

Publication

Hip/femur fractures associated with the use of benzodiazepines (anxiolytics, hypnotics and related drugs): a methodological approach to assess consistencies across databases from the PROTECT-EU project

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Results from observational studies may be inconsistent because of variations in methodological and clinical factors that may be intrinsically related to the database (DB) where the study is performed.; The objectives of this paper were to evaluate the impact of applying a common study protocol to study benzodiazepines (BZDs) (anxiolytics, hypnotics, and related drugs) and the risk of hip/femur fracture (HFF) across three European primary care DBs and to investigate any resulting discrepancies.; To measure the risk of HFF among adult users of BZDs during 2001-2009, three cohort and nested case control (NCC) studies were performed in Base de datos para la Investigación Farmacoepidemiológica en Atención Primaria (BIFAP) (Spain), Clinical Practice Research Datalink (CPRD) (UK), and Mondriaan (The Netherlands). Four different models (A-D) with increasing levels of adjustment were analyzed. The risk according to duration and type of BZD was also explored. Adjusted hazard ratios (cohort), odds ratios (NCC), and their 95% confidence intervals were estimated.; Adjusted hazard ratios (Model C) were 1.34 (1.23-1.47) in BIFAP, 1.66 (1.54-1.78) in CPRD, and 2.22 (1.55-3.29) in Mondriaan in cohort studies. Adjusted odds ratios (Model C) were 1.28 (1.16-1.42) in BIFAP, 1.60 (1.49-1.72) in CPRD, and 1.48 (0.89-2.48) in Mondriaan in NCC studies. A short-term effect was suggested in Mondriaan, but not in CPRD or BIFAP. All DBs showed an increased risk with the concomitant use of anxiolytic and hypnotic drugs.; Applying similar study methods to different populations and DBs showed an increased risk of HFF in BZDs users but differed in the magnitude of the risk, which may be because of inherent differences between DBs.

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