People with obesity are not appropriately included in clinical trials for drug approval, leading to incomplete data on the safety and effectiveness of drugs in this population.

Abstract

Obesity is associated with several comorbidities such as Type 2 Diabetes, hypertension, dyslipidemia, cancers, depression, and anxiety. Treatment of obesity and its comorbidities often require the use of prescription drugs, many of which have not been fully evaluated in people with obesity. Despite a growing body of research on this topic, the impact of obesity on the pharmacokinetics and pharmacodynamics of drugs is often under-studied by drug sponsors and regulators.

We conducted a survey of clinicaltrials.gov to assess the presence of weight- or BMI-based Inclusion/Exclusion criteria in studies of investigational drugs in 2022 as well as the scientific literature to assess whether pharmacokinetic studies have been conducted in people with obesity for a variety of commonly used drugs. We then examined whether pharmacokinetic changes were determined to be clinically relevant and if specific changes to clinical practice were recommended.

Over half of studies listed on clinicaltrials.gov in 2022 did not mention weight or BMI; when it was listed as an inclusion/exclusion criterion, it was most often used to exclude people with obesity. We also present examples in which changes to drug dosing information for patients with obesity should be made. We highlight serious gaps between what is known about the effects of obesity on drug disposition and the current use of drugs according to drug prescribing information and clinical practice.

Conclusions

There is currently no requirement to test drugs in people with obesity during the drug approval process, even when preliminary data suggests there may be altered kinetics in this population. When clinical trials Include or Exclude patients based on weight or BMI, people with obesity are Excluded from over 75% of trials. The lack of information, and subsequent underappreciation by clinicians and caretakers, on the safe and effective use of drugs in people with obesity may be contributing to poorer health outcomes in this population.

Incomplete Data and Potential Risks of Drugs in People with Obesity

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