

presented slight rash in dorsal region. The patient received one radiotherapy session. Seventeen days after starting vandetanib, he visited Emergency department for generalised erythema (on face, neck, upper and lower limbs), flushing and pruritus, related to brief sun exposure. The patient was treated with single dose intramuscular methylprednisolone and oral dexchlorpheniramine. Vandetanib and radiotherapy were discontinued. Five days later, the patient presented severe deterioration, progression of erythema and intense oedema in hands, feet and face. Deflazacort was prescribed. After diagnosis by Dermatology department of acute phototoxic eruption, treatment was started with prednisone 45 mg/day for 7 days with progressive decrease, emollients and topical methylprednisolone. Between days 26-40, gradual improvement of oedema and erythema was observed without appearance of new toxicity. Prednisone dose was reduced. Progressively, desquamation and scabs were observed on both hands, with improvement of leg and foot ulcers. Poor pain control required tapentadol 25 mg/12 hours. On day 62, there was a worsening with increased erythema since oral prednisone was reduced. Treatment with *Polypodium leucotomos*, vitamin D, C and E was initiated. On day 68, there was a significant improvement with no itchiness. Three months after symptom onset, itching and erythema had almost disappeared. Remaining hyperpigmentation of the skin was observed. Naranjo's algorithm determined a probable relationship (score 5) and reintroduction of vandetanib was discouraged.

Conclusion and Relevance Hospital pharmacist determined a probable relationship between vandetanib and severe phototoxicity reaction in a patient with MMTC. The role of hospital pharmacists is essential in pharmacovigilance and in informing patients about possible adverse events of drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-024 HAZARD VULNERABILITY ANALYSIS (HVA): EVALUATION OF RISK IN EXPERIMENTAL ONCOLOGICAL DRUGS COMPOUNDING

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Background and Importance Various clinical trials, especially in oncology and haematology, involve chemotherapeutic drugs compounding. These preparations require standard working procedures for which hospital pharmacist is responsible. Oncological drugs used in clinical trials are characterised by: low therapeutic index; unknown toxicity; dosage to be personalised on patient; assignment of number kit/placebo to specific patient; associations with other drugs not known in consolidated clinical practice. All these elements can contribute to the occurrence of potential errors.

Aim and Objectives The aim of this study is to use Hazard Vulnerability Analysis in order to classify, into high, medium, low risk, experimental protocols that provide for chemotherapeutic drugs compounding and which are currently active our hospital. For protocols classified as high risk, standard procedures will be outlined to minimise risks.

Material and Methods In order to determine the percentage risk(R%), is calculated: probability(P) that an error will occur, by calculating the number of preparation-phases; magnitude (MA) by calculating carcinogenicity, storage time of preparation and chemical incompatibility between drugs and medical devices; mitigation(MI) by calculating drug dosage, chemical-physical preparation stability, possible use of safety-devices. By applying the formula $R\% = (P/3) * [(MA+MI)/18] * 100$, protocols are defined low-risk if $R\% < 30\%$, moderate-risk if $30\% \leq R\% \leq 60\%$, High-risk if $R\% > 60\%$.

Results Among 35 active clinical-trials analysed, 18 require chemotherapeutic drugs compounding. For 33%(6/18) of protocols the probability is low; 50%(9/18) is moderate; 17%(3/18) is high. For 44%(8/18) of protocols the magnitude is low; 50%(9/18) is moderate; 6%(1/18) is high. Finally, for 6%(1/18) of protocols the mitigation is low; 88%(16/18) is moderate; 6%(1/18) is high. By applying the formula to calculate percentage risk it was found that 5/18 protocols are low risk, 10/18 moderate risk, 3/18 high risk.

Conclusion and Relevance HVA provides a systematic approach to analysing hazards that may affect hospital service. Clinical protocols classified as 'high risk' have been monitored, and standard procedures have been outlined to minimise the risks (e.g. procedures for managing vial accidental breaking, cold chain control for prepared drugs, use of software to calculate drug dosage based on body surface). These procedures are aimed at all personnel involved in preparation phase, including the hospital pharmacist. Hospital pharmacist is coordinates whole process, deals with risk management and ensures personnel/patients safety.

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5PSQ-025 IMPACT AND EVALUATION OF PHARMACOKINETIC MONITORING IN PRIMARY CARE

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Background and Importance Monitoring of narrow-margin drugs in primary care is important to optimise the efficacy and safety of treatment.

Aim and Objectives To analyse the impact of the activity and repercussions of monitoring plasma levels of antiepileptics, lithium and digoxin in primary care patients carried out by the Pharmacokinetics Area-Hospital Pharmacy Service (PA-HPS).

Material and Methods Two-month retrospective observational study of the pharmacokinetic reports of all patients who required monitoring of their plasma levels. The circuit starts with a request from the primary care physician asking for the determination of the plasma level, the blood sample is analysed by the laboratory and the PA-HPS interprets all the data from the clinical history, finally producing a pharmacokinetic report integrated in the clinical history together with the analytical.

The variables recorded from the analyses and clinical history were: age, sex, renal clearance, liver enzymes (GOT, GPT