

# Geriatric clinical pharmacology and clinical trials in the elderly

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The aging process is linked to changes in the physiological function of organs and changes in body composition that alter the pharmacokinetics of drugs and pharmacodynamic responses. Comorbidity and polypharmacy in the elderly decreases tolerability of drugs, leading to greater vulnerability to adverse drug reactions than that observed in younger adults. In geriatric pharmacotherapy, the general recommendation is dose reduction and slow titration, which is based on pharmacokinetic considerations and concern for adverse drug reactions, rather than clinical trial data. Older patients are under-represented in clinical trials. In the absence of evidence, extrapolation of risk-benefit ratios from younger adults to geriatric populations is not necessarily valid. Sound evidence through prospective clinical trials is essential, and geriatric societies, governments, and patient advocacy groups should collaborate to promote the inclusion of older people in clinical trials. It is believed that all involved in clinical trials have both an obligation and an opportunity to eliminate age discrimination in clinical trial practice.

## Introduction

The most important and common medical intervention in the elderly is drug therapy. Due to unprecedented increases in the proportion of elderly people in a population, an understanding of geriatric pharmacology has become very important for drug therapy in elderly patients. In addition to drug treatment itself for medical problems caused by aging, such as dementia and degenerative diseases, elderly patients experience many treatment-related problems compared with younger patients. Examples of such problems include reduction in physiological function, change in pharmacokinetics/pharmacodynamics, and vulnerability to adverse drug reactions, polypharmacy, drug interactions, and low compliance. Understanding the various factors that affect drug treatment outcomes in the elderly requires knowledge of basic and clinical pharmacology of geriatrics. Using this knowledge, attention should be applied to providing appropriate drug therapy.[1]

Organ function is reduced and body composition is altered with age. The pharmacokinetic processes of absorption, distribution, metabolism, and excretion differ compared with young

adults. Moreover, the elderly have greater risk of disease because of the aging process, which is accompanied by multiple chronic conditions. Drug tolerability decreases, while patients are often exposed to multiple drugs. Therefore, elderly patients are much more vulnerable to adverse drug reactions than younger adults. The fifth most common cause of hospitalization in elderly patients is related to drug use, and accounts for approximately 20% of hospitalizations.[2] Concomitant use of more than 5 drugs (polypharmacy) is observed in 20 to 40% of elderly patients.[3] Thus, the risk of adverse drug events due to drug-drug interactions is high. In addition, it is common to administer new drugs to elderly patients for the relief of an atypical symptom without appropriate evaluations; this causes new drug-induced side effects and perpetuates a vicious circle.

Prescribing for geriatric patients requires an understanding of the efficacy of medication in older people, an assessment of the risk of adverse drug events, and a decision about the dosage regimen and careful monitoring of the patient's response. This requires an evaluation of evidence through clinical trials. Given that most diseases occur in older people, and that this patient group is the major recipients of drug therapy, more research and a better evidence base through clinical trials is essential to guide clinicians who manage geriatric patients.[4] Patients older than 65 years are not well represented in clinical trials,[5] and this under-representation impacts the care of elderly patients.[6]

# Geriatric Clinical Pharmacology

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