27th ECCMID Vienna, Austria 22 – 25 April 2017

The congress of ESCMID

Session: P084 Antifungal drugs and treatment II

Category: 6c. Antifungal drugs & treatment

25 April 2017, 12:30 - 13:30
P1730

Clinical Experience with Novel Posaconazole Formulations: A Retrospective, Multi-Center Analysis of Patients treated in German Hospitals

Sebastian Heimann*[1], Werner Heinz[2], Tobias Rachow[3], Johanna Kessel[4], Oliver A. Cornely[5], Jörg-Janne Vehreschild[6]

[1]*University Hospital of Cologne; Internal Medicine I , Department of Infectious Diseases*

[2]*Universitaetsklinikum; Med. Klinik II*

[3]*Universitätsklinikum Jena; Klinik für Innere Medizin II*

[4]*University Hospital of Frankfurt*

[5]*University of Cologne, Clinical Trials Centre Cologne; Excellence Cluster on Cellular Stress Responses in Aging-Associated Diseases (Cecad); Department I of Internal Medicine*

[6]*Uniklinik Köln; Klinik I für Innere Medizin; German Center for Infection Research (Dzif), Partner Site Bonn-Cologne, Cologne*

Background: Novel formulations (gastro-resistant tablets and intravenous solution) of posaconazole (POS), a triazole broad-spectrum antifungal agent, have been approved in prophylaxis and therapy of invasive fungal diseases (IFDs). The aim of this multicenter non-interventional study was to analyze indication, treatment strategies, and effectiveness of these new options.

Material/methods: We set up a web-based registry on our platform www.ClinicalSurveys.net and centers of the Infectious Diseases Working Party of the German Society of Hematology and Medical Oncology (AGIHO) were invited to provide retrospective information on patients who received novel POS formulations. Data documentation included patient characteristics, underlying disease, treatment indication, risk factors, antifungal regimens, adverse events, plasma levels, and treatment outcome. Classification of IFDs and definition of responses to therapy and study outcomes of IFDs were based on EORTC/MSG criteria. Treatment success of antifungal prophylaxis with novel POS formulations was rated as documented by the investigators.

Results: To date, 108 hospitalized patients from four German tertiary care centers treated between 05.2014 – 03.2016 were completely documented and included into our analysis. Fifty-six patients were male (52%) and median age was 56 years (range: 24 – 78 years). The majority of patients (n= 61; 57%) had an acute myeloid leukemia as primary underlying disease, followed by acute lymphoblastic leukemia (n= 13; 12%) and myelodysplastic syndrome (n= 11; 10%). The most common risk factors for IFD were chemotherapy (n= 80; 74%), treatment with immunosuppressives (n= 79; 73%) and corticosteroids (n= 78; 72%), neutropenia (n= 70; 65%) as well as allogeneic stem cell transplantation (n= 55; 51%). In 67 (62%) and 41 patients (38%), novel POS formulations were administered as antifungal prophylaxis and treatment of IFD, respectively. During antifungal prophylaxis with novel POS formulations, no fungal breakthrough was reported. Adverse drug reactions occurred in 6 patients (9%). Of those patients who received novel POS formulations for treatment of IFD (n= 41; 38%), 16 (39%), 11 (27%), and 14 (34%) patients were treated due to possible, probable, and proven IFD, respectively. Fifteen (37%) of these 41 patients received at least one dose of intravenous POS, mostly administered for treatment of proven IFD (n= 7; 47%). Seven patients (17%) had progressive IFD under treatment with novel POS formulations and five patients (12%) with IFD died. In both groups, patients were hospitalized for 51 days (95% CI: 43 – 60 days) and 68 days (95% CI: 56 – 81 days).

Conclusions: Our study demonstrates high clinical effectiveness of antifungal prophylaxis with novel POS formulations. In patients treated for possible/probable/proven IFD, the observed tolerability and overall mortality was comparable to previous studies with other antifungals in similar patient populations.