Urine Aspergillus Antigen Detection as a Screen for Invasive Aspergillosis in Hematology Patients

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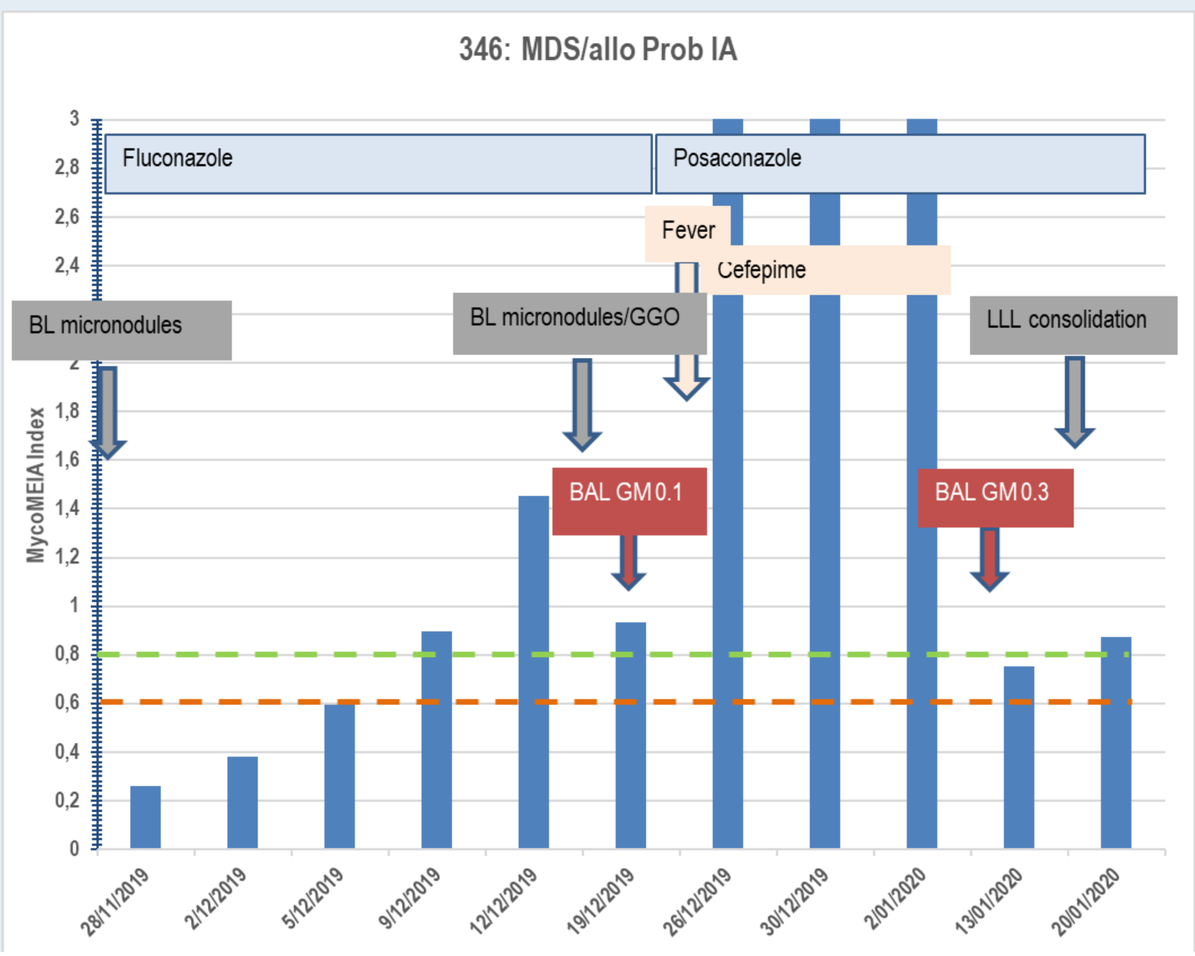
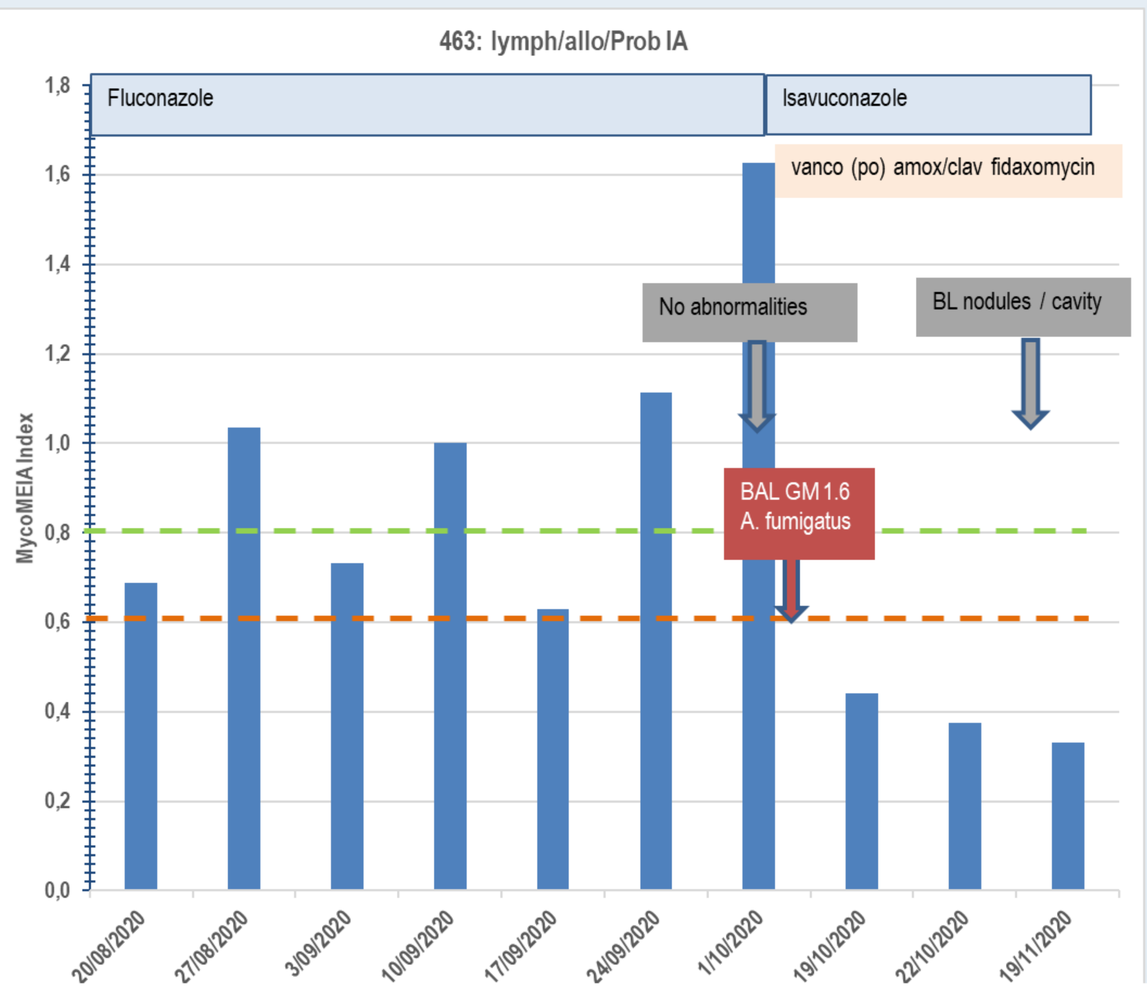
MycoMEIA

- Enzyme immunoassay that detects galactofuranose-containing Ag's in animals and humans with invasive pulmonary aspergillosis.
- A sandwich enzyme immunoassay was developed as a non-invasive test for aid to diagnose IA.
- Tested in 920 specimens from 310 different people, with sensitivity 83% (95% CI 67-93%) and specificity 93% (95% CI 84-98%) as an aid to diagnose IA.
- Early positivity suggests potential utility as a screening tool in high risk immunocompromised patients.

Methods

- We tested 200 sequential urine samples of high-risk hematology patients. 64 screening eligible urine samples from 18 cases and controls were selected.
- Patients had undergone screening with serum GM and BALs were performed with suspicion of IA.
- Results of urine tests obtained within the 2-week window prior to clinical diagnosis were considered for screening performance.
- Results were interpreted using a low index cut-off (0.6).





Diagnostics

GM EIA	0	0	0.1	0	0.5	0.9	0.8	3.9	1.7	0.2	0.1
BDG						47	42	177	135	43	39

Diagnostics

GM EIA	0.3	0.3	0.2	0.2	0.4	0.7	1.8	0.2	0.2	0.1
BDG										78

Results

- Sensitivity of MycoMEIA as a screening tool was 64.3% in our screening eligible cohort, with a NPV of 92,7%; sensitivity of serum GM was 50%
- Combining MycoMEIA with serum GM increased sensitivity to 80.0%.
- Ag expression may decrease with antifungal therapy.
- Urine was positive by MycoMEIA in 5/7 cases with positive serum GM and in 7/7 cases with positive BAL GM.
- MycoMEIA pre-dated diagnosis established with the aggressive clinical screening by a mean of 16.4 (35-2) days.

Screening	Value	95% CI
Sensitivity	64.3%	35.1–87.2
Pre test Probability 20%		
PPV	19.4%	9.0–37
NPV	78.9%	39.4–95.5
Pre test Probablity 10%		
PPV	12.5%	4.7–29.1
NPV	92.7%	79.1–97.7

Statistic	Value	95% CI
For sGM:		
Sensitivity	50%	23–77
MycoMEIA and sGM combined: Pre test Probability 10%		
Sensitivity	80.0%	51.9–95.7
Specificity	50.0%	6.8–93.2
PPV	15.1%	6.1–32.9
NPV	95.7%	84.6–98.9

Urine screening with MycoMEIA performs well to identify early IA in high-risk hematology patients.