Official Title: Risk of Aspergillus infection in patients with chronic structural lung disease

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Short Title: Risk of Aspergillus infection in patients with chronic lung disease

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Funding Source: Sichuan Provincial People's Hospital

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Study Protocol

Title: Risk of Aspergillus infection in patients with chronic structural lung disease

Objective: Identify the risk factors associated with fungal infections and investigate acute exacerbation in these patients.

Background: More attention has been paid to improving the quality of life and long-term management of patients with structural lung diseases such as chronic obstructive pulmonary disease (COPD) and bronchiectasis, whose repeated acute exacerbations lead to greater dependence on systemic and inhaled glucocorticoids. At the same time, the incidence of aspergillus pneumonia also increased.

Methodology:

- **Study Design:** The risk factors of aspergillus pneumonia were compared between aspergillus colonization group and aspergillus pneumonia group.
- **Participants:**Patients with chronic lung disease were identified as positive for Aspergillus fumigatus through sputum microscopy. According to diagnostic criteria, patients diagnosed with IPA and CPA and were assigned to the Aspergillosis pneumonia group, while the remaining patients were included in the Aspergillus colonization group. Then,Risk factors for aspergillus pneumonia, invasive pulmonary aspergillus disease, and chronic pulmonary aspergillus disease, such as the use of high-dose corticosteroids, inhaled corticosteroids, and the extent of damage to basic lung structures, were identified by comparing the aspergillus colonization group with the aspergillus infection group.
- **Procedures:**

- Patients diagnosed with chronic lung disease were screened out who were qualified by sputum microscopy and positive for aspergillus in sputum culture.
- The chest high-resolution computed tomography (HRCT), serum Aspergillus specific IgG antibody, serum aspergillus IgM antibody and serum GM test were performed.
- The risk factors of aspergillus infection group and aspergillus colonization group were compared.

- **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. **Identify independent risk factors:**
    - Independent risk factors for aspergillus infection were determined by multivariate logistic regression analysis.
3. **Comparison Between Groups:**
    - The area under ROC curve (AUC) was used to evaluate the classification effect of the binary classification model among Aspergillus pneumonia group, IPA group and CPA group.
4. **Threshold Analysis:**
    - Specific cut-off values for Aspergillus specific IgG antibody × lung structural injury image score was determined to maximize diagnostic accuracy, focusing on sensitivity, specificity, and Youden index.

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.