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Living FRIendly Summaries of the Body of Evidence Using Epistemonikos (FRISBEE)
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Topical corticosteroids or vitamin D analogues for plaque psoriasis?

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Abstract

Psoriasis is a frequent chronic inflammatory disease. The plaque variant being its most common form of presentation. Although there is still no cure, treatment alternatives that induce remission and reduce lesions are available. Topical therapies, particularly corticosteroids and vitamin D analogues, are considered effective, but it is still not clear which would be the best alternative. To answer this question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We identified eight systematic reviews including 26 studies overall, of which 22 were randomized trials relevant for the question of interest. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach. We concluded there might be little or no difference in clinical response between topical corticosteroids and topical vitamin D analogues, but topical corticosteroids are less irritating at the site of application. No studies evaluating their long term adverse effects were found.

Problem

Psoriasis is a systemic inflammatory disease, where skin is the most commonly affected organ. Although there is still no cure, there is a wide variety of treatments available that can induce remission and reduce lesions. In daily practice different alternatives are used, and therapy is adjusted according to clinical response. The most commonly used drugs, due to their greater availability, ease of application and lower costs are topical medications. Within these, corticosteroids are the most used. Even though there are many available alternatives such as tazarotene, tacrolimus, anthralin, UV light, among others, vitamin D analogues are frequently chosen. Despite vast experience with these topical therapies, there is stilll controversy about their effects.

Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information we generated a structured summary using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies, a summary of findings table following the GRADE approach and a table of other considerations for decision-making

Key messages

- There might be little or no difference in clinical response between topical corticosteroids and topical vitamin D analogues.
- Topical corticosteroids lead to fewer local adverse effects (skin irritation) than topical vitamin D analogues.
- No studies were found evaluating long-term adverse effects (cutaneous atrophy).

About the body of evidence for this question

What is the evidence. See evidence matrix in Epistemonikos later	We found eight systematic reviews, reported in nine references [1],[2],[3], [4],[5],[6],[7],[8],[9], that include 26 primary studies, reported in 32 references [10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22], [23],[24],[25],[26],[27],[28],[29],[30],[31],[32],[33],[34],[35],[36],[37], [38],[39],[40],[41]. Of these, 22 were randomized controlled trials reported in 28 references [11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22] [23],[24],[25],[26],[28],[29],[30],[31],[32],[33],[36],[37],[38],[39],[40], [41]. Four of these studies were excluded because the intervention group included also topical salicylic acid [14],[19],[33],[36].This table and the summary in general are based on the 18 randomized controlled trials that answer the question of interest [11],[13],[15],[16],[17],[20],[21], [22], [23],[24],[26],[28],[29],[32],[37],[39],[40],[41].
What types of patients were included*	All of the trials included adult patients (15 to 90 years) with plaque psoriasis in trunk and limbs, not including scalp. Trials includes patients with low, moderate and severe disease.
What types of interventions were included*	All trials used topical corticosteroids as intervention. Within them, some of high potency were used such as fluocinonide 0.05% twice a day [11], betamethasone dipropionate 0.05% once, or twice a day [13],[16],[32], [40], betamethasone 17-valerate 0.1% once [37],[39] or twice a day [15], [23],[26],[29],[41] and desoxymethasone 0.25% twice a day [21]. Also, some corticosteroids of very high potency were used such as clobetasol propionate 0.05% twice a day [22],[24] and diflorasone diacetate 0.05% twice a day [28]. As a comparison, topical treatment with a vitamin D analogue was used, including calcipotriol 50 mcg/g once [17],[20] or twice a day [11],[15],[16],[21],[22],[23],[24],[28],[29],[32],[40],[41], calcitriol 3 mcg/g twice a day [13],[26] and tacalcitol 4 mcg/g once a day [37],[39].
What types of outcomes were measured	The outcomes were pooled by the different systematic reviews as follows: • PASI (Psoriasis Area Severity Index) • TSS (Total Severity Score) • IAGI (Investigator's Assessment of Overall Global Improvement) • PAGI (Patient assessment of global improvement) • Local adverse events (skin irritation) • Systemic adverse events • Withdrawal due to adverse events (skin irritation) • Withdrawal due to treatment failure

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

Summary of findings

Information on the effects of topical corticosteroids versus vitamin D analogues is based on 15 randomized trials [11],[13],[15],[17],[20],[22],[23],[24],[26],[28],[29],[32],[37],[39],[41] that included 4238 patients overall. Nine trials reported PASI [13],[15],[17],[20],[23],[24],[29],[32],[41], nine reported IAGI [11],[13],[17],[20],[22],[26],[28],[29],[32], three reported PAGI [15],[22],[23], nine reported local adverse events [13],[15],[23],[24],[29],[32],[37], seven reported systemic adverse events and ten reported withdrawals due to adverse events [11],[13],[15],[20],[22],[23],[26],[29],[37],[39]. The summary of findings is the following:

- There might be little or no difference in PASI score between topical corticosteroids and topical vitamin D analogues. The certainty of the evidence is low.
- There might be little or no difference IAGI score between topical corticosteroids and topical vitamin D analogues. The certainty of the evidence is low.
- There might be little or no difference in PAGI score between topical corticosteroids and topical vitamin D analogues. The certainty of the evidence is low.
- Topical corticosteroids lead to fewer local adverse events (skin irritation) than topical vitamin D analogues. The certainty of the evidence is high.
- There might be little or no difference in systemic adverse events between topical corticosteroids and topical vitamin D analogues. The certainty of the evidence is low.
- Topical corticosteroids lead to fewer withdrawals due to adverse events than topical vitamin D analogues. The certainty of the evidence is high.
- No studies were found that evaluated the impact of topical corticosteroids and topical vitamin D analogues in cutaneous atrophy.

About the certainty of the evidence (GRADE)*

⊕⊕⊕⊕
High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕◯
Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate

⊕⊕◯◯
Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕◯◯◯
Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.
† Substantially different = a large enough difference that it might affect a decision.

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Topical corticosteroids versus vitamin D analogues in plaque psoriasis

Patients Plaque psoriasis (excluding scalp)
Intervention Topical vitamin D analogues
Comparison Topical corticosteroids

Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	WITH topical corticosteroids	**WITH topical vitamin D analogues**		
	Difference: patients per 1000			
PASI	PASI scale was on average 0.1 standard deviations higher than the topical corticosteroid group.		--	⊕⊕◯◯ Low[1]
	SMD: 0.10 (-0.1 to 0.29)			
IAGI	IAGI scale was on average 0.17 standard deviations higher than the topical corticosteroid group.		--	⊕⊕◯◯ Low[1]
	SMD: 0.17 (-0.02 to 0.36)			
PAGI	PAGI scale was on average 0.19 standard deviations lower than the topical corticosteroid group.		--	⊕⊕◯◯[2] Low
	SMD: -0.19 (-0.4 to 0.02)			
Local adverse events (skin irritation)	78 per 1000	154 per 1000	RR 1.98 (1.64 to 2.39)	⊕⊕⊕⊕ High
	Difference: 76 patients more per 1000 (Margin of error: from 50 to 108 more)			
Systemic adverse events	9 per 1000	8 per 1000	RR 0.84 (0.38 to 1.86)	⊕⊕◯◯[3] Low
	Difference: 1 patient less per 1000 (Margin of error: from 6 less to 8 more)			
Withdrawal rate due to adverse events (skin irritation)	8 per 1000	19 per 1000	RR 2.23 (1.17 to 4.23)	⊕⊕⊕⊕ High
	Difference: 11 patients more per 1000 (Margin of error 1 to 27 more)			
Adverse events (cutaneous atrophy)	No studies evaluated this outcome		--	--

RR= Risk ratio.
SMD: Standardized Mean Difference.
Margin of error = 95% confidence interval (CI).
GRADE: evidence grades of the GRADE Working Group (see later in this article)

* Standardized mean difference is calculated when the outcome has been measured using different scales and its clinical interpretation is difficult. A general rule is that values lower than 0.2 are of little clinical relevance, values of 0.5 of moderate clinical relevance, and values over 0.8 are of very important clinical relevance.

* The risk **WITH topical corticosteroids** is based on the risk in the control group of the trials. The risk **WITH vitamin D analogues** (and its margin of error) is calculated from relative effect (and its margin of error)

[1] The certainty of the evidence was downgraded two levels for inconsistency, because some studies demonstrated superiority of topical corticosteroids and others of topical vitamin D analogues.
[2] The certainty of the evidence was downgraded in one level for inconsistency because some studies demonstrated superiority of topical corticosteroids and others of topical vitamin D analogues, and was downgraded in one level for imprecision
[3] The certainty of the evidence was downgraded two levels for imprecision.

Other considerations for decision-making

To whom this evidence does and does not apply

- The evidence presented applies to patients with diagnosis of chronic plaque psoriasis of trunk and limbs.
- It does not include patients with scalp psoriasis, as they respond in a different way to the same treatment and generally need other types of intervention.

About the outcomes included in this summary

- The outcomes included in this summary are those considered critical for decision-making by the authors of this summary. They coincide with the outcomes mentioned by most systematic reviews and guidelines.
- We selected PASI, IAGI and PAGI because they are clinical scores that correlate with disease severity or improvement.
- Adverse events (skin irritation) and withdrawal due to adverse events were considered because they are important in the chronic use of the previously mentioned interventions.
- It should be noted that local adverse events such as cutaneous atrophy, which is mainly secondary to chronic use of topical corticosteroids, were not considered in the systematic reviews. This adverse effect might be important for decision-making.
- It might be important to consider quality of life measures such as DLQI (Dermatology Life Quality Index), however, this score was not evaluated in any of the trials included in this article.

Balance between benefits and risks, and certainty of the evidence

- Even though the certainty of the evidence is low regarding improvement of clinical scores, it would be important to consider that topical corticosteroids have fewer local adverse events regarding skin irritation and less withdrawal rate due to adverse event, with a high certainty.
- Cutaneous atrophy or other adverse events secondary to chronic use of topical corticosteroids were not reported, which would be relevant in decision making.

Resource considerations

- Topical vitamin D analogues have a higher cost compared to topical corticosteroids and their clinical benefits are unclear.

What would patients and their doctors think about this intervention

- The treatment of this condition is largely based on clinical experience. A large proportion of patients discontinue treatment with topical vitamin D analogues due to local irritation or because of its high cost, despite medical indication.
- In this context, with the information presented in this summary most clinicians should prefer topical corticosteroids over vitamin D analogues.

Differences between this summary and other sources

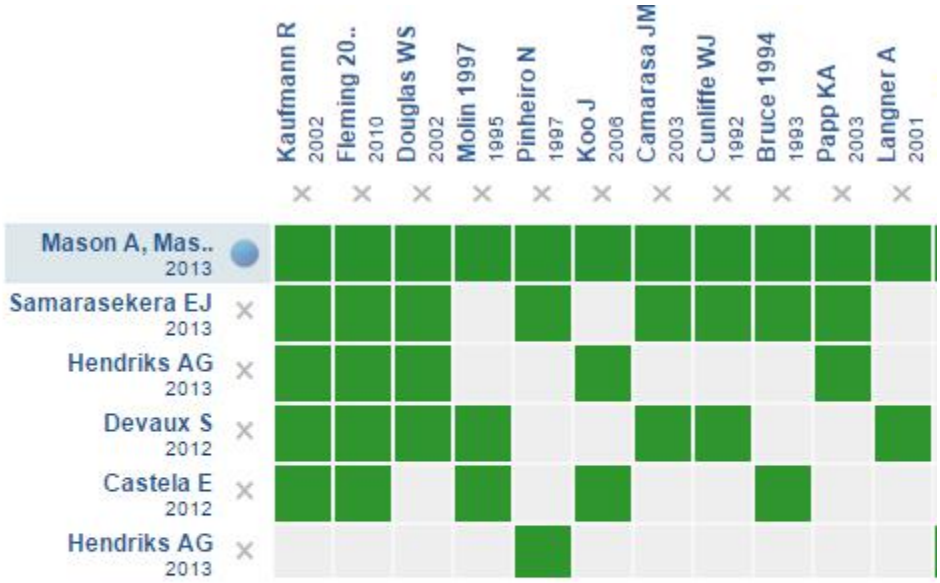
- The conclusions of this summary are consistent with most systematic reviews identified.
- The conclusions partially agree with the guidelines of the American Academy of Dermatology [42], which recommends topical corticosteroids and vitamin D analogues as first line treatment in plaque psoriasis, without recommending one over the other. However, it highlights the adverse effects of topical corticosteroids and emphasizes their use for a limited time.

Could this evidence change in the future?

- The probability that future research changes the conclusions of this summary is high, due to the uncertainty of the current evidence.
- We did not identify ongoing trials in the International clinical trials registry platform of the World Health Organization.

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



Starting from any systematic review, Epistemonikos builds a matrix based on existing connections in the database.
The author of the matrix can select relevant information for a specific health question (typically in PICO format) in order to display the information set for the question.
The *rows* represent systematic reviews that share at least one primary study, and *columns* display the studies.
The boxes in green correspond to studies included in the respective reviews.

Follow the link to access the **interactive version:** Topical corticosteroids versus vitamin D analogues in plaque psoriasis excluding scalp psoriasis

Notes

The upper portion of the matrix of evidence will display a warning of "new evidence" if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier. After creating an account in Epistemonikos, users will be able to save the matrices and to receive automated notifications any time new evidence potentially relevant for the question appears.

The details about the methods used to produce these summaries are described here http://dx.doi.org/10.5867/medwave.2014.06.5997.

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database (www.epistemonikos.org).

These summaries follow a rigorous process of internal peer review.

Conflicts of interest
The authors do not have relevant interests to declare.

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