29th ECCMID Amsterdam, Netherlands 13 – 16 April 2019

The congress of ESCMID

P2191 Diagnostic analysis of the AsperGenius PCR system alone and in combination with galactomannan determination in clinical samples of immunocompromised patients

Birgit Spiess*[1], Julian Skladny[1], Mark Reinwald[2], Tobias Boch[1], Oliver A. Cornely[3], Werner J. Heinz[4], Jörg Steinmann[5], Peter-Michael Rath[6], Natalia Merker[1], Wolf-Karsten Hofmann[1], Dieter Buchheidt[1]

[1] Department of Hematology and Oncology, University Hospital Mannheim, Heidelberg University, Mannheim, Germany, [2] Medizinische Hochschule Brandenburg Theodor Fontane, Klinikum Brandenburg, Brandenburg an der Havel, Germany, [3] Department I of Internal Medicine, University Hospital of Cologne, Cologne, Germany, [4] Department I of Internal Medicine, Clinical Center Weiden, Weiden, Germany, [5] Institute of Clinical Hygiene, Medical Microbiology and Clinical Infectiology, Medical Center Nuremberg, Private Medical Paracelsus University, Nuremberg, Germany, [6] Institute of Medical Microbiology, University Hospital Essen, Essen, Germany

Background: Invasive pulmonary aspergillosis (IPA) is an emerging and life-threatening infectious disease in immunocompromised patients. As the diagnosis of IA is rarely based on positive culture in this group of patients, biomarker assay and molecular detection of *Aspergillus* DNA and resistance mutations directly from clinical samples is crucial.

Materials/methods: The diagnostic *Aspergillus* DNA detection of the AsperGenius® real time PCR system (PathoNostics BV, Maastricht, The Netherlands) was evaluated in 32 stored in-house *Aspergillus* PCR-positive (Skladny et al., 1999) BAL, 15 biopsy and 13 cerebrospinal fluid (CSF) samples of immunocompromised, mainly hematological patients. The diagnostic accuracy of the AsperGenius® assay was furthermore determined by investigation of 82 BAL samples of 3 proven, 52 probable and 27 noIA patients.

In altogether 53 BAL samples of 1 proven, 31 probable and 21 noIA patients the diagnostic performance of the AsperGenius® system in combination with galactomannan (GM) analysis was evaluated.

Results: 75% (24/32) of our in-house *Aspergillus* DNA-positive BAL, 80% (11/15) of biopsy and 54% (7/13) of CSF samples were also tested positive in the AsperGenius® system. The detected diagnostic values of the AsperGenius® assay in BAL samples alone and in combination with GM analysis are shown in the table.

Test/combination	Sensitivity	Specificity	PPV	NPV	Odds Ratio (CI: 95%)
AsperGenius diagnostic assay	55% (30/55)	93% (25/27)	94%	50%	15 (3.2-69.7)
AsperGenius diagnostic assay OR GM ≥0.5	59% (19/32)	91% (19/21)	91%	59%	13.9 (2.8-70.1)
AsperGenius diagnostic assay OR GM ≥1.0	47% (15/32)	91% (19/21)	88%	53%	8.4 (1.7-42.1)

Table. Diagnostic performance of the AsperGenius assay alone and in combination with GM determination in BAL samples. PPV, positive predictive value; NPV, negative predictive value.

Conclusions: Investigating in-house *Aspergillus* DNA-positive clinical samples, the AsperGenius® system was less sensitive than our diagnostic in-house PCR assay. Our analysis revealed a good diagnostic AsperGenius® PCR accuracy in BAL samples with slight improvement in sensitivity in combination with GM determination (GM≥0.5). The advantage of AsperGenius® system is the time saving aspect. In summary, we consider molecular detection of *Aspergillus* DNA to be of high clinical relevance in patients with hematological malignancies.