SKIN

BRIEF ARTICLE

The Treatment of Lichen Sclerosus with Topical Roflumilast 0.3% Case Study

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ABSTRACT

Lichen Sclerosus is a chronic inflammatory skin disease predominantly affecting post-menopausal women. Currently, the first line treatment approach for lichen sclerosus is ultra potent topical corticosteroids for 12 weeks. A treatment challenge to this approach is the risk of steroid atrophy due to the use of potent topical steroids on the genital skin. We describe reduction of erythema and symptomatic improvement following treatment with topical roflumilast 0.3% once daily in a patient with lichen sclerosus who refused topical corticosteroids.

INTRODUCTION

Lichen sclerosus, a chronic inflammatory skin disease predominantly affecting post-menopausal women, presents as white plaques surrounded by an erythematous border that later may become atrophic with a shiny porcelain white appearance.[1] The pathogenesis of lichen sclerosus is not well understood; however, the inflammatory profile has been described to include increased levels of Th-1 cytokines, dense T-cell infiltration and enhanced BIC/miR-155 expression.[1] There may be a genetic predisposition to the disease as 10% of patients with lichen sclerosis have relatives with the disease.[1] The first line treatment approach for lichen sclerosus includes ultrapotent topical corticosteroids for 12 weeks. In randomized controlled studies, this approach improves between 70%-90% of patients compared to 10% in placebo groups.[1] While this treatment is supported by clinical evidence, lichen sclerosus is a chronic condition and there is substantial unmet need because of limitations on the chronic use of ultrapotent steroids on genital skin and adverse events such as skin atrophy. Roflumilast cream 0.3% is non-steroidal, highly selective, and potent topical phosphodiesterase-4 (PDE4) inhibitor approved in 2022 by the FDA for the treatment of psoriasis, including intertriginous areas, and in 2023 in a foam formulation for the treatment of seborrheic dermatitis. A case study including a patient with palmoplantar pustulosis highlights a significant improvement after using roflumilast 0.3% compared to potent topical corticosteroids. The 82-year-old female experienced complete remission within 5 weeks, with the resolution of pruritus, pain, and pustules.[2] In this case study, we report a 72-year-old woman with a 1-year history of extragenital lichen sclerosus. This patient had a history of

candidal infections and therefore refused topical steroids due to risk of steroid atrophy and candidiasis. The patient was prescribed topical roflumilast 0.3% cream once daily with symptomatic improvement.

CASE REPORT

We report the case of a 72-year-old woman who presented with a 1-year history of a treatment naïve pruritic rash on the left anterior proximal thigh. The patient had a past medical history including malignant melanoma, squamous cell carcinoma, rosacea, seasonal allergies, hyperlipidemia, and hypertension. Upon physical examination, there was a solitary atrophic white plaque with surrounding erythema and telangiectasias on the left anterior proximal thigh without vulvar involvement (**Figure 1**). A 3mm punch biopsy confirmed extragenital lichen sclerosus et atrophicus. The patient declined topical corticosteroids due to concerns for steroid atrophy and candidal infection. Treatment options were discussed with the patient and the decision was made to start topical roflumilast 0.3% cream once daily due to its anti-inflammatory non-steroidal mechanism of action. At 3 month follow up, the patient reported resolution of pruritus and improvement in her lichen sclerosis. Further examination at this visit still showed atrophic whitish plaques, however, there was a decrease in the diameter and erythema had resolved (**Figure 2**). No adverse reactions were noted. The patient was instructed to continue topical roflumilast 0.3% cream once daily for maintenance with follow up during her regularly scheduled full body exams for her history of skin cancer.

DISCUSSION

This case report of a 72-year-old woman treated with roflumilast 0.3% cream once daily for extragenital lichen sclerosus resulted in improvement within 3 months. In a disease that is often treated first line with ultra potent topical corticosteroids, this case highlights the utility of topical roflumilast 0.3% cream as a potential non-steroidal treatment option, especially in patients who are apprehensive or have a contraindication to topical corticosteroids. Clinical trials including topical roflumilast 0.3% cream reported the most common adverse events in ≥1% of patients, with the most common being diarrhea, headache, insomnia, application site pain, upper respiratory tract infections, and urinary tract infections.[3] Topical roflumilast is not associated with skin atrophy, striae, purpura, or HPA-axis suppression which can occur in patients treated with topical corticosteroids.[4] A second aspect of lichen sclerosus is the impact on quality-of-life. Patients with lichen sclerosus often suffer from anogenital pruritus and resultant limited social interactions. In this patient case, pruritus resolved with roflumilast 0.3% cream once daily. Additional research will be necessary to understand the clinical efficacy and safety of roflumilast 0.3% cream for the treatment of both genital and extragenital lichen sclerosus.

Conflict of Interest Disclosures: Writing support was provided by Arcutis Biotherapeutics Inc.

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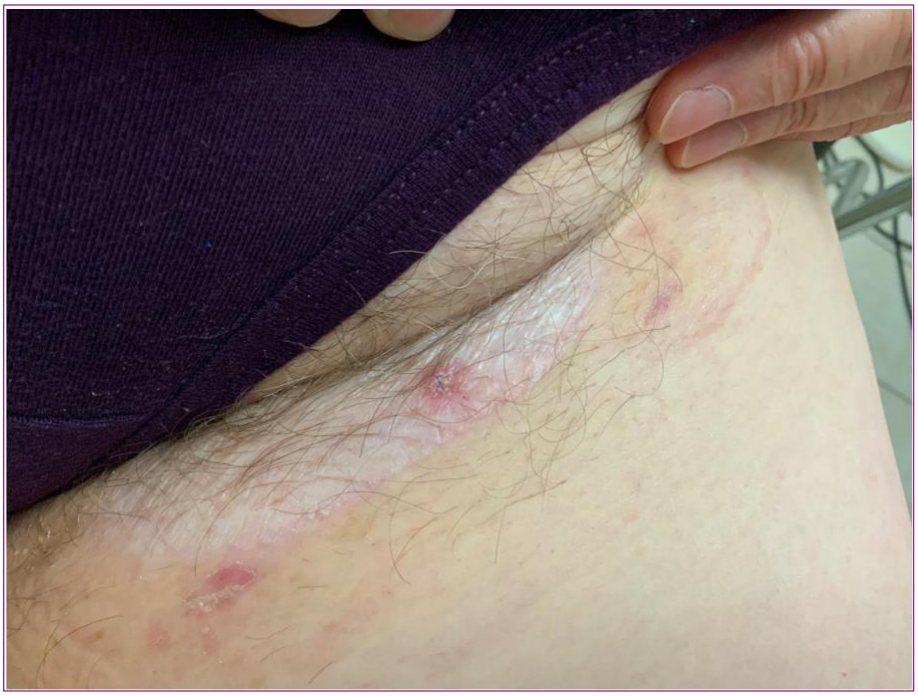

Figure 1. Solitary atrophic white plaque with surrounding erythema and telangiectasias on the left anterior proximal thigh without vulvar involvement.

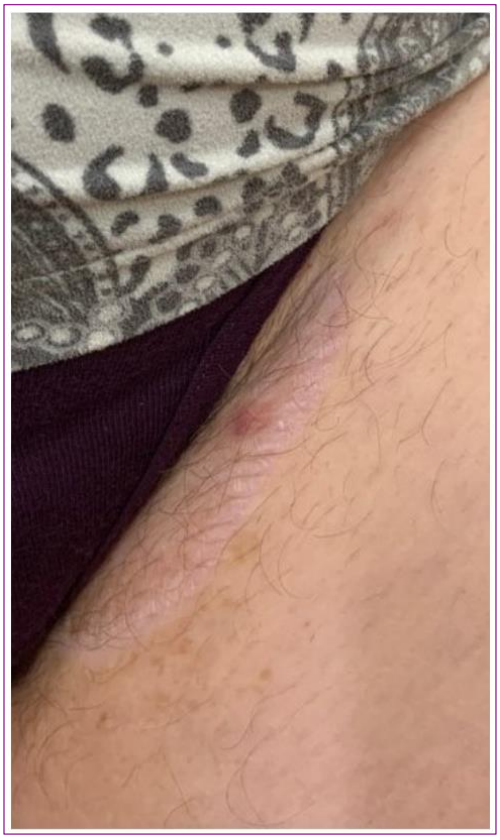

Figure 2. Atrophic whitish plaques with a decrease in the diameter and erythema resolved.

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