Gentamicin Population Pharmacokinetics in Pediatric Patients-A Prospective Study with Data Analysis Using the saemix Package in R.

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The aminoglycoside gentamicin is used for the empirical treatment of pediatric infections. It has a narrow therapeutic window. In this prospective study at University Children's Hospital Zurich, Switzerland, we aimed to characterize the pharmacokinetics of gentamicin in pediatric patients and predict plasma concentrations at typical recommended doses. We recruited 109 patients aged from 1 day to 14 years, receiving gentamicin (7.5 mg/kg at age $\geq$ 7 d or 5 mg/kg). Plasma levels were determined 30 min, 4 h and 24 h after the infusion was stopped and then transferred, together with patient data, to the secure BioMedIT node Leonhard Med. Population pharmacokinetic modeling was performed with the open-source R package saemix on the; SwissPK; cdw; platform in Leonhard Med. Data followed a two-compartment model. Bodyweight, plasma creatinine and urea were identified as covariates for clearance, with bodyweight as a covariate for central and peripheral volumes of distribution. Simulations with 7.5 mg/kg revealed a 95% CI of 13.0-21.2 mg/L plasma concentration at 30 min after the stopping of a 30-min infusion. At 24 h, 95% of simulated plasma levels were <1.8 mg/L. Our study revealed that the recommended dosing is appropriate. It showed that population pharmacokinetic modeling using R provides high flexibility in a secure environment.

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