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Commentary

Addressing Autoimmune and Immune-mediated Skin Disease Burden in Women

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According to the National Institutes of Health (NIH), more than 23.5 million people in the United States suffer from confirmed autoimmune diseases, which are a leading cause of disability (NIH Autoimmune Diseases Coordinating Committee, 2005). Recent evidence suggests that the prevalence of autoimmune biomarkers is growing in the United States, with 41 million Americans testing positive (Dinse et al., 2020). Autoimmune disorders must, therefore, be an increasing priority for health policymakers and researchers.

The majority of autoimmune diseases are more prevalent in women, who represent more than 80% of autoimmune patients, suggesting sex is an important biological variable that affects these diseases (Desai & Brinton, 2019). Furthermore, the burden of disease is arguably greater in women owing to gender and cultural influences that have psychosocial effects and create expectations of caregiving for children, partners, and parents who may suffer from these chronic conditions (Villasante Fricke & Miteva, 2015). Much is still unknown as to how and why immune-mediated diseases (broadly involving abnormal activity of the immune system) and autoimmune diseases (characterized by antigen presence) are triggered and why many of them are more prevalent, and often more severe, in women (Desai & Brinton, 2019).

Skin, as the body's largest organ, can be affected by autoimmune diseases. Because the skin is so visible and important to the body's physiological function, skin diseases and comorbidities can impact a person's physical and mental well-being and carry a large public health burden; despite this, they are relatively understudied (Khatami & San Sebastian, 2009). Gaps in understanding the biological sex differences in disease pathology can further hamper treatment and research efforts. It is, therefore, vital to increase research focus on skin diseases, particularly autoimmune and immune-mediated skin diseases that have complex and chronic health implications for those affected. Three such conditions are alopecia areata (AA), atopic dermatitis (AD), and psoriasis.

In the United States, an estimated 700,000 people have AA, a condition that results in hair loss on the scalp, face, and other areas of the body (Benigno et al., 2020). Although AA occurs equally in men and women, women are more likely to be diagnosed in adolescence or later and with concomitant autoimmune diseases (Aldhouse et al., 2020; Darwin et al., 2018). There is also significant social stigma associated with female hair loss that can influence mental health and poor patient outcomes (Aldhouse et al., 2020; Mostaghimi et al., 2021; Villasante Fricke & Miteva, 2015). Furthermore, there are currently no treatments for AA approved by the U.S. Food and Drug Administration, and insurance companies may deny claims for treatments that are perceived as cosmetic and not medically necessary.

Approximately 16.5 million people in the United States suffer from AD, which is the most common type of eczema (Fuxench et al., 2019). The prevalence of childhood AD is similar and steadily rising in boys and girls; however, among adults, it is

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more common in women than men. AD can become very burdensome owing to itching, dryness, skin pain, and an increased risk of asthma and allergies (Silverberg et al., 2018). Further, inadequate management of AD can lead to sleep disturbances and additional psychosocial sequelae.

Meanwhile, up to 30% of the estimated 8 million people in the United States with psoriasis will also develop psoriatic arthritis (PsA) (Ritchlin, Colbert, & Gladman, 2017). If left untreated, this progressive and inflammatory immune-mediated disease can result in irreversible joint damage. Although the prevalence of psoriasis and PsA are similar between sexes, women experience PsA differently than men—including peripheral polyarthritis and poorer treatment responses and remission—although little is known about why (Queiro et al., 2013).

Women are differentially and disproportionately impacted as patients, as caregivers, and sometimes as both, when it comes to autoimmune and immune-mediated skin diseases. Thus, the Society for Women's Health Research has identified a pressing need to address gaps in the study and treatment of these skin diseases. We convened an interdisciplinary working group of clinicians, researchers, patient advocates, and policy professionals to discuss the current state of science regarding sex and gender disparities in AA, AD, and PsA and to explore ways to advance the research agenda, support science-based policy to improve patient outcomes, and increase awareness and understanding of these diseases and their impacts on women's health. The strategies proposed in this discussion involve increasing research investment to elucidate the biological and psychosocial impacts of autoimmune and immune-mediated skin diseases on women's health, and implementing policy solutions that promote and protect access to treatments and clinical care that can allow women, their dependents, and their health care providers to effectively and efficiently manage these chronic conditions.

Addressing Research Gaps

Factors that predispose certain individuals to or trigger the onset of autoimmune and immune-mediated skin diseases are still not understood fully. However, a combination of biological factors and environmental factors (including behavioral factors) have been shown to play a role (Ngo, Steyn, & McCombe, 2014). Environmental factors—such as exposure to substances in air, water, and food—and lifestyle exposures to stress are possible reasons that rates of autoimmune skin diseases are increasing in the United States (Desai & Brinton, 2019; Silverberg et al., 2018). Although the overall prevalence for AA, AD, and PsA tends to be equal in men and women, there are biological factors that result in differential expression between the sexes (Queiro et al., 2013). Women often report changes in symptoms during menstruation, pregnancy, and menopause—all circumstances that are driven by female hormones. A better understanding of the biological pathways and environmental triggers will provide keys to developing therapeutic targets to better treat these chronic diseases and mitigate their growing public health burdens.

The epidemiology of these conditions should also be studied from a gendered lens that considers the cultural and social determinants that affect autoimmune skin diseases in women (Ngo et al., 2014). For example, lower health-related quality of life is common among sufferers of autoimmune skin disease, but societal expectations for dermatological beauty can disproportionately impact women, resulting in greater impairment of social and occupational activities and increased risk of depression and anxiety (Aldhouse et al., 2020; Davis & Callender, 2018). Furthermore, women are more likely to be exposed to many of the potential triggers for autoimmune disease, including stressors related to higher burden of domestic duties, chemicals found in cleaning products and makeup, pesticides, solvents, and vitamin D deficiency owing to diet or lower sun exposure (Ngo et al., 2014).

More research is needed to elucidate hormonal stimulation, drug effects, and psychosocial sequelae of autoimmune and immune-mediated skin diseases in women across the lifespan. Unfortunately, research for many skin diseases is underfunded, despite their considerable disease burdens. An analysis of skin disease research funded by the NIH between 2012 and 2013 relative to 15 corresponding skin conditions identified in a 2010 Global Burden of Disease study indicated that dermatitis (including AD) had the highest disability-adjusted life-years (DALY) ranking among skin diseases assessed, yet was ranked fifth in NIH funding (Hagstrom et al., 2015). AA was funded at number 13, despite its DALY ranking of 11. Furthermore, disparities have been documented in NIH funding for diseases that affect more women than men, regardless of the commensurate burden (Mirin, 2021).

It is, therefore, imperative that the NIH increase efforts for targeted investment in autoimmune skin disease research and prioritize addressing understudied aspects related to biological sex and genetic ancestry, as well as socioenvironmental exposures and experiences, including sexism, racism, and other forms of discrimination. Funding institutes and researchers should be appropriately trained and held accountable to NIH's Policy on Sex as a Biological Variable to ensure that relevant vertebrate animal and human studies concerning autoimmune and immune-mediated skin diseases incorporate research designs, analyses, and reporting that factor in these critical and evident differences observed between men and women (Arnegard, Whitten, Hunter, & Clayton, 2020; Libby, McGinnes, & Regensteiner, 2020).

Understanding Disease Burden

The disparities for women with autoimmune and immune-mediated skin diseases extends beyond biological differences and into systems and policies that underappreciate the external influences on gender that disproportionately shift the burden of disease on women. Common considerations for assessing disease burden toward health care policies and coverage include utilizing measures such as DALYs and quality-adjusted life-years (Silverberg et al., 2019; Villasante Fricke & Miteva, 2015). Although DALYs, quality-adjusted life-years, and claims data generate invaluable information, researchers and policymakers should not overly rely on these traditional datasets that fail to convey the full scope of costs associated with disease management—financial, physical, and psychosocial. Data regarding AA, AD, and PsA often lack the downstream effects associated with living with these conditions, such as productivity losses, comorbid disease and mental health care, and out-of-pocket costs incurred by patients and caregivers (Li, Mostaghimi, Tkachenko, & Huang, 2019; Lim et al., 2017; Vanderpuye-Orgle et al., 2015). Moreover, disease burden is not fully captured owing to underdiagnosis of these conditions, which is influenced by barriers to access, consideration for skin of color, and provider expertise, as is often the case with PsA (Lebwohl, Kavanaugh, Armstrong, & van Voorhees, 2015). Such gaps in our understanding of these diseases impact policy decisions across the health system that

drive research focus and investment, availability and access to treatments and providers, and insurance coverage.

Psychosocial Burden

It is possible that the burden of disease and care for AA, AD, and PsA have greater impacts in women than men. For example, the stigma associated with flawed skin and female hair loss can be a fundamental cause of health inequities and negative patient outcomes by increasing the risk of social isolation and marginalization, psychological distress, and delayed or avoided treatment (Hatzenbuehler, Phelan, & Link, 2013). Delays in diagnosis for a condition like PsA can lead to permanent joint damage. Therefore, recognizing and mitigating possible reluctance of patients to discuss symptoms with their providers is crucial to timely diagnosis and effective disease management.

For women with AA, the psychosocial effects of hair loss are a significant contributor to lower quality of life and higher rates of depression, anxiety, and self-isolation (Aldhouse et al., 2020; Davis & Callender, 2018). Women report limiting social interactions, avoiding new romantic or sexual relationships, and changing or limiting exercise routines owing to embarrassment and self-consciousness. All of these actions can impact physical and mental health (Mostaghimi et al., 2021). Further, autoimmune and immune-mediated skin disease symptoms and comorbidities can cause moderate to severe sleep disturbance, pain, and discomfort, resulting in absenteeism and presenteeism that limit educational or career attainment (Drucker et al., 2017).

It is important for care providers and insurance companies to understand that, for these patients, aides such as cranial protheses (wigs) and medications to improve their skin condition are not merely cosmetic, but important medical treatments for the management of the complex and systemic nature of these diseases. Although wigs are sometimes approved for patients with cancer to decrease the burden of hair loss, many patients with AA find it difficult to gain insurer approval for wigs, despite the possibility of this hair loss being sporadic, recurrent, and sometimes permanent (Mesinkovska, King, Mirmirani, Ko, & Cassella, 2020). Wigs can be costly, and inadequate insurance coverage limits access to this treatment that can effectively reduce psychosocial and financial burden on women patients (Li et al., 2019). When insurance policies fail to recognize the holistic patient experience and needs, it results in policies that compound the burden of autoimmune skin diseases.

Caregiving Burden

To fully capture the impact of these autoimmune and immune-mediated skin diseases on women and women's health and to leverage appropriate policy solutions, an acknowledgement of their effects on caregivers is warranted. Studies have shown that women tend to deprioritize their health below the health and well-being of others in their social networks (Donelan, Falik, & DesRoches, 2001). As such, even women with chronic conditions may forgo or be less adherent to long-term treatment management, attempt to save costs by choosing less effective options, or attend appointments inconsistently owing to busy schedules. With diseases of this nature, such behavior choices can lead to disease progression or flares.

Furthermore, up to 80% of women are the primary health care decision-makers for their family, and women are often the primary caregivers for their children, partners, and elderly relatives (Matoff-Stepp, Applebaum, Pooler, & Kavanagh, 2014). The weight of this responsibility can place significant mental health and financial burdens on women. Women report lost sleep, insomnia, and the need to decrease work hours, take time off, or leave their jobs altogether owing to the demands of caring for family members with chronic illness (Carroll, Balkrishnan, Feldman, Fleischer, & Manuel, 2005; Drucker et al., 2017). Caregiving can be prohibitive for social interactions and recreational activities, such as exercise or volunteering, and result in feelings of isolation and/or guilt (Meintjes & Nolte, 2015).

Economic Burden and Policy Challenges

Autoimmune disorders in the United States are estimated to cost $100 billion per year in direct and indirect health care costs, lost productivity and earnings, and associated costs (Rosenblum, Gratz, Paw, & Abbas, 2012). A report from the American Academy of Dermatology indicated the direct medical costs were $314 million for AD, $737 million for psoriasis, and $986 million for all hair and nail disorders (Lim et al., 2017). Managing autoimmune and immune-mediated skin diseases can be a complex and lifelong process; each patient is unique and responds to treatments differently. Access to high-quality care will empower patients to make unencumbered decisions about their treatment.

Care providers and patients report significant challenges to effective disease treatment and management that are directly related to economic and bureaucratic barriers (Lebwohl et al., 2015; Silverberg et al., 2018). Policymakers and payers must prioritize reducing barriers that can render effective treatments inaccessible, such as high costs and difficulties navigating health insurance processes for both providers and patients. Further, insurance companies implement formulary restrictions (e.g., step therapy and prior authorization) that can require patients to cycle through a regimented series of treatments (even if unsuccessful in the past), which can extend physical and psychological burdens on a patient longer than necessary (Park, Raza, George, Agrawal, & Ko, 2017). Step therapy requirements should be decreased or eliminated to improve treatment efficiency and access for autoimmune and immune-mediated skin patients.

Nonmedical switching and payer-mandated drug substitution are growing practices by which insurers change the coverage of a patient's medication for reasons unrelated to their health or the efficacy of the current medication (Dolinar, Kohn, Lavernia, & Nguyen, 2019). Nonmedical switching is usually exercised to control payer costs and increase profits. Particularly for chronic autoimmune and immune-mediated skin diseases that involve complex interactions across multiple organ systems, switching from one drug to another without medical necessity or patient desire can impede treatment or reverse progress. There is evidence that the more a patient switches from one biologic to another, the less effective later treatments can be and overall costs may actually increase (Nguyen et al., 2016; Weeda et al., 2019). Moreover, nonmedical switching has been associated with increased use of the health care system through emergency department visits and hospitalizations, additional office visits, and laboratory tests. Studies of autoimmune patients have found that up to 85% of patients do not wish to switch their treatment, but 67% ultimately did because their current treatment was rendered unaffordable. More than one-half of these individuals suffered from gaps in treatment during the administrative transition (Teeple et al., 2019). Furthermore, both patients and providers considered such changes to payer coverage policies to be an interference in the

provider's ability to administer the most effective personalized treatment plan for their patients (Costa et al., 2020).

Policy solutions are needed to regulate or restrict the use of practices like step therapy and non-medical switching that create barriers to access to care and hinder the shared decision-making process for quality patient care.

Conclusions

Autoimmune and immune-mediated skin diseases affect a growing number of individuals in the United States, and AA, AD, and psoriasis (as well as the most common comorbidity, PsA) are three conditions that differentially impact women. Although each disease has its own unique gaps in research and clinical care, they share common threads in the economic and psychosocial burdens imposed upon women living with these chronic diseases. There are key challenges to which policy reform can reduce barriers to access and health disparities related to these conditions. Policy solutions must go beyond basic claims data to holistically review disease burden and consider the added caregiver burden that affects women's health and quality of life. Reform that raises awareness, encourages research and medical collaborations, protects access to personalized medicine approaches to treatment, and promotes shared decision-making will provide women and their families with the necessary framework to effectively manage autoimmune and immune-mediated skin diseases and improve their quality of life.

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