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Assessing Participant Diversity in Acne Clinical Trials

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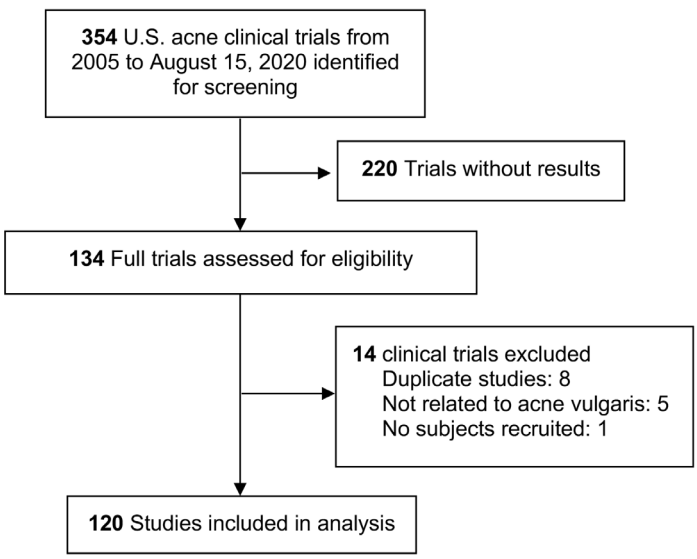
Dear Editor:

A lack of clinical trials devoted specifically to treatment protocols in minority groups and diverse individuals with skin of color (SOC) exists.[1] Treatment decisions often vary based on patient cultural preferences and have differing efficacies based on skin type.[2] As such, it is important to evaluate the diversity of participants being included in dermatology clinical trials. Acne vulgaris is a common dermatosis that affects patients of all skin types with no major racial predilection. Furthermore, significant differences in the clinical characteristics, perceptions, and treatment preferences of acne vulgaris based on patient race have been reported in the literature, making this an ideal dermatosis to evaluate diversity and SOC in dermatology clinical trials.[3,4]

A systematic review for "acne vulgaris" on www.clinicaltrials.gov was performed from 2005 to June 30, 2020. This database provided comprehensive published and unpublished clinical trial data, allowing for a representative survey of all acne trials. Inclusion criteria included studies focused on acne vulgaris or treatment of associated secondary lesions (eg, acne scars). Exclusion criteria included studies without results, studies not focused on acne vulgaris, and duplicate trials examining the same study population for multiple interventions. Any journal publications that resulted directly from the included clinical trials were also reviewed.

FIGURE 1. PRISMA diagram.



Our search yielded 354 U.S. acne trials (Figure 1). Of those, 220 did not have study results, and an additional 14 were excluded according to the exclusion criteria. A total of 120 studies were included in the study, yielding 35,472 total enrolled participants. Most of the trials enrolled fewer than 100 patients (53%, n=63; range 3–2102). Topical therapy was the most common intervention studied, followed by oral medication (66%, n=78, and 8.3%, n=10, respectively). Overall, 56% of trial participants were female. Race was reported in 42% (n=50) of trials using the National Institutes of Health racial and ethnic categories, with 72.7% of total participants Caucasian, 18.7% African American, and 4.6% Asian. Examining ethnicity, 31.2% of trial participants were Hispanic. No trials performed a sub-analysis of treatment by racial group. Only 5 trials (4.2%) were dedicated to acne treatment in populations with SOC. Trial funding and trial start year did not correlate with gender diversity or racial diversity (Table 1).

Our results demonstrate most clinical trials that disclosed race/ethnicity included a degree of diversity in recruitment. This is similar to what has been reported in reviews of published randomized controlled trials studying acne treatments.[1] However, we found that race was not reported in the majority of trials, and only five were dedicated to treatment in SOC. While post hoc analyses based on race or ethnicity in acne trials have been performed,[5] many trials that did report race were not sufficiently powered to perform racial group or skin type sub-analyses of their data, given they enrolled fewer than 20 patients. Taken together, this suggests there is a relative lack of active consideration being served to this factor.

It is well-known that differences in skin type impact treatment effectiveness.[2] This is especially relevant with acne vulgaris. A study of 208 female patients with acne vulgaris showed that age of onset, body areas involved, treatment goals, and the presence of post-inflammatory hyperpigmentation significantly differed by patient race.[4] In addition, a study of 29,928 patients with acne reported significant differences in treatment patterns based on patient race, with non-Hispanic black patients more likely to receive topical retinoids and topical antibiotics compared to oral therapies.[6] This, in part,

TABLE 1.

Summary of Clinical Trial Characteristics

Clinical Trial Characteristics	No. of All Trials	Trials Reported Race No. (%)	*P*-value*
Overall	120	50 (42%)	--
Funding	--	--	0.03
Industry	91	43 (47%)	--
Other	29	7 (24%)	--
Age group	--	--	0.59
Adult only	28	14 (50%)	--
Pediatric only	5	2 (40%)	--
Both	87	34 (39%)	--
Intervention type	--	--	0.64
Topical	78	31 (40%)	--
Oral medication	10	3 (30%)	--
Photodynamic therapy	10	5 (50%)	--
Biologic	6	3 (50%)	--
Behavioral	4	2 (50%)	--
Multiple	10	6 (60%)	--
Observational study	2	0 (0%)	--
Trial start year	--	--	0.99
Prior to 2013	69	29 (42%)	
2013 and after	51	21 (41%)	
Trial number of total participants	--	--	0.46
100 or greater	57	26 (46%)	--
Fewer than 100	63	24 (38%)	--

*Calculated by Fischer exact tests.

may be due to variations in treatment preference based on patient race.[3] In total, these differences highlight that without an emphasis on minority populations, dermatologists may not be able to optimally manage these patients. Furthermore, our study demonstrated that the majority of acne treatment research focuses on studies of topical therapies; while most acne treatment is topical, this emphasis magnifies the paucity of dedicated data for other treatments (eg, oral therapies, photodynamic therapy) in SOC.

Nearly half of dermatologists report their medical training is inadequate on conditions in SOC.[7] Modifying training materials and information in textbooks is favored to alleviate this issue[8]; however, without evidence-based treatment data from these populations, the task of curriculum reform becomes difficult. As a field, we must work to better recognize the importance of trials specifically in minority populations.

Disclosure

The authors have all contributed to and read the following manuscript and have no conflicts of interest or financial disclosures to report.

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