Poster number: P2844

Diagnosis of Invasive Aspergillosis Through Combined Detection of Galactomannan and 1,3-β-D-glucan Using Chemiluminescent Immunoassay

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Background

With the increasing number of patients who are immunosuppressed or immunocompromised, there has been a corresponding rise in invasive fungal infections over the past few decades, which are associated with high morbidity and mortality rates, ranging from 60% to 90%. Therefore, the role of early and accurate diagnosis is crucial. Conventional fungal identification relies on microscopic analysis and the growth of microorganisms in culture media. In contrast, serological testing offers a faster method for detecting the causative fungi, thereby aiding in the diagnostic decision-making process. The advantages of serology-based tests include the rapid results obtained, in contrast to culture methods, and the non-invasive nature of the samples (e.g., blood, urine, sputum), while also serving as potential prognostic markers, such as (1,3)-β-D-glucan (BDG assay) and galactomannan (GM assay). Recently, a novel chemiluminescent immunoassay (CLIA) for BDG and GM developed by Dynamiker Biotechnology (Tianjin) Co., Ltd. was introduced as a screening test for invasive aspergillosis (IA, Figure 1). This fully automated assay offers high throughput and a short detection time. In this study, we explored the diagnostic value of the combined detection of BDG-CLIA and GM-CLIA for IA.

Methods

A total of 114 patients were admitted and enrolled from March 2023 to July 2023. According to the 2019 EORTC/MSG definitions of invasive aspergillosis, the patients were divided into two groups: the IA group (67 cases) and the non-IA group (47 cases). The samples were tested in parallel using the Dynamiker BDG-CLIA and GM-CLIA assays.

Results

Compared to using BDG-CLIA alone (sensitivity 68.66%) or GM-CLIA alone (sensitivity 86.57%), the combination strategy demonstrated a significantly higher sensitivity (92.53%, $p<0.01$) in the IA group (Table 1).

Conclusion

We conclude that BDG-CLIA demonstrates modest performance in identifying IA patients. GM-CLIA exhibits superior accuracy compared to BDG-CLIA. The combination of both improves the sensitivity at the cost of specificity, and can be used as an auxiliary diagnosis for IA.

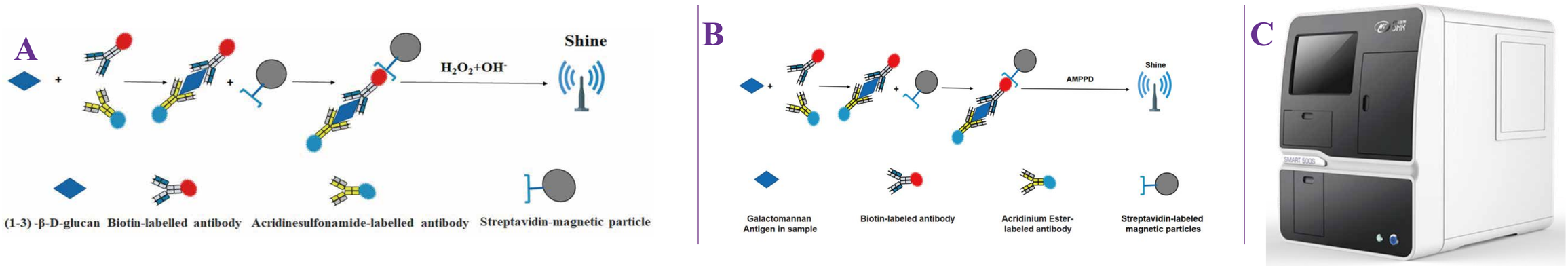

Figure 1 Detection Principle of the Dynamiker Fungus (1,3)-β-D Glucan Assay (Chemiluminescence, A) and Dynamiker *Aspergillus* Galactomannan Assay (Chemiluminescence, B); Fully Automated Chemiluminescence Analyzer (C)

Table 1 Diagnostic value of combined detection of BDG-CLIA and GM-CLIA in IA

	Sensitivity [%(95% CI)]	Specificity [%(95% CI)]	Positive predictive value [%(95% CI)]	Negative predictive value [%(95% CI)]
BDG-CLIA	68.66(56.03-79.13)	70.21(54.92-82.21)	76.67(63.66-86.22)	61.11(46.87-73.76)
GM-CLIA	86.57(75.53-93.30)	82.98(68.65-91.86)	87.88(76.96-94.25)	81.25(66.90-90.56)
Combined	92.53(82.74-97.22)	68.09(52.75-80.48)	80.52(69.60-88.33)	86.49(70.43-94.92)