Pharmacovigilance training for specialist oncology nurses-a two way evaluation

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[Treatment B/Treatment A] and 90% confidence intervals [CIs] for maximum plasma concentration (C_{max}) and area under the plasma concentration-time curve from zero to infinity ($AUC_{0-\infty}$) 1.39 [1.12, 1.72] and 1.96 [1.65, 2.32], respectively). In addition, there was an 11-fold increase in ACT-333679 exposure (geometric mean ratios [Treatment B/Treatment A] and 90% CIs for C_{max} and $AUC_{0-\infty}$ 3.63 [3.06, 4.31] and 11.09 [9.20, 13.36], respectively). All 20 subjects had at least 1 treatment-emergent adverse event (AE), with 15 subjects (75.0%) in Treatment A (selexipag), 3 subjects (15.0%) in Treatment B1 (gemfibrozil alone), and all subjects (100%) in Treatment B2 (gemfibrozil + selexipag). Frequently reported AEs were headache (90.0% of subjects), nausea (75.0% of subjects), and vomiting (60.0% of subjects). Most reported AEs were of mild or moderate intensity.

Conclusions: Concomitant administration of selexipag and strong inhibitors of CYP2C8 (e.g., gemfibrozil) should be avoided.

EFFECT OF RIFAMPICIN ON THE PHARMACOKINETICS OF SELEXIPAG, AN ORAL PROSTACYCLIN RECEPTOR AGONIST, AND ITS ACTIVE METABOLITE IN HEALTHY MALE SUBJECTS

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Background: Selexipag, an oral prostacyclin receptor agonist, and its active metabolite, ACT-333679, are metabolized by cytochrome P450 (CYP) 2C8. The present study aimed at investigating the effect of rifampicin, a CYP2C8 inducer, on the pharmacokinetics (PK) of selexipag and ACT-333679.

Methods: This was an open-label, randomized, two-treatment, two-period, crossover study including 20 healthy male subjects. The PK of selexipag and ACT-333679 following administration of 400 µg selexipag alone [Treatment A] or after multiple-dose rifampicin (600 mg once daily) [Treatment B] were explored. Safety variables (vital signs, electrocardiogram, and laboratory parameters) were assessed.

Results: 19 subjects completed the study as per protocol and one subject prematurely discontinued the study. Concomitant administration of selexipag and multiple-dose rifampicin led to no relevant change in exposure to selexipag (geometric mean ratios [Treatment B/Treatment A] and 90% confidence intervals [CIs] for maximum plasma concentration (C_{max}) and area under the plasma concentration-time curve from zero to infinity ($AUC_{0-\infty}$) 1.76 [1.44, 2.15] and 1.25 [1.11, 1.41], respectively) whereas exposure to the active metabolite, ACT-333679 decreased by half (geometric mean ratios [Treatment B/Treatment A] and 90% CIs for C_{max} and $AUC_{0-\infty}$ 1.30 [1.07, 1.57] and 0.51 [0.45, 0.59], respectively). A total of 12 subjects (60.0%) had at least 1 treatment-emergent adverse event (AE), with 8 subjects (40.0%) in Treatment A (selexipag), 4 subjects (20.0%) in Treatment B1 (rifampicin), and 6 subjects (31.6%) in Treatment B2 (rifampicin + selexipag). Frequently reported AEs were headache (45.0% of subjects), nausea (20.0% of subjects), and vomiting (10.0% of subjects). All AEs were of mild or moderate intensity.

Conclusions: Selexipag was well tolerated when administered concomitantly with rifampicin. The efficacy of selexipag might be reduced in the presence of a CYP2C8 inducer (e.g., rifampicin).

PHARMACOVIGILANCE TRAINING FOR SPECIALIST ONCOLOGY NURSES —A TWO WAY EVALUATION

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Background: In a new prescribing qualification course for specialist oncology nurses, we thought it important to emphasize pharmacovigilance and adverse drug reaction (ADR)-reporting. To this end, our aim was to develop and evaluate an ADR reporting assignment for specialist oncology nurses.

Methods: The quality of report documentation was assessed with the 'Clinical Documentation tool to assess Individual Case Safety Reports' (ClinDoc). The relevance of the reports was evaluated in terms of ADR seriousness, the listing for additional monitoring of the drug by European Medicines Agency (EMA), and lack of labelling information about the ADR. Nurses' opinions of the assignment were evaluated using an E-survey.

Results: Thirty-three ADRs were reported, 32 (97%) of which were well documented according to ClinDoc. Thirteen ADRs (39%) were 'serious' according to CIOMS criteria. In 5 cases (15%) the suspect drugs were listed for additional monitoring by EMA and in 7 cases (21%) the ADR was not mentioned in the Summary of Product Characteristics. Twenty-five (78%) of the 32 enrolled nurses completed the E-survey. Most were >45 years of age (68%), female (92%), and had extensive clinical experience (6-33 years). All agreed or completely agreed that the reporting assignment was useful, that it fitted in daily practice, and that it increased their attention for medication/patient safety. A large majority (84%) agreed the assignment changed how they dealt with ADRs.

Conclusions: Specialist oncology nurses are capable of reporting ADRs, and they considered the assignment useful. The assignment yielded valuable, relevant, and well-documented ADR reports for pharmacovigilance practice.

EARLY PHARMACOTHERAPY LEARNING EXPERIENCES IN A STUDENT-RUN CARDIOVASCULAR RISK MANAGEMENT PROGRAMME ARE BENEFICIAL TO STUDENTS AND PATIENTS

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Background: General practitioners (GPs) have an important role in cardiovascular risk management (CVRM), but care is often unstructured because of time constraints. Involving undergraduate medical students in CVRM could circumvent this problem, by offering patients and GPs a structured CVRM programme. Students could then benefit from a valuable early learning experience with a (shared) responsibility for patient care, including pharmacotherapy. Here, we describe and evaluate a student-run CVRM programme.

Methods: The student-run CVRM programme was set up in December 2014 to offer primary prevention for cardiovascular diseases to patients with known risk factors (age ≥50years, current/recent smoking history, previous high blood pressure/cholesterol). During a consultation, two undergraduate medical students assessed the patients' actual risk (by assessing blood pressure, height/weight, family history, and lifestyle) and formulated a CVRM plan, which they discussed with the patient after it had been approved by a GP.