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Clascoterone Cream 1% in Acne Management: Case Series and Real-World Canadian Experience

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Acne vulgaris is a globally prevalent dermatological condition associated with a substantial physical and psychological burden.

This case series includes 10 patients with acne vulgaris who received treatment with clascoterone cream 1% from August 2023 to May 2024. Treatment with clascoterone cream 1% was effective and well tolerated regardless of acne severity, age, gender, and ethnicity. Clascoterone led to clinical improvement when used as monotherapy, as an adjunctive treatment in combination with other topical or systemic agents or laser therapy, and as maintenance therapy to prevent acne relapse. Moreover, clascoterone helped address other concerns in several patients, including hirsutism, hidradenitis suppurativa, retinoid-induced dermatitis, androgenetic alopecia, folliculitis, and laser-induced acne flares. This recent real-world clinical experience supports the effectiveness, tolerability, and versatility of clascoterone cream 1% for patients with acne vulgaris across a variety of clinical and demographic characteristics.

Introduction

Acne vulgaris primarily affects sebaceous regions such as the face, chest, and back, driven largely by androgens that stimulate sebum production and inflammation. Treatment strategies vary based on severity, with topical agents (i.e., retinoids, benzoyl peroxide, clindamycin) used for mild acne, and systemic therapies (i.e., oral antibiotics, antiandrogens, isotretinoin) for moderate-to-severe cases.[1] The challenges with side effects and tolerability underscore the need for safer and more effective alternatives.

Clascoterone cream 1%, a topical androgen receptor inhibitor, is a first-in-class therapy approved for acne vulgaris in male and female patients ≥12 years old. It was first approved in the US in 2020 and became available in Canada in June 2023.[2,3] In Phase 3 clinical trials for moderate-to-severe acne vulgaris, clascoterone cream 1% resulted in significantly higher treatment success rates and a greater reduction in lesion counts compared with the vehicle.[4] In this case series, we share our real-world Canadian experience with clascoterone cream 1% for managing acne vulgaris.

Materials and methods

Ten patients with acne vulgaris attending a private clinic in London, ON, Canada between August 2023 and May 2024 were included in this case series (**Table 1**). The information presented was obtained from a retrospective chart review of the patients' medical records. This case series did not require informed consent because it was a retrospective chart review with anonymized data.

Case 1

A 25-year-old African American female with hormonal acne, intolerant of oral contraceptives because of migraines, was initially treated with spironolactone 50 mg daily along with topical dapsone 5% and adapalene 0.3%/benzoyl peroxide 2.5%. After minimal improvement was observed, the spironolactone dose was increased to 100 mg daily which led to better control of her acne but was accompanied by bothersome side effects such as dizziness and nocturia. Introducing clascoterone cream 1% twice daily allowed for a dose reduction and gradual tapering of spironolactone over 6 months. Her acne remained well controlled with clascoterone monotherapy.

Case 2

A 34-year-old White female with polycystic ovary syndrome experienced persistent acne despite being treated with cyproterone acetate, clindamycin 1%/benzoyl peroxide gel 5%, and tretinoin gel microsphere 0.1%. The addition of clascoterone cream 1% twice daily to her existing topical regimen resulted in excellent control of her acne. The patient also reported an improvement in facial hirsutism, noting a decrease in the appearance of coarse dark hairs on her chin.

Case 3

A 47-year-old Hispanic female with metastatic breast cancer presented with concurrent acne and mild hidradenitis suppurativa (HS). The patient's condition was previously managed with oral doxycycline 100 mg daily, benzoyl peroxide 5% acne wash, and fusidic acid 2% cream, which yielded only partial improvement. Adalimumab was deemed unsuitable due to concerns regarding immunosuppression in the context of malignancy. She was advised to apply clascoterone cream 1% twice daily to both her facial acne and HS lesions. A remarkable resolution of both conditions was observed following the addition of clascoterone at the 1-year follow-up.

Case 4

A 21-year-old White transgender individual who recently underwent female-to-male gender reassignment surgery and was receiving testosterone therapy presented with acne breakouts. They were initially treated with minocycline, clindamycin 1%/benzoyl peroxide gel 5%, and a salicylic acid cleanser, which provided minimal improvement. They declined oral isotretinoin due to concerns regarding the potential side effects. Adding clascoterone cream 1% twice daily and tazarotene lotion 0.045% every other night to their doxycycline 100 mg

Case	Age (*years*)	Gender	Race or ethnicity	Acne severity	Clinical presentation, lesion subtypes	Relevant comorbidities	Concomitant treatments	Duration of clascoterone treatment* (*months*)
1	25	Female	African American	Moderate	Acne tarda Papules and nodules on lower cheek and jawline	n/a	Spironolactone, topical dapsone	6
2	34	Female	White	Mild	Acne tarda Papules and nodules on chin and jawline	PCOS, Hirsutism	Cyproterone acetate (for PCOS), topical antibiotics, BP, topical retinoids	11
3	47	Female	Hispanic	Mild-to-moderate	Papules, pustules, and comedones on cheeks	HS	Oral antibiotics, BP, fusidic acid cream	12
4	21	Transgender	White	Moderate-to-severe	Papules, pustules, nodules, and a few cysts	n/a	Topical retinoids	9
5	35	Male	Asian	Mild	Papules, pustules, and open and closed comedones	Androgenetic alopecia	Topical retinoids	9
6	14	Female	Middle Eastern	Mild	Papules and open and closed comedones on the nose and forehead	Excessive sebum production	Topical retinoids, salicylic acid, BP	7
7	18	Male	White	Severe	Nodulocystic acne and macular erythema on the face	Retinoid-induced dermatitis	Oral isotretinoin	6
8	22	Female	White	Severe	Nodulocystic acne on the face, shoulders, and upper back	n/a	Topical retinoids	11
9	31	Female	African American	Moderate	Papules and pustules on the shoulders and back, macular hyperpigmentation	Folliculitis, PIH	Fusidic acid cream, trifarotene, BP wash	12
10	18	Male	Asian	Moderate	Papules, pustules, comedones, and a few nodules	n/a	Laser therapy	6

Table 1. Demographics and clinical characteristics of patients included in the case series; *courtesy of Wei Jing Loo, BSc, MBBS, MRCP, FRCP.*

*All patients applied clascoterone cream 1% to acne-affected areas twice daily.

Abbreviations: BP: benzoyl peroxide, **HS:** hidradenitis suppurativa, **n/a:** not applicable, **PCOS:** polycystic ovary syndrome, **PIH:** postinflammatory hyperpigmentation

daily regimen resulted in marked improvement in their acne.

Case 5

A 35-year-old Asian male with mild facial acne was prescribed trifarotene cream 0.005%, which resulted in skin dryness and irritation. In response to these adverse effects, the frequency of trifarotene application was reduced to 3 times per week, and clascoterone cream 1% twice daily was added to the regimen. This adjustment led to effective control of his acne, along with resolution of dryness and irritation. He also applied clascoterone to his scalp for androgenetic alopecia without medical direction and reported stabilization of hair loss and some evidence of hair regrowth.

Case 6

A 14-year-old Middle Eastern female with acne vulgaris complained of "oily skin". Her skincare regimen included a 5% salicylic acid cleanser and adapalene 0.3%/benzoyl peroxide 2.5%. Despite these efforts, her acne persisted, and she continued to struggle with oily skin. The patient experienced a notable improvement in her acne and decreased sebum production following the addition of clascoterone cream 1%.

Case 7

An 18-year-old White male with severe nodulocystic acne was treated with isotretinoin 40 mg daily. He experienced prominent macular erythema, irritation, and dryness. The addition of clascoterone cream 1% twice daily alleviated the side effects associated with isotretinoin therapy. After completing a 6-month course of isotretinoin, he maintained clear skin with topical clascoterone monotherapy.

Case 8

A 22-year-old White female with a history of acne conglobata had failed to respond to oral contraceptive pills, systemic antibiotics, and various topical prescription creams. Following 6 months of treatment with isotretinoin 50 mg daily, she experienced substantial clearance of her acne lesions. However, due to concerns about potential relapse, she was hesitant to discontinue isotretinoin. To address her concerns, she was prescribed clascoterone cream 1% and tazarotene lotion 0.045%. Eleven months after discontinuing isotretinoin, her acne remained well controlled.

Case 9

A 31-year-old African American female presented with a combination of acne and folliculitis on her shoulders and back. She reported inadequate control of papules and pustules on her back despite using fusidic acid cream, trifarotene, and benzoyl peroxide wash. Adding clascoterone cream 1% to her existing regimen resulted in a marked improvement in her acne and folliculitis, as well as a notable reduction in macular hyperpigmentation.

Case 10

An 18-year-old Asian male with moderate acne vulgaris on his face underwent AviClear® laser therapy but experienced a severe acne flare, consistent with "purging," after the first treatment session. Adding clascoterone cream 1% to his regimen mitigated the initial flares, and subsequent sessions were better tolerated. After completing 3 sessions of laser therapy with adjunctive clascoterone cream 1%, he achieved clear skin.

Discussion

This study underscores clascoterone's efficacy and tolerability across diverse clinical presentations, genders, and ethnicities. It can complement both topical and systemic acne therapies, reduce side effects, and function as maintenance therapy to prevent relapse.

Acne is a common adverse effect observed in transgender individuals receiving masculinizing hormone therapy.[5,6] Although clinical trials for clascoterone did not specifically include transgender patients, the use of topical antiandrogens such as clascoterone appears to be a safe option due to its lack of systemic antiandrogen activity.[4,6,7]

The American Academy of Dermatology guidelines recommend a multimodal approach that

incorporates agents with multiple mechanisms of action to address the multifactorial pathogenesis of acne.[1] In clinical studies, clascoterone cream 1% was evaluated as a monotherapy.[4] However, limited data have been published on the efficacy and safety of concomitant usage of clascoterone cream 1% with other acne treatments.[8] The findings from this case series demonstrate that clascoterone may also work well as an adjunct to other topical and systemic therapies, as well as laser treatments, or as maintenance therapy to prevent relapse. The efficacy of clascoterone in preventing acne relapse following isotretinoin therapy underscores the importance of individualized maintenance therapy strategies for patients who have completed isotretinoin treatment, particularly those with a history of severe acne or concerns about relapse.

There is growing interest in the potential applications of clascoterone for other dermatological conditions.[9,13] Previous reports have shown that clascoterone cream 1% led to substantial reductions in the number and severity of lesions in patients with HS.[9,11] Clascoterone may also benefit patients with androgenetic alopecia by competitively inhibiting dihydrotestosterone, a known pathogenic trigger in androgenetic alopecia, based on evidence from Phase 1 and Phase 2 studies.[12,13] Phase 3 studies are currently recruiting participants to evaluate the efficacy and safety of clascoterone solution for androgenetic alopecia. **Cases 2**, **3**, **5**, **6**, and **9** highlighted the potential versatility of clascoterone cream 1% in addressing multiple dermatologic concerns including hirsutism, HS, retinoid-induced dermatitis, androgenetic alopecia, and folliculitis.

Conclusion

This case series presents Canadian real-world evidence demonstrating the efficacy, safety, and tolerability of clascoterone cream 1% for managing acne vulgaris across all patients, regardless of acne severity, age, gender, or ethnicity. In clinical practice, clascoterone is highly versatile for use as monotherapy, adjunctive therapy with other topicals, systemic agents, and laser devices, as well as maintenance therapy to prevent acne relapse.

As with any case study, the results should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

Patient data courtesy of Wei Jing Loo, BSc, MBBS, MRCP, FRCP.

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