Review

OPEN

Assessing the inclusion of women of color in lichen sclerosus treatment studies: a scoping review

Jessica C. Evans, MS[a], Ekene A. Ezenwa, MD[b], Olushola L. Akinshemoyin Vaughn, MD[c,*]

ABSTRACT

Background: Vulvar lichen sclerosus (VLS) is an underrecognized chronic inflammatory skin condition with significant clinical features and potential for malignant transformation. To date, there are no studies comparing the course of this disease in women of color to other racial groups.

Objective: The objective of this study was to provide a scoping review examining racial demographic data in VLS treatment studies and specifically assessing for the inclusion of women of color.

Methods: Using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, a primary literature search was conducted using 4 databases: Ovid Medline(R), Scopus, Cochrane, and Web of Science from all years to December 2022. We included published studies with adult women diagnosed with VLS and containing a treatment arm using topical corticosteroids. Single case reports, literature reviews, systemic reviews, meta-analyses, and reports not available in English were excluded.

Results: Overall, 1340 nonduplicate studies were assessed for eligibility criteria. In total, 65 publications were included. Only 6 included racial demographic data. Black women made up at most 3.8% of the sample population and Latinx women made up at most 5.7%.

Limitations: Our review focused on a specific intervention (ie, the use of topical corticosteroids for the treatment of VLS), which may restrict the generalizability of our findings to other interventions. No risk of bias assessment was done due to the scoping nature of the review.

Conclusion: Women of color are underrepresented in studies of topical corticosteroid use in adult women with VLS. Intentional diversity in recruitment will enable the collection of data that is both more accurate and reflective of a broader spectrum of perspectives and life experiences.

Keywords: African American, corticosteroids, demographics, skin of color, treatment, vulvar lichen sclerosus

Introduction

Vulvar lichen sclerosus (VLS) is a chronic, lymphocyte-mediated skin disease that can have debilitating symptoms such as pruritus, irritation, and pain.[1] It clinically presents with ivory-white atrophic plaques with a waxy texture or epidermal wrinkling ("cigarette paper" appearance), depigmentation or hyperpigmentation, ecchymoses, resorption of the labia, narrowing of the introitus, and distortion of the vulvar architecture.[2] Once thought to be a very rare disease, recent studies have shown a higher prevalence of VLS than previously described. Goldstein et al.[3] reported a prevalence of 1 in 60 (1.7%) in a general gynecology practice. However, an exact prevalence is hard to determine for several reasons including the fact that these patients present to various specialties, are

What is known about this subject in regard to women and their families?

- Vulvar lichen sclerosus (VLS) is a chronic inflammatory condition that is localized to the vulva and can often have profound impacts on patients' quality of life.
- Without proper treatment, VLS can progress with severe architectural changes and carries a risk of developing vulvar squamous cell carcinoma.

What is new from this article as messages for women and their families?

- This scoping review highlighted an important finding that women of color are often not included and underrepresented in VLS treatment studies conferring a potential risk of inadequate treatment approaches in this population.

[a] *Department of Dermatology, University of Texas Southwestern Medical Center, Dallas, Texas*
[b] *Department of Medicine, University of Chicago Section of Dermatology, Chicago, Illinois*
[c] *Department of Dermatology, Medical College of Wisconsin, Milwaukee, Wisconsin*

** Corresponding author.*

E-mail address: akinshemoyin@mcw.edu (O. L. Akinshemoyin Vaughn).

International Journal of Women's Dermatology (2024) 10:e170

Received: 27 September 2023; Accepted 28 June 2024

Published online 29 July 2024

DOI: 10.1097/JW9.0000000000000170

often initially misdiagnosed by physicians, may feel uncomfortable discussing their symptoms, or are completely asymptomatic. Approximately 15 to 40% of women with VLS can be asymptomatic.[3,4] Some studies have reported that lichen sclerosus (LS) is less common in women of color.[3] However, one must interpret this assertion with caution as it could be skewed due to underreporting or limited access to health care. Epidemiological studies are needed to better approximate the prevalence of VLS in various racial groups.

When not recognized and treated, VLS may progress with severe architectural changes, significant impact on quality of life (QOL), and increased risk of vulvar squamous cell carcinoma (VSCC). Some studies have quoted this absolute risk to be as high as 21.88%.[5] Currently there is no cure for VLS, however, treatment is recommended not only to improve clinical signs and symptoms but to also reduce the risk of developing VSCC. First-line treatment is a high-potency topical corticosteroid ointment, such as 0.05% clobetasol.[1] Other treatments include varying potencies of topical corticosteroids, topical calcineurin inhibitors, injections (eg, platelet-rich plasma), and oral medications (eg, cyclosporine).[6]

Clinical studies concerning VLS are limited; to date, there have been no studies comparing the course of VLS in women of color to other racial groups. This is particularly important as one of the goals of treatment is to minimize the risk of squamous cell carcinoma (SCC) and people of color have been reported to have higher mortality rates from cutaneous SCC overall.[7] Certainly, there is a lack of diversity in clinical trials overall and the National Institutes of Health and Food and Drug Administration have implemented new rules to address this disparity, but the exclusion of women of color from data surrounding this most fundamental question about VLS treatment illustrates a specific need for research focused in this area.[8,9] We adopted a scoping review as our objective was to explore the landscape of current research and analyze any potential knowledge gaps. In this scoping review, we sought to examine the racial demographics of LS treatment studies in adult women and assess for the inclusion of women of color.

Materials and methods

Literature search

This study was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[10] (Fig. 1). The authors followed an informal protocol with established methodological frameworks and guidelines to ensure rigor and minimize bias. A primary literature search was conducted using Ovid Medline(R), Scopus, Cochrane, and Web of Science databases, from all years to December 2022. Our

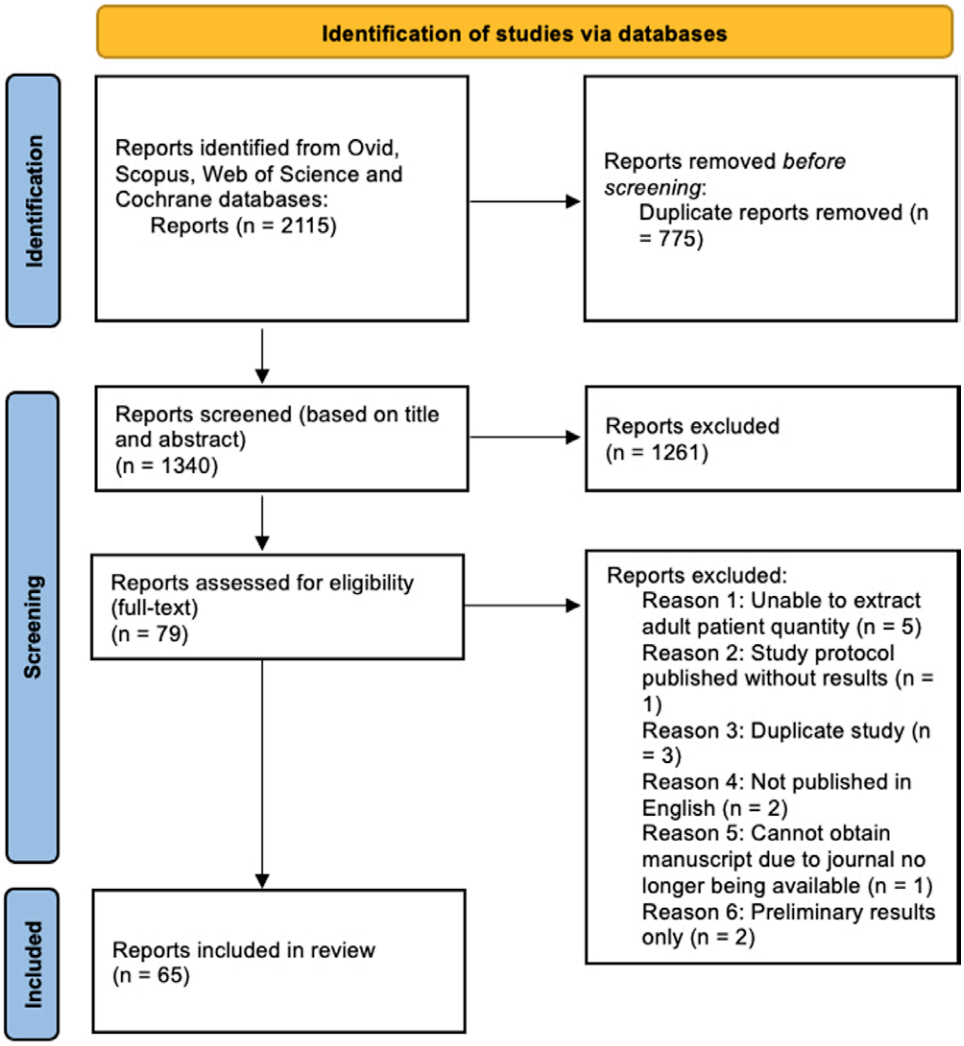

Fig. 1. Vulvar lichen sclerosus treatment studies' scoping review flow diagram. The PRISMA flow diagram for the scoping review detailing the database searches and studies that met inclusion criteria. There were 2 steps to excluding articles that did not meet inclusion criteria. We first screened titles and abstracts and excluded ones that did not meet the criteria. We then assessed the full text of the remaining articles and excluded those that did not meet our criteria.

full search strategy can be found in Supplementary Figure 1, http://links.lww.com/IJWD/A52. Two reviewers independently screened each article with the consultation of a third reviewer in cases of disagreement.

Article selection

We included cohort, case–control, and randomized controlled studies reporting data for adult women (>18 years old) with a clinical or histologic diagnosis of VLS, and the use of topical corticosteroids as a treatment arm. Single case reports, literature reviews, systematic reviews, meta-analyses, and reports not available in English were excluded.

Data extraction

Included studies were summarized by two reviewers using a data extraction form with the following variables reviewed: year, country of origin, study design, total number of participants, and if racial demographics were included. If included, then the number of patients belonging to each racial group (White, Black/African American, Latinx/Hispanic, Asian, and other), inclusion criteria, treatment arms, topical steroid used (eg, clobetasol), duration, and outcome were also extracted and recorded.

Results

Literature review

The initial literature search yielded 2115 articles published between 1946 and December 2022.

Overall, 1340 were nonduplicate articles. A total of 1261 articles were excluded based on their title and/or abstract. Of the remaining 79 articles, an additional 14 were excluded for inability to extract adult data given the inclusion of children in the sample, the study protocol being published without results, additional duplicate studies, not being available in English, the journal no longer being available, or only preliminary results being published. Ultimately, 65 articles met eligibility criteria and were included in the quantitative and qualitative analysis.

Characteristics of overall treatment studies that met the criteria

The eligible articles consisted of randomized controlled, case–control, open pilot, prospective cohort, retrospective cohort, observational cohort, and descriptive cohort studies. Countries represented included Argentina, Australia, Brazil, Canada, China, Denmark, England, France, Germany, Greece, Ireland, Israel, Italy, New Zealand, Poland, Slovenia, Switzerland, Turkey, and the United States. Sample sizes ranged from 10 to 507 with 14 studies (21.5%) having greater than 100 participants. The average sample size was 79 participants.

Characteristics of treatment studies that included racial demographics

Of the 65 eligible studies, only 6 (9.2%) included racial demographic data. The year of publication for these 6 studies ranged from 2010 to 2022. Four were from Australia; the other 2 were from the United States. Study designs consisted of prospective cohort and retrospective cohort chart review studies. Inclusion criteria were a biopsy-proven diagnosis of VLS (5/6 studies), adult women, and occasionally a specific time since the last follow-up. The most commonly used agent was augmented betamethasone dipropionate 0.05% ointment. Other agents used included clobetasol propionate 0.05% ointment, methylprednisolone aceponate 0.1% ointment, and hydrocortisone 1% ointment, though 3 studies did not specify. The average duration of the studies was 3.6 years. Outcomes measured were symptoms or signs of VLS, development of malignant neoplasms, adverse effects, compliance, and QOL/vulvar QOL index score.

Racial characteristics

The 6 studies that included racial demographic data did not specify whether these were self-reported or determined by the investigator. White women made up at least 93.9% of the sample population in 5 of the 6 studies. Three of the studies reported participants as White, Asian, or other without further characterization. Black and Latinx women were only specifically accounted for in 2 studies. For one of these studies, Black women made up 6/333 (1.8%) and Latinx women made up 19/333 (5.7%) of the sampled population. For the other, Black women made up 1/26 (3.8%) and Latinx women made up 0/26 (0.0%) of the sampled population. The full results of our data collection process are listed in Supplementary Table 1, http://links.lww.com/IJWD/A50 and Supplementary Table 2, http://links.lww.com/IJWD/A51.

Discussion

It is well-recognized that patients of color have historically been excluded from research studies.[11] In our scoping review of VLS therapeutic studies, only 9.2% of the included studies reported racial demographic data. In these studies, Black and Latinx women were severely underrepresented making up at most 5.7% of the sample population. Such disparities can lead to limited knowledge about variations in disease presentation, progression, and response to treatment.

VLS may progress with severe architectural changes, significant impact on QOL, and increased risk of VSCC. Progressive scarring can lead to clitoral phimosis and narrowing of the vaginal introitus, leading to high rates of sexual dysfunction and thus a reportedly poorer QOL in women with this condition.[2] A recent systematic review reported an absolute risk of developing VSCC as high as 21.88% (95% confidence interval: 9.28–39.97) in patients with LS.[5] Notably, Black patients are reported to have higher mortality rates (up to 29%) from SCC due to delays in diagnosis and treatment and a more aggressive biologic behavior of the malignancy.[7] In Black patients with SCC that develops within a scar, the risk of metastasis can be as high as 20 to 40%, further underscoring the need for the inclusion of women of color in VLS treatment studies.[7]

The current gold standard treatment for LS is ultrapotent topical corticosteroids, most commonly clobetasol propionate 0.05% ointment.[2] Studies report it being more effective than topical tacrolimus 0.1%, topical testosterone 2%, and phototherapy, and equally effective as mometasone furoate 0.1%.[12–15] These same studies were included in our scoping review, however, did not include racial demographic data making it difficult to assess the similarity of outcomes for women of color. In the studies that did include racial demographics, augmented betamethasone dipropionate, 0.05% ointment was the most commonly used agent, though 3 of these studies did not specify.

Several studies have shown structural and functional differences in barrier properties of African American, White, and East Asian skin.[16–18] Additionally, a recent study reported that reconstructed skin epidermis exhibited racial differences regarding stratification and differentiation between White and African skin demonstrated by histological appearance, gene expression, and quantitative proteomic analysis. These findings are important to consider, especially in skin conditions that are treated topically where structural differences may affect treatment efficacy.

Limitations of the evidence in this review include 4 of the 6 studies reporting racial demographics were from Australia, a country with a relatively low population of Black individuals, and these 4 articles shared at least one of the same authors.

Also, all studies including racial demographic data have been conducted within the past 13 years, potentially demonstrating a shift toward more racially conscious studies. Furthermore, we restricted our search to articles published in English, which may have led to language bias and the exclusion of relevant studies published in other languages. Nevertheless, we are confident that none of these methodological limitations would change the overall conclusions of this review.

In sum, women of color are underrepresented in studies of topical corticosteroid use in adult women with VLS. Recruiting diverse women for these studies will allow for more accurate and representative data. More research is still needed to further elucidate the safety and efficacy of corticosteroid treatments for VLS, specifically in women of color.

Conflicts of interest

None.

Funding

None.

Study approval

N/A

Author contributions

JCE, EAE, and OLAV participated in screening the articles, writing the manuscript, and editing the draft.

Acknowledgments

We would like to acknowledge Rita Sieracki from the Department of Librarian Services at the Medical College of Wisconsin, Milwaukee, WI for designing the search strategy for this study.

Supplementary data

Supplementary material associated with this article can be found at http://links.lww.com/IJWD/A52, http://links.lww.com/IJWD/A50, and http://links.lww.com/IJWD/A51.

References

1. Kraus CN. Vulvar lichen sclerosus. JAMA Dermatol 2022;158:1088. doi: 10.1001/JAMADERMATOL.2022.0359.
2. Krapf JM, Mitchell L, Holton MA, Goldstein AT. Vulvar lichen sclerosus: current perspectives. Int J Womens Health 2020;12:11–20. doi: 10.2147/IJWH.S191200.
3. Goldstein AT, Marinoff SC, Christopher K, Srodon M. Prevalence of vulvar lichen sclerosus in a general gynecology practice. J Reprod Med 2005;50:477–80.
4. Vieira-Baptista P, Lima-Silva J, Cavaco-Gomes J, Beires J, Martinez-De-Oliveira J. What differentiates symptomatic from asymptomatic women with lichen sclerosus? Gynecol Obstet Invest 2015;79:263–8. doi: 10.1159/000367788.
5. Leis M, Singh A, Li C, Ahluwalia R, Fleming P, Lynde CW. Risk of vulvar squamous cell carcinoma in lichen sclerosus and lichen planus: a systematic review. J Obstet Gynaecol Can 2022;44:182–92. doi: 10.1016/J.JOGC.2021.09.023.
6. Corazza M, Schettini N, Zedde P, Borghi A. Vulvar lichen sclerosus from pathophysiology to therapeutic approaches: evidence and prospects. Biomedicines 2021;9:950. doi: 10.3390/BIOMEDICINES9080950.
7. Agbai ON, Buster K, Sanchez M, et al. Skin cancer and photoprotection in people of color: a review and recommendations for physicians and the public. J Am Acad Dermatol 2014;70:748–62. doi: 10.1016/J.JAAD.2013.11.038.
8. National Institute on Minority Health and Health Disparities. National Institutes of Health Minority Health and Health Disparities strategic plan 2021 to 2025: taking the next steps. 2021. Available from: https://www.nimhd.nih.gov/docs/nimhd-strategic-plan-2021-2025.pdf
9. FDA. Diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in Clinical Trials Guidance for industry draft guidance. Available from: https://www.fda.gov/media/179593/download
10. Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018;169:467–73. doi: 10.7326/M18-0850.
11. Watson B, Robinson DHZ, Harker L, Arriola KRJ. The inclusion of African-American study participants in web-based research studies: viewpoint. J Med Internet Res 2016;18:e168. doi: 10.2196/JMIR.5486.
12. Terras S, Gambichler T, Moritz RKC, Stücker M, Kreuter A. UV-A1 phototherapy vs clobetasol propionate, 0.05%, in the treatment of vulvar lichen sclerosus: a randomized clinical trial. JAMA Dermatol 2014;150:621–7. doi: 10.1001/JAMADERMATOL.2013.7733.
13. Ayhan A, Guven S, Guvendag Guven ES, Sakinci M, Gultekin M, Kucukali T. Topical testosterone versus clobetasol for vulvar lichen sclerosus. Int J Gynaecol Obstet 2007;96:117–21. doi: 10.1016/J.IJGO.2006.09.018.
14. Virgili A, Borghi A, Toni G, Minghetti S, Corazza M. First randomized trial on clobetasol propionate and mometasone furoate in the treatment of vulvar lichen sclerosus: results of efficacy and tolerability. Br J Dermatol 2014;171:388–96. doi: 10.1111/BJD.12910.
15. Funaro D, Lovett A, Leroux N, Powell J. A double-blind, randomized prospective study evaluating topical clobetasol propionate 0.05% versus topical tacrolimus 0.1% in patients with vulvar lichen sclerosus. J Am Acad Dermatol 2014;71:84–91. doi: 10.1016/J.JAAD.2014.02.019.
16. Muizzuddin N, Hellemans L, Van Overloop L, Corstjens H, Declercq L, Maes D. Structural and functional differences in barrier properties of African American, Caucasian and East Asian skin. J Dermatol Sci 2010;59:123–8. doi: 10.1016/J.JDERMSCI.2010.06.003.
17. Berardesca E, De Rigal J, Leveque JL, Maibach HL. In vivo biophysical characterization of skin physiological differences in races. Dermatology 1991;182:89–93. doi: 10.1159/000247752.
18. Fotoh C, Elkhyat A, Mac S, Sainthillier JM, Humbert P. Cutaneous differences between Black, African or Caribbean mixed-race and Caucasian women: biometrological approach of the hydrolipidic film. Skin Res Technol 2008;14:327–35. doi: 10.1111/J.1600-0846.2008.00299.X.