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 ORIGINAL ARTICLE

Racial and Ethnic Representation in Atopic Dermatitis Clinical Trials

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ABSTRACT

Atopic dermatitis (AD) is a chronic inflammatory skin disorder afflicting approximately 31.6 million people in the United States, with a disproportionate impact on racial and ethnic minorities who often experience greater disease severity. This study aims to analyze racial and ethnic representation in recent atopic dermatitis clinical trials. A search on clinicaltrials.gov identified 73 completed AD trials with results available from January 1, 2019, to May 13, 2024, and out of these, 68 trials involving 20,679 patients provided race and ethnicity data. Out of all clinical trial participants, 65.4% identified as White, 17.3% identified as Asian, 13.4% identified as Black or African American, 0.5% identified as American Indian or Alaskan Native, 0.4% identified as Native Hawaiian or Pacific Islander, and 1.3% identified as more than one race. Hispanic or Latino participants comprised 10.8% of the clinical trial population. This study highlights an increasing trend in the inclusion of African American/Black and Asian populations in AD clinical trials; however, Hispanic participants remain notably underrepresented despite increased ethnicity reporting. These disparities emphasize the necessity of diverse representation in AD clinical trials to ensure equitable treatment outcomes, especially given the higher disease prevalence in skin of color groups. Achieving equitable representation will improve the generalizability of trial results, enhance treatment access, and reduce health inequities. Greater inclusivity in AD clinical trials is crucial for understanding the safety, efficacy, and side effects of treatments across diverse populations and should be a cornerstone of dermatologic clinical research.

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INTRODUCTION

Atopic dermatitis (AD) is the most common chronic inflammatory skin disorder globally, with an estimated prevalence of 31.6 million people in the United States (US) alone.[1,2] AD characteristically presents with dry and itchy skin prone to infection.[3] Although the pathophysiology of AD is not fully understood, it is well established that genetic predisposition, skin barrier dysfunction, immune dysregulation, and environmental factors contribute to AD pathogenesis.[4] With acute disease flares often featuring intensely pruritic papules, exudation, and peeling of the skin, AD is the primary contributor to skin-related disability.[5,6] Prevalent in both children and adults, 80% of AD sufferers experience disease onset before the age of 6, with African American/Black and Hispanic children typically experiencing more severe disease than White children.[7,8] Furthermore, there is a known higher disease prevalence among Black or African Americans compared to Whites, reported in 2019 as 19.3% vs 16.1% in children and 4.4% vs 2.1% in adults.[9] AD can lead to considerable psychological and emotional distress, significantly affecting self-esteem, quality of life, and career choices, especially in patients of color due to higher disease prevalence and severity.[7,9,10]

The growing diversity in the US underscores the crucial need for inclusivity in dermatologic research, with the US Census Bureau projecting that approximately half of the US population will be comprised of Hispanic, African American/Black, or Asian individuals by 2050.[11] Racial minorities are frequently underrepresented in dermatology clinical trials, including those focused on conditions such as acne, alopecia, hidradenitis suppurativa, nail psoriasis, psoriatic arthritis, and the majority of laser therapy applications.[12-17] A gap exists in the understanding of patient representation in atopic dermatitis clinical trials. Due to the well-documented underrepresentation of participants with skin of color in dermatologic studies and the higher incidence of atopic dermatitis among these groups, our goal is to assess racial and ethnic representation in clinical trials for AD.

MATERIALS AND METHODS

A search was conducted on May 14, 2024, of the clinical trials database (clinicaltrials.gov), an international registry maintained by the US National Library of Medicine, to locate clinical trials focused on AD. The search utilized the terms "atopic dermatitis" and "eczema" and was filtered to include only those with a "completed" status as of January 1, 2019, through May 13, 2024, and "with results" available. Studies were selected if they included participants from the US. Studies lacking data on both race and ethnicity were excluded. This methodology aligns with approaches used in previous research examining racial and ethnic representation in dermatologic clinical trials overall as well as clinical trials specifically investigating hidradenitis suppurativa.[12,14] The extracted data included the study title, National Clinical Trials (NCT) number, total participant count, and details on race and ethnicity. Percentages for race and ethnicity were calculated based on the trials that provided this specific information.

RESULTS

A total of 73 trials were identified on clinicaltrials.gov. After excluding studies lacking race or ethnicity data, 68 trials with a total of 20,679 patients were retained. Of these, 68 trials included race data, and 46 included ethnicity data. The racial distribution among trial participants was as follows: White (65.4%), Asian (17.3%), Black or African American (13.4%), American Indian or Alaskan Native (0.5%), Native Hawaiian or Pacific Islander (0.4%), and more than 1 race (1.3%; Table 1). In comparison, the 2020 US census data reports a population distribution of 61.2% White, 12.4% Black or African American, 5.9% Asian, 1.1% American Indian or Alaska Native, 0.2% Native Hawaiian or Pacific Islander, and 10.6% 2 or more races (Figure 1).[18] Regarding ethnicity, 10.8% of trial participants were Hispanic or Latino, compared to 19.5% of the US population per the 2020 census (Figure 2).[18] Although these comparisons are limited by the inclusion of clinical trials not exclusively conducted in the US, it provides a useful reference point for assessing current

TABLE 1.

Representation of Race and Ethnicity in Atopic Dermatitis Clinical Trials Compared to United States Census Demographic Data

Demographic or Parameter	Number of Study Participants, *n*	Representation in Clinical Trials, *n* (%)	2020 US Census, (%)
Race	20,679		
White	--	13,515 (65.4%)	61.2%
Black/African American	--	2,778 (13.4%)	12.3%
Asian	--	3,574 (17.3%)	5.9%
American Indian or Alaska Native	--	96 (0.5%)	1.1%
Native Hawaiian or Pacific Islander	--	79 (0.4%)	0.2%
Two or More	--	272 (1.3%)	10.6%
Ethnicity	15,912		
Hispanic/ Latino	--	1,716 (10.8%)	19.5%
Non-Hispanic	--	14,042 (88.3%)	80.5%
Unknown	--	154 (0.1%)	--

FIGURE 1. Racial representation in Atopic Dermatitis Clinical Trials compared to United States Racial Distribution.

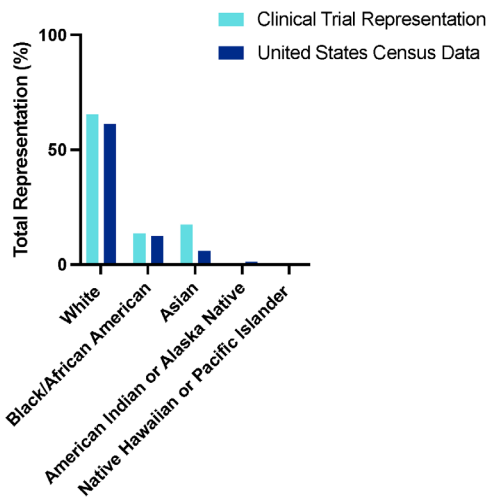
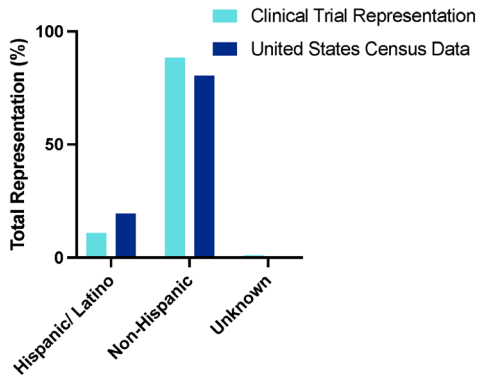


FIGURE 2. Ethnicity representation in Atopic Dermatitis Clinical Trials compared to National Ethnicity Distribution.



representation levels and for understanding the participant group from which current medical insights pertaining to AD are being derived.

DISCUSSION

This study provides a crucial, updated, and comprehensive analysis of racial and ethnic representation in recent AD clinical trials. Over the past 30 years, promoting the inclusion of women and underrepresented racial and ethnic minorities in clinical trials has been a major priority following the enactment of the National Institute of Health Revitalization Act in 1993.[19] Given the genetic heterogeneity of AD among different racial and ethnic groups, achieving equitable representation in AD clinical trials is particularly important.[9]

Our data reveal an improving trend in representation among skin of color patients in recent years, especially among Black/African Americans. Reported AD prevalence among Black or African Americans ranges between 15.1% to 19.3%, with consistently higher prevalence than White Americans.[9,20,21] Moreover, Black or African Americans are experiencing the greatest increase in eczema prevalence, rising from 10.1% to 18.4% between 1997 and 2018.[21] In a prior study analyzing global phase II/III AD clinical trials published from January 2009 to July 2019, participants of African descent comprised only 8.9% of study participants.[22] Another analysis of trials completed between January 2017 and December 2021 found Black/African Americans were underrepresented, comprising only 11.6% of the AD clinical trial patient population.[14] Comparing these results to the current study, which found that Black or African American participants comprise 13.4% of clinical trial participants, highlights the continued progress made in recent years. While this is a notable improvement, representation exceeding the US population demographics is warranted for skin of color groups given the higher disease prevalence.

We found a surprisingly low representation of Hispanic or Latino patients in AD clinical trials despite a notable increase in the number of trials reporting ethnicity data.[18] Research has shown AD is a major concern for Hispanic and Latino populations, especially children, with a prevalence as high as 25% in Latin American children.[23] Among a community that already encounters many barriers to healthcare, the impact on these children can be far-reaching, with a 3.4-fold increase in the likelihood of missing school due to AD in Hispanic children compared to their White counterparts.[23,24] An analysis of US-only AD clinical trials from 2013 to 2021 found that 21.4% of participants were Hispanic or Latino, yet 72% of the trials analyzed failed to report ethnicity data, greatly undermining the statistical power of any reported numbers.[19,25] Similarly, in another study looking at global AD clinical trials from 2009 to 2019, only 3.7% of participants identified as Hispanic, with a mere 15% of trials reporting ethnicity data.[22] Our analysis found more robust ethnicity reporting, with 63% of trials capturing ethnicity data, yet significant underrepresentation was evident, with only 10.8% of trial participants identifying as Hispanic.

Our analysis captured a considerable inclusion of Asian participants in AD clinical trials (17.3% vs the US Census reported 5.9%), well above and beyond demographic representation.[18] The prevalence of AD is on the rise globally and is a growing concern, particularly in developing industrialized nations in Asia, with prevalence in children as of 2009 reported at 10 to 20%.[26] Asians and Pacific Islanders are 7 times more likely than Whites to receive an AD diagnosis during a dermatology office visit.[9] The average prevalence of AD in specific Asian nations includes Korea (14.4%), China (12.9%), and Japan (9.9%).[26-29] Prior studies have reported 10.3% and 16.2% of participants identifying as Asian or of Asian descent in US-based and global AD clinical trials, respectively.[19,22] Our analysis incorporated global enrollment sites, with 47% of trials that enrolled participants outside the US and Canada featuring at least 1 clinical site in Asia. Despite being overrepresented based on US population demographics, the relatively high representation of Asians in AD clinical trials may reflect a prioritization by these nations to study a disease that features a unique phenotypic profile in Asian populations and afflicts many within the community.[30] Additionally, improved cost-effectiveness and the high availability of treatment-naïve patients have triggered a boom in clinical trials conducted in Asia.[31] Sri Lanka and China have seen the largest increases, at 27.1% and 23.3% respectively, between 2008 and 2017, likely influencing our findings.[31] Regardless, this increased focus on studying diseases among disproportionately impacted populations is a good benchmark to strive for with other populations similarly more prone to AD and featuring distinctive disease profiles.

Despite the higher disease prevalence in individuals with darker skin tones, a 2021 analysis of Google image results for dermatologic conditions found that only 4% of all AD Google image results featured darker skin tones.[32] In skin of color, AD can appear as violaceous, ashen gray, or dark brown with perifollicular accentuation and annular lesions, differing from its presentation in lighter skin.[33] In Asian populations, the disease tends to present with more evident demarcation, lichenification, and more pronounced scale, appearing psoriasiform.[33] On a genetic mechanistic level there are differences seen among AD patients as well. The loss of function mutation in filaggrin, which is known to play an important role in AD pathogenesis, differs in Asian, European, and African populations.[34] The 3321delA mutation is seen in Asian populations but has not been identified in European populations.[34] The predominant mutations in Europe, R501X and E2422X, are rarely observed in African and Asian populations.[34] These differing phenotypic presentations and genetic variations highlight the importance of clinical trial representation for a comprehensive understanding

of the disease. Representation in clinical trials is also of paramount importance to furthering our understanding of the safety, efficacy, and side effects of treatments. By drawing such comparisons among patient populations, it is now known narrowband ultraviolet-B light treatment for AD requires larger doses in darker skin tones for comparable efficacy.[34] Furthermore, while considered effective for all skin types by many, research has shown that topical steroids are associated with an increased risk of hypopigmentation in skin of color patients.[35] Conversely, studies have demonstrated that pimecrolimus cream 1% is equally effective regardless of ethnicity.[35] In our analysis, nearly two-thirds of AD clinical trial participants were White despite higher disease prevalence rates in skin of color groups. While these findings align with US Census population demographics, they do not account for higher disease prevalence within Black/African American, Hispanic, and Asian populations or the expected increased diversity of the future US population. To account for the distinct responses to new treatments among patients from different racial and ethnic backgrounds, it is essential to conduct randomized controlled trials (RCTs) that include a diverse patient population.[22]

Strengths of this study include our comprehensive analysis of all recent clinical trials related to AD involving US participants listed on clinicaltrials.gov. Additionally, the high level of reporting of race and ethnicity data among AD trials allowed for a robust and reliable analysis. However, there are a few limitations to this study. Many comparisons to existing analyses of clinical trial representation differ slightly in their inclusion and exclusion criteria, making direct comparisons challenging. Additionally, clinical trial enrollment in 2020 and 2021 was likely impacted by the COVID-19 pandemic. Finally, due to variability in reported AD prevalence among different races and regions, accurately comparing clinical trial representation to actual prevalence rates is difficult and as such we compared clinical trial representation to US Census data.

CONCLUSION

Our analysis highlights the important progress that has been made toward increased representation among African American/Black and Asian populations in AD clinical trials. Conversely, despite increased ethnicity reporting, our assessment uncovered significant underrepresentation of Hispanic participants within AD clinical trials, an area requiring greater focus for improvement. These findings are particularly relevant due to the increased disease prevalence among African American/Black, Asian, and Hispanic populations and the unique pathophysiological mechanisms among different racial and ethnic groups.[4,9,30,35] Given the ongoing disparities in representation in AD clinical trials, the importance of greater inclusion must continue to be emphasized and strived for, especially in conditions like AD where there is increased disease prevalence in skin of color populations. Greater inclusion is crucial for enhancing treatment access for the increasingly diverse population, improving the generalizability of clinical trial results, increasing access to cutting-edge treatments and technologies, and reducing health inequity.[14] It is our recommendation that equitable representation be a cornerstone of clinical trial research for all dermatologic conditions.

DISCLOSURES

The authors have no conflicts of interest to declare.

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