5PSQ-026 THE POTENTIAL OF PHARMACOVIGILANCE DATABASES TO ASSESS TOXICOLOGICAL RISK OF DIETARY SUPPLEMENTS AND OTHER UNSUPERVISED HEALTH PRODUCTS USED BY PATIENTS

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Background and Importance When executing the medication use review or medication reconciliation, and if there is a sudden new symptom or sign of toxicity, the potential role of health products taken by patients without the supervision of the health care professionals should not be forgotten. However, there is no standardised approach to assess toxicity of these products in everyday practice.
Aim and Objectives Our aim was to search for and evaluate methods that can be added or standardised to assess illegal or unsupervised health products from toxicological perspective. We wanted to know whether there any databases that can be used and if they are eligible for this role based on information content or applicability.
Material and Methods In addition to the literature search, we identified and reviewed four Open Access databases: EudraVigilance; US FDA Adverse Events Reporting System (FAERS); US FDA CFSAN Adverse Event Reporting System (CAERS); Health Fraud Product Database. For the initial screening we chose as a model substance cannabidiol (CBD) (excluding authorised medicines) due to its popularity and potential adverse effects.
Results We identified 371 cases in the EudraVigilance database from 2021 to 2023 (2021: 126, 2022: 196, 2023: 49). Fatal cases were 7.55% of all cases (n=28). From the concomitant medications used with CBD, clobazam was the most frequent (n=16). In the FAERS database there 276 cases were registered from 2015 to 2023, with 67.4% (n=186) being severe and 2.5% (n=7) fatal. The three most common reactions identified were: General disorders and administration site conditions (n=117), Nervous system disorders (n=103) and Psychiatric disorders (n=85). In the CAERS database 163 cases were found (2016–2023) with one fatal. The most common reactions with MedDRA preferred terms were related to gastrointestinal disorders (e.g.: diarrhoea, vomiting, nausea). In the Health Fraud Product Database CBD related cases were 33 in the period of 2019–2021.
Conclusion and Relevance The application of open access databases containing pharmacovigilance and toxicovigilance data are suitable for assessing the real-world toxicity of dietary supplements and identifying high risk products. The incorporation of our results into the clinical practice can be a competency of a clinical pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-027 VARIABILITY IN VANCOMYCIN PLASMA CONCENTRATION IN NEUTROPENIC PATIENTS

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Background and Importance There are currently conflicting results in numerous studies on the effect of neutropenia on vancomycin plasma concentrations.
Aim and Objectives To evaluate the effect of neutropenia on pharmacokinetic parameters in patients treated with vancomycin.
Material and Methods Observational and retrospective study in patients treated with vancomycin in a tertiary level hospital, between July and June 2023. The clinical history was consulted and the following variables were collected: sex, age, creatinine, neutrophil count and vancomycin trough levels in blood. Neutropenic patients were considered if their levels were less than 1.5x10^9 neutrophils/L and vancomycin clearance (CLv) was calculated by the Matzke and Moellering methods. The data were processed in the SPSS v.25 statistical program: the Shapiro Wilks test was performed as a normality test and a statistical test was carried out according to the results (Student's t-test or Mann-Whitney U-test).
Results We analysed 68 samples in 37 patients; of which 17 were male and a median age of 65 [18–90] years. Patients were classified into two groups according to the number of neutrophils, eight (11%) neutropenic patients and the 60 (89%) non-neutropenic. The Shapiro Wilks normality test showed normality in all variables, however the sample size of one group made it necessary to use a non-parametric test (Mann-Whitney U test). Mean trough levels in neutropenic patients were 9.6 (SD2.96) vs. 11 (SD7.04) in non-neutropenic patients (p=0.991). The mean CLv by Matzke and Moellering methods was 107,83 (SD39) and 88 (SD2.34) respectively in the group of neutropenic patients and in non-neutropenic patients it was 105.13 (SD39.3) and 85 (SD2.21); p=0.228 in both groups.
Conclusion and Relevance Although no statistically significant differences were found, probably due to the sample size, it can be observed that the group of neutropenic patients had lower vancomycin trough levels and a higher clearance than the non-neutropenic group. Furthermore, we can conclude that both methods of calculating Clv are similar in both groups of patients. Further studies are needed to demonstrate the effect of neutropenia on vancomycin levels and its consequences on treatment efficacy.

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5PSQ-028 CASE REPORT: ANTITUMOR ACTIVITY AND TOXICITIES OF ENTRECTINIB IN A PATIENT WITH A PRIMARY CENTRAL NEUROCYTOMA

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Background and Importance Entrectinib is an oral, CNS active, potent inhibitor of tyrosine approved for use in patients with NTRK gene fusion-positive solid tumours. Here, we report the antitumour activity and safety of entrectinib in a patient with central neurocytoma, an uncommon neoplasm with few drug treatment alternatives.
Aim and Objectives To summarise the overall safety and report the antitumour activity of entrectinib in a 50 year-old female with a primary central neurocytoma initially treated with