### Case Series

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# Role of clobetasol propionate 0.025% topical therapy in various dermatoses

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### **ABSTRACT**

The anti-inflammatory and vasoconstrictive properties of topical corticosteroids (TCs) contribute in providing therapeutic benefits in several skin conditions, including atopic eczema, localized vitiligo, psoriasis, and chronic hand eczema. Clobetasol propionate (CP) is the most common topical agent used for psoriasis management and demonstrates an efficacy superior to other TCs. A new CP 0.025% cream formulation has demonstrated hypoallergenic effects due to the absence of known contact allergens, such as propylene glycol, short-chain alcohols, and sorbitol-based emulsifiers. Lower CP serum levels and less hypothalamic–pituitary–adrenal axis suppression with CP 0.025% cream formulation than with CP 0.05% ensure better safety. The present case series discusses the clinical experience of using CP 0.025% cream in various dermatological conditions.

**Keywords:** Clobetasol propionate 0.025%, Plaque psoriasis, Psoriasis, Topical corticosteroid

### INTRODUCTION

Topical corticosteroids (TCs) are considered first-line therapy for various dermatological conditions. <sup>1</sup> Current clinical evidence supports the use of TCs in conditions including atopic eczema, localized vitiligo, psoriasis, and chronic hand eczema. <sup>2</sup> The diverse biologic properties of TCs, including anti-inflammatory properties, stabilization of cellular and lysosomal membranes, reduction in neutrophil and monocyte recruitment, and vasoconstrictive

properties, contribute in providing therapeutic benefits in many skin conditions.<sup>3</sup>

Topical corticosteroids are a part of the standard treatment of most of the topical regimens for psoriasis, regardless of severity.<sup>3</sup> Clobetasol propionate (CP) is the most common topical agent used for psoriasis management worldwide. In comparison to other TCs, it has demonstrated superior efficacy.<sup>4</sup> A new CP 0.025% cream formulation has been approved by the United States food and drug administration for the treatment of moderate-to-severe

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plaque psoriasis in patients 18 years of age or older. Unlike the previous CP formulations (0.05%), CP 0.025% cream does not contain propylene glycol, short-chain alcohols, and sorbitol-based emulsifiers, which are known contact allergens. Moreover, application of CP 0.025% cream formulation is associated with lower CP serum levels and less hypothalamic–pituitary–adrenal (HPA) axis suppression compared to the other CP 0.05% cream. The present case series discusses the in-clinic experience of using CP 0.025% in terms of its safety and efficacy in various dermatological conditions.

#### **CASE SERIES**

### Case 1: Role of CP 0.025% in Psoriasis vulgaris

A 50-year—old female presented with reddish scaly lesions accompanied by itching. She had been a patient of hypertension for the past 8 years. There was no other comorbidity or any relevant family history. Harsh winters and mental stress were the major provoking factors that caused worsening of her condition.

Her vitals were within normal limits. She had pain in her knee joints. She faced social awkwardness due to the growing patches spread over her arms. The lesions of around 10×5 cm were located on the upper and lower limbs, trunk, and scalp. There was inflammation around the lesions. The affected skin showed silvery-white scaling and was warm to touch with significant itching. Skin rashes and tenderness were absent. More than 60% of the body surface area was affected (Figure 1a).

The patient was diagnosed with plaque psoriasis. Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed to be applied to the affected skin areas twice daily for 2 weeks. Additionally, methotrexate, 15 mg per week, and antihistamines were also prescribed. The use of a moisturizing soap was advised. Two weeks after the treatment, there was a notable improvement in the clinical symptoms of the patient. Her scaling, erythema, and plaque elevation had decreased substantially. The itching severity had also decreased, improving her social wellbeing. Overall, the disease severity had improved by almost 80% and the patient was satisfied with the results (Figure 1b).

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is effective in treating psoriasis vulgaris. It shows a notable improvement in the symptoms of psoriasis without causing any side effects. Due to its low concentration, the formulation of CP cream 0.025% can be used in less severe lesions as well.

# Case 2: role of CP 0.025% in plaque psoriasis with papular rashes

A 24-year-old female presented with itch and reddish lesions over her left arm for the past 2 days. The patient

did not have any comorbidity or any relevant family history. The application of some cosmetic moisturizing cream had aggravated her symptoms. Her pulse rate and blood pressure were 80 beats/minute and 114/80 mmHg, respectively.

On local examination of the site, multiple erythematous papules with excoriation over the flexor surface of the left elbow were noted (Figure 2a). The size of the lesion was around  $6\times6$  cm. There was inflammation around the lesions and the center of the lesion appeared clear. Papular rashes were observed. Scaling and itching were present.

The patient was diagnosed with plaque psoriasis. Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed to be applied to the affected skin areas twice daily for 15 days. In addition, levocetirizine 5 mg tablet was also prescribed for 5 days.

After 15 days, there was a notable improvement in the clinical symptoms of the patient (Figure 2b). The itching had substantially reduced. Overall, Impoyz<sup>TM</sup> (CP) cream 0.025% treatment resulted in a decrease in disease severity.

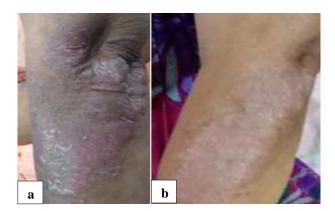


Figure 1: (a) Pretreatment image of the lesion located on the arm, and (b) post-treatment image of the lesion showing improvement.



Figure 2: (a) Pretreatment image of the lesion showing multiple erythematous papules, and (b) post-treatment image showing improvement in the lesion.

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is effective in treating plaque psoriasis. It possesses a good safety profile without any safety concerns. It can be a treatment of choice in dermatitis, psoriasis, and alopecia.

### Case 3: Management of plaque psoriasis with CP 0.025% used for a long duration

A 35-year—old male presented with itching over the dorsum of hands with scaling and redness for the past 4 months. There was no other comorbidity or any relevant family history. His vitals were within normal limits. Systemic examination showed unremarkable findings.

Multiple papules and scales were observed on the dorsum of hands. The size of the lesion was  $2 \text{ cm} \times 2 \text{ cm}$  with the center appearing erythematous and scaly (Figure 3a). Papular rashes were present with scaling and itch. There was presence of inflammation around the lesion.

The patient was diagnosed with plaque psoriasis. Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed to be applied to the affected skin areas twice daily for 20 days. An oral antihistamine tablet, levocetirizine 5 mg once daily, was prescribed for 20 days.

After 20 days, there was a notable improvement in the clinical symptoms of the patient. Itching and scaling had substantially reduced. Plaque elevation and erythema had also reduced (Figure 3b). Overall, the disease severity had decreased over the treatment period and the patient was satisfied with the outcome. There were no side effects noted despite the longer duration of the treatment.



Figure 3: (a) Pretreatment image of the lesion showing multiple papules and scales, and (b) post-treatment image of the lesion showing decrease in plaque elevation and scaling.

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is effective in treating plaque psoriasis and leads to patient satisfaction. Its

excellent safety profile makes it a preferred treatment option for long-term use.

# Case 4: remarkable benefits with CP 0.025% in a patient with psoriasis

A 25-year—old female presented with erythematous, scaly lesions accompanied by itching over cheeks and neck. There was no other comorbidity or any relevant family history. As she was a beautician by profession, her condition interfered with her ability to work.

Her vitals were within normal limits. On systemic examination, no abnormalities were detected. The  $2\times2$  cm size lesions were located on her cheeks and neck. Inflammation around the lesions was present. Papular skin rashes with itch were present (Figure 4a). The affected skin was found to be warm. Less than 10% of the body surface area was involved.

The patient was diagnosed with plaque psoriasis. Topical Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed to be applied to the affected skin areas twice daily for 2 weeks. An oral antihistamine tablet, levocetirizine 5 mg once daily, was prescribed for 2 weeks. A moisturizer was given to help alleviate the symptoms of psoriasis and moisturize dry skin while reducing skin scaling. The patient was advised to wash hands after each application, and instructions for improving personal hygiene were given.

After 2 weeks, the clinical symptoms of the patient had improved. Her erythema and plaque elevation had subsided (Figure 4b). The itching severity had also decreased, resulting in improved quality of life. Overall, the disease severity had improved, and no flare-up was noticed during the treatment.



Figure 4: (a) Pretreatment image of papular skin rashes on the cheek and neck, and (b) post-treatment image showing a decrease in erythema and plaque elevation.

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is safe and effective in managing psoriasis, including in patients who have lesions on the face. It improves symptoms of psoriasis without any

safety concerns. The desirable outcomes can be achieved with the formulation in a short duration.

# Case 5: role of CP 0.025% and apremilast 30 mg in managing scaly plaques all over the body

A 50-year—old farmer presented with itchy, scaly plaques all over the body. He had been diagnosed with mild hypertension 4 years before. No other comorbidity or significant family history was found.

The vitals (blood pressure: 120/80 mmHg; pulse rate: 82 beats/minute) were within normal limits. Multiple scaly plaques ranging from 1 cm to 15 cm in diameter were noted over the upper and lower limbs, trunk, and scalp. Inflammation around the lesion was present. The center of the lesion appeared to be scaly with fissures. Crusty rashes with scaling and itching were present. More than 40% of the body surface area was affected (Figure 5a).

The patient was diagnosed with plaque psoriasis. He was prescribed apremilast 30 mg twice daily for 1 month. Topical Impoyz<sup>TM</sup> (CP) cream 0.025% was instructed to be applied to the affected skin area twice daily for 1 week. Additionally, itraconazole 200 mg capsule was advised to be taken twice daily for 1 week. He was suggested to use a moisturizer frequently (at least three times a day).

Erythema, plaque elevation, and scaling had reduced substantially after 1 week of treatment (Figure 5b). Itching had improved markedly. The number of flare-ups or relapses had decreased. Facial redness and fissures had improved. Overall, the disease severity had improved after the treatment.

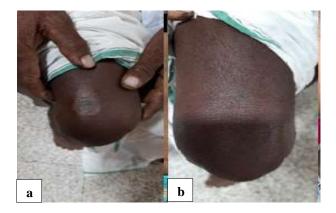


Figure 5: (a) Pretreatment image of the lesion showing crusty rashes with scaling, and (b) post-treatment image of the lesion showing decrease in erythema, plaque elevation, and scaling.

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is a safe and effective modality that can be considered as a first-line treatment for psoriasis. Topical application of CP cream 0.025% results in good on-site availability with minimal systemic

absorption due to lesser penetration in deeper skin layers. It is efficacious in many conditions, including atopic dermatitis, eczema, and lichen planus.

# Case 6: CP 0.025% for managing a case of generalized plaque psoriasis

A 26-year—old male presented with erythematous, scaly lesions all over the body for 6 weeks. He was a known case of plaque psoriasis for which he had received a mid-potent steroid. There was no other comorbidity or any significant family history. Cold and hot water baths worsened his symptoms. The physical and systemic findings were within normal limits.

The lesions were present all over the body surrounded by the inflammation. Patches, plaques, and scales (predominantly over the scalp) were noted. Erythema, edema, and scaling-like erythroderma were observed. The scaly, papular skin rashes were accompanied by itching. The affected skin was warm. More than 70% of the body surface area was involved (Figure 6a).

The patient was diagnosed with plaque psoriasis and was prescribed erythromycin 500 mg thrice daily for 5 days. Also, an oral antihistamine tablet, levocetirizine 5 mg twice daily, was prescribed for 20 days. Topical Impoyz<sup>TM</sup> (CP) cream 0.025% was instructed to be applied to the affected skin areas twice daily for 20 days. The patient was suggested to apply an emollient cream all over the body after the shower. The patient was advised to take a proteinrich diet, including meat, fish, dairy products, and legumes. The patient was asked to avoid hot water baths, and air conditioners.

Improvement in scaling was noted within a week. Erythema and plaque elevation had reduced substantially. The itch had also decreased, providing relief to the patient. The facial redness had improved with a substantially reduced number of flares. Overall, the disease severity had improved during the treatment period (Figure 6b).

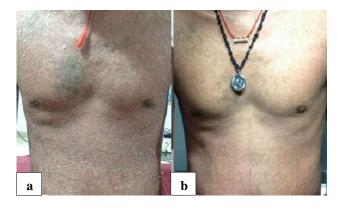


Figure 6: (a) Pretreatment image showing scaling and plaque elevation, and (b) post-treatment image showing improvement in scaling, erythema, and plaque elevation.

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is easy to apply, resulting in better treatment compliance compared to other ointment formulations in managing psoriasis. Its creamy base spreads easily, thereby providing emollient effects. At low strength (0.025%), CP shows better efficacy compared to other steroids.

# Case 7: a case of plaque psoriasis around the eye managed successfully with CP 0.025%

A 21-year-old female presented with an itchy rash near the right eye for the past 1 week. There was no other comorbidity or any significant family history. The rash and itch worsened with colder weather.

Her physical and systemic findings were within normal limits. Her condition was interfering with her work performance and social conduct. A lesion measuring 0.75 cm in size was present on the skin around the inner canthus of the right eye (Figure 7a). Inflammation around the lesion was present. Rashes were crusty and scaly in appearance and were itchy.

The patient was diagnosed with plaque psoriasis. Considering the skin around the eye is very sensitive, topical Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed as it is a low strength and effective option available. Impoyz<sup>TM</sup> Cream was advised to be applied twice daily for 1 week on the affected area. The patient was instructed not to use eye makeup during the treatment period and to avoid the use of an air conditioner.

Improvement in scaling was noted within a week. The itch disappeared and erythema reduced substantially. Overall, the disease severity had improved (Figure 7b).

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is safe to use for 1–2 weeks, especially when the lesions are present on areas with sensitive skin. Excellent outcomes were obtained within a short duration of the treatment course. Due to the low percentage (0.025%) of CP and lesser propensity of side effects, it can be a first-line choice of treatment for psoriasis.

# Case 8: a case of lichenoid-psoriasiform dermatoses managed with CP 0.025%

A 68-year—old female presented with an itchy rash on the anterior part of the scalp for the past 2 months. There was no significant comorbidity or any family history.

Her physical and systemic findings were within normal limits. The lesion of  $3\times 2$  cm size was present near the central hairline and the anterior frontal area of the scalp affecting less than 1% of the body surface area (Figure 8a). Inflammation around the lesion was present. The lesion

was scaly lichenoid and psoriasiform. A rash was present with scaling and itching. The affected area was tender and warm. Plaques were noted on the lesion.

The patient was diagnosed with lichenoid–psoriasiform dermatoses. Topical Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed to be applied to the affected skin area once daily for 15 days. The patient was asked to avoid applying sindoor (a bright-red dye traditionally worn in the hair by women as a cultural practice) for the treatment period.

Scaling and plaque elevation had completely cured. Also, the itching had disappeared. Erythema had reduced substantially (Figure 8b). Overall, the disease severity had improved during the treatment period.



Figure 7: (a) Pretreatment image of crusty and scaly lesion around the inner canthus of the right eye, and (b) post-treatment image of the lesion showing improvement.

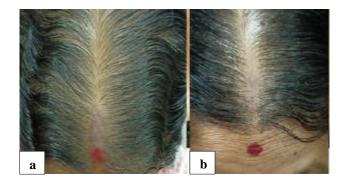


Figure 8: (a) Pretreatment image of the scaly lichenoid and psoriasiform lesion, and (b) post-treatment image showing improvement in scaling and plaque elevation.

Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is an effective treatment for psoriasis. In the case discussed, treatment with CP cream 0.025% resulted in complete resolution of the lichenoid–psoriasiform lesion within a month. It can serve as a safe and preferable option in treating patients with psoriasis.

### Case 9: a case of itchy papular lesion on the leg effectively managed with CP 0.025%

A 40-year—old female presented with an itchy, red skin lesion on the left leg for the past 3–4 weeks. There was no other comorbidity or any significant family history. Dry weather conditions aggravated her symptoms.

Her physical and systemic findings were within normal limits. The lesion of size 4×4 cm was located on the lower one-third of the shin of the left leg. There was inflammation around the lesion with the center of the lesion appearing scaly and erythematous. The papular rash with itching and scaling was noted (Figure 9a). The affected skin was warm.

The patient was diagnosed with plaque psoriasis. Topical Impoyz<sup>TM</sup> (CP) cream 0.025% was instructed to be applied to the affected skin area twice daily for 15 days. The patient was advised to use a mild, pH-balanced soap for bathing. She was advised to use an emollient during dry weather conditions.

Erythema and scaling had reduced substantially (Figure 9b). The itching had almost disappeared, providing relief to the patient. There were no flare-ups or relapse noted. Overall, the disease severity had improved by more than 80% after the treatment.

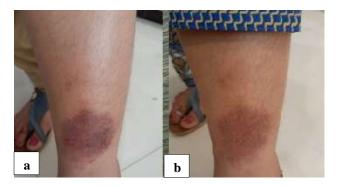


Figure 9: (a) Pretreatment image of the papular rash associated with erythema and scaling, and (b) post-treatment image of the lesion showing a reduction in erythema and scaling.

### Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% is a safe treatment and is not associated with perilesional hypopigmentation or telangiectasia. It can be considered as a first-line treatment for managing patients with psoriasis considering its efficacy and safety profile.

# Case 10: CP 0.025% for the resolution of plaque psoriasis involving lesions in multiple locations

A 45-year-old male presented with itchy, red patches that had been present for the past 10 years. He had metabolic syndrome including obesity and was a patient of diabetes.

He had attention-deficit hyperactive disorder and depression for the past 5 years for which he had been taking medication prescribed by his psychiatrist.

His physical and systemic findings were within normal limits. He was bothered about his appearance and was avoiding social gatherings. The lesions of size of around  $10\times10$  cm were located on the scalp, abdomen, back, forearms, and legs. There was no inflammation surrounding the lesions. The lesions appeared as thick red plaques with silvery scales (Figure 10a). Itch with scaling and tenderness was present.

The patient was diagnosed with plaque psoriasis. Topical Impoyz<sup>TM</sup> (CP) cream 0.025% was prescribed to be applied to the affected skin area twice daily for 1 month. The patient was advised to continue his medications for diabetes and depression.

After 1 month of treatment, scaling and plaque elevation had reduced substantially. Erythema and itching had almost disappeared (Figure 10b). Reduction in flares or relapses was noted. Overall, the disease severity had improved considerably.



Figure 10: (a) Pretreatment image of the lesion showing thick red plaques with silvery scales, and (b) post-treatment reduction of the lesions.

Expert opinion

Impoyz<sup>TM</sup> (CP) cream 0.025% can be considered as a first-line treatment in the management of psoriasis based on its efficacy and lesser propensity for side effects. It can be safely applied to a large surface area as the concentration of CP is 0.025% compared to CP 0.05% formulation. Dermatologists can be assured that the application of CP cream 0.025% only can lead to marginal systemic absorption of the drug.

### **DISCUSSION**

Psoriasis is a chronic and immune-mediated systemic disease with skin involvement that may affect a person at any age. Plaque-type psoriasis characterized by erythematous scaly plaques, round or oval, variable in size, and frequently located in scalp, lower back, umbilical region, intergluteal cleft, knees, and elbows, is the most

common form of psoriasis.<sup>4</sup> Corticosteroids are the mainstay of topical therapy for plaque psoriasis and class 1 TCs are commonly prescribed by dermatologists.<sup>3</sup>

CP is a widely used, super-potent topical steroid with proven efficacy in many chronic skin diseases. Topical application of CP can control inflammation and pruritus in psoriasis and atopic dermatitis. It can be used alone or with other topical agents if required to induce a rapid clearing of skin lesions in inflammatory dermatoses.<sup>5</sup> Two pivotal randomized controlled trials and a maximal use safety study have demonstrated efficacy, skin tolerability, and safety of CP 0.025% cream.<sup>3</sup>

A randomized, multi-center, open-label study compared the plasma concentrations of CP before and after 2 weeks of topical treatment with either CP 0.05% or CP 0.025% cream. The mean serum concentration of CP was significantly lower in the CP 0.025% group compared with the CP 0.05% group (56.3 versus 152.5 pg/ml, p=0.014). These results suggest that CP 0.025% is associated with reduced systemic exposure as compared with CP 0.05% cream that can be a safer treatment of patients with moderate-to-severe plaque psoriasis. Moreover, both the formulations showed similar marked improvement in psoriasis severity after 15 days of treatment.<sup>6</sup> CP 0.025% incorporates a specialized cream delivery vehicle that has demonstrated a 2.9-fold lower percent of HPA suppression compared with CP 0.05% cream in subjects with moderate-to-severe plaque psoriasis.3

### CONCLUSION

Several new molecules and formulations for the treatment of various skin conditions are available in the market that have a clear advantage of improved risk/benefit ratio. CP 0.025% cream has demonstrated equivalent efficacy to CP 0.05% cream formulation in reducing clinical signs and symptoms of moderate-to-severe plaque psoriasis. The additional benefits of CP 0.025% are lower systemic absorption and less HPA suppression, compared to the branded CP 0.05% cream. Moreover, the absence of contact allergens as vehicle components in CP 0.025% cream makes it a safer choice in psoriasis management. Therefore, the use of CP, 0.025% may be considered for a

safer treatment of patients with moderate-to-severe plaque psoriasis not candidates for systemic therapy or as an addon therapy to systemic therapy.

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