

Official Title: Non-Invasive Detection of Aspergillosis in Ventilated Patients: Galactomannan Analysis in Exhaled Breath Condensate

Short Title: Aspergillosis Detection via EBC-GM in Ventilated Patients

NCT Number: Pending

Study Duration: January 2, 2023 - January 10, 2024

Funding Source: Sichuan Provincial People's Hospital

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Study Protocol

Title: Non-Invasive Detection of Aspergillosis in Ventilated Patients: A Study on the Diagnostic Utility of Galactomannan Analysis in Exhaled Breath Condensate

Objective: Evaluate the effectiveness of measuring galactomannan (GM) levels in exhaled breath condensate (EBC) as a non-invasive method for diagnosing Invasive Aspergillosis Pneumonia (IPA) in mechanically ventilated patients.

Background: Given the high mortality rates associated with IPA in critically ill patients, timely and accurate diagnosis is paramount. Traditional methods, such as the analysis of bronchoalveolar lavage fluid (BALF), while effective, are invasive and pose risks to patients. This study explores the potential of EBC as a safer alternative.

Methodology:

- **Study Design:** Comparative analysis of GM levels in EBC and BALF from both a rat model and mechanically ventilated IPA patients.
- **Participants:** 75 mechanically ventilated patients suspected of IPA, with informed consent obtained.
- **Procedures:**
 - Use of a novel EBC collection device for sample gathering.
 - Comparison of GM levels in EBC and BALF, alongside cytokine profiles.
- **Ethics Approval:** Granted by the Medical Ethics Committee of Sichuan Provincial People's Hospital.

Statistical Analysis Plan

Data Analysis Strategy:

1. **Descriptive Statistics:**
 - Summarize participant characteristics using means and standard deviations for continuous variables and frequencies for categorical variables.
2. **Diagnostic Marker Evaluation:**
 - Perform logistic regression to evaluate the diagnostic utility of GM levels in EBC and BALF.
 - Receiver Operating Characteristic (ROC) curve analysis to determine the diagnostic effectiveness, identifying optimal cutoff values for sensitivity and specificity.
3. **Comparison Between Groups:**
 - Use t-tests or Mann-Whitney U tests for continuous variables and chi-square tests for categorical variables to compare the IPA and control groups across different measures (e.g., GM levels, cytokine profiles).
4. **Correlation Analysis:**
 - Assess the relationship between EBC-GM and BALF-GM levels using Pearson's or Spearman's correlation coefficients, depending on data distribution.
5. **Threshold Analysis:**
 - Determine a specific cutoff value for EBC-GM that maximizes diagnostic accuracy, focusing on sensitivity, specificity, and the Area Under the Curve (AUC) from ROC analysis.

Software: Statistical analysis will be conducted using SPSS version 25.0 or a similar statistical package.

Ethical Considerations: Data will be anonymized to protect patient confidentiality, with all procedures carried out in accordance with the Declaration of Helsinki.