FIP Seville conference abstracts 2022

80th FIP World Congress of Pharmacy and Pharmaceutical Sciences in Seville, Spain, 18 to 22 September 2022

Personalised and precision medicine

Adherence and adverse drug reactions in metastatic breast cancer patients treated with cyclin dependent kinase 4/6 inhibitors

Magdalena Krajinović[1], Lucija Benić[1], Matea Baković[2], Maja Ortner Hadžiabdić[1], Tajana Silovski[3], Natalija Dedić Plavetić[3], Miranda Sertić[1]*

[1] Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia

[2] PrimeVigilance d.o.o., United Kingdom

[3] University Hospital Centre Zagreb, Croatia

* msertic@pharma.hr

Background: Adherence to medications is crucial for an optimised clinical outcome in the management of chronic diseases. Patient beliefs about medications, side effects, cost of the medication, dosing frequency, routes of administration, comorbidities and sociodemographic factors can significantly affect adherence to chronic medications. Adherence of the patients suffering from chronic diseases, including those with cancer diagnosis has been reported suboptimal and over the years, has been a significant public health issue. However, adherence has not been evaluated in metastatic breast cancer (mBC) patients treated with newly approved drugs cyclin-dependent kinase 4/6 inhibitors (CDK4/6i) in combination with endocrine therapy.

Objectives: The aim of this observational study was to evaluate the adherence in patients with mBC treated with CDK4/6i.

Methods: A cross-sectional study was conducted in 103 adult female patients (≥ 18 years old) with diagnosed mBC treated with CDK4/6i in combination with endocrine therapy (aromatase inhibitors - anastrozole, letrozole, exemestane, or fulvestrant) in University Hospital Centre Zagreb, Department of Oncology, Breast Unit. The recruited patients completed the questionnaire by filling out Medication Adherence Report Scale (MARS-5), clinical and sociodemographic data. Patients were asked to evaluate how often they adopt non-adherent behaviour with a five-point scale, ranging from 'always' to 'never' (1–5 points). The scale total score ranged from five (lowest adherence) to 25 points (highest adherence). Collected sociodemographic data included age, marital status, education, employment status, monthly income, height, and weight. The reported clinical data were supplemented by available medical records as needed. Statistical analysis was performed by using IBM SPSS Statistics software version 25, using descriptive statistics.

Results: The median age was 59.5 (IQR 46.25 - 69) years and the median duration of illness was six (IQR 2.5 - 11) years. The most frequent combination of anticancer therapy was letrozole and ribociclib (54%), followed by fulvestrant and palbociclib (12%) and anastrozole and ribociclib (10%). Participants of the study reported the following adverse effect: stomatitis (90.1%), constipation (91.1%), vomiting (90.1%), diarrhoea (76.2%), nausea (73.3%), painful joints (69.3%) and hair loss (66.3%). The average MARS-5 score was 24.1 (SD 1.6) indicating very high adherence. The most frequent reason for non-adherence was forgetfulness, with 26.5% of the participants reporting that they sometimes (5.9%) or rarely (20.6%) forget to take their therapy. Moreover, 24.5% of the participants sometimes or rarely miss their dose.

Conclusions: This study shows a very high degree of adherence among patients with mBC treated with CDK4/6i. Despite the high incidence of adverse drug events, patients persisted in taking their medicines.

Venous thromboembolism risk in patients with hormone receptor-positive HER2-negative metastatic breast cancer treated with cyclin dependent kinase 4/6 inhibitors

Matea Baković[1], Maja Ortner Hadžiabdić[2], Tajana Silovski[3], Miranda Sertić[2*]

[1]*PrimeVigilance d.o.o., United Kingdom*

[2] *Faculty of Pharmacy and Biochemistry, University of Zagreb, Croatia*

[3]*University Hospital Centre Zagreb, Croatia*

*msertic@pharma.hr

Background: Breast cancer is the most common cancer diagnosed among women worldwide. More than 70% of breast cancers are hormone receptor (HR)-positive, for which endocrine therapy is the preferred initial treatment. Since their first approval in 2015, cyclin-dependent kinase 4/6 inhibitors (CDKIs) are widely used in clinical practice for treating metastatic HR-positive, HER2-negative breast cancer because of their remarkable improvement of survival in combination with endocrine therapy. Thromboembolism is commonly encountered in patients with cancer and is considered the second leading cause of mortality in this group of patients. Risk is much higher among patients on active anti-cancer therapy including chemotherapy, immunotherapy, targeted therapy and endocrine therapy. Thrombotic events have emerged as a significant treatment related adverse event in clinical trials, but these may underestimate actual rates observed in clinical practice with CDKIs.

Objectives: The aim of this review was to evaluate the VTE risk of CDKIs, for patients with HR-positive, HER2-negative metastatic breast cancer.

Methods: The search was conducted in PubMed, Cochrane, American Society of Clinical Oncology meeting library and European Society for Medical Oncology meeting abstract databases for studies with safety data provided on the incidence of VTE, in patients with HR-positive, HER2-negative metastatic breast cancer treated with CDKIs.

Results: The authors have identified eight eligible clinical trials (PALOMA-1, PALOMA-2, PALOMA-3, MONARCH-2, MONARCH-3, MONALEESA-2, MONALEESA-3 and MONALEESA-7), two retrospective studies and an analysis of FDA post marketing data. VTE occurred in 0.6-5% of clinical trial patients whereas incidence of VTE in the real-world population was up to 10%. Post marketing data from the FDA adverse reporting system suggest elevated rates of VTE in CDKIs compared against all other drugs in the database, and also against other oncologic drugs.

Conclusions: VTE rates with CDKIs treatment in metastatic breast cancer patients in clinical practice are two to five-fold greater than reported in registration trials. Although causal association cannot be firmly inferred, oncologists should proactively monitor the occurrence of VTE with CDKIs. Larger, real-world studies are required to define the actual relation and definitive incidence of VTE with different CDKIs.

The role of clinical pharmacists: Enhancing patient experience with precision medicine

Jayapal Show Reddy Thumma[1*], Rajendera Kakde[2]

[1]*St.Peter's Institute Of Pharmaceutical Sciences, India*

[2]*All India Council for Technical Education (AICTE), India*

*jaypalt@yahoo.com

Background: Patients gain greater awareness of their medications wherever hospitals are attached to Clinical Pharmacists' setups. Prior to this patients usually had very limited access to information on their prescriptions and medications except for from their doctors. Recently, however, many patients who were visited by Clinical Pharmacists either in hospital or community pharmacy settings are getting to understand more fully information on medication usage: the do's and don'ts, the toxicity of specific medicines, and even getting information on the elimination of toxic substances from their body once cured. This information is becoming very important for patients. The number of patients and their awareness of precision medicines are increasing, and many are ready to inform clinical pharmacists about their past medical and medication history.

Methods: The authors carried out a pilot study with 25 hospitals in India with Doctor of Pharmacy schools attached, with over 300 patient beds. A self-developed validated questionnaire was used to analyse the impact of clinical pharmacy services in the existing hospital setup. 1264 patients, 92 physicians and 32 medical insurance executives responded to the questionnaire.

Results: 38% of patients (480/1264, $p = 0.0016$) had a better learning experience when clinical pharmacists played a role in their Healthcare team. As per the survey response, the patients were happy to give full information on medications, previous diagnostic reports and family history in India with clinical pharmacy departments. Very notably (252/1264, $p = 0.0432*$), patients were taking advice even before surgeries, prophylactic drug use (401/1264, $p < 0.0001$), treatment duration (512/1263, $p < 0.0001$) and on any predicted adverse drug reactions (272/1264, $p = 0.0032$). From a medical team perspective, approximately 16% of medical insurance executives were excited to take opinions from clinical

pharmacists about the cure and type of medications delivered and also the risk involved in the patients. Similarly, around 33% of doctors were rechecking their drug prescriptions with clinical pharmacists before writing the drug forms and calculations on acute medical conditions and finding out any adverse drug reactions. This highlights the importance of clinical pharmacists in the practice of precision medicine delivery in India.

Conclusions: This study highlights the importance of clinical pharmacists' role in healthcare, and suggests the potential for them to play a very prominent role in patient's healthcare teams.