

Expert consensus: time for a change in the way we advise our patients to use topical corticosteroids

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Summary

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Topical corticosteroids form the mainstay of treatment for many skin conditions. If used appropriately, they are safe and effective, and side-effects are generally uncommon. Current advice to patients to apply topical corticosteroid preparations 'sparingly' or 'thinly' contributes to 'steroid phobia', increasing the risk of poor clinical response and treatment failure. Such cautionary advice also overlooks the fact that the vast majority of patients are prescribed topical corticosteroids of mild potency for which the evidence suggests that the risk of harm is minimal. In the patient's mind, the current advice groups all steroids together regardless of their potential for adverse effects. The advice also tends to reinforce an erroneous concern that the risks from topical corticosteroids may be similar to those from systemic corticosteroids. We propose a change to make the pharmacy labelling of topical corticosteroids more accurately reflect the low risk of harm from corticosteroids of low to moderate potency and the importance of applying sufficient medication to achieve a satisfactory clinical response. This change could provide the focus for updated, evidence-based education for healthcare professionals in prescribing of topical corticosteroids and help in the provision of more appropriate advice to patients. We recommend that patients are informed that treatment should not exceed prescribed quantities, and continuing treatment should be under careful medical supervision. We also recommend that topical corticosteroid products include clear 'fingertip unit' instructions, preferably with images of a 'fingertip unit' and a chart to show the number of units required for specific areas of the body.

Patients with skin conditions such as eczema and psoriasis who are prescribed topical corticosteroids, or combination products that contain them, are typically advised on the packaging to apply the product 'sparingly' or 'thinly'. This guidance is in line with the current British National Formulary (BNF) wording:¹ 'In order to minimise the side-effects of a topical corticosteroid, it is important to apply it thinly to affected areas only, no more frequently than twice daily, and to use the least potent formulation which is fully effective'.

The BNF warning rightly recognizes the potential for side-effects – notably skin atrophy and adrenal suppression – which have been associated with inappropriate, prolonged and/or excessive use of topical corticosteroids, especially the most potent agents.¹ However, the advice to apply 'sparingly' or 'thinly' carries with it messages of economy and caution, even danger. Certainly, there is good evidence that patients interpret this warning in a negative way, giving rise to so-called 'steroid phobia', with accompanying poor adherence to treatment.² This, in turn, results in suboptimal clinical

effectiveness and, in many cases, places an unnecessary burden on healthcare services.

In an ideal world, dermatologists, dermatology nurses, general practitioners, practice nurses and pharmacists would work together to advise and reinforce information about the correct way to apply topical corticosteroids, and to address concerns about the safety of these highly effective agents. But in the real world, expert advice, even when given, is soon forgotten and the product label is often the only reminder that patients have in front of them when using the medicine.

A meeting of the Dermatology Working Group – supported by an unrestricted grant from LEO Pharma – was set up to address concerns expressed by the Skin Care Campaign about the confusion that exists around the appropriate application of topical steroids – an issue pertinent to the majority of patients being treated for skin conditions. Having reviewed the evidence – or lack of it – concerning the harms of the most commonly prescribed topical corticosteroids, the group considered whether a revision of the advice to healthcare

professionals and to patients concerning the appropriate application of these important agents was needed.

What are the barriers to success with topical treatment?

It is much less easy to advise patients how to use a topical skin preparation correctly than it is to explain how to take a tablet by mouth. Often the advice given is inadequate, with the result that the patient is left confused – and, in the case of topical corticosteroids, even anxious – about using the preparations that have been prescribed.

Few attempts have been made to rationalize advice on applying topical therapy. The method that has gained widest acceptance has been the fingertip unit (FTU). It is over 15 years since this simple tool was devised to help doctors and patients obtain a better understanding of the amount of topical products, such as corticosteroids, they should use on different parts of the body.³ The FTU – the amount of cream or ointment expressed from a 5-mm diameter nozzle, applied from the distal skin-crease to the tip of the patient's index finger (Fig. 1) – can be used to calculate how much product is needed to cover affected areas, such as the face and neck, and hence the quantity which should be prescribed. It has the advantage of automatically correcting for body size: thus one FTU (approximately 500 mg) is sufficient to cover two adult palms and three FTUs should be sufficient for a single application to one arm irrespective of the size of the individual being treated.¹

The FTU is used in some factsheets, such as that produced by Patient UK, to help patients understand how much cream to apply (Table 1).⁴ For example, one FTU is recommended for treating the fingers, palm and back of an adult hand, or an entire arm and hand of a 3–6-month-old baby.

However, use of FTUs by physicians and awareness of them by patients is not widespread. Making patients aware of the FTU system will not solve the problem entirely, unless it is clearly explained. It is worth spending time to ensure that

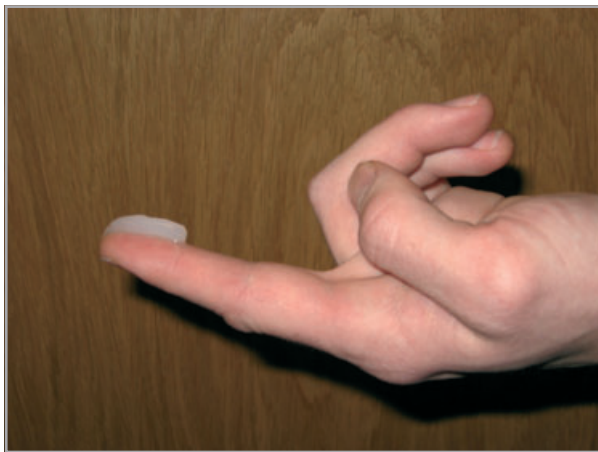


Fig 1. A fingertip unit.

Table 1 Fingertip units (FTUs) for topical corticosteroids (courtesy of Patient UK⁴)

Area of skin to be treated (adults)	Approximate size (in adult hands)	FTUs each dose (adults)
A hand and fingers (front and back)	2	1
A foot (all over)	4	2
Front of chest and abdomen	14	7
Back and buttocks	14	7
Face and neck	5	2.5
An entire arm and hand	8	4
An entire leg and foot	16	8

patients – or parents of children prescribed topical agents – are confident in using it.

Undertreatment is undoubtedly a common cause of low efficacy.⁵ However, even when patients understand how much product they should apply, concerns about drug safety, particularly of corticosteroids, often result in a failure to adhere to recommended dosages. In a U.K. survey of 200 dermatology outpatients with atopic eczema, 72.5% said they were worried about using topical corticosteroids on their own or their child's skin, and 24% admitted to having been noncompliant with treatment because of these concerns.² In addition, 9.5% of patients were worried that systemic absorption could affect growth and development. This is despite the fact that the most commonly used topical corticosteroid was hydrocortisone – a mild steroid. Furthermore, nearly a third of patients who used this preparation erroneously classified it as either strong or very strong or alternatively did not know its potency.

Further evidence of the rather poor patient understanding of the topical steroids that they are prescribed comes from another U.K. survey to determine the level of use and knowledge of commonly prescribed agents among parents or carers of 100 children attending paediatric outpatient clinics.⁶ Eighty-six per cent of patients were using low-potency topical corticosteroids, but only 41% of those who had used hydrocortisone were aware that it was of low potency, and 44% graded it as moderately potent. Of 65 who had used the moderately potent 0.05% clobetasone butyrate, 29% graded it as potent and 12% as weak. Of the 50 patients who had used 0.1% betamethasone valerate, 42% did not grade it as potent.

In the public perception, corticosteroids carry similar risks, regardless of their potency, and typical warnings to restrict the amount of topical preparation that is used, i.e. 'apply thinly' or 'apply sparingly' serve only to reinforce these concerns.

How harmful are topical corticosteroids?

Despite the deep-rooted concerns of patients (and some physicians) about the safety of topical corticosteroids, there is little evidence of harm when less potent agents are used.

In a systematic review of treatments for atopic eczema, randomized controlled trials of topical corticosteroids that

specifically gathered data on skin thinning and suppression of the pituitary–adrenal axis failed to show evidence of harm – although the studies were short term.⁷ Two longer-term studies on intermittent use of the potent topical steroid, fluticasone, found no evidence of skin thinning after 4 months^{8,9} or effects on hypothalamic–pituitary–adrenal (HPA) axis.⁹ Nor was any clinically significant skin thinning reported in a third study that compared short bursts of 0.05% fluticasone propionate and prolonged use of 0.1% hydrocortisone butyrate in children with mild or moderate atopic eczema.¹⁰

In a randomized, double-blind, comparative study of unrestricted continuous use of 1% pimecrolimus cream vs. topical corticosteroids (0.1% triamcinolone acetonide for trunk and limbs, and 1% hydrocortisone for face, neck and intertriginous areas) for 1 year in 658 adults with moderate to severe atopic eczema, 1% of those applying topical corticosteroids developed striae.¹¹

A retrospective cohort study of 35 children aged 0.7–18.7 years with a median of 6.9 years of corticosteroid treatment for atopic eczema found biochemical evidence of HPA axis suppression (decreased cortisol response) only in those using potent or very potent topical corticosteroids or those who had received corticosteroids from other routes (inhaled, intranasal or oral).¹²

Reassuring evidence about the effects of long-term use of corticosteroids on the HPA axis in patients with psoriasis comes from a study of 46 patients randomized to 0.25% desoximetasone or 0.1% betamethasone 17-valerate.¹³ Patients applied their medication to psoriatic lesions on approximately one-third of their body. Plasma cortisol levels were reduced to below normal levels in nine patients using desoximetasone during the study, but in none of the betamethasone group. Levels returned to normal spontaneously in four of the desoximetasone group. In four other patients, plasma cortisol remained suppressed at the end of 5 months of continuous therapy, but returned to normal within 7 days of stopping treatment. The last patient was lost to follow up, but had a cortisol level close to normal the last time it was measured.

In a 3-week comparative study of 40 patients using 3.5 g of either 0.05% betamethasone dipropionate cream or 0.05% clobetasol-17-propionate ointment for treatment of moderate to severe psoriasis, temporary reversible suppression of the HPA axis (low morning cortisol) was seen in eight patients – three on betamethasone and five on clobetasol.¹⁴

Giving patients appropriate advice

The advice to patients to use their topical corticosteroids sparingly or to spread them thinly is based largely on concerns related to the use of the most potent steroids. Yet, the vast majority of patients are using milder corticosteroids, for which evidence of adverse effects such as skin atrophy or HPA axis effects is lacking. Even with the more potent corticosteroids, such effects appear to be mild and – in the context of HPA axis suppression – reversible when they are used for limited periods.

If patients are to achieve maximum clinical benefit from topical corticosteroids, they must be encouraged to apply these agents appropriately.

More appropriate advice on product labelling would be ‘apply enough to cover affected areas’. This, together with advice about how often the product should be applied, conveys a simple message about the need for adequate treatment.

Such advice does not encourage indiscriminate use of topical corticosteroids. But it does remove the implied message of danger that goes with the current advice to ‘use sparingly’. In effect, it gives patients permission to use sufficient medication to treat all of the skin that is affected by their condition.

It is acknowledged that patients would still need to be informed that treatment should not exceed prescribed quantities, and continuing treatment should be under careful medical supervision.

We would also suggest that, to facilitate clarity in their use, topical corticosteroid products should include clear ‘fingertip unit’ instructions, preferably with images of a ‘fingertip unit’ and a chart to show the number of units required for specific areas of the body.

Evidence-based education for healthcare professionals

With such a change comes a need for improvements in the way doctors, nurses and pharmacists are educated about the efficacy and safety of topical corticosteroids, the differences between agents of different potency, and the importance of giving patients sufficient information to enable them to use their treatment effectively.

The FTU is a useful measure for calculating the amount of topical preparation to apply to each area (Table 1), and could be more widely used in both primary and secondary care to help patients understand doses. Patients could be provided with a personal chart of how much cream to apply and how often, and/or a body chart showing which areas to treat, and with how many FTUs (Table 2).

As the last healthcare professional to see the patient, the pharmacist has a valuable role in reinforcing the message

Table 2 Examples of data to include in information leaflets for patients prescribed topical corticosteroids

Maximum fingertip units per week
How long a prescribed tube of cream/ointment should last
Stepping up or stepping down treatment potency
Instructions on duration of course of treatment and when to re-treat
Realistic goals: e.g. ‘continue until affected skin is completely flat’
Time frames for review, if goals not achieved
Possible side-effects — what to look out for, when to stop treatment, when to seek advice, etc.
Precautions with pregnancy or breast-feeding (if any)
Useful local/national support groups (with contact details)

about correct application of topical treatment, given by doctors and nurses, and ensuring that they remember and understand what they have been told. Moreover, the community pharmacist – who usually sees people with long-term conditions more frequently than other healthcare practitioners – is ideally placed to monitor response and provide advice/reminders about correct treatment.

Conclusions

A change to the labelling of topical corticosteroids to encourage patients to use their medication more effectively could improve clinical response and reduce treatment failure. We believe that 'apply enough to cover affected areas' is a more positive instruction than 'apply sparingly' or 'apply thinly' – which carries alarmist messages that are likely to contribute to continuing steroid phobia. A change in labelling should provide the focus for educational initiatives to ensure a more multidisciplinary and evidence-based approach to the prescribing of topical products, and greater patient understanding of such issues as potency, dosing, duration and desirable outcomes of topical corticosteroid use.

Dermatology Working Group

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