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Risks of topical corticosteroid therapy and role for advanced targeted topical treatments for inflammatory skin diseases: an expert consensus panel

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Abstract

Topical corticosteroids are a first-line therapy for inflammatory skin diseases and are commonly used for chronic management. Topical corticosteroids can lead to cutaneous and systemic adverse events. The purpose of this expert consensus panel was to review published literature on the safety and efficacy of topical corticosteroids and role for advanced targeted topical therapies for inflammatory skin diseases. A comprehensive literature search was completed using a combination of keywords: "topical," "corticosteroid," "non-steroid," "efficacy," "adverse effects," "malpractice," and "inflammatory skin diseases." Articles were screened for relevance to topic of safety and efficacy of topical corticosteroids and noncorticosteroid therapies for inflammatory skin diseases. A panel of four dermatologists with expertise treating inflammatory skin diseases reviewed the articles and created consensus statements. A modified Delphi process was used to approve each statement and a strength of recommendation was assigned. The literature search produced 350 articles. A screening of the studies resulted in 24 articles that met criteria. The panel unanimously voted to adopt 10 consensus statements and recommendations. Topical corticosteroids and systemic corticosteroids are associated with numerous adverse effects, and medical-legal risks for clinicians prescribing these medications exist. Advanced targeted topical therapies have demonstrated safety and effectiveness as an alternative to corticosteroids.

Keywords: inflammatory diseases; topical; systemic; corticosteroids; chronic; non-steroid; topical therapies; psoriasis; atopic dermatitis; seborrheic dermatitis; adverse effects

Introduction

Topical corticosteroids (TCS) have long been utilized as a first-line therapy for chronic inflammatory skin diseases given their known efficacy [1,2]. However, there are limitations to their chronic use, largely related to substantial risk for adverse effects, such as localized skin atrophy, cracks or fissures, and linear [3-6]. Numerous reports striae have demonstrated the risk of systemic side effects, avascular necrosis (AVN), diabetes, and adrenal suppression [7-11]. As these outcomes can be debilitating, patients have filed a number of medical malpractice lawsuits against dermatologists in relation to chronic TCS use [12,13].

Advanced targeted topical therapies can be utilized to avoid the possibility of these adverse effects while maintaining efficacy. In fact, many TCS-experienced patients prefer non-steroidal therapy – one study reported that 76.4% of patients who have used TCS

prefer a non-steroid alternative [3]. Recent advanced targeted topical therapies include roflumilast (phosphodiesterase 4 [PDE4] inhibitor) [14] and tapinarof (aryl hydrocarbon receptor-modulating agent) [15] creams for psoriasis, crisaborole (PDE4 inhibitor [16]) ointment, roflumilast, tapinarof, and ruxolitinib (JAK1.JAK2 inhibitor [17]) creams for atopic dermatitis (AD) and delgocitinib (pan-JAK inhibitor [18,19]) for chronic hand eczema. Roflumilast foam can also be used to treat seborrheic dermatitis [20].

The purpose of this expert consensus panel was to review the published literature on the safety and efficacy of TCS and advanced targeted topical therapies for inflammatory skin diseases, with the goal of guiding clinical decision-making and enhancing patient care.

Methods

comprehensive literature search of PubMed/Scopus/Google Scholar was completed on December 18, 2024, using a combination of "steroid," keywords "topical," "non-steroid," "efficacy," "adverse effects," "malpractice," and "inflammatory skin diseases" along with the Boolean term "AND" for English-language original research articles, systematic reviews, or meta-analyses without date restrictions. This study was exempt from International Review Board approval. Articles were screened for relevance to topic of safety and efficacy of TCS and noncorticosteroid therapies for inflammatory skin diseases. Four experts with expertise in the management of inflammatory skin diseases were asked to participate in a panel. The articles that met inclusion criteria were distributed to the panelists and each member assigned them a level of evidence based on Strength Recommendation Taxonomy (SORT) criteria [21]. These levels include level-1 (good-quality, patientoriented evidence), level-2 (limited-quality, patientoriented evidence), or level-3 (other) [21].

The panel convened on December 23, 2024, to discuss the studies and create consensus statements. A modified Delphi process was utilized order to reach consensus for each statement [22], which requires a supermajority approval for adoption recommendation through multiple rounds of realtime voting. This is a regularly utilized method to create expert recommendations in dermatology [22-24]. Consensus statements were assigned a SORT criteria of A (consistent, good-quality, patient-oriented evidence), B (inconsistent, limited-quality, patientoriented evidence, or C (consensus, opinion, etc.).

Results

The literature search resulted in 350 articles that met search criteria. After comprehensive screening process, 24 articles were selected as relevant to the research questions.

For the 24 articles that were evaluated, the panel assigned level-1 evidence to 11 articles, level-2 evidence to three articles, and level-3 evidence to 10 articles (Table 1). The panel developed 10 consensus statements. Of the 10 statements, all received a unanimous (4/4) vote for adoption. Each statement was assigned a strength based on SORT criteria (Table 2).

Statement 1: Topical corticosteroids are associated with numerous cutaneous and systemic side effects. (SORT Level A)

In a prospective cohort study of patients with chronic hand eczema, 64.1% experienced skin atrophy, 41.4% had cracking/fissuring, 23.9% had bleeding, and 45.9% reported pain/stinging sensation [3]. Chronic use of TCS can result in linear striae, telangiectasias, perioral dermatitis, acne, rosacea, contact dermatitis, and skin infections [4,25-28]. There are also systemic adverse effects with TCS. Several case reports have described the development of AVN in multiple age groups [8,9]. Another study reported significantly association between TCS use and type 2 diabetes, with significantly increased risk of incident diabetes [7]. Both pediatric and adult patients can develop adrenal suppression and Cushing syndrome after long-term use of TCS [10,11,25,29-32]. In a retrospective study, patients with psoriasis affecting body surface area of 16-20% versus 10-15% had a significantly lower postcosyntropin cortisol level following use of high-potency TCS; both groups had significantly lowered cortisol levels [33]. Although one systematic review reported low evidence for increased risk of cutaneous and systemic adverse effects with TCS, this study focused only on eczema clinical trials (which have limited follow up time) and excluded other relevant studies [1]. Repeated intralesional corticosteroid injections have also been associated with similar adverse effects to TCS [34-36].

Statement 2: Systemic corticosteroids are associated with numerous cutaneous and systemic side effects. (SORT Level A)

Patients receiving higher doses and durations of corticosteroids are at increased risk of AVN [37,38]. A meta-analysis review found that 10mg/day prednisone incurred a 3.6% increase incidence of AVN and those who received a cumulative dosage >2000mg prednisone equivalents had a 6.7% incidence of AVN [37,38]. systematic review reported corticosteroids users had a 40% increased risk of gastrointestinal bleeding or perforation [39]. Systemic corticosteroids have also been associated higher likelihood of heart failure, hypertension, ischemic heart disease, diabetes, thyroid dysfunction, psychiatric symptoms(mania/hypomania/depression), acne, Cushing syndrome, and ophthalmic complications(ocular hypertension/open-angle glaucoma/cataracts) [26,40-46]. Corticosteroids can also increase risk of infections such as tuberculosis and bacterial sepsis [38,47,48].

Patients using short-term systemic corticosteroids also have the potential to develop adverse effects. One study found that vomiting, behavioral changes,

and sleep disturbances were most common after <14 days of oral corticosteroid treatment in pediatric patients [49]. There are also increased rates of gastrointestinal bleeding, sepsis, heart failure, venous thromboembolism, and fractures in patients who used oral corticosteroids for less than 30 days [50,51].

Statement 3: Use of multiple topical corticosteroids for different reasons and different parts of the body incurs burden on patients, physicians, and the healthcare system. (SORT Level C)

Areas of the body that have thinner skin (e.g., face, intertriginous areas) require lower potency corticosteroids, as risk of skin atrophy increases when TCS are applied to these areas [25]. This approach can be disease-dependent because certain conditions that occur on sensitive areas, such as lichen sclerosus, are with high-potency TCS. treated One demonstrated that consistent application of TCS for 6 weeks induced atrophy of the epidermis, with changes seen as early as one to two weeks [52].

Dermatologists commonly prescribe multiple TCS for patients with inflammatory skin diseases that involve parts of the body with varying skin thickness and this can result in polypharmacy. There is substantial application burden for patients using multiple TCS, both in terms of application instructions and duration. Patients are thus at risk of placing high-potency TCS in areas such as the face owing to confusion[53]. In addition, patients are faced with increased expenses for multiple copays and the healthcare system incurs a greater burden. One study found polypharmacy for AD patients was associated with increased AD severity, flares, and greater number of healthcare provider visits [54].

Statement 4: It is not ideal to prescribe topical corticosteroids for long-term use in a chronic condition. (SORT Level C)

Use of TCS can result in a variety of cutaneous and systemic adverse effects. Currently, US and international guidelines recommend that TCS,

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especially high- and very high-potency TCS, should be used in an acute setting for inflammatory diseases but should not be maintained as a long-term therapy [2,55,56]. When used to control flares in a short-term period (one to four weeks), higher potency TCS have a lower risk of adverse effects [55,56]. The greatest risk of systemic adverse effects occurs when high- and very high-potency TCS are applied under occlusion over a >20% body surface area for more than four weeks [56]. There are, however, some patients for whom systemic corticosteroids may need to be utilized for long-term treatment if there is no better alternative (e.g., immune-bullous disease) [57].

Statement 5: There are medical-legal risks for clinicians prescribing topical corticosteroids. (SORT Level B)

Given the abundance of adverse effects that can occur with corticosteroids, patients have pursued medical malpractice lawsuits against dermatologists [12,13,38]. Dermatology has been reported as the most common specialty involved in corticosteroidrelated medicolegal cases [13]. One study analyzed malpractice litigation trends related corticosteroids and found that 18% of cases were for dermatologic conditions and 12% were brought against dermatologists [12]. Another retrospective analysis of psoriasis malpractice litigations found that most patients were treated with TCS (37.9%) [58]. Common allegations against dermatologists have been negligence, lack of adequate informed consent, and failure to diagnose complications [12]. Long-term corticosteroid use is the third most common medication associated with malpractice claims among all specialties [13,59]. One typical case describes a of 25-year-old man who developed cataracts after being treated with corticosteroids [60]. The patient filed a lawsuit against the dermatologist and the Supreme Court of Texas ruled in favor of the defendant [60].

Statement 6: Advanced targeted topical therapies are safe for short-term treatment of inflammatory skin

diseases. (SORT Level A)

Multiple clinical trials have demonstrated the short-term safety of advanced targeted topical therapies. After 8-week treatment with roflumilast cream 0.3% for psoriasis, treatment-related treatment-emergent adverse events (TEAEs) occurred in 2.4%-5.5% of treated patients (versus 2.0%-5.3% vehicle) [14]. Only 0%-0.7% experienced serious adverse events (AEs) (similar to vehicle) [14]. Application site pain was reported in only 0.7%-1.4% [14]. For AD (roflumilast cream 0.15%), 0.9% experienced serious AEs and 1.4%-1.8% discontinued roflumilast cream 0.15% owing to any TEAE at four weeks [61]. For seborrheic dermatitis, roflumilast 0.3% foam was well-tolerated with only 2.6% experiencing treatment-related TEAEs at 8 weeks [20].

Clinical trials reported that after 12 weeks of tapinarof cream 1% for treatment of psoriasis, 50.3%-54.5% experienced TEAEs (versus 22.4%-26.2% of those treated with vehicle) and of those, 5.6%-5.8% led to discontinuation (versus 0%-0.6% vehicle) [15]. The most prevalent TEAE was folliculitis, which occurred in 17.8%-23.5% receiving tapinar of (versus 0.5%-1.2% vehicle) [15]. Similarly for AD, TEAEs were reported in 70% of those treated with tapinar of 1% (versus 38% vehicle), of which 15% were treatment-related TEAEs; the majority were mild to moderate [62,63]. In the clinical trials including patients as young as 2-years of age, treatment-related TEAEs occurred in 11.8%-12.6% (versus 6.6%-6.8% vehicle), and discontinuation rates related to AEs were low(1.5%-1.9% versus 3.0%-3.6% vehicle) [64].

Clinical trials for treatment of AD with ruxolitinib cream 1.5% reported 26.5% TEAEs at 8 weeks [17]. Of these, treatment-related AEs occurred in 4.8% (versus 11.2% vehicle), the most common being application site burning (ruxolitinib-0.8% versus vehicle-4.4%) and pruritus (ruxolitinib-0% versus vehicle-2.4%) [17]. Only 0.8% of ruxolitinib-treated patients discontinued due to TEAE (versus 3.2% vehicle) [17].

In the clinical trials for crisaborole, 94.3% of TEAEs for

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crisaborole were mild to moderate (versus 96.9% vehicle) at 28 days [16]. Most of these were considered unrelated or unlikely to be related to the treatment [16]. Application site pain was only present in 4.4% of patients (versus 1.2% vehicle), which was the only treatment-related AE that occurred in ≥1% of patients [16]. For those treating AD with delgocitinib for four weeks, 21.7% experienced AEs (versus 11.5% vehicle), of which the majority were mild [19]. Further, 4.7% of patients using delgocitinib experienced treatment-related AEs versus 1.9% using vehicle [19].

Statement 7: Advanced targeted topical therapies are safe for long-term treatment of inflammatory skin diseases. (SORT Level A)

After 52-weeks of treatment with roflumilast cream 0.3% once-daily for psoriasis, only 3.9% of patients discontinued owing to AEs [65]. Treatment-related AEs occurred in 3.6%, and ≥97% had no irritation [65]. Further, in the one-year safety analysis for tapinarof for psoriasis, AEs were consistent with prior trials, and no new safety signals were reported [66]. Most common TEAEs were folliculitis (22.7%) and contact dermatitis (5.5%), and discontinuation rates related to these were low (1.2% and 1.4%, respectively). Greater than 90% had no irritation [66]. Additionally, one-year safety analysis for ruxolitinib cream 1.5% for AD reported 7.4% experienced treatment-related AEs (62.6% experienced any TEAEs versus 67.4% vehicle) [67]. Only 1.8% experienced serious AEs, most of which were considered unrelated to ruxolitinib [67]. The exposure-adjusted incidence rate for application site reactions was higher with vehicle versus ruxolitinib [67].

For patients using crisaborole for treatment of AD for 52 weeks, 26.7% experienced TEAEs (versus 36.3% vehicle) [68]. Only 1.5% of patients reported treatment-related AEs with crisaborole (versus 3.0% vehicle), and one patient discontinued crisaborole related to AEs (versus 2.2% vehicle) [68]. After 28 weeks using delgocitinib for the treatment of AD,

50.6% of patients experienced AEs, of which none were serious or severe [19]. Only one patient discontinued delgocitinib owing to AEs [19].

Statement 8: Advanced targeted topical therapies are effective for short-term treatment of inflammatory skin diseases. (SORT Level A)

Patients using roflumilast to treat psoriasis had greater percentage of Investigator Global Assessment (IGA) success at 8 weeks versus vehicle (42.4% versus 6.1%, P<0.001) [14]. In addition, patients had intertriginous IGA success (71.2% versus 13.8%, P<0.001) and greater rate of Psoriasis Area and Severity Index-75 achievement (41.6% versus 7.6%, P<0.00) [14]. After four weeks, patients treated with roflumilast for AD had a higher rate of achieving IGA success (32.0% versus 15.2%, P<0.001) and Eczema Area and Severity Index-75 (EASI75) (43.2% versus 22.0%, P<0.001) [61]. For seborrheic dermatitis, 79.5% of roflumilast-treated patients after 8 weeks achieved IGA success (versus 58.0% vehicle, P<0.001) [20]. This statistically significant difference began as early as two weeks [20].

Patients using tapinarof for psoriasis had greater Physician's Global Assessment (PGA) response (40.2% versus 6.3%, P<0.001) and Psoriasis Area and Severity Index-75 response (47.6% versus 6.9%, P<0.001) at 12 weeks [15]. For AD, IGA responses at 12 weeks were higher in the tapinarof-treated groups (53% in 1% twice daily group, P=0.008), as were rates of EASI75 success (60% in 1% twice daily group, P=0.002) [63]. Treatment of AD with ruxolitinib also resulted in significantly more patients achieving IGA success (51.3% versus 7.6%, P<0.001) and EASI75 (61.8% versus 14.4%, P<0.001) at 8 weeks [17]. Patients reported significant reduction in itch within the first 12 hours (P<0.05) [17].

Patients using crisaborole for AD had a higher Investigator's Static Global Assessment success rate (32.8% versus 25.4% vehicle, P<0.001) and a greater percentage had Investigator's Static Global Assessment 0/1 (51.7% versus 40.6% vehicle, p<0.05) at 28 days [16]. Delgocitinib demonstrated a higher

least-squares mean percent change in EASI75 (-44.3 versus 1.7% vehicle, P<0.001) at four weeks for treatment of AD [19].

Statement 9: Advanced targeted topical therapies are effective for long-term treatment of inflammatory skin diseases. (SORT Level A)

Response of psoriasis to roflumilast was consistent over 52 weeks, with 44.8% achieving IGA 0/1 [65]. Further, of the 57.1% of patients who achieved IGA success at any point in the 52-week period, there was a 50% probability of maintaining IGA success for >10 months [65]. With regards to intertriginous involvement, 72.4% across all groups achieved Intertriginous-Investigator Global Assessment clear at week 52 [65]. Psoriasis Area and Severity Index-75 success was also maintained [65].

After 52 weeks of treatment with tapinarof for psoriasis, 40.9% of patients had complete disease clearance (PGA=0), and 34.3% of those who had PGA≥1 achieved PGA=0 [66]. In addition, tapinarof demonstrated a remittive effect of almost four months for those who achieved PGA=0 at any point and tachyphylaxis was not observed for up to 52 weeks [66].

Treatment of AD with ruxolitinib over 52 weeks resulted in 74.1%-77.8% of patients achieving IGA 0/1 [67]. In addition, mean total affected body surface area was substantially reduced four weeks after patients switched from vehicle to ruxolitinib [67].

Use of crisaborole for 52 weeks resulted in longer median time of flare-free maintenance for AD vs vehicle (111 versus 30 days, P=0.003) and mean number of flare-free days was higher, though there was no clear trend in maintenance of pruritus response [68]. When patients continued use of delgocitinib for 24 weeks, modified EASI75 and IGA improvements were maintained [19].

Statement 10: Most patients can affordably access advanced targeted topical therapies through

dermatology-focused pharmacies. (SORT Level C)

Access to advanced targeted therapies can pose a challenge for patients. There are, however, strategies most patients can use to affordably access these medications. One such strategy is direct-to-consumer dermatology-focused pharmacies from which drugs can be obtained at substantially reduced prices [69-71]. Here, drugs are offered at a substantial discount and many of the pharmacies will ship medications anywhere in the country [69]. As patients may face difficulty obtaining drugs that are not part of their insurance company/Medicare/Medicaid formulary, these pharmacies make drugs more accessible and diminishes burden on dermatologists. The pharmacies can support the work of a dermatologist by completing prior authorizations, one of the primary obstacles patients face, and identifying patients who may qualify for patient-assistance programs [70].

Conclusion

expert consensus panel completed comprehensive review of the literature and developed 10 consensus statements on the safety and efficacy of TCS and advanced targeted topical therapies for inflammatory skin diseases. TCS and systemic corticosteroids have numerous adverse effects, particularly with chronic use, and there are notable medical-legal risks for clinicians prescribing these medications. Advanced targeted topical therapies demonstrated have safety effectiveness as an alternative to corticosteroids. The panel's consensus recommendations provide a strong call to action for clinicians to make these new therapies available to their patients with chronic inflammatory skin diseases.

Potential conflicts of interest

The authors declare the following conflicts of interest: Alexandra K. Golant has received consulting or speaker fees from Regeneron, Sanofi, AbbVie, Incyte, Dermavant, Eli Lilly, Arcutis, Janssen, Amgen, and Pfizer. Raj Chovatiya has served as an advisor,

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Table 1. SORT criteria level of evidence for articles.

Article	Level of Evidence
Koshi EJ, Young K, Mostales JC, Vo KB, Burgess LP. Complications of Corticosteroid Therapy: A Comprehensive Literature Review. <i>J Pharm Technol</i> . 2022;38(6):360-367	
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Stein Gold L, Adam DN, Albrecht L, et al. Long-term safety and effectiveness of roflumilast cream 0.3% in adults with chronic plaque psoriasis: A 52-week, phase 2, open-label trial. <i>J Am Acad Dermatol</i> . 2024;91(2):273-280.		
Simpson EL, Eichenfield LF, Alonso-Llamazares J, et al. Roflumilast Cream, 0.15%, for Atopic Dermatitis in Adults and Children: INTEGUMENT-1 and INTEGUMENT-2 Randomized Clinical Trials. <i>JAMA Dermatol</i> . 2024;160(11):1161-1170.		
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Table 2. Consensus statements and recommendations.

Consensus Statement/Recommendation	Strength of Recommendation	Consensus Vote
Topical steroids are associated with numerous cutaneous and systemic side effects	А	4/4
Systemic steroids are associated with numerous cutaneous and systemic side effects	А	4/4
Use of multiple topical steroids for different reasons and different parts of the body incurs burden on patients, physicians, and the healthcare system	С	4/4
It is not ideal to prescribe topical corticosteroids for long-term use in a chronic condition	С	4/4
There are medical-legal risks for clinicians prescribing topical corticosteroids	В	4/4
Advanced targeted topical therapies are safe for short-term treatment of inflammatory skin diseases	А	4/4
Advanced targeted topical therapies are safe for long-term treatment of inflammatory skin diseases	А	4/4
Advanced targeted topical therapies are effective for short-term treatment of inflammatory skin diseases	А	4/4
Advanced targeted topical therapies are effective for long-term treatment of inflammatory skin diseases	A	4/4
Most patients can affordably access advanced targeted topical therapies through dermatology-focused pharmacies	С	4/4