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Bioavailability: An Overview

Victoria Arama*

Department of Pharmaceutical Microbiology, Faculty of Pharmacy, University of Medicine and Pharmacy, Bucharest, Romania

Editorial

A drug's bioavailability is an average number; to account for population variability, the deviation range is provided as. The bottom value of the deviation range is used to represent true bioavailability and to compute the drug dose required for the drug taker to obtain systemic concentrations comparable to the intravenous formulation. Unless the medicine is associated with a tight therapeutic window, the bottom value of the deviation range is utilised to dose without knowing the drug taker's absorption rate in order to assure the intended efficacy [1].

Definitions

In nutritional science: The idea of bioavailability lacks the well-defined standards associated with the pharmaceutical sector in nutritional research, which encompasses the intake of nutrients and non-drug dietary elements. Because utilisation and absorption are influenced by the subject's nutritional status and physiological state, the pharmacological definition does not apply to these drugs, resulting in even greater variances between individuals (inter-individual variation). As a result, bioavailability for dietary supplements is defined as the percentage of the provided chemical that can be absorbed and used or stored [1].

In environmental sciences or science: The term "bioavailability" refers to the ability of various substances in the environment to enter living organisms. It is frequently a limiting factor in crop output (due to solubility limitations or plant nutrient absorption to soil colloids) and in microbes' elimination of harmful chemicals from the food chain (due to sorption to or partitioning of otherwise degradable substances into inaccessible phases in the environment). Plant phosphorus deficit caused by precipitation with iron and aluminium phosphates at low soil pH and precipitation with calcium phosphates at high soil pH is a notable example for agriculture. Excess phosphorus fertilisers may render toxic elements in soil, such as lead from paint, inaccessible to animals ingesting polluted soil [1].

Absolute bioavailability: Absolute bioavailability compares the active drug's bioavailability in systemic circulation after non-intravenous administration (i.e., oral, buccal, ophthalmic, nasal, rectal, transdermal, subcutaneous, or sublingual administration) to the same drug's bioavailability after intravenous administration. It is the percentage of a medicine that is absorbed via non-intravenous administration versus intravenous administration of the same drug. The comparison must be dose normalised (for example, to account for differing doses or subject weights), thus the amount absorbed is rectified by dividing the matching dose administered.

Although understanding the exact degree of systemic absorption (also known as absolute bioavailability) is definitely beneficial, it is not determined as frequently as one might believe in practise. This is because it requires an intravenous reference, which is a route of administration that ensures that all of the delivered medicine reaches systemic circulation. Such investigations are expensive, not least because preclinical toxicity tests are required to assure acceptable safety, as well as the possibility of issues due to solubility constraints. However, these restrictions can be circumvented by combining a very low dose (usually a few micrograms) of an isotopically labelled medication with a therapeutic non-isotopically labelled oral dose.

Because of their differing isotopic constitutions, the intravenous and oral concentrations can be deconvoluted and used to determine the oral and intravenous pharmacokinetics from the same dosage administration. This method removes non-equivalent clearance pharmacokinetic concerns while also allowing the intravenous dose to be supplied with minimal toxicity and formulation. The approach was first used using stable isotopes like 13C and mass spectrometry to discriminate between the isotopes based on mass difference. In recent years, 14C-labeled medications have been given intravenously, with Accelerator Mass Spectrometry (AMS) being utilised to assess the isotopically tagged drug alongside mass spectrometry for the unlabelled drug.

Although there is no regulatory requirement to define intravenous pharmacokinetics or absolute bioavailability, regulatory authorities do occasionally request absolute bioavailability data from the extravascular route when bioavailability appears to be low or variable and there is a proven relationship between pharmacodynamics and pharmacokinetics at therapeutic doses. In all of these circumstances, doing an absolute bioavailability study necessitates giving the drug intravenously [2,3].

Factors influencing bioavailability

When a medicine is given by an extravascular route, its absolute bioavailability is frequently less than one (F 100 percent). Several physiological processes diminish medication availability before they enter the systemic circulation. Other medications taken concurrently may change absorption and first-pass metabolism, intestinal motility affects drug dissolution and may affect the degree of chemical breakdown of the drug by intestinal bacteria. Diseases that alter liver metabolism or gastrointestinal function will have an impact as well [4].

Other considerations could include, but are not limited to:

- The drug's physical characteristics (hydrophobicity, pKa, solubility)
- Modified release - delayed release, extended release, sustained release, etc.)
- Whether the formulation is given while eating or fasting
- Rate of gastric emptying
- Circadian variations

Bioavailability of drugs *vs.* dietary supplements

There are substantial variances in dietary supplements that effect the evaluation of their bioavailability when compared to medications. The following are some of the differences: nutritional supplements are consumed for prevention and well-being; nutritional supplements do not exhibit characteristic dose-response curves; therefore, in contrast to drug therapy, dosing intervals for nutritional supplements are not critical.

Furthermore, in compared to medicines, the application of bioavailability

***Address for Correspondence:** Victoria Arama, Department of Pharmaceutical Microbiology, Faculty of Pharmacy, University of Medicine and Pharmacy, Bucharest, Romania, E-mail: arama_v@gmail.com*

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assessments is hampered by the lack of defined methodology and restrictions surrounding the usage of dietary supplements. Bioavailability in dietary supplement clinical trials focuses mostly on statistical descriptions of mean or average AUC changes between treatment groups, with little attention paid to standard deviations or inter-individual variation. This failure raises the question of whether an individual in a group will benefit from the mean-difference comparisons. Furthermore, even if this issue were discussed, communicating the meaning of these inter-subject differences to customers and/or their physicians would be challenging [5].

Conflict Of Interest

None.

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