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Diagnostic mycology (incl molecular)

Statistical assessment of Tachypleus amoebocyte lysate for early diagnosis of invasive fungal disease at an ICU in China

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Background: (1,3)-β-D-Glucan (BG) is a component of the cell walls of most pathogenic fungi in significant amounts with some notable exceptions such as Cryptococcus and Zygomycetes. Measurement of BG, of which test reagent usually derived from Limulus Amebocyte Lysate, is a useful adjunct for diagnosis of fungemia and deep-seated mycoses, and for direction of drug usage as well. However, different test reagents derived from different breeds of horseshoe crab may cause discrepancy. Additionally, the diagnostic performance of Amebocyte Lysate of Tachypleus (TAL), an Asian horseshoe crab from the East China Sea, still lacks. The aim of this research was to investigate its feasibility of BG assay and the contribution to early diagnosis of invasive fungal infections (IFI).

Material/methods: A retrospective study was conducted by Tianjin Third Central Hospital to evaluate the diagnostic indices of TAL for BG assay. The device of MB-80M kinetic tube reader and detection kits of *Goldstream*® Fungus (1,3)-β-D-glucan Test GKT-12/25M were used to quantitatively detect the content of BG in serum. Patients with invasive fungal disease (IFD) were classified based on current European Organization for Research and Treatment of Cancer-Mycoses Study Group (EORTC/MSG) criteria, independent of BG assay.

Results: All 247 patients with high risk factors for IFI identified in the earlier study or with suspected IFI were evaluated. Of the 51 proven or probable IFD patients, 43 cases were positive, 2 cases under gray zone, and 6 were negative when diagnosed using BG assay; and of the 196 negative results, 161 cases were negative, 10 case under gray zone, and 23 cases were positive. The sensitivity and specificity for BG were 84.1% and 82.1% respectively.

Conclusions: TAL, derived from the horseshoe crab from the East China Sea, for serum BG assay is clinically available and has been shown to be a useful diagnostic adjunct for IFI.