Adverse drug reactions on sexual functioning: a systemic overview

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Background Adverse drug reactions (ADRs) that diminish sexual functioning can seriously affect a person?s quality of li fe and may also affect drug adherence. Among health care professionals knowledge and awareness for sexual ADRs and their consequences for patients might not always be sufficient. Moreover, sexual morbidity may be undertreated and not adequately discussed.
Purpose The aim of this study is to provide clinicians with a systematic overview of drugs with sexual ADRs as registered in their Summary of Products Characteristics (SmPC) and their incidence rates and to create a first step in the awareness of sexual ADRs.
Method This study is a systematic review of drugs with sexual ADRs registered in SmPCs. Search terms for sexual ADRs were selected with the Medical Dictionary for Regulatory Activities (MedDRA®). The PROTECT Adverse Drug R eaction database and the website of the Dutch national registration authority were searched with the search terms to list centrally and nationally authorised drugs that are registered with sexual ADRs. Information on incidence rate, and specifications for gender, age or a pharmacological class effect were searched in section 4.8 of the SmPCs and collected to provide a comprehensive overview.
Findings 346 drugs with at least one sexual ADR were identified. Drug class Nervous system (N) was represented most with 105 drugs, followed by the Cardiovascular system (C) with 89 drugs. For 16 drugs an incidence rate for sexual ADR of above 10% was reported and for 101 drugs an incidence rate above 1%. For the most frequently used drugs with registered sexual ADRs in the Netherlands, diclofenac and simvastatin, no incidence rates were reported in the SmPC. Differences in sexual ADRs for females and males were explicitly stated in the SmPC for 19 drugs. A pharmacological class effect was stated for 13 drug classes. However, the consistency of mentioning this pharmacological class effect in the individual SmPCs varied. The SmPCs of finasteride and dutasteride mention that treatment with these drugs could lead to permanent sexual ADRs after the treatment cessation.
Conclusion This study showed that sexual ADRs are common and occur substantially in frequently used drugs. Many sexual ADRs occur commonly in users, but only a few very commonly. Most often, the incidence is unknown. As sexual ADRs may decrease patients' quality of life and could interfere with treatment adherence, they should be addressed and considered in clinical practice to optimize drug treatment for individual patients.