detected in observational studies. Some studies found that patients with renal impairment, hepatic failure, advanced age, or low body weight had higher exposure and adverse reactions rates. In contrast, lower concentrations and therapeutic failure were associated with obese patients, young patients, and patients who had undergone renal replacement techniques. In critically ill patients, the inter-individual and intra-individual variability was even greater, suggesting that this population is at an even higher risk of underexposure and overexposure. Therapeutic drug monitoring may be warranted in a large proportion of patients given that the Monte Carlo simulations demonstrated that the one-size-fits-all labeled dosing of 600 mg every 12 h could lead to toxicity or therapeutic failure for high values of the minimum inhibitory concentration of the target pathogen. Further research on covariates, including renal function, hepatic function, and drug–drug interactions related to P-glycoprotein could help to explain variability and improve linezolid dosing regimens.

Indicaciones TDM Linezolid:

- Pacientes críticos
- Insuficiencia renal
- Obesos
- Pediatría

International Journal of Antimicrobial Agents 59 (2022) 106572

Contents lists available at ScienceDirect

International Journal of Antimicrobial Agents

journal homepage: www.elsevier.com/locate/ijantimicag

Population pharmacokinetics and toxicodynamics of continuously infused linezolid in critically ill patients

Sebastian G. Wicha[a,*], Andrea Mair[b], Ute Chiriac[c], Otto R. Frey[d], Thomas Fuchs[e], Max Gaasch[e], Stefan Hagel[f], Daniel C. Richter[g], Jason A. Roberts[h,i,j], Anka C. Röhr[d], Markus A. Weigand[g], Alexander Brinkmann[e]

This study evaluated population PK of linezolid as well as the association between linezolid PK and platelet counts under continuous infusion in critically ill patients. Standard dosing or other dosing levels in relation to renal function and body weight led to insufficient PK/PD target attainment. In order to ascertain sufficient drug exposure to treat the infection and to proactively prevent the occurrence of thrombocytopenia, rather than adjusting the dose after thrombocytopenia has occurred, TDM-guided dosing of linezolid may be useful. Future studies that compare TDM-guided dosing of linezolid with standard dosing are warranted.

Frontiers in Pharmacology 2022 13 Article Number 844567

Dosage Strategy of Linezolid According to the Trough Concentration Target and Renal Function in Chinese Critically Ill Patients

Wu F., Zhang X.-S., Dai Y., Zhou Z.-Y., Zhang C.-H., Han L., Xu F.-M., Wang Y.-X., Shi D.-W., Lin G.-Y., Yu X.-B., Chen F.

View author addresses

TABLE 3 | Simulated probability of attaining linezolid trough concentrations associated with efficacy and toxicity stratified by renal function.

Linezolid dosage regimen	%Probability			
	CrCL <30 ml/min	CrCL 30–59 ml/min	CrCL 60–89 ml/min	CrCL ≥90 ml/min
600 mg q24h	76.30	**84.17**	59.47	48.30
600 mg q12h	49.13	56.90	**81.20**	**79.33**
600 mg q8h	0.33	1.43	24.13	29.8
450 mg q24h	**88.40**	81.17	48.30	32.30
450 mg q12h	67.97	66.57	71.33	61.10
450 mg q8h	3.13	10.27	39.67	63.43
300 mg q24h	76	56.67	20.93	14.4
300 mg q12h	81.10	69.27	53.33	38.40
300 mg q8h	26.67	47.50	65.07	77.80

Abbreviations; CrCL, estimated creatinine clearance (CrCL) calculated using the Cockcroft–Gault equation.
The bold values are the values with the highest PTA of the dosage regimen stratified by renal function.

Otros antibióticos

Teicoplanina, colistina, beta-lactámicos…

Clinical Pharmacokinetics (2021) 60:1495–1508
https://doi.org/10.1007/s40262-021-01063-5

REVIEW ARTICLE

Clinical Pharmacokinetics and Pharmacodynamics of Cefiderocol

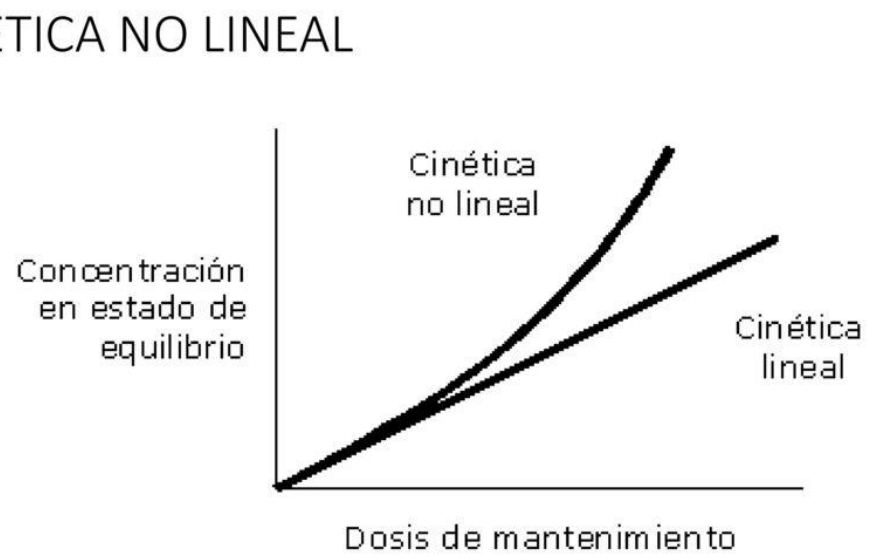
Muhammad Bilal[1,2] · Lobna El Tabei[1] · Sören Büsker[1] · Christian Krauss[1] · Uwe Fuhr[1] · Max Taubert[1]

Accepted: 26 July 2021 / Published online: 22 August 2021

Abstract
Cefiderocol is a new broad-spectrum cephalosporin antibiotic with promising activity against various Gram-negative bacteria including carbapenem-resistant strains. A chlorocatechol group in the C-3 side chain provides cefiderocol with a siderophore activity, improving its stability against β-lactamases and facilitating the transportation of cefiderocol across outer bacterial membranes. Cefiderocol shows linear pharmacokinetics over a broad range of clinically relevant doses, with unchanged renal excretion constituting the main route of elimination. Geometric means (coefficient of variation) of the volume of distribution and clearance in individuals with normal kidney function were 15.8 (15%) L and 4.70 (27%) L/h, respectively. In patients with end-stage renal disease, clearance was 1.10 (24%) L/h. Time above the minimum inhibitory concentration is the main predictor of efficacy. There is no evidence for clinically relevant interactions of cefiderocol with other drugs mediated by metabolizing enzymes or drug transporters. Simulations based on population pharmacokinetic modeling suggest that dosing regimens should be adjusted based on kidney function to optimize therapeutic exposure to cefiderocol. Clinical efficacy trials indicated that cefiderocol is non-inferior to imipenem/cilastatin in the treatment of complicated urinary tract infections and acute uncomplicated pyelonephritis, and to meropenem in the treatment of nosocomial pneumonia. In the one study currently available, cefiderocol performed similarly to the best available therapy in the treatment of severe carbapenem-resistant Gram-negative infections regarding clinical and microbiological efficacy. In summary, cefiderocol shows favorable pharmacokinetic/pharmacodynamic properties and an acceptable safety profile, suggesting that cefiderocol might be a viable option to treat infections with bacteria resistant to other antibiotics.

Voriconazol

Cmin – Eficacia/Toxicidad.
MT [1,5 – 5,5] mcg/mL. Cinética no lineal
Monitorización 5º-7º día



Pauta oral: Carga 400mg c/12h X2. Mantenimiento 200mg c/12h
Pauta IV: Carga 6mg/kg/12h X2. Mantenimiento 4mg/kg/12h.

Importancia determinación farmacogenética

ANÁLISIS CLÍNICOS / BIOQUÍMICA CLÍNICA

GENÉTICA

Unidad de Referencia Regional de Diagnóstico Avanzado de Enfermedades Raras

Centro de Referencia Nacional CSUR de Cardiopatías Familiares

Debido a la complejidad y las potenciales implicaciones se recomienda que las pruebas genéticas se acompañen del correspondiente consejo genético. Los estudios de DNA no constituyen pruebas definitivas en todos los individuos. Deben tenerse en cuenta posibles factores como variantes genéticas raras que puedan interferir en el análisis. Imprecisiones en los antecedentes familiares pueden dar lugar a inexactitudes diagnósticas.

Metabolización farmacológica:

- Análisis Farmacogenético:

Este estudio farmacogenético predice una modificación de la actividad de CYP1A2, CYP2B6, CYP2C19, CYP3A5 y MDR1.

- Gen CYP2C19:

Heterocigoto CYP2C19 *1/*17. Actividad enzimática incrementada. Predicción Fenotípica: Metabolizador Ultrarrápido

ANALISIS DE SANGRE

PRUEBA	MEDIDA	UNIDAD	VALORES DE REFERENCIA
FARMACOLOGÍA			
VORICONAZOL	4.7	µg/mL	
COMENTARIO FARMACOCINETICO	(!)		

Concentración de voriconazol (4,7 mcg/mL) dentro del margen terapéutico, concordante con pauta posológica actual. Se recomienda mantener la misma pauta posológica de 350-0-400mg IV. Repetir monitorización en 7 días. Un saludo.

Otros antifúngicos

Isavuconazol: Cmin – Eficacia/Toxicidad. MT [1 – 4.5] mcg/mL

REVIEW ARTICLE

Antifungal Drugs TDM: Trends and Update

Kably, Benjamin PharmD[*,†]; Launay, Manon PharmD, PhD[‡]; Derobertmasure, Audrey MSc[*]; Lefeuvre, Sandrine PharmD, PhD[§]; Dannaoui, Eric MD, PhD[†,¶]; Billaud, Eliane M. PharmD, PhD[*,†]

Author Information

Therapeutic Drug Monitoring: February 2022 - Volume 44 - Issue 1 - p 166-197
doi: 10.1097/FTD.0000000000000952

TDM seems to be crucial for curative and/or long-term maintenance treatment in highly variable patients. TDM poses fewer cost issues than the drugs themselves or subsequent treatment issues. The integration of clinical pharmacology into multidisciplinary management is now increasingly seen as a part of patient care.

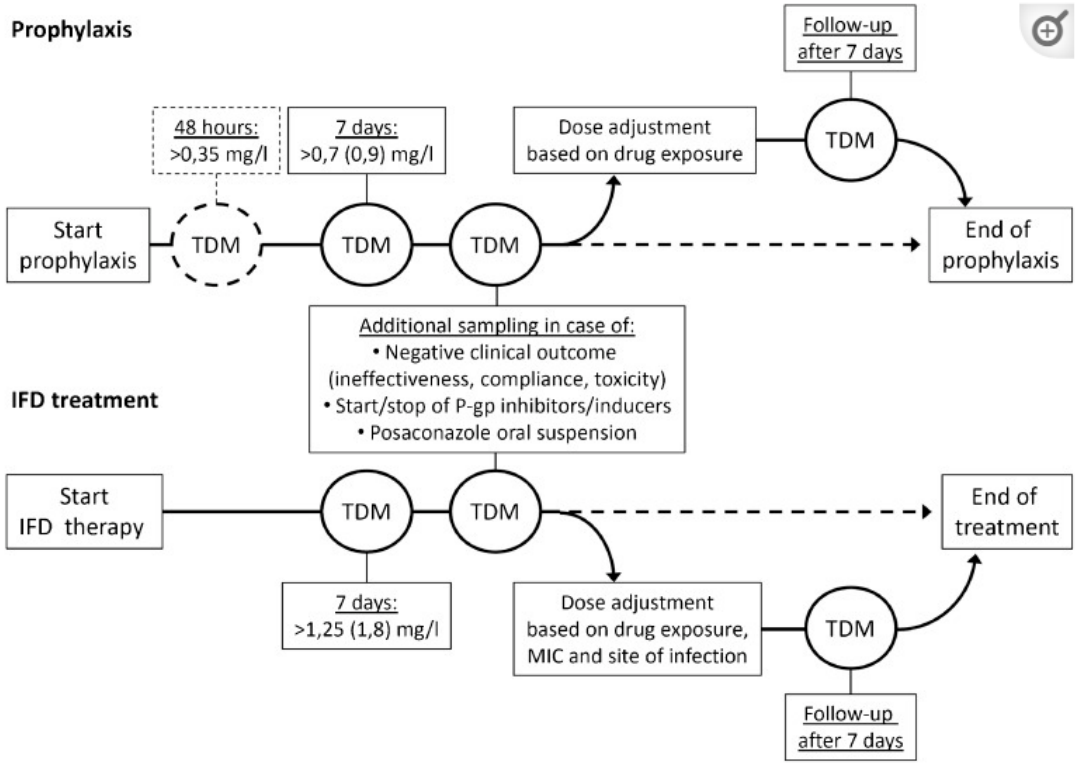
Posaconazol: Cmin – Eficacia/Toxicidad. MT >0,7-1 mcg/mL

PMC full text:

Curr Fungal Infect Rep. 2016; 10: 51–61.

Published online 2016 May 7. doi: 10.1007/s12281-016-0255-4

Fig. 1



Therapeutic drug monitoring (TDM) of posaconazole. TDM is recommended after 7 days of treatment for posaconazole in case of the salvage treatment of invasive fungal

EQUINOCANDINAS:

- Eficacia dependiente de concentración.
- Toxicidad independiente de concentración.

REVIEW ARTICLE

Therapeutic Drug Monitoring of the Echinocandin Antifungal Agents: Is There a Role in Clinical Practice? A Position Statement of the Anti-Infective Drugs Committee of the International Association of Therapeutic Drug Monitoring and Clinical Toxicology

Kim, Hannah Yejin PhD[*,†,‡]; Baldelli, Sara ChemD[§]; Märtson, Anne-Grete PhD[¶]; Stocker, Sophie PhD[**,††]; Alffenaar, Jan-Willem PhD[*,†,‡]; Cattaneo, Dario PhD[§,††]; Marriott, Deborah J.E. FRACP[**,‡‡]

Author Information

Factor	Anidulafungin		Rezafungin	
	Pharmacokinetic effect	Dose adjustment recommendation	Pharmacokinetic effect	Dose adjustment recommendation
Critical illness	Suboptimal drug exposure (approximately 30% lower compared with healthy subjects)	Dose increase implied, but not defined	Not available	Not defined
Liver impairment	No clinically significant effect reported	None	Not available	Not defined
Hypoalbuminemia	No clinically significant effect reported	None	Not available	Not defined
Hyperbilirubinemia	No clinically significant effect reported	None	Not available	Not defined
Renal impairment	No clinically significant effect reported	None	Not available	Not defined
Intermittent hemodialysis	Not available	Not defined	Not available	Not defined
CRRT	No clinically significant effect reported	None	No clinically significant effect reported	None
ECMO	No clinically significant effect reported	None	Not available	Not defined
Obesity	Limited data: Decreased AUC by 25%–35% in patients with BMI >40 kg/m^2 (or BW 140 kg) compared with the general population.	Not defined in current PI, but some suggest increased loading and maintenance doses by 25% in patients >140 kg	Not available	Not defined

FARMACOCINETICA CLINICA

Servicio de Farmacia. Complejo Asistencial de Zamora. Tfno. 48687

Nombre: _____

Apellidos: _____

NHC: _____

Edad:

Peso:

Talla:

Dr.: _____

Servicio: _____

Fecha: _____

Diagnóstico: _____

Motivo de la petición: _____Efectos secundarios: No☐ Si☐ _____

Datos analíticos. Fecha: __/__/__

Cr: _____ ClCr: _____ Urea: _____

K: _____ Albúmina: _____ PCR: _____

Ultima dosis:
Fecha: __/__/__ Hora: _____
Tiempo de infusión: _____

Extracción:
Fecha: __/__/__ Hora: _____
Enfermera responsable: _____

Medicamento	Vía	Dosis (mg) Horario de administración	Inicio de tratamiento	Margen terapéutico	Concentración determinada
Adalimumab				Cmin: 5-12 µg/mL	
Amicacina				Cmin: 1-4 µg/mL; Cmax: 25-35µg/mL	
Carbamazepina				Cmin: 4-12µg/mL	
Ciclosporina				Cmin: 100-300 ng/mL	
Digoxina				Cmin: 0,6-1,2 ng/mL	
Everólimus				Cmin: 3-8 ng/mL	
Fenitoina				Cmin: 10-20 µg/mL	
Fenobarbital				Cmin: 15-40 µg/mL	
Gentamicina				Cmin: 0,5-1,5 µg/mL; Cmax: 6-12 µg/mL	
Infliximab				Cmin (sem14): 5-10 µg/mL Cmin (>sem14): 3-10 µg/mL	
Metotrexato				C24h <10^{-5}M / C48h <10^{-6}M / C72h <10^{-7}M	
Sirólimus				Cmin: 5-15 ng/mL	
Tacrolimus				Cmin: 5-15 ng/mL	
Teofilina				Cmin: 10-20 µg/mL	

Futuro ¿próximo?

Integración farmacogenética – farmacocinética – clínica.

5. Ideas a llevarnos a casa

- Variabilidad farmacocinética → Individualización posológica
- Importancia del tiempo de muestreo
- Siempre que sea posible, evitar sacar niveles a través de vías de administración
- Adjuntar el volante de farmacocinética facilita el trabajo y disminuye errores
- Cuando un tratamiento se suspenda… anular también solicitud de monitorización. Tiempo y dinero

¡MUCHAS GRACIAS!

alvarocorral@saludcastillayleon.es
Ext. 48687