

Introduction

- Lichen planus (LP) is a chronic inflammatory condition with a global estimated prevalence ranging from 0.5% to 1%.¹
- Classic presentation includes flat-topped, violaceous papules on the skin, exhibiting various morphological variants.
- Over 20 different clinical manifestations of LP have been described.²
- LP manifests across all skin types, but preferentially affects middle-aged adults, with no known gender predisposition.
- LP is often self-limiting, but relentless pruritus and painful mucosal erosions cause significant morbidity.
- LP patients may be more likely to experience depression and reduced quality of life.³

Objectives

1. To promote awareness about the complexities involved in diagnosing LP within skin of color (SOC) populations, while addressing the reported lack of confidence in managing LP in SOC populations.⁴
2. To evaluate and analyze the existing data on the racial and ethnic distribution of LP clinical trials in the United States (U.S.).
3. To compare the demographic composition of U.S. LP clinical trials with the racial and ethnic demographics reported in the 2022 U.S. Census data.
4. To contribute insights into any disparities or discrepancies between the demographic representation in clinical trials and the broader population.

Methods

- In November 2023, the authors searched the “https://clinicaltrials.gov” database using the following filters⁵:
 - Condition: Lichen Planus
 - Country: United States
 - Recruitment: Complete
 - Study Type: Interventional (Clinical Trial)
 - Study Results: With Results
- Of the 11 identified clinical trials, 9 met our inclusion criteria with a total of 341 participants (Table 1)

Results

Racial Representation of Lichen Planus Clinical Trials (n = 341)							
American Indian or Alaska Native	Asian	Native Hawaiian or Other Pacific Islander	Black or African American	White	More than one race	Unknown or Not Reported	Other
0.29% (1)	2.35% (8)	0.00% (0)	8.78% (30)	71.55% (244)	0.00% (0)	17.01% (58)	0.00% (0)
Ethnic Representation of Lichen Planus Clinical Trials (n = 341)							
Hispanic or Latino		Not Hispanic or Latino		Unknown or Not Reported			
7.62% (26)		25.51% (87)		66.86% (228)			

Table 1. Demographic Makeup of United States Lichen Planus Clinical Trials

- Gender breakdown:
 - Identified as female → 74.2% (n = 253)
 - Identified as male → 25.8% (n = 88)
- Comparison to U.S. Census data:
 - **Underrepresented** populations-
 - Black/AA (8.78 vs. 13.6%)
 - Hispanic or Latino (7.62 vs. 19.1%)
 - Asian (2.35 vs. 6.3%)
 - American Indian or Alaska Native (0.29 vs. 1.3%)
 - Native Hawaiian or Other Pacific Islander (0.0 vs. 0.3%)
 - **Closely represented** populations-
 - White (71.55 vs. 75.5%)

Discussion

- **Underrepresentation of minority groups:**
 - Our study reveals a significant underrepresentation of several minority groups in LP clinical trials when compared to U.S. census data.
- **Importance of diversity in LP clinical trials:**
 - The distinct variations in the "classic" clinical presentation of LP across different skin complexions underscore the crucial need for diverse representation in clinical trials.
- **Clinical implications of underrepresentation:**
 - The observed misalignment between trial demographics and the diverse population affected by LP raises concerns about potential misdiagnosis or delayed diagnoses, particularly in SOC patients.
- **Addressing disparities for better patient outcomes:**
 - Bridging the gap in trial participant diversity is essential for gaining comprehensive insights into the full spectrum of LP among all patients, ultimately contributing to adequate care for all.

Conclusion

- Increasing diversity in clinical trial participants is a critical step towards developing tailored interventions that effectively address the unique challenges and presentations of LP within diverse patient populations.
- Diversity in clinical trials may also fosters cultural sensitivity in the development of interventions. Acknowledging the cultural variations in how LP is perceived and managed ensures that healthcare providers can deliver care that aligns with the cultural contexts of diverse patient groups.
- Including individuals from various racial and ethnic backgrounds enhances the generalizability of study findings. This broadens the applicability of interventions beyond specific demographics, contributing to a more universally effective approach to LP management.
- Ensuring diversity in clinical trials is not only scientifically advantageous but also ethically imperative. It promotes equity in healthcare research, avoiding the perpetuation of healthcare disparities and ensuring that advancements benefit all patient populations.

