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Disparities in Hidradenitis Suppurativa Clinical Trials: An Updated Review of ClinicalTrials.gov From 2020 to 2024

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ABSTRACT

Background: There is a notable lack of diversity in dermatologic studies, even concerning conditions that are known to have a higher prevalence in the skin of color (SOC) population, such as hidradenitis suppurativa (HS). This study updates the current literature on SOC representation in dermatology by analyzing the demographics and locations of HS clinical trials from 2020 to 2024, during which there were significant advancements in therapeutics.

Methods: A search of the term "hidradenitis suppurativa" was conducted on the ClinicalTrials.gov website for trials initiated between June 2020 and December 2024.

Results: Five clinical trials totaling 411 participants were included. Caucasian/White participants (n=281, 68.4%) comprised the majority, followed by African American/Black (n=93, 22.6%) participants. In comparison to HS trials from 2008 to 2020, the 5 recent trials between 2020 and 2024 demonstrated a significant ($P<0.001$) increase (14.9% vs 22.6%, respectively) in the percentage of Black participants. Most US clinical trial sites (n=38, 59.3%) were located in cities with moderate (12.6-49.9%) to high (>50%) Black populations.

Conclusions: The increase in the proportion of Black participants in HS clinical trials from 2008–2020 to 2020–2024 demonstrates a promising outlook for improved representation in HS clinical trials. Nonetheless, an underrepresentation of Black participants in HS clinical trials continues to persist, highlighting the necessity for continued efforts in the inclusion of SOC individuals in clinical research.

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INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic skin disease characterized by debilitating symptoms associated with the highest comorbidity burden and lowest quality of life among dermatologic conditions.[1] HS largely affects the African American (AA)/Black population, with epidemiology studies demonstrating the highest prevalence in Black populations.[2] In the United States (US), Black patients with HS have been shown to have a higher disease burden, manifesting as higher disease severity, healthcare utilization, and number of surgeries compared to other racial groups.[3] Despite this, there are notable disparities in the enrollment of Black participants in HS clinical trials. A study by Okeke et al. analyzing demographics of HS trials from 2008 to 2020 found that Black participants made up a minority (14.9%) of the participants.4 Since 2020, significant therapeutic advancements, notably FDA approvals of secukinumab, an interleukin-17A (IL-17A) inhibitor, and bimekizumab, a monoclonal antibody targeting IL-17A and IL-17F, have emerged.[5,6] This study updates the current literature on Black patient representation in HS clinical trials with the advent of multiple biologic therapies and explores possible barriers to inclusion.

MATERIALS AND METHODS

A search for "hidradenitis suppurativa" was conducted on ClinicalTrials.gov for clinical trials with a start date between June 1, 2020, and December 1, 2024. Trials were included if they reported at least one of the following: race, ethnicity, or Fitzpatrick skin type (FST), and if they had at least one US location. In total, 5 trials were included. Trials were excluded if they lacked sufficient demographic data or if they were ongoing.

Patient characteristics (sex, race, ethnicity, Hurley stage) and trial characteristics (intervention type, phase, location) were collected from each trial. Data was retrieved using both ClinicalTrials.gov and PubMed by utilizing the NCT number, trial title, or authors' names to locate the corresponding articles. Black population densities at trial sites were categorized as "very low" (0.0-0.9% of population), "low" (1-12.5%), "moderate" (12.6-49.9%), or "high" (>50%) as defined by Okeke et al.[4] Race categories included American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, Black, White, Multiracial, and Unknown/Not reported.

The proportion of Black participants was compared to White participants using a Chi-squared test of independence. A one-sample Chi-squared test (α level = 0.05) was also used to compare the proportion of Black subjects first to the calculated expected rates of enrollment using prevalence rates, then to the previously reported rates in HS trials from 2008 to 2020.[4] The expected proportion of Black subjects with HS (32.6%) was determined using previously reported race-specific prevalence rates by Garg et al.[7] All statistical analyses were conducted on IBM SPSS Statistics Version 29.0.2.0 and specified a priori.

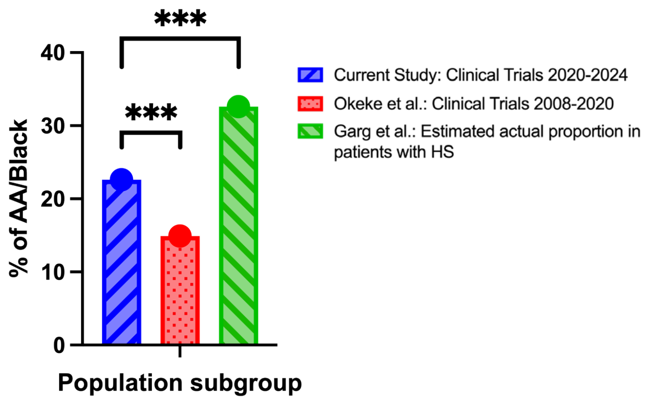
RESULTS

Five clinical trials with a total of 411 participants met the inclusion criteria. White participants comprised the majority of the trials (n=281, 68.4%), followed by Black (n=93, 22.6%), Asian (n=20, 4.9%), Other/Unknown (n=10, 2.4%), multiracial (n=4, 1%), American Indian or Alaskan Native (n=2, 0.5%), and Native Hawaiian/Other Pacific Islander (n=1, 0.2%). The difference in proportion between the White and Black participants was significant (*P*<0.001). No trials reported FST data.

The majority of the US clinical trial sites (n=38, 59.3%) were located in cities with moderate to high Black populations, while the minority (n=26, 40.7%) were located in areas with very low to low Black populations (Table 1).

There was a significant increase in the proportion of Black participants in HS trials from 2008–2020 to 2020–2024 (14.9% vs 22.6%, *P*<0.001; Figure 1).[4] Overall, however, Black participants were significantly underrepresented compared to the expected proportion of Black patients with HS in the US (*P*<0.001, Figure 1).

FIGURE 1. Comparison of the proportion of Black individuals in HS clinical trials from 2020 to 2024, HS clinical trials from 2008 to 2020[4] and HS population data.[7]



***$p<0.001$

AA: African American

DISCUSSION

Our findings show that Black participant enrollment in HS clinical trials has increased since 2020, reflecting some progress in skin of color (SOC) representation. However, Black subjects continue to be significantly underrepresented relative to the disease prevalence in this population. White participants were enrolled at three times the rate of Black participants, despite HS being twice as prevalent in Black individuals.[1] These findings align with general trends seen in clinical trial research, where the majority of prior published studies on HS have been on largely White cohorts.[8] As Black patients have higher rates of comorbidities (including cardiovascular disease, diabetes, hypertension, and obesity), they face a higher risk for severe and chronic HS symptoms compared to White patients.[8,9] Furthermore, Black patients with HS tend to present with significantly higher Hurley stage of disease and greater outpatient visit rates compared to their White counterparts.[10,11,12] They are also more likely to experience significant delays in diagnosis and reduced access to dermatologic care compared to White and Hispanic patients.[13]

Barriers to Enrollment

The underrepresentation of minority groups in clinical trials is multifaceted, influenced by multiple systemic, interpersonal, and individual-level barriers. At the systemic level, structural barriers to participation include geographic accessibility and restrictive exclusion criteria that may disproportionately impact certain populations.[4,14] Our findings show that more than half (59.3%) of the 64 HS trial locations across the US were in areas with moderate to high Black populations (≥12.6%), an increase from 49% in trials conducted from 2008-2020.[4] This shift may have contributed to the overall rise in Black participant enrollment. However, other systemic barriers, such as exclusion criteria, may still disfavor SOC participant enrollment.[14] For example, exclusion criteria such as prior biologic medication use (in two trials), presence of more than 20 draining fistulas (in two trials), or opioid use for HS-related pain during the study could disproportionately exclude Black patients, who tend to have a more severe disease presentation. Additionally, Black patients have been found to be prescribed biologic therapy at higher rates than patients of other races for conditions such as asthma, potentially further limiting their eligibility.[15] Other exclusion criteria, such as a known history of HIV, Hepatitis B, or Hepatitis C (in one trial), may impact certain racial groups more than others. A report published by the US Department of Health and Human Services Office of Minority Health in 2022 demonstrated that Black patients have higher rates of Hepatitis B and are over seven times more likely to be diagnosed with HIV compared to White patients.[16] Lastly, the exclusion of participants with uncontrolled depression or suicidal thoughts (in one trial), may be another potential barrier for SOC patient participation, as major depression and its risk factors are more prevalent among Black and Hispanic patients.[17] While some exclusions are necessary to minimize the effect of confounding variables on

TABLE 1.

Hidradenitis Suppurativa Clinical Trials 2020-2024: Locations, Participant Characteristics, and Demographics of US Trial Locations

Clinical Trial Sponsor, Year Completed, (NCT #)	University of Miami, 2022 (NCT04648631)	Boehringer Ingelheim, 2022 (NCT04762277)	Eli Lilly and Company, 2022 (NCT04493502)	AbbVie, 2022 (NCT04430855)	Incyte Corporation, 2023 (NCT04476043)
Intervention type, Intervention, Phase	Device, Antibiofilm surfactant wound gel, Phase N/A	Drug, Spesolimab, Phase 2	Drug, LY3041658, Phase 2	Drug, Upadacitinib, Phase 2	Drug, Povorcitinib, Phase 2
Total Study Locations, n	15[a]	25[b,c]	20[d,e]	26[f,g]	40[h,i]
HS participants, n	15	52	67	68	209
Sex, n (%)					
Female	13 (86.7%)	31(59.6%)	47 (70.1%)	53 (77.9%)	158 (75.6%)
Male	2 (13.3%)	21 (40.4%)	20 (29.9%)	15 (22.1%)	51 (24.4%)
Ethnicity, n (%)					
Hispanic or Latino	N/A	2 (3.8%)	13 (19.4%)	14 (20.6%)	28 (13.4%)
Not Hispanic or Latino	N/A	44 (84.6%)	50 (74.6%)	54 (79.4%)	179 (85.6%)
Other/Unknown	N/A	6 (11.5%)	4 (6%)	0 (0%)	2 (1%)
Race, n (%)					
American Indian or Alaskan Native	0 (0%)	0 (0%)	0 (0%)	1 (1.5%)	1 (0.5%)
Asian	1 (6.7%)	6 (11.5%)	1 (1.5%)	6 (8.8%)	6 (2.9%)
Native Hawaiian	0 (0%)	1 (1.9%)	0 (0%)	0 (0%)	0 (0%)
Black or AA	2 (13.3%)	4 (7.7%)	17 (25.4%)	19 (27.9%)	51 (24.4%)
White or Caucasian	12 (80%)	35 (67.4%)	46 (68.6%)	41 (60.3%)	147 (70.3%)
Multiracial	0 (0%)	0 (0%)	3 (4.5%)	1 (1.5%)	0 (0%)
Other/Unknown	0 (0%)	6 (11.5%)	0 (0%)	0 (0%)	4 (1.9%)
Hurley Stage, n (%)					
Hurley Stage I	N/A	N/A	N/A	1 (1.5)	N/A
Hurley Stage II	N/A	N/A	N/A	35 (51.4%)	N/A
Hurley Stage III	N/A	N/A	N/A	32 (47.1%)	N/A
# of Clinical Trial Locations in US Cities, Grouped by AA/Black Population Level, n (%)					
Very Low[j]	0 (0%)	1 (20%)	1 (6.7%)	0 (0%)	2 (8%)
Low[k]	0 (0%)	1 (20%)	5 (33.3%)	6 (33.3%)	10 (40%)
Moderate[l]	1 (100%)	3 (60%)	9 (60%)	12 (66.7%)	11 (44%)
High[m]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

US, United States, HS, hidradenitis suppurativa, AA, African American

[a] Miami, FL

[b] Non-US Countries: Australia, Belgium, Canada, Czechia, France, Germany, Italy, Netherlands, Norway, Poland, Spain

[c] US Cities: Los Angeles, CA, Indianapolis, IN, Rochester, MN, Oklahoma City, OK, Pittsburgh, PA

[d] Non-US Country: Australia

[e] US Cities: Rogers, AR, Fountain Valley, CA, Los Angeles, CA, Hollywood, FL, Miami, FL, Tampa, FL, Marietta, GA, Sandy Springs, GA, Beverly, MA, Boston, MA, Saint Louis, MO, Portsmouth, NH, Durham, NC, Cincinnati, OH, Cleveland, OH

[f] Non-US Countries: Canada, Japan, Puerto Rico

[g] US Cities: Phoenix, AZ, Little Rock, AR, San Diego, CA, Boca Raton, FL, Miami, FL, Tampa, FL, Skokie, IL Indianapolis, IN, Boston, MA, Saint Louis, MO, East Windsor, NJ, Durham, NC, Cleveland, OH, Tulsa, OK, Pittsburgh, PA, Charleston, SC, Houston, TX, Spokane, WA

[h] Non-US Countries: Canada, France, Germany, Poland, Spain

[i] US Cities: Hoover, AL, Gilbert, AZ, Phoenix, AZ, Fountain Valley, CA, Fremont, CA, Huntington Beach, CA, Newbury Park, CA Sacramento, CA, Cromwell, CT, Coral Gables, FL, Miami, FL, Tampa, FL, Tampa, FL (2nd location), Atlanta, GA, West Lafayette, IN, Baton Rouge, LA, New Orleans, LA, Boston, MA, Fort Gratiot, MI, Saint Louis, MO, the Bronx, NY, Chapel Hill, NC, Winston-Salem, NC, Hershey, PA, Bellaire, TX

[j] Cities with 0.0-0.9% AA/Black population

[k] Cities with 1-12.5% AA/Black population

[l] Cities with 12.6-49.9% AA/Black population

[m] Cities with >50% AA/Black population

TABLE 2.

Summary of Participant Characteristics and Locations of Hidradenitis Suppurativa Clinical Trials	
Total Clinical Trials (# of participants)	**5 (411)**
Trials that Reported Sex (# of participants)	5 (411)
Sex	# of Participants (%)
Female	302 (73.5%)
Male	109 (26.5%)
Trials that Reported Ethnicity (# of participants)	3 (344)
Ethnicity	# of Participants (%)
Hispanic or Latino	55 (16%)
Not Hispanic or Latino	283 (82.3%)
Other/Unknown	6 (1.7%)
Trials that Reported Race (# of participants)	5 (411)
Race	# of Participants (%)
American Indian or Alaskan Native	2 (0.5%)
Asian	20 (4.9%)
Native Hawaiian/Other Pacific Islander	1 (0.2%)
AA/Black	93 (22.6%)
Caucasian/White	281 (68.4%)
Multiracial	4 (1%)
Other/Unknown	10 (2.4%)
Trials that Reported FST (# of participants)	0 (0)
Trials that Reported Hurley Stage (# of participants)	2 (89)
Hurley Stage	# of Participants (%)
Hurley Stage 1	1 (1.5%)
Hurley Stage 2	35 (51.5%)
Hurley Stage 3	32 (47.1%)
# of Clinical Trial Locations in US Cities, Grouped by AA/Black Population Level	# of Trial Sites (%)
Very Low AA/Black Populationa	4 (6.3%)
Low AA/Black Populationb	22 (34.4%)
Moderate AA/Black Populationc	36 (56.2%)
High AA/Black Populationd	2 (3.1%)

FST, Fitzpatrick Skin Type, AA, African American
[a] Cities with 0.0-0.9% AA/Black population
[b] Cities with 1-12.5% AA/Black population
[c] Cities with 12.6-49.9% AA/Black population
[d] Cities with >50% AA/Black population

the study and to prevent undue risks in immunocompromised populations, awareness of their potential impact on enrollment is important.

At the interpersonal level, implicit bias by the investigators or referring clinicians may further contribute to trial disparities.[18] A retrospective study by Case et al found significant differences in the probability of a patient receiving screening for cardiovascular clinical trials. In their study, White patients were nearly twice as likely as Black patients to be screened for cardiovascular clinical trials (18.9%, vs 9.3%). At the individual level, barriers may include discomfort with or distrust of the clinical trials process, communication issues, perceived harm, and time/resource constraints.[19]

Additionally, systemic and interpersonal barriers seen specifically in HS patients from minority groups included longer time to first consultation, longer time to diagnosis, and a greater likelihood of misdiagnosis, which may limit trial participation.[20] Within dermatology, minority groups also face unequal access to healthcare, potentially lowering exposure to clinical trial opportunities.[21] Identifying and eliminating such barriers to enrollment through improved patient education and increased provider awareness of bias is necessary for equitable SOC representation in HS research.

Importance of Representation

Inclusion of representative populations in clinical trial research is particularly crucial for HS, given the disproportionate impact of the disease in Black patients. Differences in disease severity, time to diagnosis, comorbidities, and outcomes underscore the importance of enrolling a diverse population of patients for clinical trials. Particularly in the age of new therapies such as biologics, it is vital to ensure that populations with a high disease prevalence and disease burden are included to ensure the safety and efficacy of the new drugs in these populations, as responses to treatment may differ based on background and associated comorbidities. Lastly, increasing diversity in trials may help to increase trust in the healthcare system, which is a critical factor in treatment adherence and outcomes, and may help improve disparities in HS patients.[22,23]

Limitations/Strengths

This study is primarily limited by its four-year timespan, leading to fewer trials compared to Okeke et al's study, which included trials spanning over a decade.[4] As such, the smaller scope of our study introduces a risk for increased variability, skewing, and an over- or under-estimation of the effects or the sizes of the groups. Additionally, eligible studies were identified using ClinicalTrials.gov as the sole database, potentially omitting relevant clinical trials. A key strength of this study is the use of race-specific prevalence rates of HS, which are not always available for many dermatologic conditions. Using race-specific prevalence rates offers a more accurate representation of the demographics of the disease. An additional strength of this study is the cross-referencing of PubMed done to obtain data for the identified clinical trials, potentially mitigating the effects of reporting bias as prior studies have shown that the majority of clinical trials do not publish results or link associated articles on ClinicalTrials.gov.[24]

CONCLUSION

The overall 7.7% increase in the proportion of Black participants in HS clinical trials since 2020 demonstrates a promising outlook for SOC representation in HS clinical trials. Nonetheless, there remains an overall disparity between the enrollment of Black and White HS participants, despite the higher prevalence and severity of this disease in the former population. There is a need for continued efforts to address underrepresentation and ensure equitable inclusion of individuals with SOC in future HS clinical trial research.

DISCLOSURES

The authors have no conflicts of interest to declare.

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