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Review Article

Clobetasol propionate 0.025% cream in the management of steroid responsive dermatoses: an expert opinion

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ABSTRACT

Topical corticosteroids play a key role in managing steroid responsive dermatoses (SRD). Current topical corticosteroid therapies are associated with various disadvantages. The current consensus article aims at providing a collation of evidence-based literature and clinical insights of the experts, regarding the efficacy, safety and usage of clobetasol propionate (CP) 0.025% cream in the management of SRD like plaque psoriasis. Clinical evidences suggest that the novel formulation of CP 0.025% cream has comparable efficacy and a better safety profile vs CP 0.05% cream in the management of plaque psoriasis. According to the doctors' experience, CP 0.025% can be used as first-line treatment for the management of SRD. In children 12-18-year-olds, CP 0.025% may be used cautiously, considering risk-benefit ratio. CP 0.025% may also be used as a maintenance therapy, after disease is brought under control with systemic therapy. Using moisturisers, salicylic acid, calcipotriol or tacrolimus as concomitant therapy with CP 0.025% cream may be beneficial in the management of SRD. In various comorbidities like diabetes and hypertension, CP 0.025% cream may be a better alternative verses CP 0.05% cream. Clinical evidences and experts suggest that for management of SRD, clobetasol propionate 0.025% cream can be recommended as a formulation with comparable efficacy and better safety profile versus CP 0.05% cream.

Keywords: Topical corticosteroids, Steroid responsive dermatoses, Clobetasol propionate

INTRODUCTION

Over the past several decades, topical corticosteroids have been playing a key role in the management of dermatological disorders.[1] Topical corticosteroids are beneficial in conditions involving hyper-proliferation, immunological, and inflammatory properties.[2] US food and drug administration (FDA) has approved use of these agents for patients presenting with inflammatory and pruritic manifestations of SRD. SRD includes psoriasis, atopic dermatitis, allergic contact dermatitis, irritant contact dermatitis, dyshidrotic eczema, lichen planus, cutaneous lupus and granuloma annulare.[1] For the novel topical corticosteroid formulations, the FDA-approved indication mentions the disease state and age group for which it can be prescribed. Therefore, the potent and newer topical corticosteroid formulations are commonly studied in adults with plaque psoriasis.[1]

ROLE OF SUPER-POTENT CORTICOSTEROIDS IN MANAGING STUBBORN AND CUTANEOUS PLAQUES

For treating skin diseases of the face, groin, axillary areas, and in infants and children, low potency corticosteroids are commonly used, whereas, in adults, for treating skin problems associated with all the other areas, the initial therapy includes mid- and higher-potency corticosteroids. For managing stubborn, cutaneous plaques or lesions on the palms, soles, and/or scalp, super-potent corticosteroids are mainly used. Besides, in clinical practice, potent and super-potent corticosteroids are often used to achieve a faster resolution of lesions.[3]

TOPICAL CORTICOSTEROIDS: FACTORS INFLUENCING SUCCESS OR FAILURE OF A TREATMENT

The success or failure of any topical corticosteroid is influenced by multiple factors, including potency and anticipated efficacy of specific topical corticosteroid, vehicle formulation and patient preference. The pharmacokinetic properties of topical corticosteroids, including skin penetration, active ingredient release/skin delivery and skin tolerability are determined by the formulation. In addition to this, the cosmetic acceptability and treatment adherence is influenced by the vehicle used in the formulation.[1]

Disadvantages with current topical corticosteroid therapies:

Disadvantages with current topical corticosteroid therapies were as (a) serious local, systemic, and psychological side effects associated with abuse and misuse of topical corticosteroids, more common with high potency corticosteroids; (b) a rapid increase in misuse of topical steroids on the face among Indians; (c) steroid-phobia; (d) long-term use of highly potent topical corticosteroids on thin skin or on inflamed surfaces leads to systemic adverse effects; and (e) topical steroid misuse is a leading cause for increasing prevalence of atypical presentations of fungal infections in India.[4,5]

Thus, there is a need for better options that retain efficacy and ensure better safety. Additionally, using a different formulation approach can improve the risk-benefit ratio.

A literature search was performed using databases Pubmed and Google Scholar. Relevant articles were identified using keywords like ‘topical corticosteroids’ ‘CP’, ‘moisturiser’, ‘salicylic acid’ ‘calcipotriol’ and ‘tacrolimus’. After screening, 15 relevant articles were identified and included in the document.

Clobetasol propionate 0.025% cream: efficacious for management of SRD in clinical practice

Of all topical steroids, clobetasol propionate (CP) is the most potent corticosteroid.[6] CP, a super-potent corticosteroid, is used for the management of SRDs such as atopic dermatitis, psoriasis and vulvar lichen sclerosus. CP exerts anti-inflammatory, immunosuppressive and antimitotic effect.[7] These mechanisms of action affect growth, differentiation and function of various cells resulting in inhibition of cytokine production.[6] In patients ≥18 years of age, CP 0.025% cream, recently approved by FDA, is applied twice a day for the treatment of moderate-to-severe plaque psoriasis. CP 0.025% cream does not contain common contact allergens like propylene glycol (PEG), short-chain alcohols (e.g., ethanol), and sorbitan sesquioleate, which are used in many topical corticosteroid formulations.[1]

Efficacy and potency

In a phase-2a investigator-blinded study, researchers compared the efficacy of CP 0.025% formulations (formulation 5 and 13) versus currently marketed CP 0.05% cream in Indian patients (aged ≥18 years) with moderate-to-severe psoriasis involving at least 25% body surface area (BSA). The patients were randomized 1:1:1 to receive CP 0.025% formulation 5, or 13, or CP 0.05% cream; twice daily for 28 days. Efficacy was evaluated by the psoriasis global assessment (PGA) score. The results of the study revealed that PGA success rates (clear or almost clear), at the end of the treatment, were higher with 0.025% formulations and were as follows: 5 (38.9%) and 13 (36.8%) versus 0.05% cream (30.8%).[8]

In another phase II study conducted in United States, Draelos et al compared the efficacy of CP 0.025% cream versus CP 0.05% cream in patients (≥18 years) with a clinical diagnosis of stable (at least 3 months) plaque-type psoriasis, that involved 20% to 50% of the BSA (Investigator Global Assessment (IGA) grade of at least 3). The patients used either CP 0.025% cream or CP 0.05% cream for 15 consecutive days. The primary efficacy assessment was IGA score.

After 15 days of treatment, both the treatment groups displayed similar marked improvement in psoriasis severity. About 50% of the subjects in each treatment group had IGA score of 2 (mild), while, 16.7% in the 0.05% group and 18.1% in 0.025% group had a score of 0 or 1 (none or minimal).[9]

These studies suggest that in patients with plaque-type psoriasis, CP 0.025% cream has an efficacy comparable to super-potent CP 0.05% cream.[1,9] However, clinical evidences supporting the use of CP 0.025% in the paediatric population are lacking. In addition, there are no evidences supporting the use of CP 0.025% in SRDs other than plaque psoriasis.

Experts' opinion

According to the experts CP 0.025% cream can be classified between super-potent and highly-potent steroid, so as to enable its use by paediatricians. As per the clinical experience, it has been suggested that with respect to (w. r. t) efficacy, CP 0.025% cream is a super-potent steroid, while, w. r. t safety, it is better than other superpotent topical steroids with more benefits and lesser risk.

The expert panel opined that CP, a super-potent corticosteroid, is efficacious in the management of SRD. Experts, in their routine clinical practice, use CP 0.025% cream for the management of various SRDs like chronic plaque psoriasis, vitiligo, adult and paediatric atopic dermatitis, chronic hypertrophic eczema, hypertrophic lichen planus, seborrhoeic dermatitis, contact allergic dermatitis, discoid lupus erythematosus, lichen simplex chronicus, alopecia areata (including beard) and granuloma annulare. In clinical practice, among paediatric patients, CP 0.025% cream is also found to be beneficial in the management of psoriasis, vitiligo, granuloma annulare and chronic eczema.

As per an expert's experience, in clinical practice, along with other SRDs, CP 0.025% cream (at night) concomitantly with ammonium lactate/lactic acid (in morning) is found to be beneficial in management of extensive macular amyloidosis (non-facial).

Experts' conclusion-1

The expert panel agreed that as per the clinical experience, CP 0.025% cream may be used in the management of SRDs like chronic plaque psoriasis, vitiligo, adult atopic dermatitis, chronic hypertrophic eczema, lichen planus, seborrhoeic dermatitis, contact allergic dermatitis, discoid lupus erythematosus, lichen simplex chronicus, alopecia areata (including beard) and granuloma annulare in clinical practice, as an alternate option to standard CP 0.05% cream.

In clinical practice, it may also be beneficial in the management of psoriasis, vitiligo, granuloma annulare and chronic eczema in the paediatric population. Experts also mentioned that at present, CP 0.025% cream is licensed only for use in management of moderate to severe plaque psoriasis, and opinion is purely based on clinical experience of the experts.

Safety of CP 0.025% in clinical practice

In a study, researchers compared the safety of CP 0.025% cream among adults with moderate-to-severe plaque psoriasis (20 to 50% of BSA) versus CP 0.05% cream, both used twice daily for 14 days.

On day 15, the percent of subjects with hypothalamic-pituitary axis (HPA) suppression was higher in CP 0.05% group (36.4%) versus CP 0.025% group (12.5%). In addition to this, a 2.7-fold increase in plasma CP level was observed with CP 0.05% vs CP 0.025% cream (p=0.014). This suggests that CP 0.025% cream is safe and tolerable in the management of moderate-to-severe plaque psoriasis.[1]

Experts' opinion

Experts agreed that in clinical practice, CP 0.025% cream demonstrates a good safety profile among patients with SRD. Extended use of CP 0.025% (beyond 6-8 weeks) was not found to be associated with local side effects like atrophy, hypo-pigmentation, telangiectasia (usually seen with CP). However, few experts observed telangiectasia and atrophy when CP 0.025% was used along with moisturisers. This may be due to PEG in the moisturizer which enhances the absorption of CP resulting in local side effects.

Expert's conclusion-2

The experts panel concluded that, based on the clinical experiences, for the management of SRD, CP 0.025% cream can be considered as a safer alternative to CP 0.05% cream.

Usage of CP 0.025% cream in patients with SRD

In patients ≥18 years, CP 0.025% cream is indicated for the treatment of moderate to severe plaque psoriasis. A thin layer of CP 0.025% cream, twice daily, must be applied to the affected skin areas and rubbed in gently and completely. It should not be used if atrophy is present at the treatment site. The cream should not be used on the face, scalp, axilla, groin, or other intertriginous areas.[10]

Experts' opinion

Experts opined that in patients ≥18 years, CP 0.025% cream can be used as a first-line treatment for the management of routinely seen SRDs, including lichen planus, eczema, lichen simplex chronicus, alopecia areata (scalp and beard), granuloma annulare (in children), contact allergic dermatitis, seborrheic dermatitis, plaque psoriasis (including paediatric), discoid lupus erythematosus and vitiligo (including paediatrics) (CP 0.025%- morning and tacrolimus- evening) for 4-6 weeks (beneficial up to 8-weeks). On good response, a twice weekly maintenance regimen of CP 0.025% (intermittent use) has also shown good results (for up to 6-months) in clinical practice with no local side effects like atrophy, hypo-pigmentation or telangiectasia (usually seen with CP). It is clinically beneficial in immediate relief of flare-ups. For palmar plantar keratosis/psoriasis, CP 0.025% can be used as a second-line therapy. It is a good alternative to betamethasone.

Experts also opined that CP 0.025% could be given as step-down therapy to patients with severe psoriasis or

vitiligo (where surface area is more), that has been dealt with by potent steroids, steroids in combination with salicylic acid or systemic therapy. In such scenario, the treatment duration could be 4-6 weeks (later followed by once-a-day application).

The safety profile of CP 0.025% cream enables one to use it for a longer period of time versus CP 0.05% (used for maximum 3-weeks). In paediatric patients and patients with large areas of involvement or deranged barrier function, CP 0.025% cream could be a safer therapeutic option. CP 0.025% cream is also used as weekend therapy after control of the disease. Besides, when vitiligo is treated with systemic steroids and if the patient is stable, then CP 0.025% can be used as maintenance therapy in certain areas (not for large areas).

Experts opined that CP 0.025% cream should not be used in children <12 years; while in children 12-18 years, it may be used cautiously (not as first-line treatment). However, CP 0.025% cream can be used as alternative in children with very severe wide-spread atopic dermatitis, who cannot afford cyclosporine and cannot be given systemic steroids.

Expert's conclusion-3

The experts' panel agreed that, as per their clinical practice, CP 0.025% cream can be used as first-line treatment for the management of routinely seen SRD for a duration of 4-6 weeks. CP 0.025% can also be used as weekend therapy or maintenance therapy, after disease is controlled by systemic therapy. In children aged 12-18 years, CP 0.025% cream can be used cautiously (not as first-line treatment).

Clinical experience of CP 0.025% cream with concomitant therapy

Moisturizer

To treat various SRDs dermatoses such as atopic disorders as well as other types of dermatitis, moisturizers are commonly used. Apart from skin moistening agents, moisturizers act as anti-inflammatory, antipruritic and antimitotic agents and facilitate wound healing.[11]

Expert's opinion

Experts opined that moisturizers are an integral part of all SRD treatments. CP 0.025% cream can be used concomitantly with moisturizers. Moisturizers can be applied in the morning and CP 0.025% cream can be applied at night. This regimen of applying moisturizer and CP 0.025% should be followed, because even if CP 0.025% cream is applied 1 hour after using moisturizer, the PEG present in the moisturizer may enhance the absorption of CP into skin layers and lead to side effects like hypopigmentation. This may result in reduced safety benefit of CP 0.025% cream.

Salicylic acid

Salicylic acid is usually used concomitantly with topical corticosteroids for the management of SRD like psoriasis. Salicylic acid, by disrupting keratinocyte-keratinocyte binding, acts as a topical keratolytic. In addition, by lowering the pH it softens the stratum corneum. Use of salicylic acid along with the corticosteroids has demonstrated an increased penetration in the skin.[3]

Expert's opinion

Experts opined that using salicylic acid in the morning and CP 0.025% cream at night is beneficial in managing plaque psoriasis. In clinical practice, for management of palmar plantar psoriasis, experts prescribe 12% or 18% salicylic acid in the night and CP 0.025% cream in the morning.

Calcipotriol

Topical corticosteroids are efficacious in rapid healing of psoriatic lesions. However, their long-term use must be avoided. For long-term use, calcipotriol may be considered as a safe alternative, but demonstrates lower initial efficacy vs topical corticosteroids. In a study, Austad et al showed that for the treatment of plaque psoriasis, using topical CP twice a day for 2 weeks, followed by treatment with calcipotriol ointment (twice a day) for 4 weeks was superior vs calcipotriol ointment alone.[12]

Expert's opinion

For treating limited plaques of psoriasis on the extremities, the experts suggest that using CP 0.025% cream at night with calcipotriol in the morning, followed by stopping CP 0.025% cream and continuing calcipotriol is beneficial.

In routine clinical practice, for treating psoriasis, experts recommended using calcipotriol for 5 days a week, followed by CP 0.025% cream for 2 days (for as long as 8-10 weeks).

Tacrolimus

Topical tacrolimus is used as an immunomodulator. It acts by inhibiting calcineurin action, which in turn results in prevention of T-cell activation and the production of various inflammatory cytokines. It is used for managing inflammatory and immunologic skin disorders.[13] Topical tacrolimus is an FDA approved medication, used for the treatment of atopic dermatitis (eczema). In addition to this, the practitioner uses tacrolimus to treat different types of psoriasis including plaque psoriasis (on the face and other delicate areas like the genitals) and inverse

psoriasis (armpits, skin under the breasts, groin, or face). Tacrolimus is also found to be beneficial in the management of vitiligo and lichen planus.[13-15] If used as directed, tacrolimus demonstrates a good safety profile. Using corticosteroids along with tacrolimus increases the effectiveness of the later. Among patients using tacrolimus, no increased risk of cancer is observed by the dermatologists.[14]

Expert's opinion

In routine clinical practice, experts have found the concomitant therapy of CP 0.025% cream with tacrolimus, extremely useful in cases of lichen planus. Besides, in patients with extensive vitiligo, CP 0.025% cream can be used in the night, whereas tacrolimus can be applied in the morning.

Expert's conclusion-4

Experts agreed that using moisturiser, salicylic acid, calcipotriol or tacrolimus (usually in morning) as concomitant therapy with CP 0.025% cream (at night) is beneficial in the management of SRDs in routine clinical practice.

Key points to be considered while using CP 0.025% cream

Topical corticosteroids lead to hypopigmentation.[4]

Expert's opinion

In clinical practice the experts did not report hypopigmentation in patients using CP 0.025% cream beyond 4-6 weeks, as seen with CP 0.05%.

Vehicle component and super-potency rating in topical corticosteroid product

The potency ranking of topical corticosteroid formulation is influenced by multiple properties including topical corticosteroid itself, concentration and vehicle properties, and its concentration. The use of PEG as an excipient has led to a marked increase in penetration, and in turn the potency of the topical corticosteroid. PEG is used in 60% of topical corticosteroid products and is a common contact allergen.[1]

Disadvantages of PEG-1

The disadvantages of PEG-1 were as follows (a) PEG, by disrupting intercellular lipids and increasing the partitioning of active ingredient and solvent, induces epidermal barrier dysfunction; (b) besides, the topical corticosteroid leads to decreased stratum corneum lipid synthesis; and (c) PEG, at concentrations of >25% can cause unintended alteration of the cutaneous microbiome with antibacterial and antifungal properties. It also induces allergic reactions at concentration of >10%. To overcome the problems associated with PEG, newer vehicles are developed, that optimise topical corticosteroid potency without using this vehicle.[1] Use of diethylene glycol monoethyl ether (DEGEE) as a vehicle in CP 0.025% cream alters the absorption by increasing active ingredient penetration and/or limiting the systemic uptake of dissolved active ingredient. DEGEE, increases the solubility and intracutaneous deposition of topical corticosteroids with the benefit of lower systemic exposure. DEGEE provides numerous advantages versus propylene glycol and ethanol. The advantages are detailed in Figure 1.[1]

Physical properties	Biologic properties
• Colourless hygroscopic liquid • Has compatibilty with commonly used solvents, including oleic acid, propylene glycol, and ethanol • Easy to spread without streaking	• Non-allergic, non-irritating and non-carcinogenic • Enhances solubility and intracutaneous penetration of CP • Exerts intracutaneous depot effect with reduced systemic exposure • No systemic toxicity observed due to systemic absorption of DEGEE (5%–40% DEGEE concentration in available products) after topical application • Compatible with lipids of skin surface

Figure 1: Properties of DEGEEs relevant to use as a solvent in topical formulations.[1]

Evidence demonstrates that in subjects with moderate-to-severe plaque psoriasis, after 2-week twice daily treatment with CP 0.025% cream, a 2.7-fold greater reduction in serum CP concentration and 2.9-fold lower percent of hypothalamic-pituitary axis (HPA) suppression versus CP 0.05% cream was observed. The use of DEGEE as a vehicle in CP 0.025% cream modifies the penetration and provides a reservoir effect.[1]

Expert's opinion

Experts opined that CP 0.025% cream gets accumulated in the epidermis and not the dermis layer of the skin. The

low strength of CP (0.025%) stays for a longer duration with no side effects. As per the vasoconstrictor assay data, the vasoconstrictor effect of CP 0.025% cream is lower vs betamethasone dipropionate augmented and CP 0.05% cream, suggesting that lesser CP 0.025% cream enters into the dermis. Experts suggested that even though the potency is high and side effects are less, the patient must be explained about appropriate use of CP 0.025% cream.

Expert's conclusion-5

The experts agreed that the CP 0.025% cream demonstrates lesser systemic side effects vs other super-potent steroids and CP 0.05% cream in clinical practice.

Overall clinical experience of experts

Expert opinion

Experts opined that CP 0.025% cream has similar efficacy compared to CP 0.05% cream and higher safety in SRDs.

They suggested that the use of CP 0.025% in various comorbidities like diabetes and hypertension would not be a concern as the systemic side effects with CP 0.025% are less. CP 0.025% cream can be recommended for longer durations (more than 4 weeks) with less safety concerns as compared to CP 0.05%.

Expert's conclusion-6

Experts agreed that as CP 0.025% cream has low systemic side effects and can be used in patients with comorbidities like diabetes and hypertension without any concern. They also opined that it has comparable efficacy and wider margin of safety (can be used beyond 4 weeks) versus CP 0.05% cream.

CONCLUSION

Topical corticosteroids play a key role in managing SRDs. The novel formulation of CP 0.025% cream has shown comparable efficacy and a better safety profile vs CP 0.05% cream in moderate to severe plaque psoriasis. In clinical practice, among patients ≥18 years, experts are prescribing CP 0.025% cream as first-line treatment for the management of routinely seen SRDs including lichen planus, eczema, lichen simplex chronicus, alopecia areata (scalp and beard) and granuloma annulare (in children), contact allergic dermatitis, seborrheic dermatitis, plaque psoriasis (including paediatric), discoid lupus erythematosus and vitiligo (including paediatrics) (for 4-6 weeks). CP 0.025% cream can also be used as weekend therapy or maintenance therapy, after disease is under control with systemic therapy or another super potent steroid. Using moisturisers, salicylic acid, calcipotriol or tacrolimus as concomitant therapy with CP 0.025% cream is beneficial in the management of SRDs. Therefore, this suggests that CP 0.025% cream can be recommended as a formulation with comparable efficacy and better safety profile versus CP 0.05% cream.

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