Galactomannan lateral flow assay for the diagnosis of invasive Aspergillosis among clinically suspected patients in tertiary care center, Jodhpur, Rajasthan

Introduction: Invasive aspergillosis is one of the potentially life-threatening diseases in immunocompromised patients. Early diagnosis and prompt treatment improve patient survival. The gold standard method—conventional microscopy and culture—have low sensitivity and a long turnaround time. Serum Galactomannan (GM), a polysaccharide that forms a major component of Aspergillus cell wall and is released by the fungus during invasive growth is established as a reliable biomarker, which is available as Enzyme Linked Immunosorbent (ELISA). The limitations of ELISA are high cost, expertise, and difficulty in
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To overcome these limitations, a qualitative Galactomannan Lateral Flow Assay (GM-LFA), a sandwich immunochromatographic test, recently approved by European CE, is evaluated in our study.

Objective: To establish the diagnosis of Invasive Aspergillosis according to EORTC/MSGERC Definitions of Invasive Fungal Diseases 2021 guidelines and comparison of GM-LFA with conventional microscopy and culture.

Method: We performed a retrospective study from October 2021 to March 2022 on serum and bronchoalveolar lavage fluid (BAL) samples. GM-LFA (IMMY silica Aspergillus Galactomannan LFA) was performed and the results are read after 10 mins with a cube reader according to the manufacturer’s instructions and compared with conventional microscopy and culture.

Result: During the 6 months study period, 185 samples (14 BAL and 171 serum) were collected from 148 patients. A total of 17/185 (9.18%) samples from 16 patients were positive by GM-LFA, of those 5 (29.41%) are BAL, and 12 (70.58%) are serum samples. One patient tested positive for Galactomannan on both BAL and serum.

Among assay positive samples, 11/7 (17.64%) samples were positive by microscopy and culture, which grew 2 Aspergillus fumigatus and 1 Aspergillus niger.

Treatment details of 5 patients could be traced, of which 4 patients improved clinically and radiologically after Inj. voriconazole and 1 patient died before starting treatment.

According to EORTC/MSGERC Definitions of Invasive Fungal Diseases 2021 guidelines, 17 patients belong to the proven and probable invasive aspergillosis category, in which 16 patients were GM-LFA-positive and the remaining 131 patients had no evidence of invasive aspergillosis disease.

Conclusion: GM-LFA is a cost-effective, easy, convenient, and rapid procedure. We recommend its use for the diagnosis of invasive Aspergillosis in routine healthcare settings, especially where GM-ELISA is not available or affordable.