doi:10.36849/JDD.7087

BRIEF COMMUNICATION

Journal of Drugs in Dermatology

Skin of Color Representation in Clinical Trials: An Analysis of Clinicaltrials.gov From 2008 to 2022

Jennifer Jacobs BS,[a] Jamie Lebhar BME,[a] Carrie Diamond BA,[a] Chandler W. Rundle MD,[b] Christopher Stamey MD[a,b]

[a]Duke University School of Medicine, Durham, NC

[b]Duke University Health System, Department of Dermatology, Durham, NC

ABSTRACT

There is a plethora of dermatologic clinical trials; however, little is known regarding the representation of skin of color (SOC) populations. We evaluated the 15 most prevalent skin conditions in SOC patients and their representation in clinical trials over 14 years (2008–2022) to address the lack of research regarding dermatologic clinical trials and SOC inclusion. There have been 1,419 clinical trials conducted over the last 14 years regarding the 15 dermatologic conditions most commonly affecting SOC. Despite the prevalence of these conditions in SOC, Black/African American participation was greater than 50% in clinical trials for two conditions, keloids (77.9%) and seborrheic dermatitis (55.3%). Due to the disparities in inclusion, clinical trial data is difficult to extrapolate the results to SOC patients, limiting therapeutic options and potentially contributing to worse outcomes for such patients. Our study confirms that there is limited data available in clinical trials with respect to race, ethnicity, and FST. Further, it highlights how essential it is for SOC to be both adequately represented and reported in research regarding dermatologic skin conditions to ensure equality and equity in dermatologic care.

J Drugs Dermatol. 2023;22(3):310-311. doi:10.36849/JDD.7087

INTRODUCTION

The skin of color (SOC) population in the United States (US) is increasing.[1] However, SOC is not well represented in dermatology textbooks, resources, or resident education.[2] SOC representation in clinical trials is understudied, with only SOC subpopulations being studied in hidradenitis suppurativa and scar formation following laser surgery,[3,4] and there is a lack of research assessing types of diseases investigated in clinical trials and their inclusion of SOC participants.[1] We evaluated the 15 most prevalent skin conditions in patients with SOC and their representation in clinical trials over 12 years.

MATERIALS AND METHODS

The top 15 skin conditions affecting SOC (Table 1) were used as search terms on clinicaltrials.gov. Trials conducted from 01/01/2008 to 03/01/2022 were evaluated. Only those with at least one location within the US were included. The aggregate number of trials per disease, number completed, and number with published results were recorded. Race, ethnicity, and Fitzpatrick skin type (FST) were recorded. Studies that did not report race, ethnicity, or FST were excluded.

There have been 1,419 clinical trials conducted over the last 14 years regarding the 15 dermatologic conditions. For these conditions, 447 clinical trials were completed with published results, and 278 (62.2%) had specifically identified the race, ethnicity, or FST demographics. Among the 278 trials, there were a total of 84,815 participants stratified by race, 49,883 by ethnicity, and 8,219 by FST (Table 1). 69.1% of participants were White/Caucasian, compared to 16.5% African American/Black participants.

This study evaluated the current landscape of SOC representation in clinical trials over the last 14 years. Our data analysis revealed that despite the prevalence of these conditions in SOC, Black/African Americans comprised greater than 50% of participants in only two conditions, keloids (77.9%) and seborrheic dermatitis (55.3%), respectively. Though prior studies evaluating diversity of participants in dermatology clinical trials reported findings of increasing racial diversity[1] (herein 8 conditions had less than 20% participation of Black/African American patients in trials. Decreasing participation of White/Caucasian patients was seen with 69.1% participation, consistent with prior literature.[5]

RESULTS

While representation in clinical trials is multifaceted, it may reflect healthcare disparities for SOC populations, including access to care and opportunities to participate in research trials.[1] Disparities in inclusion makes it difficult to extrapolate the results to SOC patients and can limit therapeutic options and contribute to worse outcomes. This study provides a reminder and catalyst for future clinical trials and research to diversify study populations and report demographic information of their respective participants.

TABLE 1.

Clinical Trials Participant Characteristics: Race, Ethnicity, and Fitzpatrick Skin Type by Disease

Skin Condition	Abscess	Acne	Alopecia	"Atopic Dermatitis"	Cellulitis	"Contact Dermatitis"	Dermatophytosis	Dyschromia	Folliculitis	Hirsutism	Keloid	"Sebaceous Cyst"	"Seborrheic Dermatitis"	"Seborrheic Keratosis"	Vitiligo	Total
Total Number of Clinical Trials	86	373	176	439	81	31	94	4	7	7	48	1	14	12	46	1419
Studies with Race/ Ethnicity/FST	20	102	20	78	20	4	17	0	1	0	4	0	1	8	3	278
Race, Number of Participants (%)																
American Indian or Alaska Native	6 (0.1)	179 (0.5)	12 (0.5)	76 (0.4)	53 (0.6)	1 (0.6)	9 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (0.2)	1 (0.5)	340 (0.4)
Asian	87 (1.1)	2194 (5.6)	237 (10.8)	3076 (15.4)	541 (5.7)	14 (8.8)	31 (0.8)	0 (0)	4 (10.5)	0 (0)	5 (6.5)	0 (0)	0 (0)	10 (0.6)	7 (3.5)	6206 (7.3)
Native Hawaiian/ Other Pacific Islander	7 (0.1)	112 (0.3)	8 (0.4)	72 (0.4)	22 (0.2)	0 (0)	6 (0.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	227 (0.3)
African American/ Black	1948 (23.9)	6791 (17.3)	198 (9.1)	3220 (16.1)	1108 (11.8)	11 (6.9)	622 (17.0)	0 (0)	10 (26.3)	0 (0)	60 (77.9)	0 (0)	16 (53.3)	30 (1.8)	18 (8.9)	14032 (16.5)
Caucasian/ White	4885 (60.0)	27796 (70.9)	1676 (76.7)	12864 (64.3)	6565 (69.8)	117 (73.1)	2831 (77.2)	0 (0)	18 (47.4)	0 (0)	10 (13.0)	0 (0)	14 (46.7)	1656 (97.2)	163 (80.7)	58595 (69.1)
Multiracial	14 (0.2)	670 (1.7)	8 (0.4)	184 (0.9)	59 (0.6)	12 (7.5)	12 (0.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.1)	0 (0)	960 (1.1)
Hispanic	935 (11.5)	725 (1.8)	12 (0.5)	10 (.0005)	113 (1.2)	0 (0)	132 (3.6)	0 (0)	5 (13.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1932 (2.3)
Other/ Unknown	255 (3.1)	723 (1.8)	35 (1.6)	512 (2.6)	948 (10.1)	5 (3.1)	25 (0.7)	0 (0)	1 (2.6)	0 (0)	2 (2.6)	0 (0)	0 (0)	4 (0.2)	13 (6.4)	2523 (3.0)
Ethnicity, Number of Participants (%)																
Hispanic or Latino	372 (37.4)	7830 (29.4)	170 (13.2)	2124 (15.5)	680 (22.5)	44 (28.9)	767 (34.5)	0 (0)	0 (0)	0 (0)	6 (13.6)	0 (0)	0 (0)	59 (3.7)	46 (22.8)	12098 (24.3)
Not Hispanic or Latino	622 (62.5)	18716 (70.3)	1106 (85.7)	11503 (83.7)	2345 (77.5)	108 (71.1)	1454 (65.5)	0 (0)	0 (0)	0 (0)	38 (86.4)	0 (0)	0 (0)	1480 (93.4)	141 (69.8)	37513 (75.2)
Other/ Unknown	1 (0.1)	81 (0.3)	14 (1.1)	114 (0.8)	1 (.0003)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	46 (2.9)	15 (7.4)	272 (0.5)
Fitzpatrick Skin Type, Number of Participants (%)																
1	0 (0)	333 (4.2)	2 (2.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	6 (3.1)	341 (4.1)
2	0 (0)	1702 (21.4)	26 (29.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	55 (28.8)	1783 (21.7)
3	0 (0)	2203 (27.7)	28 (32.2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	66 (34.6)	2297 (27.9)
4	0 (0)	1870 (23.5)	13 (14.9)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	40 (20.9)	1923 (23.4)
5	0 (0)	1044(13.1)	14 (16.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	13 (6.8)	1071 (13.0)
6	0 (0)	789 (9.9)	4 (4.6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	11 (5.8)	804 (9.8)

Limitations of this study include low numbers of clinical trials for specific skin conditions. Further limitations include the exclusion of trials that were incomplete or did not report their findings publicly. Furthermore, this study did not include information on location of clinical trials in the US.

DISCUSSION

There is limited data available in clinical trials with respect to race, ethnicity, and FST and SOC needs to be adequately represented and reported in research regarding dermatologic skin conditions to ensure equality and equity in dermatologic care.

DISCLOSURES

The authors of this manuscript have no conflicts of interest to declare.

REFERENCES

1. Omar D, Syder N, Brown-Korsah JB, et al. Racial and ethnic disparities in clinical research and the dermatology workforce. *J Am Acad Dermatol.* 2022;4:S0190-9622(22)00544-8.
2. Barve A, Shah M, Sheth P. Skin of color images in pediatric dermatology textbooks. *Pediatr Dermatol.* 2021;38 (Suppl 2):144-5.
3. Rambhia PH, Yan BY, Barilla S, et al. Racial and ethnic diversity in clinical trials of laser treatments for scars. *J Am Acad Dermatol.* 2022;87(5):1178-1179.
4. Okeke CAV, Perry JD, Simmonds FC, et al. Clinical trials and skin of color: The example of hidradenitis suppurativa. *Dermatology.* 2022;238(1):180-184.
5. Charrow A, Xia FD, Joyce C, et al. Diversity in dermatology clinical trials: A systematic review. *JAMA Dermatol.* 2017;153(2):193-198.

AUTHOR CORRESPONDENCE

Christopher Stamey MD
E-mail:..... Christopher.stamey@duke.edu