

Abstract

Human immunodeficiency virus (HIV) is a major virus affecting approximately 38 million people worldwide. HIV is also known to negatively influence the functional capacity of the pulmonary system and increase pulmonary morbidity. Despite the deleterious effects of HIV on pulmonary function, researchers continue to exclude pulmonary conditions from HIV clinical trials. This study investigated the proportional relationship of included and excluded pulmonary conditions in HIV clinical trials. Of 335 pulmonary terms identified in the inclusion and exclusion criteria of clinical trials found on clinicaltrials.gov, 288 (85.97%) were excluded. While this relationship wasn't statistically significant ($p > .05$), there was a notable difference and strong correlation between the inclusion and exclusion frequencies. Based on these results, additional HIV clinical trials should emphasize the effectiveness of treatments in those with comorbid pulmonary conditions.

Background

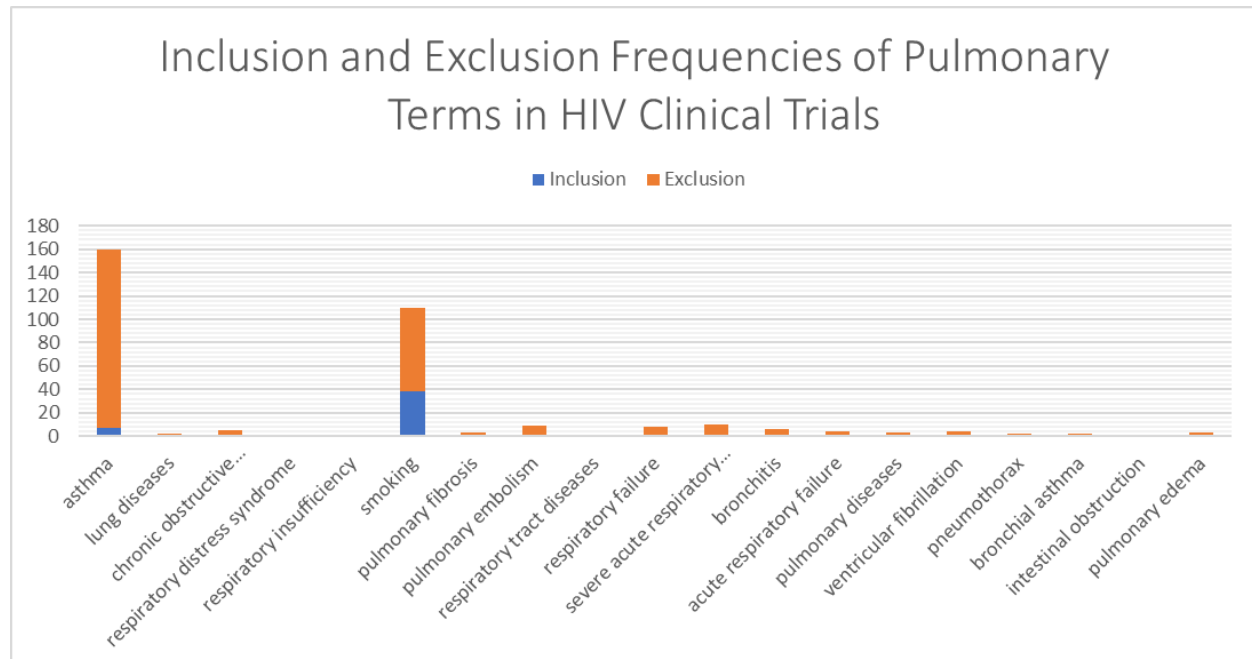
Human immunodeficiency virus (HIV) is an impactful virus that affects millions of people worldwide. Since its origin, treatment outcomes for HIV have improved although these improvements have caused increases in pulmonary comorbidities. For example, HIV patients experience a higher prevalence of asthma than those without HIV. Additionally, HIV is considered synergistic to many of the corresponding risk factors for asthma (Kirenga et al., 2018, 1-9). While limited, some research suggests that patients with comorbid HIV and asthma may benefit from specialized treatment methods (Curto et al., 2020, 2414-2416).

Due to the complexity of HIV and the multitude of comorbidities prevalent in patients, it's often challenging to diagnose or treat comorbidities effectively (Fitzpatrick et al., 2018, 277). It's clear that HIV is related to an increase in the prevalence of pulmonary comorbidities. This study aims to clarify whether co-treatment HIV clinical trials tend to exclude patients with such conditions.

Methods

Researchers analyzed all available HIV clinical trials using clinicaltrials.gov to investigate the frequency of pulmonary conditions within the inclusion and exclusion criteria. Data was collected using Python3.9.10 and included trials from 1990 until present. Inclusion and exclusion frequencies were analyzed collectively and by each respective pulmonary term for further analysis. Microsoft Excel was used to further organize the data and to determine the significance of the results. Data analysis included a one-tail t-test and Pearson correlation. Results were interpreted and notable trends are illustrated in Figure 1.

Figure 1. Comparison of inclusion and exclusion frequencies and proportions of pulmonary terms in HIV clinical trials.



Results and Discussion

This study found a notable disparity between the inclusion and exclusion frequency of pulmonary terms in HIV clinical trials. In total, 335 pulmonary terms were identified in the inclusion and exclusion criteria, with 288 (85.97%) excluded compared to 47 (14.03%) included. Asthma was the most profound pulmonary condition reported, accounting for 153 of the 288 excluded terms (53.13%), is illustrated in Figure 1. In total, pulmonary terms were 6.13 times more likely to be excluded from HIV clinical trials. The data analysis did not consider the overall results to be statistically significant ($p > .05$) even though this high exclusion rate could be considered clinically significant given the relationship of HIV and pulmonary disorders. The Pearson correlation yielded a large effect (0.533), showing the inclusion and exclusion frequencies had a clear relationship.

Overall, the results of this study reveal that clinical trials fail to commonly include patients with pulmonary comorbidities. Considering the increased risk of pulmonary comorbidities and risk factor prevalence among HIV patients, the proportional representation of patients with HIV and comorbid pulmonary conditions is extremely sparse. Future clinical trials should emphasize the inclusion of HIV patients with comorbid pulmonary conditions, most notably asthma, to improve treatment outcomes in a notable demographic.

References

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