Racial, Ethnic, and Sex Disparities in Nail Psoriasis Clinical Trials: A Systematic Review

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Keywords

Nail · Disease in skin of color · Nail psoriasis · Nail inflammatory disease · Clinical trials

Abstract

Introduction: Nail psoriasis (NP) disproportionately affects quality of life in females versus males. Demographics of NP research cohorts are not well characterized. In this systematic review, we characterize the representation of racial/ethnic groups and women in NP randomized clinical trials (RCTs). **Methods:** A systematic search of MEDLINE was performed; RCTs of NP pharmacologic treatments or cutaneous psoriasis/psoriatic arthritis with the number of NP patients described were included. **Results:** Overall, 45 RCTs were analyzed, with 91.1% reporting sex, and 67.9% of participants were men. 7/41 (17%) studies reporting sex included ≥45% female participants. Of 45 RCTs, 35.6% reported race and/or ethnicity. Of the 22 studies with ≥1 US-based site, 13 (59%) reported race/ethnicity; 3 out of 23 (13%) studies with <1 US-based site reported these data. Enrollment of nonwhite participants was significantly lower than representation within the US census (13.4% vs. 39.9%; $p < 0.001$). Treatment type, route of administration, location with ≥1 US-based site,

funding, and journal type were significantly associated with race/ethnicity reporting ($p < 0.05$ all comparisons). **Discussion/Conclusion:** Reporting of racial/ethnic demographics is lacking in NP RCTs. Women and racial/ethnic minorities remain underrepresented in NP research. There is a need for increased reporting and diversification of NP clinical trial participants.

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Introduction

Nail involvement is common in psoriasis [1], with an estimated lifetime incidence of 80–90% and varying prevalence 10–82% [2–7]. Nail psoriasis (NP) has substantial impact on patient quality of life (QOL), with women affected more often than men [8, 9]. Psoriasis may be more severe [10] and have greater QOL impact amongst racial/ethnic minorities compared to whites [11]. In a US survey-based study of psoriatic patients, African Americans ($N = 27$) reported 3–10 palms of involvement (3–10% of body surface area) as opposed to 1–2 palms (1–2% of body surface area) for Caucasians ($N = 541$) [10]. In addition, in a retrospective study of 848 psoriatic patients,

Asians and Hispanics had more severe disease than whites ($p < 0.0001$ and $p = 0.16$, respectively) [12]. Despite the growing number of effective psoriasis therapies, under-treatment is prevalent [13], especially among racial/ethnic minorities. In the USA, black Medicare beneficiaries with moderate to severe psoriasis are 70% less likely to be treated with biologic therapy compared with whites [14]. US ambulatory healthcare utilization for psoriasis is also low among non-Hispanic ethnic minorities compared with whites [15].

The racial/ethnic composition of the USA is growing, and it is projected that by 2044, 50% of the US population will belong to a minority group [16]. Women and racial/ethnic minorities are still underrepresented in US clinical trials despite national efforts to diversify research cohorts [17]. As per the 1993 National Institutes of Health (NIH) revitalization act [18], racial/ethnic minorities and women must be included in all NIH-funded research unless a justification is approved. Since 2001, NIH-defined phase III clinical trials must include valid subgroup analysis by sex/gender and/or race/ethnicity if a difference in outcome is expected amongst groups [18]. Since 2017, subgroup analyses must be publicly available on ClinicalTrials.gov [19].

Despite prevalence and QOL impact, to date, there are no studies characterizing races, ethnicities, and sexes of NP clinical trial participants. Ensuring inclusion of diverse populations in clinical trials is essential to produce generalizable knowledge and therapies pertinent to all populations. In this systematic review, we analyze the racial/ethnic and sex composition NP randomized clinical trial (RCT) participants.

Methods and Materials

This review was prospectively registered on the PROSPERO database (CRD42020213662) and was executed based on the PRISMA reporting guidelines. A literature search of the MEDLINE database, via PubMed and Ovid, of RCTs on pharmacologic treatments of NP was performed on February 12, 2021. No limited time frame was used. Combinations and variations of the terms “psoriasis” and “nails” were utilized (online suppl. Appendix 1; for all online suppl. material, see www.karger.com/doi/10.1159/000520469). Studies were first independently screened based on title and abstract by 2 authors (J.W.R. and Y.Q.). Both authors then independently reviewed full-text articles for eligibility and extracted data from eligible studies. Any discrepancies were resolved by a third author (S.R.L.).

RCTs were included if they examined pharmacologic treatment(s) for NP and/or cutaneous psoriasis/psoriatic arthritis where the number of patients with NP was described. Studies were excluded if they were not human studies, not pertaining to phar-

macologic treatments of NP and/or cutaneous psoriasis/psoriatic arthritis, non-RCT, and not in English language. Publications reporting secondary, interim, or post hoc analyses of excluded RCTs were included. Open-label extension studies of excluded RCTs were included.

The following data were extracted: author; year of publication; country; study design; funding source; journal type; treatment type (conventional, small molecule, or biologic) and route of administration (local, intralesional, or systemic); total number of patients and number of patients with NP; participants' age, race, and ethnicity. All studies were divided into 2 groups: ≥ 1 US-based site and < 1 US-based site. Funding source was categorized based on the ClinicalTrials.gov designations as (1) industry, (2) government, or (3) university or other nonprofit or nonfederal organizations.

Race and Ethnicity

Reporting of race and ethnicity was based on constructs outlined by the Office of Management and Budget guidelines for federal data [20] with 5 race categories: American Indian/Alaska Native, Asian, black/African American, Native Hawaiian/Other Pacific Islander, and white. Individuals identified by 2 or more races were categorized as mixed race. Ethnicity was categorized as “Hispanic/Latino” or “non-Hispanic/Latino.” All participants identified by a race other than white, including those categorized as “other,” and Hispanic ethnicity were considered nonwhite for bivariate analysis.

Statistical Analysis

Extracted data were tabulated in Microsoft Excel 2020 and reported in a descriptive manner, using counts and percentages. Representation for each racial/ethnic group was calculated with the total number of participants among the studies that reported information on that racial/ethnic group as the denominator and the number of participants reported in the racial/ethnic group as the numerator. Therefore, the denominator used for calculating the proportion of each racial/ethnic group varied. Representation of men and women was calculated with the total number of participants among all studies that reported sex as the denominator and the number of male/female participants as the numerator. A different denominator of US-based studies was used for analysis of racial/ethnic representation. Counts and percentages of treatment type, route of administration, year of publication (published in 2000 or earlier), country (with ≥ 1 or < 1 US-based site), funding source, and journal type were presented overall and by reporting of race/ethnicity and sex representation. Studies assessing biologic and/or small molecule therapies were compared to those examining conventional treatments, and studies funded by industry were compared to those with other funding types. The proportion of race/ethnicity reporting was noted for each specific group. χ^2 or Fisher's exact test, as appropriate, was used to determine statistical significance of study differences by reporting of race/ethnicity and sex representation. Similar to categorization used by Charrow et al. [21], studies composed of $< 45\%$ female participants were considered underrepresented of sex. One-sample proportion tests were used to compare representation of women across all studies to the 45% threshold value and representation across racial/ethnic groups in studies with ≥ 1 US-based site to the overall demographics of the USA using the Census Bureau estimates for 2019 [22]. Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA).

Fig. 1. Flow diagram for selection of studies. NP, nail psoriasis; PsO, psoriasis; PsA, psoriatic arthritis; RCT, randomized clinical trial; OLE, open-label extension.

Results

The initial database search identified 396 studies, with 189 duplicates. After screening for title and abstract, 105 studies were assessed for eligibility against inclusion and exclusion criteria. Seven additional articles were included from searching references of the included articles. A total of 45 RCTs reporting on 12,943 patients (mean age 44.4 years; age range: 18–88 years), 9,751 of whom had NP, were analyzed (Fig. 1; online suppl. Appendix 2). Of the 45 RCTs, 22 had ≥ 1 US-based site and 23 studies had < 1 US-based site. Of note, all demographics herein reported are from all study participants and not from patients with NP exclusively as this information is generally reported for the complete number of patients in each study.

Reporting of Race and Ethnicity

Race and/or ethnicity data were reported in 16 (36%) of 45 RCTs, with 15 (94%) reporting race alone and 1 (6%) study reporting race and ethnicity. Of all studies reporting race, 7 (44%) reported categories as other than white/Caucasian and “other.” None of the included studies stated whether race/ethnicity was self-reported. Thirteen of the 22 studies (59%) conducted partially or exclusively in the USA reported racial and/or ethnic data, while 3/23 studies (13%) conducted outside the USA reported these data.

Treatment type, route of administration, location with ≥ 1 US-based site, funding type, and journal type were significantly associated with reporting of racial and/or ethnic data ($p < 0.05$ for all comparisons; Table 1). Articles examining biologic and/or small molecule therapies were more likely to report racial/ethnic demographics compared to those examining conventional treatments (15/28 [54%] vs. 1/17 [6%]; $p = 0.001$). Of all routes of administration, studies assessing systemic treatments had the highest rate of race/ethnicity reporting (16/32 [50%]). Studies with ≥ 1 US-based site were more likely to report race/ethnicity than those with < 1 US-based site (13/22 [59%] vs. 3/23 [13%]; $p = 0.001$). Industry-funded studies were more likely to report race/ethnicity than studies with other funding types (15/30 [50%] vs. 1/15 [7%]; $p = 0.004$). Of all journal types, articles in rheumatology journals had the highest rate of race/ethnicity reporting (5/5 [100%]), while 10/35 (29%) studies in dermatology journals reported this information.

Racial and Ethnic Composition of Trials

Across all studies with ≥ 1 US-based site reporting race and/or ethnicity, 7,032 of 8,118 (86.6%) subjects were white, 397 (8.4%) Asian, 92 (2.3%) black/African American, 5 (0.6%) American Indian/Alaska Native, and 1 (0.1%) Native Hawaiian/Other Pacific Islander (Table 2).

Table 1. Study characteristics by the reporting of race and/or ethnicity

Variable	Categories	Yes (N = 16), n (%)	No (N = 29), n (%)	p value	Test
Treatment type	Biologic	11 (48)	12 (52)	0.001	Fisher
	Conventional	1 (6)	16 (94)		
	Small molecule	3 (75)	1 (25)		
	Small molecule and biologic	1 (100)	0 (0)		
Route	Intralesional and topical	0 (0)	1 (100)	0.002	Fisher
	Systemic	16 (50)	16 (50)		
	Topical	0 (0)	12 (100)		
Published in 2000 or before	No	16 (40)	24 (60)	0.14	Fisher
	Yes	0 (0)	5 (100)		
With ≥1 US-based site	No	3 (13)	20 (87)	0.001	χ ²
	Yes	13 (59)	9 (41)		
Funding type	Government	0 (0)	3 (100)	0.018	Fisher
	Industry	15 (50)	15 (50)		
	No funding	1 (25)	3 (75)		
	Not reported	0 (0)	8 (100)		
Journal type	Dermatology	10 (29)	25 (71)	0.006	Fisher
	General medicine	0 (0)	2 (100)		
	General pharmacology	1 (33)	2 (67)		
	Rheumatology	5 (100)	0 (0)		

Table 2. Comparison of representation of racial/ethnic groups in NP RCTs with ≥1 US-based site to national estimates

Racial/ethnic group	Studies reporting on each racial/ethnic group, n	Participants in studies reporting each racial/ethnic group, n	Representation in NP RCTs with ≥1 US-based site (participants, N = 8,118), n (%) ^a	Prevalence estimates from the 2019 US census, %	p value ^b
White/Caucasian	13	8,118	7,032 (86.6)	60.1	<0.001
Nonwhite	13	8,118	1086 (13.4)	39.9	<0.001
Black/African American	5	3,936	92 (2.3)	13.4	<0.001
Asian	7	4,719	397 (8.4)	5.9	<0.001
American Indian or Alaska Native	1	809	5 (0.6)	1.3	0.087
Native Hawaiian or Pacific Islander	1	809	1 (0.1)	0.2	<0.001
Multiple races	1	809	6 (0.7)	2.8	<0.001
Hispanic or Latino	1	809	93 (11.5)	18.5	<0.001

NP, nail psoriasis; RCTs, randomized clinical trials. ^aRepresentation of each racial/ethnic group is calculated with the total number of participants among studies that reported information on that racial/ethnic group as the denominator. ^bp value from the one-sample proportion test.

For 91 subjects, race was recorded as “other.” Six (0.7%) participants were recorded as “mixed race.” Ninety-three of 8,118 (11.5%) study participants were Hispanic or Latino (Table 2). Of the 3 studies with <1 US-based site that reported racial/ethnic demographics, 2 reported white race exclusively and 1 study included white participants only.

Comparison with National Demographics

Figure 2 shows a comparison of the racial/ethnic representation among NP RCTs with ≥1 US-based site to the national prevalence estimates by the racial/ethnic group from 2019 Census Bureau data [22]. Enrollment of non-white participants was significantly lower than representation within the US census (13.4% vs. 39.9%; $p < 0.001$; Table 2). Black participants represented 2.3% of enroll-

Fig. 2. Trends in racial/ethnic representation in nail psoriasis RCTs compared with national estimates. National estimates were obtained from 2019 Census Bureau data. RCTs, randomized clinical trials.

ment, which was significantly lower than the 13.4% within the US census ($p < 0.001$). A similar pattern was seen for all racial/ethnic minority groups except for Asians. Asians were overrepresented in NP RCTs compared with the national prevalence estimate (8.4% vs. 5.9%; $p < 0.001$; Table 2).

Reporting and Distribution of Sex

Of 45 studies analyzed, 41 (91%) reported participants' sexes. The majority of subjects were male (8,632 of 12,717 [67.9%]). Enrollment of female participants in NP RCTs (32.1%) was significantly lower than the 45% threshold value ($p < 0.001$). No statistically significant associations were found between treatment type, route of administration, year of publication, location, funding type, journal type, and sex reporting ($p > 0.05$ for all comparisons; Table 3).

Of 41 RCTs that reported participants' sex, 7 (17%) included at least 45% female participants. Inclusion of

≥45% women in NP RCTs was not statistically significantly associated with treatment type, route of administration, year of publication, location, funding type, or journal type ($p > 0.05$ for all comparisons; Table 3).

Discussion

To our knowledge, this is the first study characterizing the racial/ethnic and sex composition of NP RCTs. Our systematic review demonstrates that racial/ethnic minorities and women are underrepresented in NP research. Nonwhite groups comprise approximately 40% of the US population [22], but represented only 13.4% of all NP participants in studies with ≥1 US-based site. Systematic reviews assessing the racial/ethnic composition of clinical trials on cancer [23], rheumatoid arthritis [24], Alzheimer's disease [25], and cardiovascular disease [26] have also shown underrepresentation of racial/ethnic minority

Table 3. Study characteristics by the reporting of sex and the inclusion of ≥45% female participants in nail psoriasis randomized clinical trials

Variable	Categories	Reporting of sex (N = 45)			Inclusion of ≥45% female participants (N = 41) ^a		
		yes (N = 41), n (%)	no (N = 4), n (%)	p value ^b	yes (N = 7), n (%)	no (N = 34), n (%)	p value ^b
Treatment type	Biologic	21 (91)	2 (9)	>0.99	4 (19)	17 (81)	>0.99
	Conventional	15 (88)	2 (12)		3 (20)	12 (80)	
	Small molecule	4 (100)	0 (0)		0 (0)	4 (100)	
	Small molecule and biologic	1 (100)	0 (0)		0 (0)	1 (100)	
Route	Intralesional and topical	1 (100)	0 (0)	0.36	0 (0)	1 (100)	0.71
	Systemic	30 (94)	2 (6)		6 (20)	24 (80)	
	Topical	10 (83)	2 (17)		1 (10)	9 (90)	
Published in 2000 or before	No	36 (90)	4 (10)	>0.99	7 (19)	29 (81)	0.57
	Yes	5 (100)	0 (0)		0 (0)	5 (100)	
With ≥1 US-based site	No	21 (91)	2 (9)	>0.99	3 (14)	18 (86)	0.7
	Yes	20 (91)	2 (9)		4 (20)	16 (80)	
Funding type	Government	3 (100)	0 (0)	0.4	0 (0)	3 (100)	>0.99
	Industry	28 (93)	2 (7)		5 (18)	23 (82)	
	No funding	4 (100)	0 (0)		1 (25)	3 (75)	
	Not reported	6 (75)	2 (25)		1 (17)	5 (83)	
Journal type	Dermatology	31 (87)	4 (11)	>0.99	4 (13)	27 (87)	0.09
	General medicine	2 (100)	0 (0)		0 (0)	2 (100)	
	General pharmacology	3 (100)	0 (0)		0 (0)	3 (100)	
	Rheumatology	5 (100)	0 (0)		3 (60)	2 (40)	

^a Among 41 studies that reported data on participants' sex. ^b p values from χ^2 or Fisher exact tests as appropriate.

groups. In a recent systematic review examining the racial/ethnic composition of RCTs on various skin diseases, psoriasis studies were least diverse, with 84.3% of subjects being white [21]. Our study showed that across all NP RCTs, 32.1% of participants were female.

Several factors may be contributing to the lack of diversity in NP RCTs. First, according to the 2009–2010 US National Health and Nutrition Examination Survey (NHANES), psoriasis is less prevalent in African Americans (1.9%) and Hispanics (1.6%) than white/Caucasians (3.6%) [27, 28]. Second, a large portion of non-US studies were based in Europe, where there is a smaller proportion of nonwhite individuals. In addition, unwillingness of racial/ethnic minority groups to participate in research may also play a role. In the USA, African Americans and Hispanics experience higher levels of physician distrust compared with whites [29]. Reported unfamiliarity toward biologics in African Americans [30] may also hinder black patients from enrolling in NP RCTs for biologic therapies.

The negative impact of NP on QOL is greatest among females [8], and yet only 32.1% of participants across all included NP RCTs were women. Women face more strict inclusion/exclusion criteria than men for enrollment in NP RCTs assessing biologic therapies. For example, contraception is typically required during trials, which may discourage women of childbearing age from participating in NP research. There is gender bias in RCTs assessing biologic therapies for psoriasis [31]. Higher severity of psoriasis in men versus women may explain why a higher proportion of men with psoriasis are treated with biologics [32, 33]. Lower disease severity in women may decrease eligibility for biologics RCTs. Since many NP RCTs analyze data from larger cutaneous psoriasis studies, it was expected that similar gender bias also occurred in NP research.

Reporting of racial/ethnic demographics is lacking in NP RCTs. While there have been national efforts to increase diversity in US RCTs, over 40% of studies with ≥1 US-based site included in this review did not report these

data. Since most included RCTs (30 of 45 [67%]) were industry funded, NIH legislation mandating diversification of research cohorts was not applicable. The current US Food and Drug Administration (FDA) policy requires sponsors of investigational new drugs to report on and present safety and efficacy data by race/ethnicity of participants [34]. However, this policy applies only to investigational new drugs and not industry-funded NP research. As opposed to the NIH, FDA policies do not mandate inclusion of diverse populations [34]. The reporting of racial/ethnic demographics amongst non-US RCTs was even sparser, with only 13% of studies reporting these data. Most of these studies were conducted in Europe, where legislation comparable to NIH or FDA policies is lacking. European trials are 5 times less likely to report on ethnicity compared with US-based studies [35].

Our study shows that current policies fail to promote reporting of racial/ethnic demographics and inclusion of diverse study populations in NP RCTs. There are, however, several opportunities for improvement. This study demonstrated a statistically significant association between treatment type, route of administration, location with ≥ 1 US-based site, funding type, and journal type with reporting of race and/or ethnicity. Study sponsors, as well as journal editors, are uniquely positioned to advocate for diversity in NP research. These findings may guide study sponsors, editors, and other policy makers in the development of strategies to increase participation of minority groups in NP RCTs.

This study has several limitations. Demographics represent patients with NP and cutaneous psoriasis and/or psoriatic arthritis and not NP exclusively. Including only RCTs may have biased our sample toward higher-quality studies and did not account for other studies, which may have had less diverse participants, potentially overestimating reality. Searching the MEDLINE database exclusively may have restricted included trials. Defining race and ethnicity is a complex task, sometimes requiring genetic, social, and anthropological exploration. Although RCTs are encouraged to report these data using practical mutually exclusive categories, this method may be too simplistic [36].

Conclusions

Our study demonstrated that racial/ethnic minorities and women remain underrepresented in NP RCTs, despite the disproportionate QOL impact in the latter. RCTs are the mainstay for development of safe and effective

treatments for NP. Therefore, it is crucial to include diverse populations in NP research cohorts to ensure that all individuals have access to new, safer, and more effective treatments. Our results emphasize the need for more stringent regulations to increase reporting of race/ethnicity and to diversify NP study populations. Study sponsors, journal editors, and policy makers are encouraged to advocate for reporting of race and ethnicity in NP RCTs.

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Statement of Ethics

Ethical approval was not required for this systematic review because all data are publicly available. The study protocol was registered in the International Prospective Register of Systematic Reviews (CRD42020213662).

Conflict of Interest Statement

Dr. Jose W. Ricardo, Yuqing Qiu, and Dr. Shari R. Lipner have no conflicts of interest relevant to the content of this manuscript.

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Author Contributions

Jose W. Ricardo was responsible for data extraction, writing of the manuscript, and figure and data spreadsheet extraction creation. Jose W. Ricardo and Yuqing Qiu screened abstract and full-text articles and conducted data extraction, independently. Any discrepancies between the 2 authors were resolved by Shari Lipner. Jose W. Ricardo and Yuqing Qiu performed the statistical analysis. Shari Lipner is the senior author who conceived the study, wrote the manuscript, and performed critical revision for important intellectual content. All authors reviewed the manuscript.

Data Availability Statement

The datasets supporting the findings of the present systematic review are available from the corresponding author upon reasonable request. All findings herein presented are derived from the articles listed in the online supplementary material.

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