Research and Reviews: Drug Delivery

Methods and Examples of Clinical Pharmacodynamics and Pharmacokinetic Studies

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Perspective

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ABOUT THE STUDY

The quantitative study of the link between drug exposure (concentrations or dose) and pharmacologic or toxicologic responses is known as pharmacodynamics. To explain the dose-concentration-response time course, PK/PD analysis integrates PK and PD model components. Because dose and time-dependent effects on PK and responses are common in biopharmaceuticals, PK/PD models are especially useful. PK/PD models for biopharmaceuticals (including small molecules) have advanced in sophistication, and newer mechanistic PK/PD models can contain essential features of physiology that allow extrapolation across species and disease indications. PK/PD models can also be used to simulate and test potential drug effects on biology, which is especially useful in early molecule design and engineering for "biobetter" molecules with improved molecule characteristics (i.e. stability, improved FcRn binding) or target interactions (i.e. improved affinity, different binding epitope).

A large number of investigations have discovered that after a concentration of four to five times the organism's MIC is attained, vancomycin's bactericidal action is concentration independent. Finding a pharmacodynamic metric that can predict vancomycin treatment success has been difficult, but clinical investigations suggest that the 24 hour AUC/MIC ratio is the strongest predictor of efficacy. Higher rates of clinical success and faster bacterial eradication were linked to an AUC_{24}/MIC ratio of 400.55 in patients with MRSA pneumonia. However, no correlation was discovered between percentage of time above the MIC and response in this trial.

The following considerations should be taken into account when interpreting data from investigations on vancomycin pharmacodynamics: Because vancomycin susceptibility is determined by methods that differ significantly from the standard broth microdilution method (e.g., Etest vancomycin MICs are onefold or 0.5-1.5 log_2 dilution higher than broth microdilution MICs, whereas automated methods like Sensititre (Thermo Scientific/TREK Diagnostic Systems; Oakwood, OH) and Vitek-2 (BioMérieux, Durham, NC) tend to underestimate the MICs value); Because AUC is not computed in practical practise, trough level is employed as a surrogate marker; in patients with serious infections, particularly those caused by MRSA, vancomycin levels may be used to change the dose to achieve the target serum level; For less serious MRSA infections, such as most Acute Bacterial Skin and Skin Structure Infections (ABSSSI), optimal optimization of vancomycin dose does not appear to be required; dosing based on renal function and actual patient weight appears to be acceptable. It is not suggested to measure the peak value; Low trough vancomycin levels (less than 10 g/mL) have been linked to the emergence of hVISA isolates.

The IDSA, the American Society of Health-System Pharmacists, and the Society of Infectious Diseases Pharmacists published a consensus in 2009 that recommends a trough vancomycin concentration of 15 to 20 g/mL for serious MRSA infections like endocarditis, bacteremia, arthritis, osteomyelitis, meningitis, pneumonia, and severe ABSSSI. 56 The recommended goal plateau concentration for people taking vancomycin as a continuous infusion has been 20 to 25 g/mL.

The suggested trough serum levels of 15 to 20 g/mL have been linked to a 24 hour AUC (standard deviation) of 418 152,46, resulting in a vancomycin AUC/MIC ratio of 400 if the infecting strain's MIC is 1 g/mL. In patients with normal renal function, a vancomycin dose of 15 to 20 mg/kg every 8 to 12 hours is usually sufficient to achieve these levels. Indeed, a recent prospective study discovered that dosing vancomycin based on AUC calculation rather than through concentration was linked to decreased rates of nephrotoxicity, shorter therapy duration, and overall vancomycin exposure.