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Literature Scan: Topical Corticosteroids

Month/Year of Review: March 2015

Date of Last Review: March 2013

Source Document: OSU College of Pharmacy

Current Status of PDL Class: See Appendix 1.

Conclusions and Recommendations:

- Select preferred agents based on comparative costs in executive session.
- At least one agent in each of the potency categories (Appendix 1) should be preferred.
- No further review or research needed.

Previous Conclusions and Recommendations:

- Evidence does not support a difference in efficacy/effectiveness.
- Evidence does not support a difference in harms/adverse events.
- Consider covering at least one representative from each potency group.

Methods:

A Medline literature search for new systematic reviews and head-to-head randomized controlled trials (RCTs) assessing clinically relevant outcomes were conducted. The Medline search strategy used for this literature scan is available in **Appendix 3**, which includes dates, search terms and limits used. The OHSU Drug Effectiveness Review Project, Agency for Healthcare Research and Quality (AHRQ), Cochrane Collection, National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, BMJ Clinical Evidence, Dynamed, and the Canadian Agency for Drugs and Technologies in Health (CADTH) resources were manually searched for high quality and relevant systematic reviews. When necessary, systematic reviews are critically appraised for quality using the AMSTAR tool and clinical practice guidelines using the AGREE tool. The FDA website was searched for new drugs, indications, and safety alerts. Finally, the AHRQ National Guideline Clearinghouse was searched for updated and recent evidence-based guidelines. The primary focus of the evidence is on high quality systematic reviews and evidence-based guidelines. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources. A summary of potentially relevant trials are available in **Appendix 2**.

New Systematic Reviews:

1. A 2013 Cochrane Collaboration systematic review evaluated topical treatments for chronic plaque psoriasis^{1,2} The review included 177 RCTs (n=34,808). Results demonstrated that most treatments were more effective than placebo, including vitamin-D analogues and topical corticosteroids. Potent topical corticosteroids were similarly effective; however, betamethasone twice daily was significantly more effective than betamethasone once daily. Very potent steroids had a great overall effect than potent steroids. The only very potent steroids evaluated were clobetasol and halobetasol and they resulted in similar results. Combination therapy with a vitamin D analogue plus corticosteroid was more effective than either individual product used as monotherapy. Overall, there was no statistically significant difference between vitamin D analogues and potent corticosteroids for psoriasis of the body, but corticosteroids appear more effective for treating psoriasis of the scalp.^{1,2} The authors concluded that corticosteroids perform at least as well as vitamin D analogues and they are associated with a lower incidence of local adverse events.
2. A good quality systematic review by Hendriks, et al. also reviewed the efficacy and safety of first-line topical treatments for chronic plaque psoriasis.³ A total of 45 studies were included in the analysis. Overall, the combination of steroids and vitamin D analogues were found to be more effective than either as monotherapy. There was no significant difference between the combination of clobetasol with either calcipotriene ointment or calcitriol. Another systematic review confirmed that the combination of vitamin D analogues plus topical steroids is more effective than vitamin D analogues alone.⁴
3. A systematic review evaluated the treatment of palmoplantar pustular psoriasis, which is a variant of psoriasis associated with psoriatic arthritis.⁷ Twenty nine articles were included and the main outcomes were improvement in more than 70% of initial disease severity and clearance of disease. Topical corticosteroids appeared to relieve symptoms; no therapy was proven to suppress the disease completely. Based on the limited evidence, the overall recommendations were mostly based on expert opinion. It was recommended that first line therapy include potent or very potent topical corticosteroids.
4. A 2014 Cochrane Collaboration systematic review compared the effectiveness of topical corticosteroids for treating phimosis in boys.⁵ A total of 12 studies (n=1395) found low quality evidence that compared with placebo, topical corticosteroids significantly increased complete or partial clinical resolution of phimosis (RR 2.45; 95% CI 1.84 to 3.26). However, due to inadequate reporting it was difficult to assess the quality of the clinical trials. Topical corticosteroids remain a first line option before surgery to correct phimosis in boys. There was no difference or preference between topical corticosteroids included in the analysis.
5. Topical corticosteroids as adjunctive therapy for bacterial keratitis were evaluated in a 2014 Cochrane Collaboration systematic review.⁶ Only four RCTs met inclusion criteria for the review (n=611). None of the trials found any difference between corticosteroids and placebo in visual acuity. The authors concluded that there is inadequate evidence to support the use of topical corticosteroids for the treatment of bacterial keratitis.

New Guidelines:

Guidelines for the management of atopic dermatitis in pediatric and adults with topical therapies were published in 2014 by the American Academy of Dermatology.⁷ Recommendations for the use of topical corticosteroids are provided as followed:

- Topical corticosteroids are recommended for individuals who have failed to respond to good skin care and regular use of emollients alone (Strength of recommendation: A; Level of evidence I).
- Patient age, areas of body patient preference and cost of medication should be considered when choosing a particular agent.
- Twice-daily application is generally recommended.
- No specific monitoring for systemic side effects is routinely recommended.
- Intermittent use of topical corticosteroids as maintenance therapy (1-2x week) on areas that commonly flare is recommended to help prevent relapses.

New FDA Drug Approvals: None identified.

New FDA Safety Alerts: None identified.

References:

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9. Camplone G, D'Agostino M, De Simone C, et al. Efficacy and maintenance strategies of two-compound formulation calcipotriol and betamethasone dipropionate gel (Xamiol gel) in the treatment of scalp psoriasis: results from a study in 885 patients. *Journal of Dermatological Treatment.* 2014;25(1):30-33. doi:10.3109/09546634.2013.800182.
10. Feldman SR, Winkelman W, Baum E, Preston N. Predicting improvement in signs and symptoms of plaque psoriasis after 1 week of treatment with clobetasol propionate 0.05% spray. *Journal of Drugs in Dermatology.* 2013;12(12):1456-1460.
11. Fukaya M, Kimata H. Topical clofibrate improves symptoms in patients with atopic dermatitis and reduces serum TARC levels: a randomized, double-blind, placebo-controlled pilot study. *Journal of Drugs in Dermatology.* 2014;13(3):259-263.

Appendix 1: Current Status on Preferred Drug List

- Preferred Agents: ALCOMETASONE CREAM/OINTMENT, BETAMETHASONE CREAM/LOTION/OINTMENT (ALPHATREX), CLOBETASOL CREAM/OINTMENT, DESONIDE CREAM/OINTMENT, FLUCINOLONE CREAM/SOLUTION, FLUCINOLONE ACETONIDE, HYDROCORTISONE CREAM/OINTMENT/SOLUTION, TRIAMCINOLONE CREAM/OINTMENT
- Non Preferred Drugs: AMCINOMIDE CREAM/OINTMENT/LOTION, BETAMETHASONE/PROPYLENE GLYCOL, CLOCORTOLONE (Cloderm), DESOXIMETASONE , DIFLORASONE DIACETATE (APEXICON E) FLURANDRENOLIDE (CORDAN),, halcinomide (HALOG), HALOBETASOL, MOMETASONE, HYDROCORTISONE/ALOE/VIT E/A & D (ANTI-ITCH CREAM), PREDNICARBATE (DERMATOP), TRIAMCINOLONE/UREA/HYDROCORTISONE OINTMENT (AQUAPHILIC)

Relative Potencies of Topical Corticosteroids

Class	Drug	Dosage form(s)	Strength (%)
I. Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
II. High potency	Halobetasol propionate	Cream, ointment	0.05
	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
III-IV. Medium potency	Triamcinolone acetonide	Cream, ointment	0.5
	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
V. Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
VI. Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
VII. Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Appendix 2: New Clinical Trials

Twenty-three potentially relevant clinical trials were evaluated from the literature search. After further review, all trials were placebo controlled or non-randomized trials and were therefore excluded.

Appendix 3: Medline Search Strategy

1 topical corticosteroid.mp.914

2 aclometasone.mp.3

3 Betamethasone/ or Administration, Topical/ 21212

4 Betamethasone/ and Administration, Topical/ 234

5 Clobetasol/ 704

6 Fluocinolone Acetonide/ 310

7Hydrocortisone/ or hydrocortisone cream.mp. 24006

8 Triamcinolone Acetonide/2672

9 Betamethasone 2082

10 Fluocortolone/ or clocortolone.mp. 44

11 diflorasone.mp. 16

12 flurandrenolide.mp. or Flurandrenolone 9

13 halobetasol.mp. 25

14 prednicarbate.mp. 73

15 topical corticosteroids.mp. 1932

16 psoriasis.mp. or Psoriasis 17033

17 Dermatitis, Allergic Contact/ or Dermatitis/ or Dermatitis, Contact/ or Dermatitis, Atopic 23038

18 1 or 2 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 31810

16 or 17 38981

20 18 and 19 1409

21 limit 20 to (english language and humans and yr="2013 -Current" and (controlled clinical trial or meta analysis or randomized controlled trial or systematic reviews)) 23