

TITLE

Bias and precision of two designing regimens programs: a comparison of PKclin versus PKS

AUTORS

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1. BACKGROUND AND OBJECTIVE

Pharmacokinetics programs are used for designing regimens to individual patients. Therefore, this study compares the prediction capacity of PKClin v3 versus PKS v1.10.

2. DESIGN

A demographic data for 36 adult “patients” (38.8±10.4 y/o) was simulated. Using NONMEM V individual pharmacokinetic parameters and plasma concentrations for gentamicin 240 mg daily, for before (Cmin) and after (Cmax) the 4th dose were simulated for this population. For each patient, individual plasma concentrations were fitted using both programs (PKClin v3 and PKS v1.10); statistical validation using paired t-test ($p < 0.005$) was established.

3. SETTINGS

Both programs fit the data using a monocompartmental model with simplex algorithm and Bayesian method. In order to show the differences between the pharmacokinetic parameters and plasma concentrations, precision and bias were obtained.

4. MAIN OUTCOME MEASURES

Individual values of clearance (Cl) and distribution volume (Vd) were obtained. Therefore these parameters allowed to predict Cmin and Cmax for each patient.

5. RESULTS

The paired t-test showed statistical differences between both programs for evaluated parameters. On the one hand, PKclin improved the bias of Cl (PKclin 10%, PKS 19%; PKclin is 47% better than PKS) and the precision of Vd (PKclin 2.05 L, PKS 2.54 L; PKclin is 20% better than PKS). On the other hand, Pkclin showed improvements in the bias of Cmin (54%) and in the precision of Cmin (69%), but with a worse bias in Cmax (50%).

6. CONCLUSIONS

Both programs predict with tolerable bias and precision pharmacokinetic parameters and levels of gentamicin. Therefore, both could be used to design individualization regimens.