

Abstract

Human immunodeficiency virus (HIV) is a major virus known mostly for its progression toward acquired immunodeficiency syndrome (AIDS). While the progression of HIV can result in more serious diseases, this virus can also be responsible for metabolic changes and conditions, including diabetes. This study aimed to investigate whether clinical trials have studied the effects of concurrent treatment of HIV and comorbid diabetes by analyzing the inclusion and exclusion frequencies of diabetes terms in HIV clinical trials. The results indicated that there was a large correlation between the inclusion and exclusion of diabetes-related conditions in HIV clinical trials and near statistical significance ($p = .056$), with a greater proportion of those conditions being excluded. The results of this study suggest that a greater proportion of clinical trials should include diabetics or those with diabetes-related symptoms to delay the progression of both diseases and improve quality of life.

Background

Human immunodeficiency virus (HIV) is well-known for its increased likelihood of early mortality, often correspondent with its progression into acquired immunodeficiency syndrome (AIDS). While more severe conditions and symptoms may result from HIV, many patients infected with the virus are also at an increased risk of other chronic diseases such as diabetes. In fact, HIV infection is associated with an increased risk of insulin resistance and the typical treatments, such as antiretroviral medicine (ART), are associated with additional metabolic implications and an increased risk of diabetes mellitus (Noubissi et al., 2018, 1-8). While no known cure exists, treatments for HIV have generally prolonged the lifespan of HIV/AIDS patients although some research suggests that those with comorbid diabetes may need treatment dosage modifications (Morrow et al., 2020, 483).

The relationship between HIV and diabetes risk is concerning, yet there is still a limited understanding regarding the effectiveness of treatment in those living with both diseases. While it appears that longevity may be improved through concurrent treatment, quality of life is not affected with consistency amongst patients. To date, no HIV cure exists despite improvements in treatment outcomes. Given this and the increased risk of metabolic conditions, clinical trials should target a greater volume of patients living with both HIV and diabetes to better understand treatment effectiveness to consistently improve quality of life.

Methods

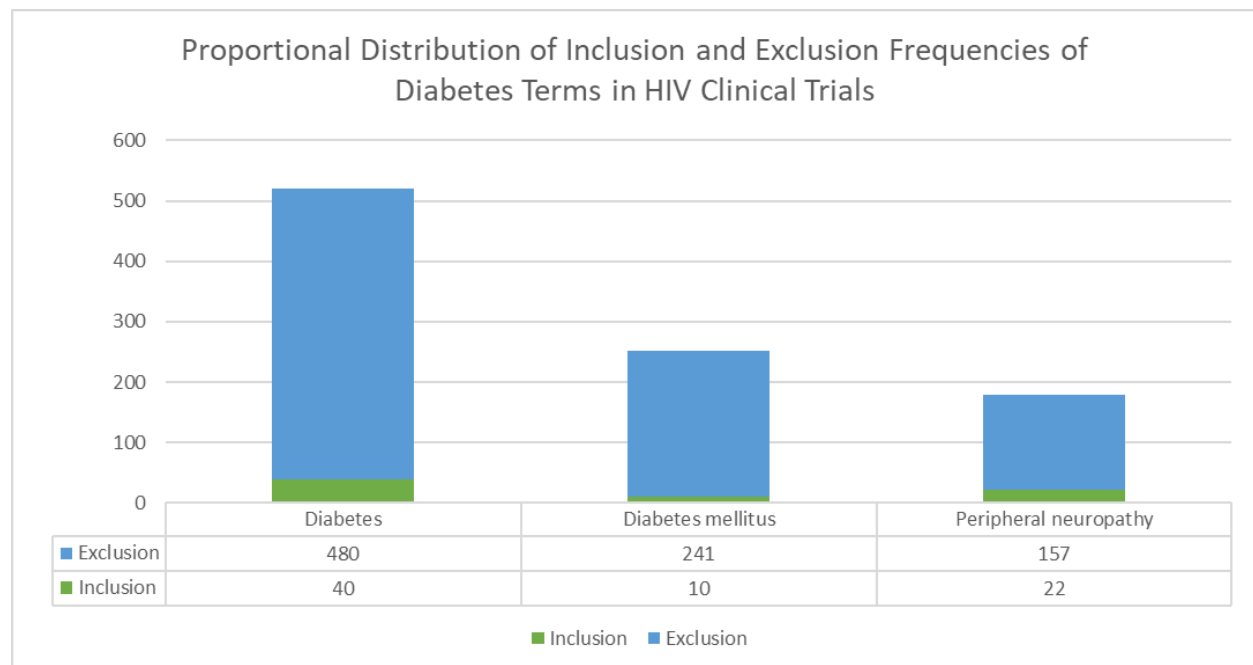
The aim of this study was to investigate the magnitude and proportion of diabetes with the inclusion and exclusion criteria of HIV clinical trials. This study used Python3.9.10 to collect the inclusion and exclusion frequencies of diabetes terms in completed interventional clinical trials on clinicaltrials.gov from 1990 to 2022. All terms were tallied, organized, and analyzed using Microsoft Excel.

Researchers used the collected data to conduct three data analyses using Microsoft Excel. The statistical analyses included a regression analysis, Pearson correlation, and t-test paired two sample for means. Relevant statistical data is provided in Table 1 while an illustration of the inclusion and exclusion frequencies of diabetes terms within HIV clinical trials is provided in Figure 1.

Table 1. T-test paired for two sample means using the inclusion and exclusion criteria of cardiology terms in HIV clinical trials.

Analysis	Significance
Regression (F)	0.0000000616997
Pearson Correlation	0.940319809
P(T<=t) one-tail	0.056339993

Figure 1. Comparison of inclusion and exclusion frequencies of renal-related terms in hypertension clinical trials.



Results and Discussion

This study collected a total of 1008 diabetes terms within HIV clinical trials. Of those, 915 (90.77%) were excluded from HIV clinical trials while only 93 (9.23%) were included in such trials. As shown in Figure 1, diabetes mellitus, diabetes, and peripheral neuropathy made up the majority of diabetes terms with 241, 480, and 157 terms each, respectively. The regression analysis identified a significant difference ($p < .001$) between the inclusion and exclusion frequencies which was further supported with a large effect by the Pearson correlation coefficient (0.94). A t-test paired two sample for means was also conducted but did not yield statistically significant results, as shown in Table 1.

There is a clear relationship between HIV and diabetes. Despite existing knowledge relating the two conditions and the implications on potential treatment methods, few clinical trials investigate populations with both conditions. This study demonstrates the need for a greater inclusion of diabetes patients or those living with diabetes-related symptoms in HIV clinical trials. Until a cure is found for HIV, researchers must focus on improving the quality of life among patients with comorbid conditions such as diabetes.

References

- Morrow, Mary, Ryan P. Coyle, Stacey S. Coleman, Austin Saderup, Jia-Hua Zheng, Lucas Ellison, Lane R. Bushman et al. "Lower cumulative antiretroviral exposure in people living with HIV and diabetes mellitus." *Journal of acquired immune deficiency syndromes (1999)* 85, no. 4 (2020): 483.
- Noubissi, Emile Camille, Jean-Claude Katte, and Eugene Sobngwi. "Diabetes and HIV." *Current diabetes reports* 18, no. 11 (2018): 1-8.
- Zuñiga, Julie Ann, Adam Sales, Dong Eun Jang, Chelsi West Ohueri, Greer Burkholder, Richard Moore, Thibaut Davy-Méndez, Katerina Christopoulos, and Alexandra A. García. "Self-Management Model fails to Predict Quality of Life for People Living with Dual Diagnosis of HIV and Diabetes." *AIDS and Behavior* 26, no. 2 (2022): 488-495.