The use of topical steroid preparations in oral medicine in the UK

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In brief

Discusses when to use topical corticosteroids.

Provides background on the different choices of topical corticosteroids.

Discusses the support of patients using topical corticosteroids.

Topical corticosteroids (TCs) are the most commonly prescribed drugs in oral medicine practice. Use in management of immune-driven inflammatory oral mucosal disease is predominantly off-label and poorly supported by evidence, yet oral medicine specialists have considerable collective experience of prescribing, administering and managing these medications. TCs are also prescribed by others in healthcare including general dental practitioners. Successful TC use is influenced by accurate diagnosis, TC choice (potency and formulation), patient acceptability (including ease of use, taste and texture), frequency of application, duration of treatment, adverse effects, patient support and medication regulations and access. The aim of this review is to provide an overview of TC use in oral medicine practice. Recommendations are based on collective experience to help selection of the appropriate TC to maximise therapeutic efficacy and minimise the potential for adverse effects. This is within an understanding of medicines regulation and preparation availability when prescribing in both secondary and primary care.

Introduction

Topical corticosteroids (TCs) are the most commonly prescribed drugs in oral medicine practice; probably no other drug group has such a profound impact on care in this aspect of oral healthcare. Use in management of inflammatory oral mucosal disease is predominantly off-label and poorly supported by evidence.[1–3] Nevertheless, as TCs have been used to treat oral mucosal lesions for over 50 years,[4] oral medicine specialists have considerable collective experience of prescribing, administering and managing these medications in partnership with pharmacists. TCs are also prescribed by primary care and other healthcare practitioners either independently or as part of shared care. TCs are widely used to treat a diverse range of immune-driven inflammatory mucosal lesions.[5] Systemic interventions should be reserved for those with severe refractory disease under the care of a specialist with consideration of whether TC and adjunctive topical treatments have been optimised.

Most TCs are synthetic variants of the naturally occurring glucocorticoid hydrocortisone, which along with TCs bind glucocorticoid receptors expressed on nearly all cell types. Binding leads to regulation of a wide range of genes essential to immune function, as well as promoting vasoconstriction. The aim of TC use is to suppress inflammation and in turn reduce morbidity associated with the condition.[6] It is worth emphasising that treatment with TCs is for symptom control and is not curative. Discontinuing treatment is often followed by recurrence of symptoms and for some, control requires prolonged therapy.

Key factors for successful use of TCs include accurate diagnosis, selecting the correct drug, potency and formulation, patient acceptability (including ease of use, taste and texture), frequency of application, duration of treatment, adverse effects within an understanding of medicines regulation and preparation availability.[7]

Our aim is to provide an overview of TCs used in oral medicine practice. Different formulations and their potencies are considered, with descriptions of directions for use, adverse reactions and recommendations based on collective experiential use. We also highlight important issues related to the regulation of medicines and preparation availability when prescribing in both primary and secondary care. A flow diagram (Fig. 1) helps guide readers through the clinical decision-making process.

Diagnosis

TCs have important roles in management of commonly presenting immune-driven inflammatory conditions such as recurrent aphthous stomatitis and lichen planus, as well as rarer conditions including pemphigoid, pemphigus and erythema multiforme, Behçet's disease and orofacial granulomatosis. When making a diagnosis, consideration should be given to the need for a specialist opinion. It is important to prescribe a TC only after making a definitive diagnosis. Although TCs may provide temporary benefits when used empirically, their use can make a definitive diagnosis difficult and may expose the patient to adverse effects.

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Aims of care

There needs to be clarity on the aims of care and how TCs fit with the needs of each patient. The main objective of TC use is to reduce inflammation and through this alleviate symptoms such as pain and swelling. Lesion appearance and symptomatic impact on a patient do not always correlate. For a given patient there can be variation too. For example, a minor aphthous ulcer in a buccal sulcus may cause minimal if any discomfort, whereas a similar ulcer involving the ventrolateral tongue may be painful.

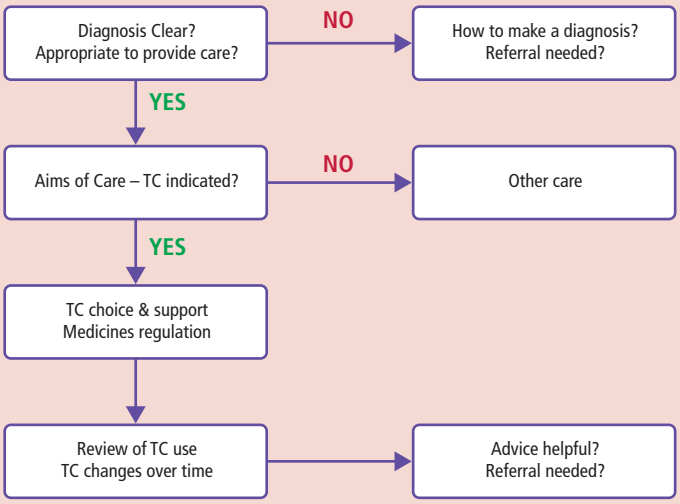
For conditions where TCs are applicable, full consideration should also be given to associated interventions such as optimising oral hygiene (including consideration of toothpastes that are SLS-free, have mild flavours and include fluoride), use of topical analgesia (for example, benzydamine HCl) or topical antimicrobials (for example, chlorhexidine) and other approaches such as soft biteguards. For many patients TCs can be used alone, in others they are used alongside immune-modulatory therapy.

Topical corticosteroid choice

Where there is clarity on diagnosis, and TC use is indicated, there are several factors that determine choice including training, currency of practice, experience and clinical and pharmacy support. General dental practitioners (GDPs) should refer patients for specialist opinion when there is lack of response to mild potency TCs. Higher potency TCs should not be prescribed or advised for long-term use without specialist advice. Choice will also be determined by patient factors such as age and patient preferences which will be influenced by ease of use, taste and texture, work patterns and health beliefs.

Examples of TCs are summarised in Tables 1 & 2. Two brief clinical cases illustrate pertinent points raised in the following text (Boxes 1 and 2).

Fig. 1 A flowchart of key clinical decisions for TC use in controlling symptoms associated with conditions that fall within the scope of oral medicine practice



TC potency, formulations and frequency of use

The pharmacological properties of individual TCs vary hugely reflecting changes to the core steroid molecule, which alter potency, tissue penetration and rate of metabolism that impact on clinical effectiveness, but also adverse events. The TC potency index is an imperfect but useful indicator of the pharmacological 'power' of a drug and is influenced, for example, by site-specific halogenation of the main steroid molecule.[8]

TC treatment success is linked to the length of time that the drug comes into direct contact with the lesion.[9] This is influenced by the formulation used to place and retain the TC at the lesion site, frequency of application and duration of treatment. The frequency of application may be titrated against symptoms reflecting the sporadic need (for example, aphthous stomatitis) or relapsing and remitting disease activity (for example, lichen planus).

Table 1 First line TCs prescribed in primary care. The 4-point 'potency' scale used is an indicative guide (mild/moderate/potent/very potent). The directions for use are in outline form and further relevant information is included in the text

Drug name (salt) Access	Potency	Formulation	Dose	Directions for use
For mild symptomatic relief				
Hydrocortisone (sodium succinate) OTC[a]	Mild	2.5 mg muco-adhesive buccal tablets	2.5 mg BD QID	Dissolve one tablet close to the developing aphthous ulcer
Hydrocortisone OTC[a]	Mild	1% cream	BD	Apply to the lesion
For moderate to severe symptomatic relief				
Betamethasone POM[b]	Potent	Soluble tablets 500 µg (Betnesol)	500 µg up to QID	Dissolve one tablet in 10–20 mls of water (two to four teaspoons) to make up a mouthwash
Beclometasone propionate POM[b]	Potent	Inhaler 50 µg/metered dose (Clenil Modulite)	50–100 µg BD	Apply 1 to 2 sprays to the lesion

[a]OTC: available over-the-counter; [b]POM: prescription only medicine; BD - twice a day; QID - four times a day

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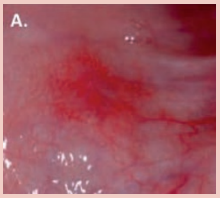
Table 2 Examples of TCs prescribed in secondary care. The 4-point 'potency' scale used is an indicative guide (mild/moderate/potent/very potent). The directions for use are in outline form and further relevant information is included in the text

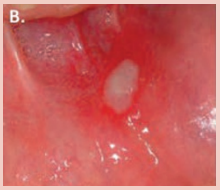
Drug name (salt) Access	Potency	Formulation	Dose	Directions for use
For mild symptomatic relief				
Triamcinolone acetonide 'Special'[a]	Moderate	0.1% in Orabase via 'specials' suppliers (see main text)	QID	Apply to lesion
Betamethasone POM[b]	Potent	0.1% ointment (Betnovate)	BD	Apply to the lesion plain or mixed with Orabase paste
Prednisolone POM[b]	Potent	Plain tablets 5 mg	5 mg up to QID	Disperse[c] one tablet in 10–20mls of water (two to four teaspoons) to make up a mouthwash
Prednisolone (Sodium phosphate) POM[b]	Potent	Soluble tablets 5 mg (Predsol)	5 mg up to QID	Dissolve one tablet in 10–20 mls of water (two to four teaspoons) to make up a mouthwash
Fluticasone propionate POM[b]	Potent	Nasules (unit dose) 400 µg/unit (Flixonase)	400 µg up to QID	Open 1 plastic caplet and place the liquid contents in 10–20mls of water (two to four teaspoons) to make up a mouthwash
Fluticasone propionate POM[b]	Potent	Nasal spray 50 µg/dose (Flixonase)	50–100 µg up to QID	Apply one spray to the lesion
Fluocinolone acetonide POM[b]	Potent	0.025% – 0.05% cream/ ointment (Synalar)	BD	Apply to lesion for 2 weeks only
Clobetasol propionate POM[b]	Very potent	0.025% – 0.05% cream/ ointment (Dermovate)	BD	Apply to lesion for 2 weeks only

[a]Special: Medicines specially manufactured for an individual patient – see text for further detail; [b]POM: prescription only medicine; [c]Disperse: plain prednisolone tablets do not include a sodium phosphate salt and do not dissolve in water; ensure the tablets are fully dispersed within water before using as a mouthwash. This may take two to five minutes; agitation may be required.

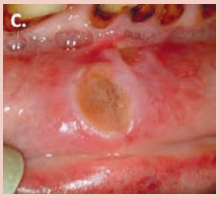
Box 1 Case 1: Minor aphthous ulceration



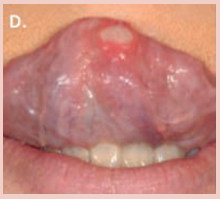
A short-lived focal patch of inflammation may be recognised by the patient as a sensitive or tingling area; early application of a TC at this stage can lead to a smaller, shorter-lasting ulcer.



A typical aphthous ulcer with surrounding inflammation early after ulceration started; TC use may still be beneficial.

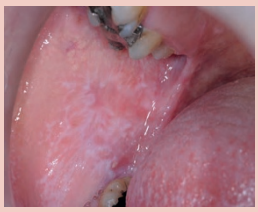


In the later stages as an aphthous ulcer heals there is little inflammation; TC use is too late.



Aphthous ulceration involving the tongue will not be suitable for localised TCs such as muco-adhesive tablets, pastes or ointments, which work well for labial mucosa (A C); a TC mouth rinse will be a better choice.

Box 2 Case 2: Lichen planus



Lichen planus is often widespread with a bilateral distribution that often makes a TC mouth rinse the first choice. The relapsing and remitting symptoms over time mean that TC use should be titrated (for example, frequency of use) to ensure TC exposure is reduced to the lowest level that will control symptoms with complete breaks from treatment if possible.

Several TC formulations are used in the oral cavity including aqueous solutions for use as rinses or sprays and semi-solid preparations such as pastes, creams and ointments. Formulation choice depends on lesion features including size and site as well as patient preference.

TC rinses and sprays

TCs in aqueous solution applied as a rinse or mouthwash is a frequently used approach. Advantages include an ability to control the time that a TC comes into contact with the oral mucosa regardless of lesion size or location.

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Betamethasone soluble 500 µg tablets can be made into TC rinse by dissolving one tablet in 10–20 mls water (two to four teaspoons). The TC rinse should be held over the sore areas of the mouth for up to 5 minutes, although not all users can achieve this length of time. The rinse should then be spat out and not swallowed. It is best to avoid eating or drinking for up to 30 minutes after rinse use where practicable.

Rinses are often easier to use in the mouth than ointments, pastes or creams, particularly for mobile tissues such as the tongue or where access may be difficult, such as the soft palate. A drawback is that all mucosa, diseased and healthy, comes into contact with the TC.[9] The risk of systemic corticosteroid absorption via oral mucosa is low for oral rinses, but there is the possibility of involuntary ingestion if the rinse is not spat out fully. Steroid preparations containing sodium phosphate salts, such as betamethasone soluble tablets and prednisolone soluble 5 mg tablets are highly soluble in water and readily absorbed from the gastrointestinal tract. Hence, rinses may not be suitable for children under seven years if they cannot reliably spit out after rinsing. Rinses are also not suitable for patients with impaired neuromuscular function that might affect the swallowing mechanism.[9] The practicalities of preparing and using a TC rinse can be difficult for some, for example when at work.

Aqueous TC solutions presented as sprays are typically delivered by metered dose sprays used primarily for allergic rhinitis such as hayfever. TCs can also be delivered in a targeted way using metered dose inhalers (MDIs) used primarily for respiratory conditions such as asthma. An example of a metered dose inhaler is Beclometasone propionate (Clenil Modulite). Inhalers and sprays have the advantage of being portable and easy to use.

TC creams, ointments, and pastes

Semi-solid TC formulations are appropriate for treating small, isolated lesions that are accessible. The degree of adhesion to the intended site is a major factor. The majority of semi-solid TC formulations are creams and ointments that have been prepared for use on skin rather than oral mucosa.

TC creams are emulsions of water/oil and so flow more easily than ointments, but this can make localisation difficult. Creams require preservatives (such as chlorocresol, benzylalcohol and imidurea [a formaldehyde releasing preservative]) to extend shelf-life and these can cause adverse reactions in susceptible patients.[7]

TC ointments are primarily oil-based and are greasy/waxy reflecting that they contain little or no water. This can make controlled application to oral mucosa difficult. There is the potential for most of the TC ointment to be quickly removed from the application site by saliva (85–90% loss).[9] TC ointments can be useful for gingival, buccal/labial sulci or labial mucosal lesions, but are of limited use for mobile tissues such as tongue lesions. Some patients do not like the texture of TC ointments.[9]

Different strategies can be used to localise and increase TC ointment exposure at the intended site. An adhesive paste such as Orabase, a concentrated suspension of water, oil and powder which contains no pharmacologically-active ingredients, can be combined with TCs. Patients are advised to mix equal quantities of the TC ointment with Orabase paste immediately before careful application to the target area; rubbing the medicine against the lesions may cause irritation. The 'finger tip unit' (FTU) approach can help clinicians advise patients on how much ointment to apply.[10] A FTU is defined as the amount that can be squeezed onto the finger tip to the first crease of the finger with a 5 mm diameter nozzle with one FTU equalling 0.5 g ointment (or cream).[11] The FTU is used throughout the world to reduce variation in applied dose of a TC and to encourage adherence to therapy.[10]

The previously licenced Adcortyl in Orabase paste (0.1% triamcinolone acetonide) is no longer available in the UK following withdrawal on commercial grounds in 2008. This preparation had been the preferred TC for many. It remains possible to access 0.1% triamcinolone acetonide in Orabase paste either via some pharmaceutical specials manufacturers,[12] typically on recommendation of a specialist, or via import, for example, the Canadian preparation Oracort. Patients may buy commercially available preparations over-the-counter when abroad. Purchasing via unregistered and non-UK online pharmacies comes with risks including lack of product assurance, and should be avoided.

For a small number of patients, TC ointment and cream localisation can be achieved using a removable prosthesis. For example, a customised tray/occlusal splint can be useful for lesions confined to the gingivae or palate, particularly where lesions are widespread. This approach allows control of TC contact time with the areas to be treated; however, it should only be used under the direction of a specialist. In a few patients an existing full denture can be used in place of a tray/occlusal splint.[9]

TC adverse events

If used as intended then the majority of TCs used in oral medicine practice are safe with few reported adverse effects. Adverse effects associated with TC use on skin, such as epithelial atrophy, altered pigmentation and delayed wound healing, are not clearly documented following TC use on oral mucosa. Oral candidosis is a recognised side effect of oral TC therapy, especially if predisposing factors such as co-morbid illness, dentures or smoking are present. Candidosis can be managed by addressing risk factors and with antifungals either alone or in combination with chlorhexidine mouthwash.

Preservatives in TCs can cause irritation and hypersensitivity reactions. TC creams contain preservatives which are absent from TC ointments and pastes.[7] Soluble betamethasone tablets, used to make mouth rinses, contain sodium benzoate as a preservative. Benzoates may be associated with orofacial granulomatosis (OFG) and should be avoided in OFG-associated ulceration.

Oral TCs can be absorbed and in some instances may have a measurable systemic effect, with the potential risk of adrenal suppression and other serious side effects associated with systemic corticosteroids. In oral medicine practice this is most evident with clobetasol proprionate (CP), a highly potent TC that should only be used under specialist direction.[9] Inappropriate TC ingestion, for example of a mouth rinse, will result in unwanted systemic exposure. Adrenal suppression (presence of inhibition of the hypothalamic-pituitary-adrenal axis) can be assessed by measuring basal plasma cortisol levels. The use of highly potent agents should be for as short a time as possible with downward dose titration according to response to minimise adverse effects. The need to emphasise appropriate TC use and check patient understanding is essential.

Adverse reactions to TCs should be reported via the Yellow Card Scheme if considered serious.[13] A serious reaction is one that is: disabling or incapacitating; involves or prolongs hospitalisation; causes a congenital abnormality; is fatal; or is medically significant.

Further prescribing issues for TCs

TCs and medicines regulation

In the UK the Medicines and Healthcare products Regulatory Agency (MHRA) licences (authorises) medicines.[14] The licence or Marketing Authorisation (MA)

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defines the terms of use for the medicine and provides assurance that the medicine:

- Has been assessed for efficacy, safety, and quality
- Has been manufactured to appropriate quality standards
- Is accompanied by appropriate product information and labelling.

Many TCs used in oral medicine practice do not have a UK MA and are referred to as 'unlicenced'. Unlicenced medicines fall into different categories:

- 'Specials': medicines specifically manufactured for an individual patient (for example, 0.1% triamcinolone acetonide in Orabase paste) that are prepared using raw materials or licenced medicines such as solutions for injection or capsules
- Imported medicines: medicines that have an MA outside the UK, such as Oracort (0.1% triamcinolone in Orabase) licenced for mouth ulceration in Canada
- Unlicenced use of licenced medicines ('off-label use'): medicines that have a UK MA but are not being used for the indication for which they are licenced – for example, beclometasone (Clenil Modulite) inhaler or betamethasone (Betnesol) soluble 500 microgram tablets used to prepare a mouth rinse.

Prescribing an unlicenced TC

Prescribing medicines outside the recommendations of their marketing authorisation is acceptable, but with important considerations. The General Medical Council advise prescribers to:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- Make a clear, accurate and legible record of all medicines prescribed and, if not following common practice, the reasons for prescribing an unlicenced medicine.

The General Dental Council (GDC) has issued no similar guidance for dentists', however, the concepts are covered within *A competency framework for all prescribers*.[15]

Unlicenced or off-label TCs and shared care

Unlicenced or off-label TCs may be initiated by an oral medicine specialist with an ongoing, long-term need for repeat prescription, which may be taken on by a primary care practitioner. General Medical Practitioner (GMP) are familiar with shared care arrangements.

The GMC provides guidance[16] to doctors that include the following themes:

- Decisions about who should take responsibility for continuing care, or treatment after initial diagnosis or assessment should be based on the patient's best interests
- Shared care requires the agreement of all parties, including the patient
- If prescribing at the recommendation of another healthcare professional, the prescriber must be satisfied that the prescription is needed, appropriate for the patient and within the limits of their competence
- If recommending that another healthcare professional prescribes a medicine for your patient, you must consider their competence, knowledge of the patient and the medicine. If sharing responsibility for a patient's care with a colleague, you should:
  - Keep yourself informed about the medicines prescribed
  - Be able to recognise serious and frequently occurring adverse side effects
  - Make sure appropriate clinical monitoring arrangements are in place.

Drug costs

There are considerable variations in cost between TC formulations. Prices listed in the BNF are indicative of relative costs and are regularly updated.[10] However, it is also important to recognise, particularly when discussing with patients, that BNF prices do not reflect over-the-counter prices as they do not take into account VAT, professional fees and other overheads. Prices for extemporaneously prepared medicines are not in the BNF and vary depending on production costs and how many patients are able to use the medication prepared in a batch. Note that the price of 'specials' and imported medicines can be very high.

Supporting TC use

Patient understanding and engagement is essential for optimum use and benefit of any TC. Less than full concordance may explain different clinical efficacy and/or adverse effect profiles when the same TC is given for similar indications in two different patients. Patient-orientated information including rationale and directions for use, are particularly important given that TCs are often used off-label. Oral medicine specialists in the British Society for Oral Medicine (BSOM) have recently, collectively agreed standardised prescribing information for commonly prescribed TCs, which can be accessed from the BSOM website.[17] As a general rule patients should be advised not to eat, drink or rinse their mouth out for up to 30 minutes after TC use to reduce the likelihood of the TC preparation being removed from the treatment site.

Review of TC effectiveness

The benefits and limitations of TC use should be reviewed in a timely way to inform decision-making about the need for continuation or alteration. Patients will make value judgements informed by perceived benefits, such as reduced pain, weighed against any disadvantages such as difficulty of use and cost (for example, prescription fees) within the context of their understanding of how to use the medication and their health beliefs.[18] Objective measures of clinical outcome have been validated, but are not used widely.[19,20.]

It is important to recognise that TCs can change lesion appearance independent of the main aims of treatment, such as pain relief. For example, white lesions (hyperkeratosis) in lichen planus have an unpredictable response to TCs, and in some cases, the white colour even increases in intensity. The appearance of some lesions may change only a little. Mucosal atrophy manifests as a fragile and delicate mucosa with a reddened appearance. After TC use there can be pain reduction, yet the atrophic areas may have unchanged appearances. Conversion of a painful erosive lesion into a non-painful atrophic lesion is considered a TC treatment success even though the oral mucosa has not returned to a normal appearance.[9] These issues should be taken into consideration in order to avoid unnecessary TC overuse or confusion about treatment effectiveness.

Diminished therapeutic benefit from a drug is a recognised, but poorly understood phenomenon that may occur rapidly (tachyphylaxis) or more slowly (tolerance). Diminished therapeutic benefit to TCs is poorly described and understood with respect to oral medicine practice. When patients describe reduced effectiveness to a particular TC, consideration should be given to switching to another preparation.

Conclusions

TCs have important roles in the management of immune-driven inflammatory mucosal conditions that fall within oral medicine practice. To maximise benefits and minimise

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the risk of adverse effects, an individualised patient approach to TC selection is essential; consideration should be given to potency, formulation, patient acceptability and preference, availability, and medicines regulations.

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