doi:10.36849/JDD.8379

 ORIGINAL ARTICLE

Gender, Racial, and Fitzpatrick Skin Type Representation in Melasma Clinical Trials

Jennifer Y. Wang BA,[a,b] Kayla Zafar BA,[b,c] David Bitterman BA,[b,d] Paras Patel BA,[b,e] Margaret Kabakova BS,[a,b] Marc Cohen MD,[a] Jared Jagdeo MD MS[a,b]

[a]Department of Dermatology, State University of New York, Downstate Health Sciences University, Brooklyn, NY
[b]Dermatology Service, Veterans Affairs New York Harbor Healthcare System - Brooklyn Campus, Brooklyn, NY
[c]St. George's University School of Medicine, Grenada, West Indies
[d]New York Medical College, Valhalla, NY
[e]Rowan University School of Osteopathic Medicine, Stratford, NJ

ABSTRACT

Melasma, a symmetric pigmentary disorder, is more prevalent in women and individuals with darker skin tones. Despite its global prevalence, there is a notable gap in the understanding of gender, racial, and Fitzpatrick skin type (FST) representation in melasma clinical trials. We conducted a comprehensive search of the United States (US) National Library of Medicine clinical trials database (ClinicalTrials.gov) on March 2nd, 2024, to identify melasma clinical trials. The aim of this study was to assess the demographic representation of participants enrolled in melasma clinical trials. Out of 56 trials identified, 19 met the inclusion criteria, comprising 614 patients. Our analysis revealed a predominant representation of female patients (96.58%) and a diverse representation of racial and ethnic groups, with a majority of Hispanic or Latino patients (43.10%), followed by Asian (23.71%), White (15.52%), and Black or African American patients (14.66%). Fitzpatrick skin types III and IV were most common among trial participants, totaling over 75% of trial participants. The identified gender, racial, and FST representation suggest a deliberate effort towards more inclusive research practices in dermatology. This trend towards inclusivity sets a valuable precedent for improving representation in research for other dermatological conditions that disproportionately impact skin of color patients.

J Drugs Dermatol. 2025;24(1):19-22. doi:10.36849/JDD.8379

INTRODUCTION

Melasma, a symmetric pigmentary disorder, develops primarily on the face.[1] Melasma typically presents as light brown to dark brown macules and patches on the forehead, malar region, and chin.[1] Melasma is more prevalent in women and individuals with darker skin tones.[1] Melasma is attributed to multiple etiologies, including ultraviolet (UV) sun exposure, hormonal influences, pregnancy, cosmetics, birth control, and antiseizure or phototoxic drugs.[1-3] Although the precise age of onset varies, melasma generally occurs between 20 to 30 years of age.[3] The global prevalence worldwide is estimated to be around 1%, while in higher-risk populations, the prevalence has been found to range from 9% to 50%.[2] Melasma not only leads to considerable psychological and emotional distress but also significantly affects a patient's quality of life.[4,5] This impact is particularly pronounced in patients with skin of color, who experience a higher frequency of melasma and greater associated morbidity.[4,5]

The prevalence of melasma varies by race, and existing data on melasma prevalence is often limited to the demographics of specific locations where studies are performed. The prevalence of melasma in Latino populations ranges from 8.2% to 8.8%, while an Arab-American population in Michigan showed a 15.5% prevalence rate.[6,7,8] In contrast, the prevalence of melasma was found to be 4% in a black population in Durban, South Africa.[9] The prevalence of melasma was found to be 2.9% in Saudi Arabia and 1.5% in Ethiopia.[10,11] The prevalence in India is as high as 41.1%.[12] Asian countries such as Nepal and China also report prevalence rates of 6.8% and 13.6%, respectively.[13,14]

As the demographic landscape of the United States continues to diversify, with one in three Americans projected to be a race other than White by 2060, the need for inclusivity in dermatologic research becomes increasingly necessary.[15] Racial minorities are often underrepresented in dermatology clinical trials, including trials involving hidradenitis suppurativa (HS), nail psoriasis, psoriatic arthritis, and laser treatments for scars.[16-20] There is currently a gap in knowledge pertaining to patient representation in melasma clinical trials. Given the documented underrepresentation of skin of color participants in dermatologic clinical trials and the higher prevalence of melasma within these populations, we aim to analyze gender, racial, and Fitzpatrick skin type (FST) representation in melasma clinical trials.[16-20]

MATERIALS AND METHODS

The US National Library of Medicine clinical trials database (ClinicalTrials.gov), an international registry of clinical trials, was searched on March 2nd, 2024, to identify melasma clinical trials. We searched the term "melasma" and filtered for "completed" status. For trials that did not report their results on ClinicalTrials.gov, we searched for the corresponding publication. Trials that did not provide gender, racial, or Fitzpatrick skin type data were excluded. Similar methods have been used in other publications analyzing racial and ethnic representation in HS clinical trials.[19] The following information was obtained: title, year, total number of participants, gender, race or Hispanic origin, and FST. Calculations for race or Hispanic origin and FST percentages were made using only the trials that reported this specific data.

RESULTS

A total of 56 trials were identified on ClinicalTrials.gov. After removing all studies that did not include gender, racial or Hispanic origin, or FST data, 19 trials remained (total of 614 patients). Out of the included clinical trials, 19 trials reported gender data, 9 included race or Hispanic origin data, and 15 included FST data. Female patients comprised the majority of participants (96.58%; Figure 1). Hispanic or Latino patients comprised 43.10% of trial participants, followed by Asian (23.71%), White (15.52%), and Black or African American patients (14.66%; Table 1). There were no American Indian or Alaska Native and Native Hawaiian or Pacific Islander participants in any of the included clinical trials. In contrast, the demographic composition of the United States according to the 2023 census data was 75.5% White, 19.1% Hispanic/Latino, 13.6% Black, 6.3% Asian, 3.0% Native Hawaiian or Pacific Islander, and 1.3% American Indian or Alaska Native (Figure 2).[21]

FIGURE 1. Gender representation in Melasma Clinical Trials compared to National Gender Distribution.

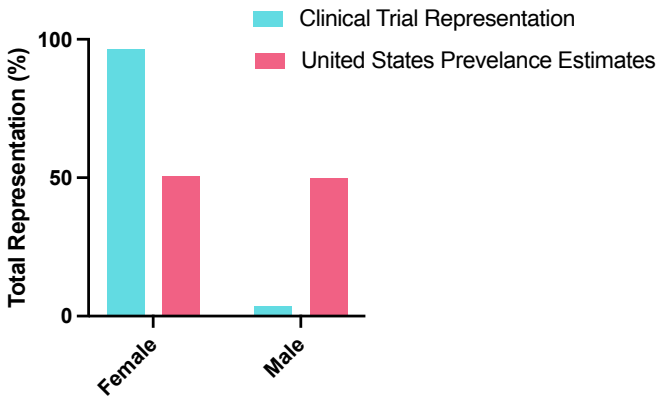
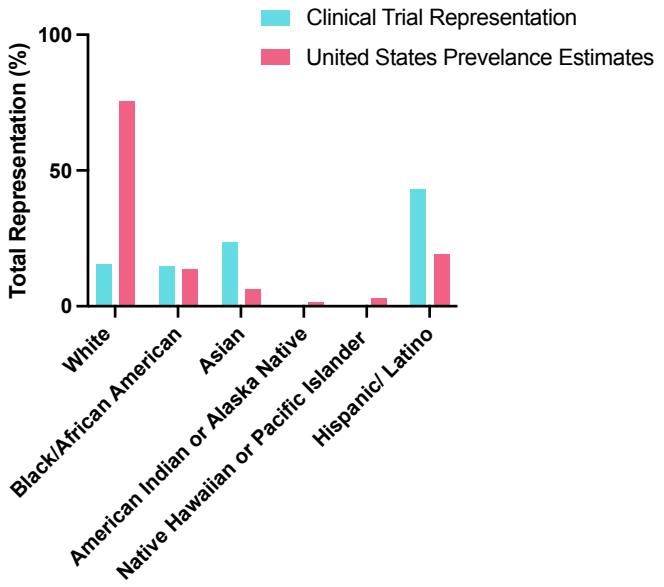


TABLE 1.

Comparison of Representation of Gender, Racial, and Fitzpatrick Skin Type in Melasma Clinical Trials Compared to National Census Demographic Data

Demographic or Parameter	Number of Study Participants, *n*	Representation in Clinical Trials, *n* (%)	Prevalence from the 2023 US Census[21], (%)
Gender	614		
Female	--	593 (96.58%)	50.4%
Male	--	21 (3.42%)	49.6%
Race and Hispanic Origin	232		
White	--	36 (15.52%)	75.5%
Black/African American	--	34 (14.66%)	13.6%
Asian	--	55 (23.71%)	6.3%
American Indian or Alaska Native	--	0 (0.00%)	1.3%
Native Hawaiian or Pacific Islander	--	0 (0.00%)	3.0%
Hispanic/ Latino	--	100 (43.10%)	19.1%
Other	--	3 (1.29%)	--
Unknown	--	4 (1.72%)	--
Fitzpatrick Skin Type	545		
I	--	0 (0.00%)	--
II	--	45 (8.26%)	--
III	--	164 (30.09%)	--
IV	--	250 (45.87%)	--
V	--	84 (15.41%)	--
VI	--	2 (0.37%)	--
VI	--		--

FIGURE 2. Racial and Hispanic origin representation in Melasma Clinical Trials compared with National Race and Hispanic Origin Distribution.



Out of the studies that included Fitzpatrick skin type data, 8.26% were type II, 30.09% were type III, 45.87% were type IV, 15.41% were type V, and 0.37% were type VI. None of the participants in the clinical trials was FST I.

DISCUSSION

To our knowledge, this is the first study to analyze gender, racial, and Fitzpatrick skin type representation in melasma clinical trials. Firstly, our data reveals a low representation of male participants in melasma clinical trials, aligning with the broader observation of melasma being less prevalent in males.[22] Previous research has identified a trend of predominant female representation in dermatology clinical trials, with women constituting 54.9% of participants, a figure significantly lower than the 96.58% observed in the current study.[23] The clinical trials identified in this study appropriately emphasize female representation as melasma is a female-predominant disorder.[22] Nonetheless, it may be beneficial to have male representation in clinical trials, as the prevalence of melasma in males varies across studies.[24-27] Brazil has a prevalence of melasma ranging from 2.5% to 6.0% in men.[24,25] The prevalence of melasma in India has been found to range from 26% to 32% in men.[26,27] It is important for men to be included in clinical trials as melasma has an equally negative impact on the quality of life for men as it does for women.[22] Melasma may also be underdiagnosed in men, as they are less likely to seek treatment compared to women.[28]

The current study revealed a higher proportion of Hispanic/Latino and Asian patients and a lower proportion of White patients in melasma clinical trials, likely reflecting the known higher prevalence of melasma among these populations.[1] This contrasts with trends observed in other dermatologic studies, which typically report a predominance of White participants and an underrepresentation of Hispanic/Latino and Black/African American populations.[16-19] When compared to the latest US census, Black/African Americans were found to be the most underrepresented racial group across all dermatology clinical trials, including psoriasis, eczema, non-melanoma skin cancer, melanoma, aesthetics, and rosacea trials.[16] Similarly, skin of color patients are underrepresented in clinical trials for HS, psoriatic arthritis, and nail psoriasis.[17-19] Similar to melasma, HS is more common in skin of color, yet this population is underrepresented in HS clinical trials.[19] Further studies regarding HS may be necessary to accurately reflect a more diverse patient population.

Given the variability in melasma prevalence across different races and geographical regions, directly comparing clinical trial representation to true prevalence rates proves challenging. Instead, we compared clinical trial representation to US Census data. While this comparison has its limitations due to the inclusion of non-US clinical trials, it may offer a valuable point of reference for determining suitable representation levels. The increased inclusion of Black/African American, Asian, and Hispanic/Latino patients in melasma clinical trials compared to US census data possibly reflects a targeted effort to recruit populations traditionally affected by melasma, with some studies even specifying Hispanic/Latino ethnicity as an inclusion criterion for enrollment.[29,30] We advocate for this practice of including a sample population that is most representative of the larger population impacted by the disease of interest to maximize a study's external validity.

The majority of melasma clinical trial participants were found to have FST III and IV, mirroring the condition's prevalence in this population.[31] In a study with 302 melasma patients in Brazil, 34% of patients had FST III, 38% had FST IV and 16% had FST V.[32] Similarly, a study in Tunisia consisting of 188 melasma patients demonstrated that 14% of patients had FST III, 45% had FST IV, and 40% had FST V.[33] Another study in Brazil with 953 melasma patients showed a distribution of 13% patients with FST II, 36% with FST III, 40% with FST IV and 10% with FST V.[24] These findings suggest that the representation of FSTs in melasma clinical trials closely mirrors the condition's prevalence in different skin types. However, it should be noted that FST does not necessarily correlate to race.[34] For example, an East Asian woman may be clinically identified as an FST type II, but Asian skin is generally considered to be non-White. This distinction highlights the need for nuanced approaches that consider both diversity of skin type and race in clinical trials.

A lack of diversity in clinical trial participation can significantly impede our understanding of the effectiveness, safety, and potential side effects of melasma treatments across different

demographic groups.[35] For instance, the response to treatment and the incidence of side effects may vary significantly between different skin types and racial backgrounds.[36] One randomized clinical trial on LED red light therapy showed that adverse events, including dyspigmentation and blistering, vary significantly based on skin pigmentation and race, with individuals of color exhibiting a lower tolerance to treatment.[36] Approaches to treatment must also be tailored; for instance, sunscreen, a critical aspect of melasma management, is frequently underutilized and perceived as unnecessary by skin of color patients.[37,38]

A strength of this study is that we analyzed all melasma-related clinical trials on ClinicalTrials.gov. A limitation of the study is that due to a lack of race and ethnicity data in melasma literature, we were unable to compare race and ethnic representation to prevalence rates of melasma. Another limitation is inconsistent reporting of demographic data, with some studies providing only FSTs or only racial and Hispanic origin information, but not both. Standardization of these parameters would be useful. Hispanic classification also varied between studies, with some including it under race and others under ethnicity. In our study, we grouped Hispanic with race, aligning with the US Census category of "race and Hispanic origin" to maintain consistency. Additionally, accurately categorizing gender and race may be challenging, as these classifications may not always clearly fit all individuals.

This study demonstrates that women, Hispanic/Latino and Asian patients, and individuals with Fitzpatrick skin types III and IV are predominantly represented in melasma clinical trials. These findings are particularly relevant, considering the higher prevalence of melasma within these groups. This diverse inclusion may be due to increased awareness and effort by researchers to include populations commonly impacted with melasma, reflecting a positive shift towards inclusivity in dermatological research. Other dermatologic conditions predominantly impacting skin of color patients should adopt similarly inclusive approaches to patient representation as that seen in melasma clinical studies.

DISCLOSURES

The authors have no conflicts of interest to disclose.

REFERENCES

1. Ogbechie-Godec OA, Elbuluk N. Melasma: an up-to-date comprehensive review. *Dermatol Ther (Heidelb).* 2017;7(3):305-318.
2. Sheth VM, Pandya AG. Melasma: a comprehensive update: part I. *J Am Acad Dermatol.* 2011;65(4):689-697.
3. StatPearls. Melasma. Available at: https://www.ncbi.nlm.nih.gov/books/NBK459271/. Accessed March 8, 2024.
4. Grimes PE. Management of hyperpigmentation in darker racial ethnic groups. *Semin Cutan Med Surg.* 2009;28(2):77-85.
5. Saedi N, Ganesan AK. Treating hyperpigmentation in darker-skinned patients. *J Drugs Dermatol.* 2013;12(5):563-7.
6. Werlinger KD, Guevara IL, González CM, et al. Prevalence of self-diagnosed melasma among premenopausal Latino women in Dallas and Fort Worth, Tex. *Arch Dermatol.* 2007;143(3):424-5.
7. Sanchez MR. Cutaneous diseases in Latinos. Dermatol Clin. 2003;21(4):689-97.
8. El-Essawi D, Musial JL, Hammad A, et al. A survey of skin disease and skin-related issues in Arab Americans. *J Am Acad Dermatol.* 2007;56(6):933-8.
9. Dlova NC, Mankahla A, Madala N, et al. The spectrum of skin diseases in a black population in Durban, KwaZulu-Natal, South Africa. *Int J Dermatol.* 2015;54(3):279-85.
10. Parthasaradhi A, Al Gufai AF. The pattern of skin diseases in Hail Region, Saudi Arabia. *Ann Saudi Med.* 1998;18(6):558-61.
11. Hiletework M. Skin diseases seen in Kazanchis health center. *Ethiop Med J.* 1998;36(4):245-54.
12. Shenoi SD, Davis SV, Rao S, et al. Dermatoses among paddy field workers--a descriptive, cross-sectional pilot study. *Indian J Dermatol Venereol Leprol.* 2005;71(4):254-8.
13. Walker SL, Shah M, Hubbard VG, et al. Skin disease is common in rural Nepal: results of a point prevalence study. *Br J Dermatol.* 2008;158(2):334-8.
14. Wang R, Wang T, Cao L, et al. Prevalence of melasma in Chinese Han and Chinese Yi: a survey in Liangshan district. *Chin J Dermatovenereol.* 2010;24(6):546–548
15. US Census Bureau. Demographic Turning Points for the United States: Population Projections for 2020 to 2060. Available at: https://www.census.gov/library/publications/2020/demo/p25-1144.html.
16. Mineroff J, Nguyen JK, Jagdeo J. Racial and ethnic underrepresentation in dermatology clinical trials. *J Am Acad Dermatol.* 2023;89(2):293-300. doi:10.1016/j.jaad.2023.04.011.
17. Ricardo JW, Qiu Y, Lipner SR. Racial, ethnic, and sex disparities in nail psoriasis clinical trials: a systematic review. *Skin Appendage Disord.* 2022;8(3):171-178.
18. Shwe S, Nguyen C, Bhutani T. Racial disparities in clinical trials of biologic treatments for psoriatic arthritis. *J Am Acad Dermatol.* 2022;87(4):910-912.
19. Elhage KG, Davis MS, Hakimi M, et al. Ethnoracial representation in hidradenitis suppurativa clinical trials. *Arch Dermatol Res.* 2023;315(6):1793-1796.
20. 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.
21. United States Census Bureau. QuickFacts United States. Available at: https://www.census.gov/quickfacts/fact/table/US/PST045223. Accessed March 6, 2024.
22. Sarkar R, Ailawadi P, Garg S. Melasma in men: a review of clinical, etiological, and management issues. *J Clin Aesthet Dermatol.* 2018;11(2):53-59.
23. Charrow A, Xia FD, Joyce C, Mostaghimi A. Diversity in dermatology clinical trials: a systematic review. *JAMA Dermatol.* 2017;153(2):193-198.
24. Hexsel D, Lacerda DA, Cavalcante AS, et al. Epidemiology of melasma in Brazilian patients: a multicenter study. *Int J Dermatol.* 2014;53(4):440-4.
25. Ishiy PS, Silva LR, Penha M, et al. Skin diseases reported by workers from UNESP campus at Rubião Jr, Botucatu-SP (Brazil). *An Bras Dermatol.* 2014;89(3):529-31.
26. Yalamanchili R, Shastry V, Betkerur J. Clinico-epidemiological Study and Quality of Life Assessment in Melasma. *Indian J Dermatol.* 2015;60(5):519.
27. Sarkar R, Jain RK, Puri P. Melasma in Indian males. Dermatol Surg. 2003;29(2):204.
28. Alexa B. Steuer JMC, John G. Zampella. Utilization of dermatological care by men in the United States. *J Am Acad Dermatol.* 2019;81(4)(1):AB1454.
29. Armstrong AW, Soliman AM, Betts KA, et al. Comparative efficacy and relative ranking of biologics and oral therapies for moderate-to-severe plaque psoriasis: a network meta-analysis. *Dermatol Ther (Heidelb).* 2021;11(3):885-905.
30. Kodali S, Guevara IL, Carrigan CR, et al. A prospective, randomized, split-face, controlled trial of salicylic acid peels in the treatment of melasma in Latin American women. *J Am Acad Dermatol.* 2010;63(6):1030-5.
31. Mahajan VK, Patil A, Blicharz L, et al. Medical therapies for melasma. *J Cosmet Dermatol.* 2022;21(9):3707-3728.
32. Tamega Ade A, Miot LD, Bonfietti C, et al. Clinical patterns and epidemiological characteristics of facial melasma in Brazilian women. *J Eur Acad Dermatol Venereol.* 2013;27(2):151-6.
33. Guinot C, Cheffai S, Latreille J, et al. Aggravating factors for melasma: a prospective study in 197 Tunisian patients. *J Eur Acad Dermatol Venereol.* 2010;24(9):1060-9.
34. Ware OR, Dawson JE, Shinohara MM, et al. Racial limitations of fitzpatrick skin type. *Cutis.* 2020;105(2):77-80.
35. Schwartz AL, Alsan M, Morris AA, et al. Why diverse clinical trial participation matters. *N Engl J Med.* 2023;388(14):1252-1254.
36. Jagdeo J, Nguyen JK, Ho D, et al. Safety of light emitting diode-red light on human skin: Two randomized controlled trials. *J Biophotonics.* 2020;13(3):e201960014.
37. Desai SR, Alexis AF, Elbuluk N, et al. Best practices in the treatment of melasma with a focus on patients with skin of color. *J Am Acad Dermatol.* 2024;90(2):269-279.
38. Martin A, Liu J, Thatiparthi A, et al. Asian Americans are less likely to wear sunscreen compared with non-Hispanic whites. *J Am Acad Dermatol.* 2022;86(1):167-169.

AUTHOR CORRESPONDENCE

Jared Jagdeo MD MS
E-mail:..... jrjagdeo@gmail.com