Performance evaluation of the new FungaDia ELISA kit for the detection of Aspergillus Galactomannan

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Introduction

FungaDia-Aspergillus ELISA is a new enzyme-linked immunosorbent assay for the detection of galactomannan in serum and bronchoalveolar lavage (BAL) samples, developed by the company GaDia SA. This test is a complement to the FugaDia-Aspergillus immuno-chromatographic test (ICT).

Material and method

The retrospective clinical evaluation was conducted at the University Hospital of Grenoble in January 2022 on 203 characterized and archived serum samples and 33 BAL samples. These samples were collected between 2021 and 2022 and included CAPA (COVID-Associated Pulmonary Aspergillosis) patients. The FungaDia-Aspergillus test was performed according to the manufacturer's instructions on an Evolis (Bio-Rad) automated test system. The threshold of FungaDia-Aspergillus was set at 0.5 for serum and BAL samples, according to the manufacturer's instructions. The threshold of the reference test (Platelia Aspergillus, BIORAD) was 0.5 for serum and 1.0 for BAL. Sensitivity, specificity, positive and negative predictive values (PPV, NPV) using the Platelia ELISA kit (Bio-Rad) results as reference were calculated.

Results and discussion

The FungaDia-Aspergillus ELISA was easily adapted on the Evolis automated system. For the 203 serum samples, the sensitivity was 90.7% (CI95: 78.9-96.5%), the specificity 99.3% (CI95: 95.8- 100%) and the PPV and NPV 98.0% and 96.7%, respectively.
Sensitivity was increased to 98.0% (CI95: 87.8-100%) when the clinical diagnosis was taken into account (see table below). Indeed, 4 sera negative with FungaDia, and positive with Platelia are in fact false positives of Platelia (interference with gamma globulins or other). These observations indicate that the GaDia FungaDia-Aspergillus test seems to be more specific than the BioRad Platelia test, respectively 99.3% (152/153) for FungaDia versus 97.4% for Platelia (149/153).

Platelia (BioRad)/Clinical diagnostic

		+	-
FungaDia ELISA	+	49	1
	-	1	152
Sensitivity:	98,0%	(CI95%: 87.8-100%)	
Specificity:	99,3%	(CI95%: 95.9-100%)	
PPV:	98,0%	(CI95%: 88.4-99.9%)	
NPV:	99,3%	(CI95%: 95.9-100%)	

For BAL samples (n=33), no discordant results were observed between FungaDia and Platelia, with a sensitivity and specificity of 100%. The confidence intervals are quite large due to the low number of positive BAL samples. In this study, no interference was observed with Gamma globulins with FungaDia.

The FungaDia-Aspergillus rapid test (immunochromatographic assay) was compared to gold standard ELISA Platelia (BioRad). A total of 153 serum samples and 31 LBA were analyzed using the new rapid test kit.
The Sensitivity of the rapid test kit was 77.6% (CI95 : 63.0-96.7%), the specificity was 99.3% (CI95 : 95.8- 100%) and PPV and NPV de 90.5% et 90.1%, respectively.The correlation coefficient kappa between rapid test FungaDia-Aspergillus ICA and Platelia (ELISA) was 0.766.

Platelia (BioRad)/Clinical diagnostic

		+	-
FungaDia ICA	+	38	4
	-	11	100
Sensitivity:	77,6%	(CI95%: 63.0-87.8%)	
Specificity:	96,2%	(CI95%: 89.9-98.8%)	
PPV:	90,5%	(CI95%: 76.5-96.9%)	
NPV:	90,1%	(CI95%: 82.6-94.7%)	

The performance of the new FungaDia kit is similar to the performance of the current reference kit (Platelia), with potentially improved specificity. Larger clinical evaluations on prospectively collected samples are still needed to confirm these encouraging initial results.