Guidelines on use of Corticosteroids in General Practice: A Review

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A B S T R A C T
The authors of this study gathered their ideas in an aim to prepare at least general guidelines on prescribing of corticosteroids and summarizing the existing guidelines. Corticosteroids being widely used powerful anti-inflammatory & immunosuppressive agents and have become cornerstone of therapy in acute and chronic inflammatory diseases. Hence, the decision to use Corticosteroids should be made when a presumptive diagnosis has been made & when available information suggests a reasonable possibility of benefit. Criteria to corticosteroids use should be clearly identified and should be objective or quantifiable. Chance of significant side effects increases with the dose and duration of treatment and so the minimum dose necessary to control the disease should be given and later dose titration should be done. Geriatrics and pediatrics group of population, patients with chronic disorders are needed to be isolated for corticosteroids therapy and must be provided with corticosteroids card.

Keywords: Adverse events, Corticosteroids, Immunosuppressant, Guidelines, Monitoring

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1. Introduction
Corticosteroids, particularly Glucocorticoids (often just called “Steroids”), the so called ‘wonder drugs’ after their discovery in 1948, had found their use for almost every conceivable malady till their hazards came to light [1]. They are widely prescribed in modern medicine, forming a part of standard treatment for a wide range of disorders. Data from the United Kingdom suggests that nearly 1% of the total adult population use oral glucocorticoids [2]. Worldwide 1% - 3% of adults receive long-term GC therapy [3]. Corticosteroids being widely used powerful anti-inflammatory & immunosuppressive agents and have become cornerstone of therapy in acute and chronic inflammatory diseases. Though corticosteroids are life-saving drugs, they produce adverse reactions which may be mild to life threatening. Considerable attention should be given to relative risks & benefits, benefits definitely outweighing the risks & individualization of treatment is necessary. So, care should be exercised in the rational selection of steroids [4].

The decision to use Corticosteroids should be made when a presumptive diagnosis has been made & when available information suggests a reasonable possibility of benefit. Criteria to use should be clearly identified and should be objective or quantifiable [2,4]. Certain pharmacodynamic and pharmacokinetic properties of corticosteroids suggest need for attention before prescribing. The properties are a) Shorter half-lives of corticosteroids which require greater frequency of administration, b) Higher accumulation index need dosing adjustment; gradually decreasing order, c) Corticosteroids increase risk of irreversible adverse events such as, hypertension, diabetes, glaucoma, cataracts etc. Hence, require constant monitoring, d) Greater binding properties shows higher prevalence of drug-drug interaction with concurrent prescribed drugs and e) most of the cases need prescribing for long duration that suggest to provide proper counseling and corticosteroids card.

Every year on 14th November, the World Diabetes Day is celebrated to provide awareness regarding healthy eating, prevention, risk factors, and complications. However, corticosteroids are one of the major classes of drug causing diabetes or condition like diabetes. Similarly, hypertension is the 2nd most cause of death that is precipitated by corticosteroids use. Hence, a specific guideline is needed to update the information and take steps in prescribing. The authors of this study gathered their ideas in an aim to prepare atleast general guidelines on prescribing of corticosteroids and summarizing the existing guidelines. This study also aimed to identify any deficiencies in their pattern of use and patient related factors so that effective interventions or modifications can be suggested if necessary, because its objectives and limitations should always be clearly defined prior to the commencement of steroid therapy.

2. Systemic Corticosteroids
Short courses of systemic, preferably parenteral corticosteroids are used to manage exacerbations, acute International Journal of Medicine and Pharmaceutical Research condition or emergency such as asthma, COPD, hypersensitivity reactions etc. for which the dexamethasone is drug of choice. However, long-term oral corticosteroids are sometimes used to manage stable patient conditions. In reviewing the literature, a uniform approach is not available for treatment with corticosteroids. In general it is important to remember following recommendations: [5,7,8,9]

- Corticosteroids are not recommended in paediatric population especially in treatment of respiratory tract symptoms. However, they can be used under emergency conditions with caution. There is no objective evidence of efficacy of corticosteroids regimen. [10,11,12]
- To minimise high risk of adverse events oral route is suggested rather than parenteral [13]. Inhalation is choice of route of administration in treatment of emergency conditions [15].
- Most commonly used corticosteroids are Prednisone and prednisolone and found safer among others.
- Corticosteroids cause flaring up of infections such as chickenpox or measles in infected children. These medicines can also slow or stop growth in children and in growing teenagers, especially when they are used for a long time, as it affects bone-mineral density.
- Most clinical trials that have specially evaluated the use of oral corticosteroids to manage flare-up have been conducted in patients attending emergency departments. Oral corticosteroids courses of 5-10 days are effective in regaining control over asthma after an acute flare-up. A 5 days course of prednisolone at 40 mg/day may be as effective as a 10 days course in children.
- Health care professionals should be counselled regarding reporting of any adverse events because corticosteroids can cause life threatening condition.
- Older patients may be more likely to develop high blood pressure or osteoporosis (bone disease) from corticosteroids. Women are especially at risk of developing bone disease. Hip bones are being more commonly affected. [16,17,18]
- Special instruction is required for patients using alcohol or tobacco. Food may interact with corticosteroids hence warn before administration e.g. Grapefruit Juice.
- Possibly prescribe less number of drugs per prescription so as to avoid drug-drug interactions. It is also recommended to update profile of drug-drug interaction. Taking oral corticosteroids with food helps to prevent stomach upset.
- Oral corticosteroids are as effective as IV corticosteroids in the management of most of acute condition not requiring ICU admission.
- Abruptly ceasing oral corticosteroids after a short course appears to be equally effective as tapering the dose over a longer period. Tapering the dose does not reduce the risk of suppression of adrenal function. Dose should be reduced if oral
corticosteroids have been taken for more than week. [16,19]

Use in pregnancy/lactating women [20]:
- Women who are taking corticosteroids have to feed their baby just before taking the drug and only after 4 hrs after the dose because peak plasma level of systemic corticosteroids occur approximately 2 hrs after initial dose.
- Infant has to be monitored for the growth and development if 10 day high dose corticosteroid treatment regimen is recommended. Studies in animals have shown that corticosteroids cause birth defects.

Steroid Use and Abuse [21]:
The standard definition of substance abuse is when the costs outweigh the benefits, yet the individual keeps on using. This phenomenon is actually quite rare when it comes to steroid users. Although less frequent, there have still been cases of corticosteroid abuse in which doctors have overdosed a patient who then exhibits a number of unwanted side effects. Typically, these substances are used within hospitals and clinics to treat a range of inflammatory skin diseases. If taken in a controlled manner, they can help an individual heal rapidly, especially if prescribed for a short period of time. Without the proper safety precautions, however, these substances are very dangerous.

Inhalation Corticosteroids
At low doses, inhalation corticosteroids are found safer but at higher doses over a long periods, can precipitate systemic side effects. The study suggesting that use lowest effective dose of inhalation corticosteroids. [6,16,17,22,23]
- Where there is dose equivalence, consider prescribing the lowest cost inhaler that the patient can use effectively. The systemic side effects of corticosteroids are well known. Hence, it is strongly recommended that all patients should be made aware of the potential risks and given an inhaled corticosteroid safety warning card about adrenal suppression.
- It is necessary to calculate potential total daily dose of corticosteroids and for those patients on higher doses of inhalation corticosteroids or more than two inhalation corticosteroids prescribed, a corticosteroids safety card is recommended. Also, special attention should be given for such patients.
- At equipotent doses, there is no difference in the safety profile of different inhaled corticosteroids.
- Patients who smoke may require higher doses of ICS compared with non-smokers for the same therapeutic effect. It is therefore important that all smokers using an ICS should be offered help to stop smoking, as this may reduce the dose required by the patient and minimise the risk of side effects.
- Health care professionals need to check inhaler technique every time so as improving delivery of inhalation corticosteroids to the lungs may be more effective than increasing the dose. Thus it is imperative that inhaler technique is checked at all times and appropriate changes made. Encourage patients to use appropriate breathing techniques according to inhaler device e.g.: ‘slow and steady’ for an aerosol inhaler, “quick and deep” for a dry powder inhaler.
- Proper, in detail inhalation technique should be counselled, especially for those on aerosol formulation.
- Studies on the prescribing of fluticasonestates that, doses between 250-500 mcg, twice daily should only be prescribed for moderate to severe asthma but on demand of higher doses, should only be prescribed by a specialist in asthma where risks outweigh benefits.
- Once a patient has achieved good asthma control on higher doses of inhaled corticosteroids for a period of time (e.g.3 months), consider stepping down the dose of inhaled corticosteroid by 25%.
- Commonly, nasal corticosteroids shown to prescribing in an acute condition (exacerbation) of many reasons which need to cessation of dosing on stable patient condition or tapering the dose.
- Data showing that most of the patients tolerating well in an acute condition, high dose with few or no side effects.
- Long-term use to treat a condition such as asthma can cause oral thrush. This is a fungal infection that develops inside the mouth. Rinsing your mouth out with water after using inhaled corticosteroids can help prevent oral thrush or other side effects. Patients receiving corticosteroids therapy, should be counselled on smoking cessation or avoidance, limiting excessive alcohol intake, weight bearing activities.[24]

3. Topical Corticosteroids [7,25,26,27,28]
Suitable condition for corticosteroids use:
As per British National Formulary, topical corticosteroids are indicated for inflammatory condition of the skin other than infections (bacteria/viral/fungal) and Common indications are eczema, contact dermatitis, insect sting, eczema of scabies. Use of systemic and potent steroid in psoriasis should be avoided or given only under specialist supervision. Potent topical steroid should generally be avoided on the face and skin flexures except under special circumstances by specialist supervision. Topical steroids should not be used routinely on clinically infected skin unless the infection is being treated. They are contraindicated in an ulcerative condition, rosacea, urticaria, acne vulgaris and pruritus of unknown cause.
- Steroids should not be used regularly for more than 4 weeks without review.
- Do not use potent steroids regularly for more than 7 days.
- Do not use more than 100g per month of a moderately potent steroid preparation.
- Attempts should be made to rotate steroids with alternative treatments.
- Use of potent and very potent steroids should be supervised by dermatologists.
**Safety of topical corticosteroids:**
Data suggesting that most of the topical preparations having wide margin of safety. However, incorrect use can cause tertiary disorders. Local and systemic side-effects are rarely seen when mild and moderate potency steroids are used. Although the risk is higher with more potent agents, topical steroid use was not associated with an increase in serious side-effects in several short-term studies (six weeks or less). The risk of systemic side-effects increases when steroids are used for prolonged periods on areas of thin skin, such as the face, or on inflamed or raw surfaces. Skin occlusion also increases steroid absorption, as well as the risk of bacterial overgrowth. Moisten or cream-soaked bandaging may be useful for treating particularly thick skin, e.g. on the hands or feet.

**Balancing the risks and benefits ratio:**
When emollients do not provide sufficient relief, topical corticosteroids can be applicable for short term to treat acute exacerbation of eczema, psoriatic plagues. Dose is always a matter of concern, should be possibly smallest amount. If topical steroids are required for maintenance, there should be periods each year when they are withdrawn for as long as possible and emollients used on their own. Whatever approach is taken, it is essential that patients are maintained on the weakest possible steroid, or preferably on an emollient regimen only.

**Variation of dosage form:**
Pharmacists suggest to prescribing topical corticosteroids in the form of ointment rather than cream because it produces a deeper, more pro- longed emollient effectand higher efficacy rate. However, creams are only choice to apply on face. Scalp formulations such as lotions may also be useful. Although, lotions containing alcoholic solutions dry quickly, aqueous lotions are better tolerated on very sore skin.

**Dose & duration of regimen:**
Improvement should be seen within 3-7 days, once or twice daily, of starting topical steroids. Once satisfactory improvement is seen, treatment can be tapered by using less potent steroid preparations, down to emollients only if possible. If the condition does not improve after 3-7 days of steroid use, diagnosis should be reassessed and other potential causes examined. There may be need to prescribe one more corticosteroid as per tolerance. Relapse or vigorous rebound of psoriasis may occur after stopping potent topical steroids. This may even precipitate unstable or severe pustular psoriasis. Flares of eczema may also occur if steroids are stopped abruptly. Topical steroids should be withdrawn gradually, decreasing the potency in a stepwise manner. A review of studies concluded that comparing once daily with twice daily use of various potent and moderately potent steroids, found both regimens to be similarly effective.

**Amount of single application**
A simple, practical guide to how much topical steroid to apply to different areas of the body is the fingertip unit (FTU). An FTU is the amount of ointment or cream that covers the distal third of the index finger. The number of FTUs to adequately cover different areas of the body with a topical steroid according to age.Patient counseling: A proper counseling of patients or their relatives, is recommended for successful treatment of skin condition. It should cover the following:

- How much to apply? (e.g. fingertip unit)
- When & where to apply? (e.g. once or twice daily, at affected parts)
- How to apply (e.g. with slight massage)
- How long to apply? (e.g. as directed by physician)
- How often to apply them in relation to other treatments
- Such information could be written down on a ‘skin care plan’. Patient information leaflets with instructions may also be helpful, but should not replace personal explanation.

**Caution with topical steroid [30]:**
No more frequently than twice daily, apply thinly to the affected area only

- Use the least potent formulation which is fully effective
- Avoid prolonged use on the face and keep away from eyes
- Caution in children and during pregnancy

**Paediatrics use [30]:**
Children, especially babies, are at high risk to the side-effects of topical steroids. Studies concluded that growth retardation may occur in up to 10% of children referred to hospital with atopic eczema. A mild steroid, such as 1% hydrocortisone ointment, should be adequate to control most cases of eczema in children. More potent steroids should only be prescribed on the recommendation of a dermatologist, and only for short periods in order to gain control of the disease.

**Ophthalmic Corticosteroids [31,32]**
Ophthalmic corticosteroids are used to treat eye problems such as mycotic corneal ulcer, herpes zoster ophthalmicus, non-ulcerative keratitis, conjunctivitis, keratitis, sceritis and uveitis there by preventing permanent eye damage. They are also used to treat redness, irritation and other eye discomfort. They are available sterile form in different types of dosage forms such as suspension, ointment, solution, emulsion, gels and jellies. (See table 1)

- Before starting with the treatment it is necessary to discuss proper handling, use and unusual side effects of medicines.
- Possibly they should be avoided in paediatric age group because of their sensitivity to ophthalmic corticosteroids.
- Data was not found on specific information regarding the use and expected side effects of ophthalmic corticosteroids.
- Studies have not been done in humans regarding birth defects of these medicines but animal test shows positive result when these drops are used.
- There have not been reported to cause problems in nursing babies.
- Patient with diabetes of any type are at higher risk to develop cataracts or glaucoma. However, if necessary use under close observation and with caution.
Tuberculosis, herpes infections are other consequences, should be monitored.

Patient should not apply corticosteroids while using contact lenses because it may increase the chance of infection.

Health care professionals must observe eye condition for patients who are on long term corticosteroids.

If the corticosteroids therapy does not improve conditions under treatment after 5-7 days should be stopped abruptly and modified.

Washing eye with fresh and cool water is beneficial first aid to avoid eye irritation with ophthalmic corticosteroids.

4. Guidelines for Corticosteroids Use

They are widely used in palliative care in an attempt to relieve both specific and non-specific symptoms associated with advanced malignancy. Hence, prescribing must be principally based on following. [33,34,35]

- The lowest effective doses for the least possible time which have a clear indication/objective and consider all alternatives before starting.
- Consider prior steroid use, effectiveness and side effects.
- Clarify the individual risk-benefit ratio:
- Ensure specified indications/ doses reflect current evidence base/ best practice.
- Discuss risk factors/incidence of adverse effects with the patient to ‘gain consent’.
- Prescribe total dose in the first half of the day to avoid sleep disturbance i.e. as a single morning dose or split into 2 morning doses if numerous tablets required.
- Always consider prescribing prophylactic gastric protection e.g. proton pump inhibitor even if no history of peptic ulcer disease / NSAID use.
- Consider prophylactic anti-fungal e.g. Nystatin (100000 units) 1ml qds.
- Document a clear steroid plan e.g. indication, expected outcome, predicted time scale of response and date of review in patient’s records/ all medical correspondence – including discharge letters.
- Be aware of interactions with concurrent medications.(see table 6)
- Continually evaluate: if no effect of steroid trial up to 7 days, stop abruptly. If response is equivocal (usually maximal between 3-7 days) consider a trial of up to 3 weeks.
- If the steroids are felt to be effective after the first week of treatment, continue at that dose for 2-4 weeks maximum and plan to taper.
- Consider additional doses for physiological stressors e.g. pain, infection, trauma. This also applies to patients who have recently discontinued steroids.

Guidelines on Antenatal Corticosteroids (Pregnancy)

A study concluded that a single course of antenatal corticosteroids treatment may enhance fetal maturation before preterm birth and decrease the rate of respiratory distress syndrome, intraventricular haemorrhage and neonatal death. However, can cause less neonatal mortality, fewer common neurological and abdominal complications such as, cerebroventricular haemorrhage and necrotising enterocolitis. The use of antenatal steroid are most effective in reducing the incidence of respiratory distress syndrome in pregnancies that deliver 24 hours after and up to 7 days after administration of the second dose of antenatal corticosteroids. When administering antenatal corticosteroid practitioners should be aware of the short term effect on the fetus including a reduction in fetal heart rate variability, and also fetal body movements and breathing activity may be reduced for 2-3 days. Administer one dose of Betamethasone (Celestone Chronodose) 11.4mg by intramuscular injection and repeat this dose 24 hours later is suggesting regimen. Precaution should be taken when antenatal corticosteroids are administered to a woman with HTN and diabetes of any type. [33, 36, 37]

Guidelines on Prevention of Drug-Drug Interaction

Never use any drug unless there is a good indication. If the patient is pregnant do not use a drug unless the need for it is imperative.

- Ask if the patient is already taking other drugs including self-medication drugs; Interaction may occur.
- Age may alter the metabolism or excretion of drugs, for which dosage adjustment may be required. Genetic factors may also be responsible for variations in metabolism, which should be considered.
- Prescribe as few drugs as possible and give very clear instructions to the elderly or any patient who are likely to misunderstand complicated instructions.
- When possible use a familiar drug than a new drug which may show unexpected events.
- If any serious interaction is liable to occur, warn the patient to report it to the concerned authorities immediately.
- Be aware of interactions with concurrent medications.

Monitoring Parameters [38]

- Measure blood pressure , blood sugar, Body weight
- Ocular pressure and vision
- Full history including psychiatric, smoking, alcohol, and drugs
- Chickenpox -history of, check antibodies if necessary, and advise against contact with chickenpox and shingles
- Tuberculosis -history of tuberculosis, chest x ray, and tuberculin test
- Osteoporosis -dual energy x ray absorptiometry scan, weight bearing exercise, ensure adequate intake of calcium and vitamin D, hormone replacement if appropriate
- Peptic ulcer disease-history of peptic ulcer disease, prophylaxis if in high risk group
Suggestions may help to minimize some side effects [5].

- Time being administration
- Early dietary modification—low calorie, low sodium, and high potassium
- Awareness of possible errors of judgment on high doses.

5. **Summary**

- Once started on corticosteroids the patient should be regularly reviewed to assess the response to the treatment with adjustments to keep the dose at a minimum.
- The adverse effects of glucocorticoid therapy should be considered and discussed with the patient before glucocorticoid therapy is started.
- The risk of more serious side effects increases with higher dosages or longer courses of corticosteroids. These side effects should improve if the dosage is reduced.
- If corticosteroids are to be used for a more prolonged period of time, a “corticosteroids card” is to be issued to every patient, with the date of commencement of treatment, the initial dosage and the subsequent reductions and maintenance regimens.
- Initial steroid dose/dosage reduction/long-term dosing depends on underlying rheumatic disease, disease activity, patient response.
- Comorbidity should be evaluated: hypertension, DM, peptic ulcer, fractures and osteoporosis, cataract/glaucoma, infection, dyslipidaemia.
- Body weight, BP, edema, serum lipid, blood glucose, ocular pressure, cardiac insufficiency etc. are major parameters to monitor.
- Children should be monitored for growth. It is recommended to prescribe medication and calcium and vitamin D supplements, which help strengthen bones and can compensate for the effects of prednisolone.
- Stomach ulcers can be another problem for people who take high doses of oral corticosteroids on a long-term basis. To protect against stomach ulcers, prescribed medication called proton pump inhibitor (PPI). This reduces the amount of acid in stomach, which makes it less vulnerable to developing stomach ulcers.
- Select better strategy to treat adverse drug reactions with corticosteroids which may be dechallenging the concurrent drug or antagonist administration.
- Corticosteroids that are injected into muscles and joints may cause some pain and swelling at site of injection, which should be monitored.
- Extra care should be taken when applying steroids to sites such as the face, as these areas are more susceptible to skin thinning. Choice of agent is made according to patient need, remembering that all topical products must be cosmetically acceptable. Ointments are preferable to creams as they have a deeper, more prolonged emollient effect and increase the penetration of steroid.
- Diagnosis should be reassessed and, if appropriate, another steroid considered if no improvement is seen within 3-7 days of starting a topical steroid.
- Patients receiving corticosteroids therapy, should be counselled on smoking cessation or avoidance, limiting excessive alcohol intake, weight bearing activities.

**Table 1: Classification for corticosteroids [10,39,40]**

<table>
<thead>
<tr>
<th>A)</th>
<th>Based on duration of action</th>
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<tbody>
<tr>
<td><strong>Short acting (&lt;12 hrs)</strong></td>
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<tr>
<td>Hydrocortisone</td>
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<td>Cortisone</td>
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<td><strong>Intermediate acting (12-36 hrs)</strong></td>
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<td>Prednisolone</td>
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<td>Methyl Prednisolone</td>
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<td>Triamcinolone</td>
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<td>Deflazacort</td>
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<td><strong>Long acting (&gt;36 hrs)</strong></td>
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<tr>
<td>Dexamethasone</td>
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<tr>
<td>Betamethasone</td>
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<th>B)</th>
<th>Inhalation Corticosteroids</th>
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<tbody>
<tr>
<td>Beclometasone</td>
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<tr>
<td>Budesonide</td>
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<td>Ciclesonide</td>
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<td>Fluticasone</td>
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<th>C)</th>
<th>Parenteral Corticosteroids</th>
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<tr>
<td>Hydrocortisone Sodium Succinate</td>
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<td>Dexamethasone Sodium Phosphate</td>
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<tr>
<td>Betamethasone Sodium Phosphate</td>
<td></td>
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<tr>
<td>Methylprednisolone Sodium Succinate</td>
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<tr>
<td>Methylprednisolone Acetate</td>
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<th>Nasal Corticosteroids</th>
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<td>Budesonide</td>
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<td>Fluticasone</td>
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<td>Mometasone</td>
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<th>E)</th>
<th>Ophthalmic Corticosteroids</th>
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<td>Betamethasone</td>
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<td>Dexamethasone</td>
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<td>Fluorometholone</td>
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<td>Prednisolone</td>
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<th>F)</th>
<th>Topical Corticosteroids</th>
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<tr>
<td><strong>Group-I: Weakly Potent</strong></td>
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<tr>
<td>Hydrocortisone</td>
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<tr>
<td><strong>Group-II: Moderately Potent</strong></td>
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<tr>
<td>Betamethasone valerate</td>
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<td>Clobetasone</td>
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<td><strong>Group-III: Potent</strong></td>
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<tr>
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<tr>
<td>Betamethasone dipropionate (0.025%)</td>
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<td>Diflucortesone</td>
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<td>Flumisolone</td>
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<td>Fluticasone</td>
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<tr>
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<td>Mometasone</td>
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<tr>
<td><strong>Group-IV: Very Potent</strong></td>
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<tr>
<td>Betamethasone dipropionate (0.05%)</td>
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<tr>
<td>Clobetasol</td>
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<td>Diflucortolone</td>
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6. Conclusion

The anti-inflammatory effects of corticosteroids cannot be separated from their metabolic effects as all cells use the same glucocorticoid receptor; therefore when corticosteroids are prescribed measures should be taken to minimise their side effects. Clearly, the chance of significant side effects increases with the dose and duration of treatment and so the minimum dose necessary to control the disease should be given and later dose titration should be done. Either topical or inhalation corticosteroids can be used for chronic therapy if there is a good evidence as showing better risk-benefit profile. However, dose and application is required to be counselled to the patient by health care professionals. Pharmaceutical industries should design and formulate topical corticosteroids that cover large area of skin. Authors also suggest to use injection as per guidelines, in accurate doses (mg/ml) and appropriate frequency. Geriatrics and pediatrics group of population, patients with chronic disorders are needed to be isolated for corticosteroids therapy and must be provided with corticosteroids card (See figure 1). There are insufficient data to support preparing proper guidelines. However these guidelines will help to encourage rational use of corticosteroids.

7. Reference


