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Importance of Bioavailability and Bioequivalence of Drugs

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INTRODUCTION

Bioavailability refers to the extent and speed with which the active part (drug or metabolite) enters the systemic circulation and thus accesses the site of action. Chemical equivalence indicates that the medicines contain the same active ingredient in the same quantity and meet current official standards; however, the inactive ingredients in medicines may differ. Bioequivalence indicates that pharmaceutical products, when administered to the same patient at the same dosage regimen, result in equivalent concentrations of the drug in plasma and tissues. Therapeutic equivalence means that drugs, when given to the same patient on the same dosing schedule, have the same therapeutic and adverse effects. The bioavailability of a drug is largely determined by the properties of the dosage form, which partly depend on its design and manufacture. Differences in bioavailability between formulations of a particular drug can have clinical significance; therefore it is essential to know whether drug formulations are equivalent.

DESCRIPTION

Bioequivalent products must be therapeutically equivalent. Therapeutic non-equivalence (eg: more side effects, less efficacy) is usually identified during long-term treatment when patients stabilized on one formulation receive a non-equivalent substitute. Chemical reactions that reduce absorption can reduce bioavailability. They include complex formation (eg: between tetracycline and polyvalent metal ions), hydrolysis by gastric acid or digestive enzymes (eg: hydrolysis of penicillin and chloramphenicol palmitate), conjugation in the gut wall (eg: sulfoconjugation of isoproterenol), adsorption to other drugs (eg: digoxin to cholestyramine) and metabolism by luminal micro flora. Insufficient time for absorption in the gastrointestinal (GI) tract is a common cause of low bioavailability.

Oral bioavailability is the fraction of an orally administered drug that reaches the systemic circulation. After intravenous administration, a drug is immediately and completely available in the bloodstream and can be distributed through the systemic circulation to the point where a pharmacological effect occurs. When a drug is administered orally, it must cross other barriers to reach systemic circulation, which can significantly reduce the final volume of a drug in the bloodstream. Oral bioavailability is one of the most important properties in drug design and development. The high oral bioavailability reduces the amount of an administered drug needed to achieve the desired pharmacological effect and thus could reduce the risk of side effects and toxicity. Low oral bioavailability can result in low efficacy and greater inter-individual variability, leading to unpredictable drug responses.

CONCLUSION

The plasma concentration of the drug increases with the degree of absorption; the maximum (peak) plasma concentration is reached when the rate of elimination of the drug is equal to the rate of absorption. Determining bioavailability based on peak plasma concentrations can be misleading because drug elimination begins as soon as the drug enters the bloodstream. Peak time (when peak plasma drug concentration occurs) is the most widely used general index of absorption rate; the slower the absorption, the later the rush hour. For drugs that are primarily excreted unchanged in the urine, bioavailability can be estimated by measuring the total amount of drug excreted after a single dose. Ideally, urine is collected over a period of 7-10 elimination half-lives to achieve complete urinary recovery of absorbed drug. After multiple administrations, the bioavailability can be estimated by measuring the unchanged active substance recovered in the urine over a 24 hour period at steady state.

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CONFLICT OF INTEREST

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