

■ **BERICHTE + ANALYSEN + MEINUNGEN**

Wie Modellierung und Simulation evidenzbasierte Dosisindividualisierung unterstützen kann

Einfluss der Populationspharmakokinetik auf Dosierungsempfehlungen aus Leitlinien

Dr. André Schäftlein, Universität des Saarlandes, Saarbrücken

Literaturverzeichnis

1. Höffken G, Lorent J, Kern W, Welte T, Bauer T, editors. S3-Leitlinie zu Epidemiologie, Diagnostik, antimikrobieller Therapie und Management von erwachsenen Patienten mit ambulant erworbenen tiefen Atemwegsinfektionen: Kurzfassung. 2. ed. Stuttgart.
2. Zhang J, Xu J, Liu Y-B, Xiao Z, Huang J-A, Si B, et al. Population pharmacokinetics of oral levofloxacin 500 mg once-daily dosage in community-acquired lower respiratory tract infections: results of a prospective multicenter study in China. *J Infect Chemother*. 2009;15:293–300.
3. Tanigawara Y, Nomura H, Kagimoto N, Okumura K, Hori R. Premarketing population pharmacokinetic study of levofloxacin in normal subjects and patients with infectious diseases. *Biol Pharm Bull*. 1995;18:315–20.
4. Preston SL, Drusano GL, Berman AL, Fowler CL, Chow AT, Dornseif B, et al. Levofloxacin population pharmacokinetics and creation of a demographic model for prediction of individual drug clearance in patients with serious community-acquired infection. *Antimicrob Agents Chemother*. 1998;42:1098–104.
5. Schäftlein A. Neue Wege in der Modellierung von Mikrodialysatdaten im Menschen: Charakterisierung der klinischen ADMER-Prozesse von Moxifloxacin, Levofloxacin und Linezolid in Gesunden und Hochrisikopopulationen. 2013.
6. FDA. Guidance for Industry Population Pharmacokinetics Guidance for Industry Population Pharmacokinetics. 1999;(February).
7. Beal SL. Population pharmacokinetic data and parameter estimation based on their first two statistical moments. *Drug metabolism reviews* [Internet]. 1984 Jan [cited 2013 Jul 21];15(1-2):173–93. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/6745081>
8. Tornøe CW, Agersø H, Jonsson EN, Madsen H, Nielsen HA. Non-linear mixed-effects pharmacokinetic/pharmacodynamic modelling in NLME using differential equations. *Computer*

methods and programs in biomedicine [Internet]. 2004 Oct [cited 2013 Jul 21];76(1):31–40. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/15313540>

9. Drusano GL, Forrest A, Snyder MJ, Reed MD, Blumer JL. An evaluation of optimal sampling strategy and adaptive study design. *Clinical Pharmacology and Therapeutics* [Internet]. 1988 Aug [cited 2016 Jan 19];44(2):232–8. Available from: <http://doi.wiley.com/10.1038/clpt.1988.142>
10. Beal SL, Boeckmann AJ, Lewis B, Sheiner LB. *NONMEM Users Guide*. Ellicott City; 2010.
11. *Monolix Users Guide version 4.3.2*. 2014; Available from: <http://www.lixoft.eu/wp-content/resources/docs/UsersGuide.pdf>
12. Bates D, Maechler M, Bolker B, Team RDC, editors. *Lme4: Mixed-effects Modeling with R*. Wien; 2012.
13. Wann LS, Curtis AB, January CT, Ellenbogen KA, Lowe JE, Estes NAM, et al. 2011 ACCF/AHA/HRS focused update on the management of patients with atrial fibrillation (updating the 2006 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* [Internet]. 2011 Jan 4 [cited 2016 Jan 19];123(1):104–23. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21173346>
14. January CT, Wann LS, Alpert JS, Calkins H, Cleveland JC, Cigarroa JE, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Circulation* [Internet]. 2014 Apr 10 [cited 2014 Dec 2]; Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24682347>
15. Connolly SJ, Ezekowitz MD, Yusuf S, Eikelboom J, Oldgren J, Parekh A, et al. Dabigatran versus warfarin in patients with atrial fibrillation. *The New England Journal of Medicine* [Internet]. 2009 Sep 17 [cited 2015 Feb 21; 361(12):1139–51. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19717844>
16. Lehr T, Haertter S, Liesenfeld K-H, Staab A, Clemens A, Reilly PA, et al. Dabigatran etexilate in atrial fibrillation patients with severe renal impairment: dose identification using pharmacokinetic modeling and simulation. *Journal of clinical pharmacology* [Internet]. 2012 Sep [cited 2016 Jan 19];52(9):1373–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21956604>
17. Mueck W, Lensing AWA, Agnelli G, Decousus H, Prandoni P, Misselwitz F. Rivaroxaban: population pharmacokinetic analyses in patients treated for acute deep-vein thrombosis and exposure simulations in patients with atrial fibrillation treated for stroke prevention. *Clinical pharmacokinetics* [Internet]. 2011 Oct [cited 2015 Dec 16];50(10):675–86. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21895039>
18. Bayer AG. *Xarelto® 20 mg Fachinformation*. 2015.
19. Salazar DE, Mendell J, Kastrissios H, Green M, Carrothers TJ, Song S, et al. Modelling and simulation of edoxaban exposure and response relationships in patients with atrial fibrillation. *Thrombosis and haemostasis* [Internet]. 2012 May [cited 2016 Jan 19];107(5):925–36. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22398655>

20. Daiichi sankyo. Lixiana 15 mg Fachinformation. 2015.
21. Wicha SG, Kees MG, Solms A, Minichmayr IK, Kratzer A, Kloft C. TDMx: a novel web-based open-access support tool for optimising antimicrobial dosing regimens in clinical routine. International journal of antimicrobial agents [Internet]. 2015 Apr [cited 2016 Jan 20];45(4):442–4. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25631677>

ENDE